

MRL Applications Manual

(IUCLID 6 VERSION 6.X)

European Food Safety Authority (EFSA)

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Introduction

REGULATORY BACKGROUND FOR MRL APPLICATIONS

The **procedures** for MRLs applications are set by the **Regulation (EC) No 396/2005**¹ on maximum residue levels of pesticides in or on food and feed of plant and animal origin (Articles 6 to 11 and Article 14(1)).

Article 8(1)(g) of Regulation (EC) No 1107/2009² on the placing of plant protection products on the market refers to, where relevant, the inclusion of a copy of the MRL application, in accordance with Article 7 of Regulation (EC) No 396/2005, in the dossier for the approval of an active substance.

The **purpose of an MRL application** can be one (or more than one) of the following:

- amend existing residue definition
- delete maximum residue level(s)
- evaluation of confirmatory data following review according to Article 12
- include active substance/product combinations into Annex VII
- include an active substance in Annex IV
- set import tolerance(s) (changing current EU MRL listed in Annex II or III)
- set import tolerance(s) (new active substance not mentioned in Annex II/III/IV)
- set specific maximum residue level(s) (changing current EU MRL listed in Annex II or III)

WHEN PLANNING A DOSSIER SUBMISSION IT IS RECOMMENDED TO CHECK EFSA APPLICANTS TOOLKIT FOR THE LATEST RESOURCES TO SUPPORT DOSSIER PREPARATION (<https://www.efsa.europa.eu/en/applications/toolkit>)

DATA REQUIREMENTS FOR MRL APPLICATIONS

The **data requirements** for an MRL application dossier are indicated in the **Regulation (EU) No 283/2013**³ ("new" data requirements) setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and in the Commission **Regulation (EU) No 544/2011**⁴ ("old" data requirements) implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances.

Following the entry into force of the **Transparency Regulation** (Regulation (EU) 2019/1381⁵), the General Food Law has been amended by introducing **new requirements regarding transparency of submitted data**, including the **submission of the dossiers for MRL applications using IUCLID format**.

¹ Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC

² Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

³ Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market

⁴ Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances

⁵ Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC

These new requirements, as implemented by the **Practical Arrangements**⁶ laid down by EFSA, are reflected in the **EFSA "Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances and on the MRL application procedure"**⁷ and apply to all **MRL applications submitted as of 27 March 2021**.

Applicants are required to create a new "Mixture" dataset and select the Working context '**EU_PPP MRL application**'.

STRUCTURE OF THE IUCLID DOSSIER

The **IUCLID dossier for an MRL application** shall contain:

1. a **MIXTURE DATASET**: with data on the representative mixture (including the GAP, as a mandatory document);
2. an **ACTIVE SUBSTANCE DATASET**: with data on the TARGET active substance; The active substance dataset and table of contents (TOC) is equivalent to the data requirements in Reg. 283/2013;
3. (if appropriate) **one/several METABOLITE dataset(s)**: with data on the relevant metabolite(s);
4. (if appropriate) **OTHER SUBSTANCES** relevant FOR ASSESSMENT **dataset**: with data on any substance of concern (e.g. relevant impurities)

Safeners, synergists and co-formulants can be entered in the Mixture composition document (Section 1.2) as "reference substances" even when they are mixtures (e.g. a co-formulant dissolved in a solvent). Information on the alternative co-formulants should be entered similarly to other co-formulants.

For reporting **metabolites** complete the [FLEXIBLE SUMMARY.Metabolites](#) document and link the relevant metabolite datasets.

Note: the table of contents is identical for metabolite and other substance datasets

The dataset in which a study is to be completed is **dependent on the test material**. All studies should generally be reported only once. The cross-reference function can be used for studies in the same dataset to avoid duplicate data entry. In case of studies including parent and metabolites the following approaches should be used:

- If the test material is the **parent substance**, studies should be included under the **parent/active substance dataset**;
- If the test material is the **metabolite**, studies should be reported under the **metabolite dataset**;
- If the test material is a **mixture of parent and metabolite**, studies should be reported under the **parent/active substance dataset**;
- If the test material is a **mixture of metabolites**, the studies should be reported under the **predominant compound dataset**;
- If there are several test materials in one study, the test material entity for the main tested compound should be selected as the "Test material information field". Other test material entities can be selected in "Other test material information". The study should be included under the main tested compound dataset.

COMPONENTS OF A DATASET

⁶ <https://www.efsa.europa.eu/en/corporate/pub/tr-practical-arrangements>

⁷ <https://www.efsa.europa.eu/en/applications/pesticides/regulationsandguidance>

IUCLID documents: data must be reported in the relevant IUCLID documents (Endpoint summaries, Endpoint study records, Flexible records, Flexible summaries, etc).

Direct instructions on the **compilation of the fields** of each of the IUCLID documents are given in this manual in the relevant IUCLID dossier section. Instructions provided for the Active substance dataset are applicable also to the Metabolite dataset and to Other substances for assessment dataset.

OECD harmonised templates (OHTs) are designed to be used in a wide range of regulatory contexts. More information on OHTs can be found on the [OECD website](https://www.oecd.org/ehs/templates/)⁸. For EU_PPP these documents are used in the different datasets and for microorganism and/or chemicals. For each endpoint study summary and endpoint record there is a 'Purpose' paragraph indicating the regulatory data requirement/s covered by the document. It can also include specific instructions that in some cases can be valid either for microorganisms or for chemicals (depending on the working context), see example below:

Acute toxicity oral

Chemical Active: *The acute oral toxicity of the active substance shall always be reported.*

Chemical Product: *A test for acute oral toxicity shall be carried out unless the applicant can justify an alternative approach under Regulation (EC) No 1272/2008. In the latter case, acute oral toxicity of all components shall be provided or reliably predicted with a validated method. Consideration shall be given to the possible effects of components on the toxic potential of the total mixture.*

Microorganism Active: *The acute oral toxicity study should permit the identification of effects following a single exposure to the microorganism, including an assessment of toxicity, pathogenicity and infectiveness, and evaluation of the clearance of the microorganism.*

Microorganism Product: *An acute oral test with the plant protection product shall always be carried out only if the applicant cannot justify an alternative approach under Regulation (EC) No 1272/2008.*

When no study is provided for a data requirement/endpoint, a detailed **justification for data waiving** must be completed in the endpoint study record. Only a short description of the justification for data waiving should be reported in the relevant endpoint summary to avoid duplication of information. The validation tool of IUCLID will check for completeness of the mandatory sections according to the validation rules indicated in this manual.

Attached files: In line with the provisions of the Transparency Regulation, **full study reports** (including publications and QSAR, QMRF or QPRF reporting forms) must be provided as attachments to the literature reference entities. The literature reference entity allows different types of attachments to be uploaded. Only one attachment with the Attachment type = 'full study report' is permitted. Other **supporting materials** (e.g. excel templates, kinetic fitting reports, MSS/DER composers xml files) can also be added as attachments completing the 'Attachment type' to classify the material. Notification of study identifiers (NoS ID) for completed studies can be reported in the literature reference entity.

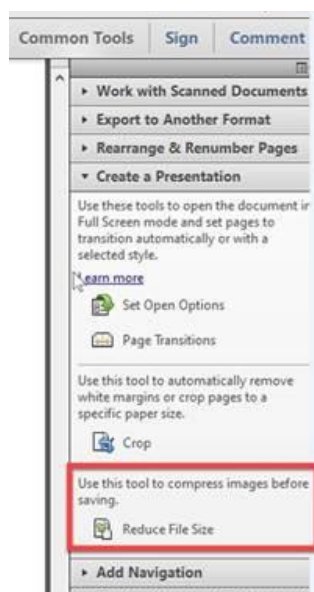
For details on copyright rules please see section "Data source ([Literature Reference](#))– common block" section of this manual.

Attachments greater than 100MB cannot be uploaded into IUCLID. In such cases, please follow the instructions below. Reducing the size of attachments in IUCLID documents will result in better performance for dossier processing steps and it is therefore always recommended as best practice.

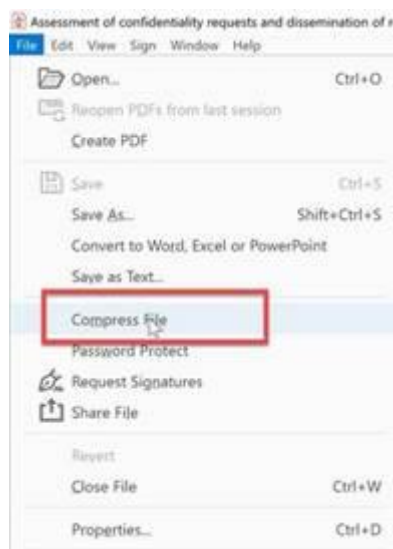
1. Generate the attachment report for the dossier / dataset to be submitted to get an overview of all the attachments. The most detailed report is shown below and the ftl files can be downloaded from the IUCLID 6 website. Similar reports for datasets are also available.

List of Attachments (dossiers only)			This report extracts all attachments from a substance or mixture dataset or dossier (only to be generated with dossiers)
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- a. These attachment reports that generate a .csv file (that can be opened in Excel) and lists all attachments with their size and type is available.
2. Identify all the PDF attachments that have an excessive size (e.g. >100MB)
3. Download the large PDF attachments and use Adobe features to reduce the PDF file size
 - a. In the past this feature was called "*Reduce File Size*" in Adobe



- b. In latest Adobe you can find the following menu item: "*Compress File*"



4. Upload smaller version of the PDF as attachment to the dataset

This approach can be applied to PDF attachments only, though similar size reduction solution can be applied for other attachment types as well: e.g. extremely large images (with some loss in resolution quality).

Supporting documents: the required supporting documents listed by TOC section in the table below must be provided as attachments to the dossier:

<u>Table of Content</u>	<u>Attachment</u>
<u>Active substance DATASET</u>	<u>Endpoint summary/Flexible summary</u>
1.8 Method of manufacture (synthesis pathway) of the active substance	Document J including Template 1.1 Template for presentation the assessment for the equivalence of batches https://zenodo.org/record/4557367#.YZYwU2DMJPY
4. Analytical methods	Template 4.1 - Template for the overview table for analytical methods for risk assessment" (https://doi.org/10.5281/zenodo.4556992) (attached to the endpoint summary)
5.1 Studies on absorption, distribution, metabolism and excretion in mammals	DER composer xml file (attached to the literature entity of the endpoint study record)
5.4 Genotoxicity testing	Template 5.3 - Template for a summary table integrating experimental evidence on genotoxicity for metabolites http://doi.org/10.5281/zenodo.4557333 (attached optionally to endpoint summary)
5.8 Other toxicological studies	Template 5.4 - Template summary table on the assessment of the toxicological profile of metabolites https://zenodo.org/record/4557354#.YYqZb2DMJPY (attached to the endpoint summary)
5.8.4 Intermediate effects - mechanistic information	Any additional documents relevant for the submission, e.g: GLP Expert judgement- Scientific publication - (Q)SAR: supporting information - Data analysis file (calculation of parameters) - Data supporting the reliability and sensitivity of the method - Specific information on the test material or test system - Justification - Expert judgement – Other. For test guidelines that provide a reporting template (data analysis file), that file must be completed and can be uploaded here if not yet done in the results section (attached to endpoint summary).
6.2.1 Metabolism of residues in plants and in rotational crops	-Template 6.2 Template for reporting metabolism studies https://zenodo.org/record/4621090#.YZt9DtDMJPY (optionally attached to the endpoint summary) -MSS composer xml file (attached to the literature entity of the endpoint study record)
6.2.2 Metabolism of residues in livestock (incl. fish)	-Template 6.2 Template for reporting metabolism studies https://zenodo.org/record/4621090#.YZt9DtDMJPY (optionally attached to the endpoint summary) -MSS composer xml file (attached to the literature entity of the endpoint study record)
6.3 Magnitude of residues in plants	Sanitised version of OECD calculator (attached to the endpoint summary)

6.4 Feeding studies	Template 6.4 Excel animal burden calculator https://zenodo.org/record/827275#.YYqcuGDMJPY (attached to the endpoint summary)
6.5.3 Magnitude of residues in processed commodities	Template 6.5 for reporting trials on magnitude of residues in process commodities https://zenodo.org/record/4621131#.YYqdR2DMJPY (attached to the endpoint summary)
6.7.2 Proposed maximum residue levels	Sanitised version of OECD calculator (attached to the endpoint summary)
6.9 Estimation of the potential and actual exposure through diet and other sources	Template 6.6 PRIMo rev 3.1 - Pesticide Residue Intake Model calculator https://zenodo.org/record/4447293#.YYqd6mDMJPY (attached to the endpoint summary)
9.1 Literature data	Bibliographic results of the literature searches
11.1 Assessment from other authorities	Relevant only for import tolerance: <ul style="list-style-type: none"> • Evidence of registration in the exporting country (copy of legislation) • Registered use pattern in the exporting country (labels) • Legislation in the exporting country concerning the MRL (copy of legislation)
11.2 Other reports	<ul style="list-style-type: none"> • Administrative documents such as cover letters (attached to the "Reports and administrative information" field). <i>Important note:</i> such letters do not need to be provided via email or post, but solely attached in the respective IUCLID section. Duplication of information should be avoided. Applicants are invited to provide data as attachments only in case they cannot be entered in a specific IUCLID document.
11.4 Endocrine disrupting properties	Appendix E.1 to the Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009 https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/j.efsa.2018.5311 (attached to the flexible record)

In the working context of "EU PPP MRL application", a GAP document is mandatory. In addition, the **mandatory sections** are Section 4, Section 6.1, Section 6.2.1, Section 6.2.2, Section 6.3, Section 6.4, Section 6.5.1, Section 6.5.3, Section 6.9 and Section 6.10.1. For sections 4, 6.1, 6.2.1, 6.2.2, 6.3, 6.4, 6.5.1, 6.5.3 and 6.10.1, applicants are requested to complete at least one endpoint study record and one endpoint summary. For sections 6.7.1 and 6.7.2. one flexible summary is required. For Section 6.9, only an endpoint summary is required. Although not mandatory, the other sections of the table of content should be carefully checked and applicant should evaluate if data or information is needed for those other Sections.

MRL DOSSIERS SUBMITTED AS PART OF AN ACTIVE SUBSTANCE APPROVAL OR RENEWAL PROCESS

As explained in the Administrative guidance⁹, when the applicant submits an MRL dossier as part of an approval or renewal process, a separate dossier (EU PPP MRL application) should generally be created in IUCLID. The dossier supporting the approval or renewal process and the one supporting the MRL application should be provided at the same time but submitted separately in the EFSA central submission system.¹⁰

As for any stand-alone MRL application, the purpose of the MRL application submitted as part of the peer-review should be indicated in the dossier header of the MRL dossier following the instructions in IUCLID. The link between the active substance dossier and the MRL dossier should be indicated in both dossier headers (i.e. active substance and MRL). In the dossier headers, the applicant should tick the check box under the section "Other submission related information" and specify the submission number of the other dossier (please also refer to the dedicated Chapter on MRL Dossier header).

Further specific instructions are given in the section hereafter on the "overview of the main cases" (see Case 3).

⁹ Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances and on the maximum residue level (MRL) application procedure

¹⁰ For technical reasons, the MRL submission will have to be done before the dossier submission to allow the system to link the two items.

OVERVIEW OF THE MAIN CASES AND HOW THEY SHOULD BE HANDLED IN IUCLID:

If the MRL dossier is submitted AFTER the active substance approval/renewal, go to **CASE 1**.

If the MRL dossier is submitted for a NOT APPROVED active substance, go to **CASE 2**.

If the MRL dossier is submitted AS PART OF the active substance approval/renewal, go to **CASE 3**.

For the specific purpose of application: "delete maximum residue level(s)", go to **CASE 4**.

CASE 1- MRL dossiers submitted AFTER an active substance approval/renewal:

These instructions are valid for all the following purposes of application: setting specific maximum residue level(s), evaluation of confirmatory data following review according to Article 12, include an active substance in Annex IV, amending residue definition, setting import tolerances (for EU approved substance).

If the MRL dossier is submitted AFTER the active substance approval/renewal, it should be a 'stand-alone' MRL dossier. Such a dossier follows the standard rules defined above. Therefore, at least one GAP document should be submitted and all mandatory endpoints (study records and summaries) of Section 4 and Section 6 should be addressed by the applicant. Although not mandatory, the other sections of the table of content should be carefully checked and applicant should evaluate if data or information is needed for those other Sections (e.g. Section 5: Toxicological and metabolism studies on the active substance).

The new studies submitted in the context of the MRL dossier shall be reported and fully summarised in the study records (including full and sanitized version of any reports used to support the dossier). However, when MRL requests are done after an active substance approval/renewal, it is acknowledged that several studies were already reported and assessed in the context of the approval/renewal of the active substance. Reference can be made to the previous evaluation frameworks (case 1.1) or to studies already in IUCLID that can be reused in the context of the MRL dossier (case 1.2). In this case there is no need to provide full summaries and study reports, nor MSS files for existing metabolism studies that were already reviewed.

In all cases, the background information linked to the existing MRL in EU shall be reported in Section 11.1 (Assessment from other Authorities: Assessments in Europe). See also specific instructions in the dedicated Chapter 11.1 of the present manual.

For import tolerances (IT) requests, it is highlighted that all background information linked to the assessment in the third country (evidence of registration in the exporting country, residue definition in the exporting country, existing MRL in exporting country, legislation in the third country, etc), shall be compiled in Section 11.1 (Assessment from other Authorities: Assessments outside Europe). See also specific instructions in the dedicated Chapter 11.1 of the present manual.

1.1 – If the active substance approval/renewal dossier was not submitted in IUCLID

In the first year of IUCLID being used for EU PPP MRL applications, it is likely that MRL dossiers will be submitted for active substances for which approval/renewal will have been assessed before IUCLID.

For those endpoints that are addressed by studies already assessed in a previous active substance approval/renewal (and not available in IUCLID), it is not requested to provide full summaries and study report(s). Nevertheless, applicant should indicate whether and how each mandatory endpoint is addressed. When those studies are used to address a data requirement, the following approach is proposed:

- **In the endpoint study records**, applicant should use the "data waiving" field with the option "other justification". In the field "justification for data waiving", select "other" and specify "supporting studies assessed previously in another context". In the "remark" field, specify in which context the studies were assessed. Finally, in the chapter "Applicant's summary and conclusion", please discuss and conclude whether the endpoint is addressed in the context of the MRL dossier.

- **In the endpoint summaries:** applicant should highlight whether the Section is addressed in the context to the present application and summarise the new endpoint derived in the context to the present application (e.g. new MRLs proposals, new consumer exposure)

1.2 - If the active substance approval/renewal dossier was previously submitted in IUCLID

This scenario is unlikely to happen in 2021. But should it happen, the active substance IUCLID dataset created in the context on the approval/renewal of the substance can be reused and updated for the context of the new MRL dossier, adding eventually new studies.

It is however required to go through all the endpoints (study records and summaries) and update them if necessary.

CASE 2- Setting import tolerances (IT) for an active substance NOT approved in the EU:

The principles of a stand-alone MRL dossier described in case 1 also apply. In addition to the mandatory endpoints of Section 4 and Section 6, it is sensible that other sections (e.g. Section 5: Toxicological and metabolism studies on the active substance) also need to be addressed by the applicant by means of new studies. Therefore, although not mandatory, the other sections of the table of content should be carefully checked and applicant should evaluate if data or information is needed for all the other Sections.

For all those studies never assessed in the context of EU approval/renewal of the active substance, the endpoint study records should be fully completed, including full and sanitized version of any reports used to support the application.

For import tolerances (IT) requests, it highlighted that all background information linked to the assessment in the third country (evidence of registration in the exporting country, residue definition in the exporting country, existing MRL in exporting country, legislation in the third country, etc), shall be compiled in Section 11.1 (Assessment from other Authorities: Assessments outside Europe). See also specific instructions in the dedicated Chapter 11.1 of the present manual.

CASE 3- MRL dossiers submitted AS PART OF approval/renewal of the active substance:

3.1 - Setting specific maximum residue level(s) or changing current EU MRLs (under the approval/renewal dossier):

3.1-a: If the **GAP(s) relevant for the MRL dossier is/are identical to the representative use(s)** of the approval/renewal dossier, it is **not required to create a separate MRL dossier**. In such case, the MRL proposal(s) can be directly derived in the approval/renewal dossier, highlighting the rationale of the proposed new MRLs in the endpoint summary 6.7.2.

The fact that MRL changes are proposed in the dossier (based on the representative uses assessed in the dossier) may be simply highlighted in the dossier header, as a remark under the purpose of the application:

Purpose of the application



renewal of an active substance for use in plant protection products



including modification of existing MRL(s) based on the representative use(s) |

All background information linked to the existing MRL in EU shall be reported in Section 11.1 (Assessment from other Authorities: Assessments in Europe). See also specific instructions in the dedicated Chapter 11.1 of the present manual.

3.1-b: If the **GAP(s) relevant for the MRL dossier is/are different compared to the representative use(s)** of the approval/renewal dossier, **a separate MRL dossier is required**. Respective GAP documents must be created in the approval/renewal dossier and in the MRL dossier.

In the MRL dossier submitted as part of the approval/renewal, it is not required to submit all the studies already submitted in the approval/renewal dossier. However, the dataset created for the approval/renewal dossier can be reused. The core studies (e.g. storage stability studies, metabolism studies, toxicological studies) related to the approval/renewal of the active substance should be included in the approval/renewal dossier. This can be repeated in the MRL dossier. However, the study records that are specifically linked to the MRL dossier (e.g. studies on magnitude of residues in plant commodities related to GAPs for which MRLs are proposed), should only be included in the MRL dossier.

All endpoint summaries should be addressed separately in each dossier. Typically, the core endpoints of Section 6.1 (storage stability) and Section 6.2 (metabolism in plants, rotational crops and livestock) should be exhaustively summarised in the approval/renewal dossier, considering all the available studies. In the MRL dossier, a copy/paste of these endpoint summaries can be made for these sections (6.1 and 6.2) but a statement as to whether those sections were sufficiently elucidated in the context of the MRL dossier has to be made in the respective endpoint summaries of the MRL dossier. Furthermore, the endpoint summaries of Sections 6.3 (magnitude of residues in plants), 6.4 (magnitude of residues in livestock commodities), 6.5 (effect of processing), 6.7 (proposed residue definitions and MRLs), 6.9 (dietary exposure), 6.10.1 (effect on residue level in pollen and bee products) should be compiled for the specific scenario of the MRL dossier.

3.2 - Evaluation of confirmatory data following review according to Article 12 (under the renewal dossier):

The submission of confirmatory data for art.12 **should be done in a separate MRL dossier**, using the relevant purpose of application in the dossier header of the EU PPP MRL application. This option gives the possibility to the applicant to clearly identify the GAPs to be assessed for the MRL assessment and to report specific studies (e.g. residue trials) outside the core active substance dossier. The GAPs can be the same as the ones assessed in the reasoned opinion on the MRL review or adjusted GAPs, as defined in the

"COMMISSION WORKING DOCUMENT on the evaluation of data submitted to confirm MRLs following the review of existing MRLs"¹¹.

The data gaps identified in article 12 review for the core studies (e.g. metabolism study) should be addressed in the approval/renewal dossier and there is no need to repeat those study records in the MRL dossier. However, applicants should use the respective endpoint summaries of the MRL dossier to clearly state which data gaps of the MRL review were addressed or not addressed. This exercise of checking which data gaps of the MRL review have been addressed should be done in the MRL dossier.

The background information linked to the existing MRL in EU shall be reported in Section 11.1 (Assessment from other Authorities: Assessments in Europe). See also specific instructions in the dedicated Chapter 11.1 of the present manual.

3.3 - Amend existing residue definition (under the renewal dossier):

If the assessment of the renewal of an active substance triggers the need to modify the previous residue definitions, this should be highlighted directly in the endpoint summary of Section 6.7.1 (proposed residue definitions) **of the renewal dossier**. There is **no need to submit a separate MRL dossier** in IUCLID.

When a change of residue definition is proposed, it highlighted that the existing residue definitions shall be reported in Section 11.1 (Assessment from other Authorities: Assessment in Europe). See also specific instructions in the dedicated Chapter 11.1 of the present manual.

3.4- Include an active substance in Annex IV (under the approval/renewal dossier):

If the assessment of the approval/renewal of an active substance leads to a proposal to include an active substance in Annex IV of Regulation 396/2005, this should be highlighted directly in the endpoint summaries (Section 6 and Section 6.7.2) **of the approval/renewal dossier**. In such case, there is **no need to submit a separate MRL dossier** in IUCLID.

3.5- Setting import tolerances (under the approval/renewal dossier):

The submission of an import tolerance (IT) request **should be done in a separate MRL dossier**, using the relevant purpose of application in the dossier header of the EU PPP MRL application. This option gives the possibility to the applicant to clearly identify the GAPS to be assessed for the IT request and to report specific studies (e.g. residue trials) outside the core active substance dossier.

For IT requests, it highlighted that all background information linked to the assessment in the third country (evidence of registration in the exporting country, residue definition in the exporting country, existing MRL in exporting country, legislation in the third country, etc), shall be compiled in Section 11.1 (Assessment from other Authorities: Assessments outside Europe). See also specific instructions in the dedicated Chapter 11.1 of the present manual.

CASE 4 - MRL dossiers submitted to delete maximum residue level(s):

It is acknowledged that a GAP document might not be necessary to submit a request for deleting MRLs. Nevertheless, for sake of completeness, it is required to create a GAP document and to go through all the endpoints, also for this specific purpose. The study waiver can be used for the non-relevant endpoints.

¹¹ https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_mrl_guidelines_sanco-10235-2016.pdf

Letter of Access

In relation to sharing of studies among companies which own separate data and which give data citation rights (Letter of Access) to each other for active renewal purposes, the approach would be as follows.

To indicate that a Company has a letter of access, follow these instructions in relation to the "Data Source (Literature Reference)" compilation:

- In the reference field: indicate the data is linked to a letter of access
- In the data access field: indicate that data submitter has a letter of access
- In the data protection claimed field: indicate data protection was claimed by the data owner
- In the Attached document field: upload the letter of access in the literature reference entity and set type to 'Letter of access'

VALIDATION ASSISTANT

Before submitting a dossier, it is important to run validation assistant to check the dossier is technically complete. The [rules](#) applied are dependent on the information included in the Dossier Header, make sure this is completed correctly. It is important to resolve all validation assistant warnings, this will support the 'admissibility check' of the RMS. If you cannot resolve all the warnings re-run validation assistant, download the excel file and include in this file the justification for not resolving the warning and provide this directly to the RMS. Note missing studies for a specific data requirement/endpoint should be justified using the data waiver section in the relevant endpoint study record.

If the report shows a **business rule failure** (anything starting with BR, e.g. BR_PPP_033) this will prevent the applicant from successfully submitting the dossier. If the report shows a **validation warning** (anything starting with QLT, e.g. QLT_PPP_001) the applicant will be able to submit the dossier but will most likely not pass the admissibility check.

View Dossiers Validate Create dossier

Working context

EU PPP Maximum residue levels (MRL) applica

EU PPP Maximum residue levels (MRL) application

MRL

1 Identity of the product / active substance information* 2

1.1 Identity of the product 1

1.2 Product composition / active substance information* 1

UUID: 2c0676b1-beac-4620-a032-94ef7a9eeca1

Mixture/Product name*

MRL

Public name

None

Legal entity owner*

None None

Producer of plant protection product | Parma | Italy

Third party

None None None

Validation assistant report

Submission checks 1 Quality checks 95

Business rules 1 Completeness check rules 0

Mixture 1 Dossier header

Dossier header is incomplete. European reference number field must be filled in and the format must be UUID.

REPORT GENERATOR

The [Report Generator](#) extracts data from single IUCLID dossiers or datasets and presents these data in structured and user-friendly formats such as PDF, RTF or CSV.

A variety of reports are available by default in IUCLID6 under the section "*Default IUCLID reports*" of Report Generator. These include specific reports for PPP (e.g. the MRL application report) as well as cross-domain reports that can be of interest for PPP applications (e.g. list of attachments, list of references, list of confidentiality claims). To run the reports, please follow the instructions in [section 21 of the IUCLID manual](#).

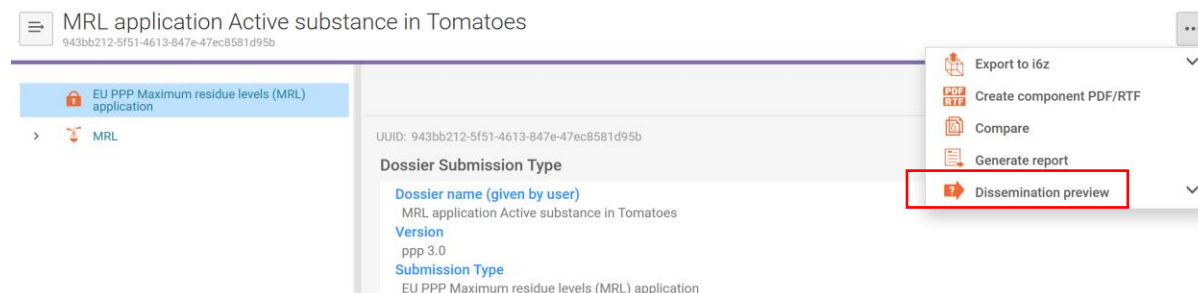
Additionally, the templates to create PPP-specific reports are published in Zenodo Knowledge Junction and new versions including changes and bug fixes are published regularly. These templates can be uploaded in Report Manager as indicated in [section 21.1 of the IUCLID manual](#) and appear under the section "*Uploaded IUCLID reports*" of Report Generator.

In order to support transparency and ensure consistency between submitted and evaluated data, Report Generator should be used to create all documents required for or supporting the evaluation of PPP applications when the corresponding templates become available e.g. GAP table, MRL application report.

PUBLICATION OF DOSSIER

Information not meant to be published, e.g. names of authors of unpublished vertebrate studies, along with information claimed to be confidential, is removed from the dossier, described in the published filter rules. The non-confidential version of the dossier is then made available via the OpenEFSA Portal (<https://open.efsa.europa.eu/>). Dossier filtering is an automated process.

Prior to submitting a dossier the 'View report and create filtered dossier' function under 'Dissemination Preview' can be used to create a filtered dossier.



Although a visual check of the filtered dossier can be useful to check how the published dossier will look, it is recommended to also use the dissemination preview excel file to filter for sensitive documents and check the publication status of each completed field in that document. All fields with the outcome = Published will be visible in the dossier available on the OpenEFSA portal

	A	B	C	D	E	F	G	H
1	entity	sectionName	documentName	field	outcome	sourceDocumentKey	referencedDocumentKey	path
2	Dossier		Efsa basic	EU PPP Basic substance	Not published	de84bbd8-7acf-42db-b09a-c3735c1f94b5/de84bbd8-7acf-42db	DOSSIER/EU_PPP_BASIC_SUBSTANCE	NA
3	Dossier		Efsa basic	EU PPP Basic substance	Not published	de84bbd8-7acf-42db-b09a-c3735c1f94b5/de84bbd8-7acf-42db	DOSSIER/EU_PPP_BASIC_SUBSTANCE	LEI
4	Dossier		Efsa basic	EU PPP Basic substance	Not published	de84bbd8-7acf-42db-b09a-c3735c1f94b5/de84bbd8-7acf-42db	DOSSIER/EU_PPP_BASIC_SUBSTANCE	RE
5	Dossier		Efsa basic	EU PPP Basic substance / Basic substance a	Published	de84bbd8-7acf-42db-b09a-c3735c1f94b5/de84bbd8-7acf-42db	DOSSIER/EU_PPP_BASIC_SUBSTANCE	Be
6	Dossier		Efsa basic	EU PPP Basic substance / Basic substance a	Published	de84bbd8-7acf-42db-b09a-c3735c1f94b5/de84bbd8-7acf-42db	DOSSIER/EU_PPP_BASIC_SUBSTANCE	Be
7	Mixture/Product	1 Identity and applicant	efsa test basic 1	Mixture / Mixture/Product name	Published	69295a37-e087-4416-aa8e-8f840b506c95/de84bbd8-7acf-42db	MIXTURE.MixtureName	
8	Mixture/Product	1 Identity and applicant	efsa test basic 1	Mixture / Legal entity owner	Published	69295a37-e087-4416-aa8e-8f840b506c95/de84bbd8-7acf-42db	MIXTURE.OwnerLegalEntity	
9	Mixture/Product	1 Identity and applicant	efsa test basic 1	Mixture / Contact persons / 1	Not published	69295a37-e087-4416-aa8e-8f840b506c95/de84bbd8-7acf-42db	MIXTURE.ContactPersons[0]	
10	Mixture/Product	1 Identity and applicant	efsa test basic 1	Mixture / Contact persons / 2	Not published	69295a37-e087-4416-aa8e-8f840b506c95/de84bbd8-7acf-42db	MIXTURE.ContactPersons[1]	
11	Mixture/Product	1 Identity and applicant	efsa test basic 1	Mixture / Role in the supply chain / Manufact	Published	69295a37-e087-4416-aa8e-8f840b506c95/de84bbd8-7acf-42db	MIXTURE.RoleInSupplyChain.Manufact	
12	Flexible Record	2 Preparation of the substance for use	Mixture composition.001	Composition (mixture) / Components / 1 / Ne	Published	3fe10c84-2eb8-4c8c-961c-4094f25d-7eb4-412d-af25-767d92b	FLEXIBLE_RECORD/MixtureComposition	
13	Flexible Record	2 Preparation of the substance for use	Mixture composition.001	Composition (mixture) / Components / 1 / Fu	Published	3fe10c84-2eb8-4c8c-961c-4094f25d-7eb4-412d-af25-767d92b	FLEXIBLE_RECORD/MixtureComposition	
14	Flexible Record	2 Preparation of the substance for use	Mixture composition.001	Composition (mixture) / Components / 1 / Ty	Published	3fe10c84-2eb8-4c8c-961c-4094f25d-7eb4-412d-af25-767d92b	FLEXIBLE_RECORD/MixtureComposition	
15	Flexible Record	2 Preparation of the substance for use	Mixture composition.001	Composition (mixture) / Components / 2 / Ne	Published	3fe10c84-2eb8-4c8c-961c-4094f25d-7eb4-412d-af25-767d92b	FLEXIBLE_RECORD/MixtureComposition	
16	Flexible Record	2 Preparation of the substance for use	Mixture composition.001	Composition (mixture) / Components / 2 / Fu	Published	3fe10c84-2eb8-4c8c-961c-4094f25d-7eb4-412d-af25-767d92b	FLEXIBLE_RECORD/MixtureComposition	
17	Flexible Summary	4 Application template, studies, bibliograph	Application template, studies, bibliography and confidentiality requests.001	Not published	523f00ff-59c3-438e-bfce-b8fe32da782b/de84bbd8-7acf-42db-l	FLEXIBLE_SUMMARY/SummaryEvaluatic		
18	Legal entity		Breaking Bad	Legal entity / General information / Legal ent	Published	ECHA-fc3c9382-ed4a-4990-bdf2-70041a08dd23/de84bbd8-7acf-42db	LEGAL_ENTITY.GeneralInfo.LegalEntityNi	
19	Legal entity		Breaking Bad	Legal entity / General information / Address	Published	ECHA-fc3c9382-ed4a-4990-bdf2-70041a08dd23/de84bbd8-7acf-42db	LEGAL_ENTITY.GeneralInfo.ContactAddr	
20	Legal entity		Breaking Bad	Legal entity / General information / Address	Published	ECHA-fc3c9382-ed4a-4990-bdf2-70041a08dd23/de84bbd8-7acf-42db	LEGAL_ENTITY.GeneralInfo.ContactAddr	
21	Legal entity		Breaking Bad	Legal entity / General information / Address	Published	ECHA-fc3c9382-ed4a-4990-bdf2-70041a08dd23/de84bbd8-7acf-42db	LEGAL_ENTITY.GeneralInfo.ContactAddr	
22	Legal entity		Breaking Bad	Legal entity / General information / Address	Published	ECHA-fc3c9382-ed4a-4990-bdf2-70041a08dd23/de84bbd8-7acf-42db	LEGAL_ENTITY.GeneralInfo.ContactAddr	
23	Legal entity		Breaking Bad	Legal entity / General information / Address	Published	ECHA-fc3c9382-ed4a-4990-bdf2-70041a08dd23/de84bbd8-7acf-42db	LEGAL_ENTITY.GeneralInfo.ContactAddr	
24	Legal entity		Breaking Bad	Legal entity / General information / Address	Published	ECHA-fc3c9382-ed4a-4990-bdf2-70041a08dd23/de84bbd8-7acf-42db	LEGAL_ENTITY.GeneralInfo.ContactAddr	
25	Reference substance		Water	Reference substance / Reference substance r	Published	8340efb6-efea-4086-9cb6-4667854d269b/de84bbd8-7acf-42db	REFERENCE_SUBSTANCE.ReferenceSubst	
26	Reference substance		Water	Reference substance / IUPAC name	Published	8340efb6-efea-4086-9cb6-4667854d269b/de84bbd8-7acf-42db	REFERENCE_SUBSTANCE.IupacName	
27	Reference substance		Water	Reference substance / Inventory / CAS numbr	Published	8340efb6-efea-4086-9cb6-4667854d269b/de84bbd8-7acf-42db	REFERENCE_SUBSTANCE.Inventory.CASN	
28	Reference substance		Bis(2-(2-methoxyethoxy)ethyl) etl	Reference substance / Reference substance r	Published	4094f25d-7eb4-412d-af25-767d92b5cee0/de84bbd8-7acf-42db	REFERENCE_SUBSTANCE.ReferenceSubst	
29	Reference substance		Bis(2-(2-methoxyethoxy)ethyl) etl	Reference substance / IUPAC name	Published	4094f25d-7eb4-412d-af25-767d92b5cee0/de84bbd8-7acf-42db	REFERENCE_SUBSTANCE.IupacName	
30	Reference substance		Bis(2-(2-methoxyethoxy)ethyl) etl	Reference substance / Inventory / inventory i	Published	4094f25d-7eb4-412d-af25-767d92b5cee0/de84bbd8-7acf-42db	REFERENCE_SUBSTANCE.Inventory.inven	
31	Reference substance		Bis(2-(2-methoxyethoxy)ethyl) etl	Reference substance / Inventory / CAS numbr	Published	4094f25d-7eb4-412d-af25-767d92b5cee0/de84bbd8-7acf-42db	REFERENCE_SUBSTANCE.Inventory.CASN	
32	Contact		kon; Breaking Bad		Not published	d4e869be-ba1f-45dd-bba7-4b2a074a6eb2/de84bbd8-7acf-42db	CONTACT	
33	Contact		tds; Breaking bad		Not published	dbc9040f-57c4-471d-af76-1760772e417f/de84bbd8-7acf-42db	CONTACT	

Note! The Dissemination preview works on **dossiers** and **not datasets**.

If report generator is being used to prepare reports for inclusion in the dossier a sanitised version of the report can be created by running report generator on the filtered dossier.

THE SUBMISSION PORTAL

When preparing a dossier for submission please ensure that your dossier is compliant with the published portal submission rules. European Food Safety Authority. (2021). IUCLID submission rules for PPP dossiers (1.0). Zenodo. <https://doi.org/10.5281/zenodo.5141356>

Ensure the correct legal entities are assigned in the datasets and in the dossier header. During the submission process the “DOSSIER EU PPP MRL application” subject legality is checked. The owner of the dossier must be indicated in the **Mixture document**. If a third party consultant has prepared the dossier the legal entity of the consultant must also be indicated (see below).

UUID: 3541e6f9-4f20-4e61-9957-501c4deab044

Mixture/Product name*

TOPIK_ACR


Public name

Product A

Legal entity owner*


 Producer of plant protection product | Parma | Italy

Third party

 Consultant ABC | Roma | Italy | 98645235438 465985

During the processing of dossier submissions in the portal the information on the active substance is taken from the MIXTURE.composition document. It is essential this is filled in before you submit your first dossier. For every submission there is a check that the Legal Entity and the Active Substance are the same for a given European Reference Number.

Ensure that the submitter has the role of Submission Portal Manager: If the submitter is a user of the Legal Entity owner organisation, ask the Legal Entity Manager to give the user the Submission Portal Manager role.

Username	Name	Email	User roles
 EFSA_DGSANTE	EFSA Pilot DG SANTE	iuclid6@echa.europa.eu	IUCLID Beta Full Access Submission Portal Manager

If the submitter is a third-party consultant then they need to ask the Legal Entity Manager of the owner/lead applicant organisation to add the submitter as a foreign user with the role Submission Portal Manager

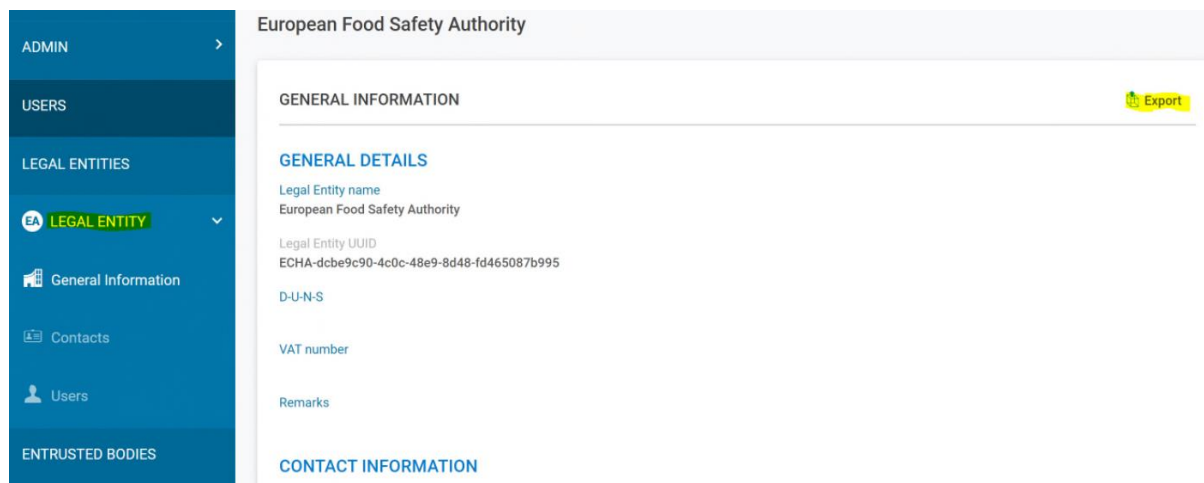
Please see this short explanatory video for more information on foreign users:

<https://www.youtube.com/watch?v=YH5edrjBkxI&list=PLGDvgn1aAEEbL7dMwwWAjoAiK-DgoJmZrY&index=9>

Please note that by submitting the dossier as a foreign user this person only has access to the submission report in the submission portal and would therefore see the substance name and other basic information. There is no follow-up communication within IUCLID/the submission portal as all subsequent steps are managed by email using the main contact person(s) for the dossier i.e. the third party consultant.

If the dossier is being prepared by an organisation other than the Legal entity owner the recommended approach is that the Legal entity owner exports their legal entity details and provides them to the organisation authoring the dossier. This legal entity information can be exported from within ECHA's Identity Management solution (IDM) and not from within IUCLID. Exporting from IDM ensures alignment with Legal Entity in ECHA IDM when the dossier is submitted.

Exporting the Legal Entity: To view the details, please visit: <https://ulem.echa.europa.eu/ui/dashboard>. Log in with a user account that has the Legal Entity Manager role assigned. Navigate to the Legal Entities tab (on the left) and from the updated central page select the legal entity of the dossier. From the page, find the Export button to export the legal entity details.

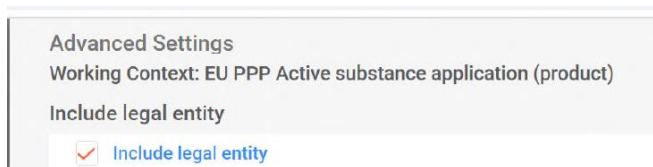


The Legal Entity information will be exported as a IUCLID i6z file which you can then import in IUCLID.

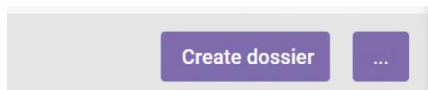
Importing the Legal Entity in IUCLID: The organisation authoring the dossier should add this legal entity to their Legal Entity inventory and use this legal entity in the dossier. The easiest way to import the legal

entity details is from the IUCLID dashboard landing page and to import it directly¹², i.e. either by dragging the file onto the import box or by browsing for it.

If the Legal entity owner is not in the dossier header, you will need to recreate the dossier and ensure the 'Include legal entity' is checked from the advanced settings of the 'Create dossier' function.




The advanced settings can be accessed from the 'three dots' button




Proceed to submission: If you are using the [IUCLID 6 ECHA Cloud services](#) to author the dossier, simply use 'Create Dossier' and 'Proceed to submission' function. Then follow the submission portal steps listed below. This is the recommended approach for MRL dossiers.

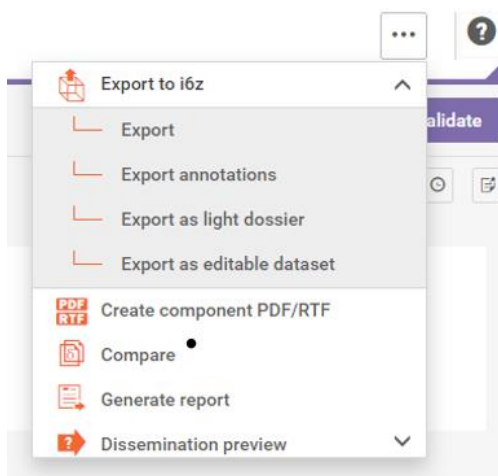


 Dossier creation was completed successfully.



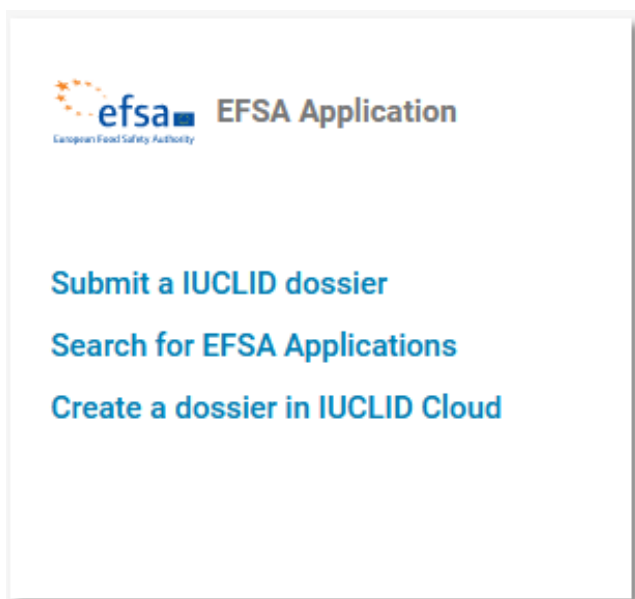
Export dossier: For Client or Server versions of IUCLID the dossier should be exported as an **i6z file** (the ZIP format for IUCLID). The **export** is accessed from the top level of the application window.

¹² It can also be imported through the Configuration management page () and using the Legal Entity section of Inventory Manager



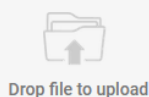
For the first submission of a dossier the standard '**Export**' function should be used.

The submission portal: Log in to the submission portal and upload the i6z file. Do not forget to switch legal entity if you are submitting for another organization. Please note the speed of your submission will be dependent on the size of your dossier and the upload speed of your internet connection. It is important that you check the submission report for your dossier submission. If the Submission event in the report shows "Dossier received by EFSA" then your submission is complete. If the Submission event is 'Dossier failed validation checks' your dossier has been rejected. In this case, 'View Validation report' to identify the issues with your submission, update the dossier and repeat the submission process. **Once a valid submission is received EFSA, RMS and EC are informed via an automatic e-mail. Confirmation of IUCLID submissions via email or letter is NOT necessary as the automatic email notification is sufficient as submission proof. Any cover letters should be added in the respective IUCLID sections (see paragraph above). Dossier submissions via any route other than the Submission Portal will not be accepted for evaluation.**



Please upload your dossier for submission. Only i6z files are permitted for upload.

Note that currently only **PCN, SCIP and PPP dossiers** can be submitted.



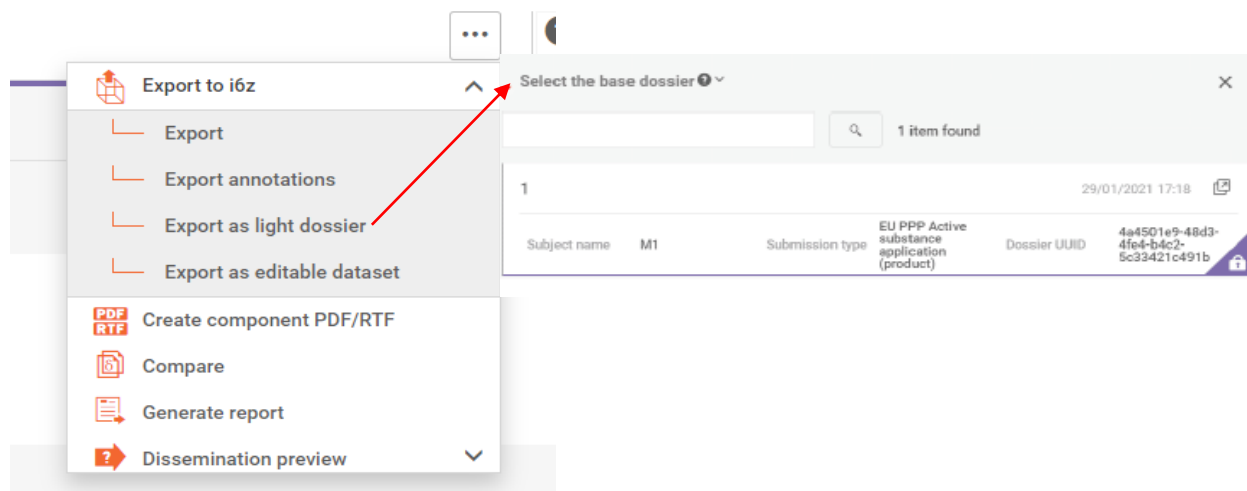
or

Browse

Submission events

04/01/2022 16:02 Dossier submitted
04/01/2022 16:02 Dossier passed validation checks
04/01/2022 16:02 Dossier received by EFSA

Export as a light dossier (preferred option for resubmissions): This is the preferred option in case of a resubmission since the file that is generated is always smaller than the full dossier. A light dossier includes the full IUCLID dossier with the exception of the attachments that had been provided previously (in the base dossier) and have not been modified.



This option can also be used to sequentially load a large dossier if issues importing a dossier into the submission portal are encountered. The first submission should include as a minimum the Mixture dataset, a completed mixture composition dataset including the active substance component with a completed substance and reference substance document. Once this dossier has 'Dossier received by EFSA' status additional datasets (e.g. metabolites, other representative formulations) can be linked to the main Mixture dataset and exported as 'light dossier' until the full dossier has been submitted.

RESUBMISSION OF APPLICATIONS

Applications should be prepared in accordance with the relevant legal provisions in place and **all data should be provided as complete as possible already in the initial dossier**. Nevertheless, after submission of an application, applicants **may be required to re-submit the IUCLID dossiers** in the following cases:

1. RE-SUBMISSIONS FOLLOWING REQUEST FROM RELEVANT REGULATORY BODY (RMS/EMS/EC/EFSA).

In the cases foreseen by the legislation, applicants may be required to submit an updated IUCLID dossier upon specific request by the relevant regulatory body.

It is important to highlight that the relevant regulatory body will only consider in their assessments dossier versions resulting from a specific request. **Versions submitted by the applicant without having been requested, will not be considered taken into consideration in the assessment phase.**

When sending requests for updates to the APPL, the relevant regulatory body should always inform EFSA (FDP@efsa.europa.eu).

For clear identification of the dossier, in addition to the EU reference number, the UUID of the dossier/s should be stated in each report submitted by the applicant.

Before re-submission, applicants should **always check if a newer IUCLID release is available**, to ensure a valid submission taking into account potential new business rules and validation checks included in the latest IUCLID update.

Any change in the dossier **should be limited to addressing specific requests from the relevant regulatory body**.

The applicant should respect the confidentiality decisions previously agreed with EFSA and submit new **confidentiality claims limited to the newly provided information only**.

1.1 Request for update during admissibility check

In the context of the admissibility check, the relevant regulatory body must ensure the compliance of the application with the requirements of the applicable regulations.

The admissibility check includes:

- 1) the **completeness check** against the **data requirements**
- 2) the check on the **Notification of Studies**
- 3) a light **check** on the presence of **key elements in confidentiality requests** submitted by the applicant
 - a. sanitised personal data
 - b. for confidentiality requests submitted, background documents and justification

For each of the checked points, the relevant regulatory body may ask the applicant to provide additional information¹³. It is important to highlight that the relevant regulatory body should judge the importance of the missing data and whether this will have an impact on their admissibility decision (e.g in case of missing studies), leading to a decision of non-admissibility. The relevant regulatory body should also consider that a first version of the dossier will be published “as is” immediately after the declaration of admissibility.

1.2 Request for update of confidentiality claims after declaration of admissibility

In the context of the confidentiality check performed after declaration of admissibility, the applicant may be required to submit an updated version of the IUCLID dossier following the decision taken on confidentiality claims submitted.

1.3 Request for update during application evaluation

Once an application has been declared admissible, in the context of the application evaluation, the relevant regulatory body may ask the applicant to provide additional information¹⁴. This additional information must be submitted in the form of an updated dossier in IUCLID.

1.4 Request for update of confidentiality claims after conclusion of the evaluation

In the context of the confidentiality check performed after the conclusion of the evaluation process, the applicant may be required to submit an updated version of the IUCLID dossier.

2. SPONTANEOUS RE-SUBMISSIONS

In case of **changes in the administrative information** of applications, the applicant should inform relevant regulatory body via email and update the IUCLID dossier (update limited to specific administrative change).

[Confidentiality of dossiers submitted via IUCLID](#)

CATEGORIES OF IUCLID FIELDS AND ASSOCIATED FILTER RULES

The information contained in IUCLID fields is automatically disclosed by EFSA, in accordance with the published filtering rules, once the application has been deemed admissible or valid. Confidentiality requests submitted by applicants on MRL dossiers are assessed by **EFSA**. Confidentiality requests are permitted only with regard to fields that correspond to the items listed in Article 39(2) of Regulation EC No 178/2002. These are:

¹³ According to Art 9 of Regulation (EC) No 1107/2009, for **new active substance applications and request for amendment of approval conditions**

According to Art 8 of Regulation (EU) 2020/1740 for **renewal applications**

According to SANCO Guidance on MRL setting procedure (SANTE/2015/10595 Rev. 6.1), for **MRL applications**

According to Article 32b of Regulation (EC) No 178/2002 as amended by Regulation (EU) 2019/1381, for **all applications**

¹⁴ According to Art 11 of Regulation (EC) No 1107/2009 for **new active substance applications**

According to art 11 of Regulation (EU) 2020/1740, for **renewal applications**

According to SANCO Guidance on MRL setting procedure (SANTE/2015/10595 Rev. 6.1) for **MRL applications**

According to Article 32b of Regulation (EC) No 178/2002 as amended by Regulation (EU) 2019/1381, for **all applications**

- a. the manufacturing or production process, including the method and innovative aspects thereof, as well as other technical and industrial specifications inherent to that process or method, except for information which is relevant to the assessment of safety;
- b. commercial links between a producer or importer and the applicant or the authorisation holder, where applicable;
- c. commercial information revealing sourcing, market shares or business strategy of the applicant; and
- d. quantitative composition of the subject matter of the request, except for information which is relevant to the assessment of safety.

Note that if your confidentiality request has been accepted for an active substance dossier you should mention this in the justification box pertaining to your MRL confidentiality request by referring to the relevant confidentiality decision, including the legal ground invoked and the justification provided by the applicant as well as the reasoning relied on by the competent authority concerned to accept that request, and this will be taken into account during the confidentiality assessment. However, this does not absolve applicants from the requirement to provide a verifiable justification supporting their confidentiality request in compliance with Article 9(4)(b) and Article 10 of EFSA's Practical Arrangements concerning transparency and confidentiality and having regard to the practical instructions set out in this Manual.

EFSA will assess each confidentiality request, by performing an individual examination of the information claimed as being confidential by the applicant and of the relevant justification provided. Confidentiality requests are processed by EFSA in accordance with EFSA's [Practical Arrangements concerning transparency and confidentiality](#). Where EFSA adopts a confidentiality decision rejecting partially or entirely the confidentiality requests, a second version of the dossier is to be published after the completion of the confidentiality assessment and in accordance with the confidentiality decision.

Each IUCLID field has been assigned a **filter rule** (see column C in the "Filter rules" sheet of the [filtering excel file](#)).

There are three main rule types:

- **"PUBLISHED"**: information provided under fields subject to this filter rule are published by default (for example, information provided in "Attached(Sanitised)DocumentsForPublication" and "LegalEntity" (hence, **no personal information should be provided in "LegalEntity"** – more details are available [here](#))).
- **"NOT_PUBLISHED"**: information provided under fields subject to this filter rule are NOT published by default (for example, information provided under "AttachedConfidentialDocument"¹⁵ and "AttachedStudyReport" and personal contact details).
- **"UNLESS_CONF"**: if the CBI flag has been set to request confidentiality in an entity, document, section, row or field, the field(s) with the **"UNLESS_CONF"** rule will be redacted during the filtering and publication process. In general; **"UNLESS_CONF"** applies to endpoint study records / flexible records and is rarely used in endpoint/flexible summaries. The underlying rationale is that endpoint

15 With the exception of the field with the path description "FLEXIBLE_RECORD.SubstanceComposition.GeneralInformation.AttachedDescription.AttachedDocument" which is published in accordance with the filter rule **"PUBLISHED"**, since no corresponding field with the field name "Attached(Sanitised)DocumentsForPublication" exists. This does not mean that information regarding the description of the substance composition cannot be claimed confidential.

summaries contain information that is key to the safety assessment and should not include confidential information. Please note that fields subject to the "**UNLESS_CONF**" rule will be published on the OpenEFSA Portal, unless a confidentiality request has been submitted by the applicant and accepted by EFSA. Information on additional specific rules applied to a limited set of fields (e.g. redaction of author names) is available in the published filter rule excel file.

Before submitting a confidentiality request, always verify whether the relevant field(s) you intend to claim confidential can be subject to a confidentiality request, by consulting the filter rules for MRL IUCLID dossiers. Any confidentiality request submitted in relation to fields not governed by the filter rule 'UNLESS_CONF' will, in principle, be automatically rejected as inadmissible.

SUBMISSION OF CONFIDENTIALITY REQUESTS IN IUCLID

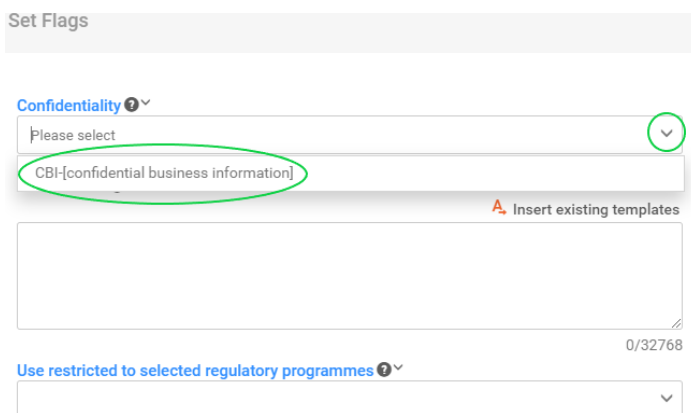
Confidentiality requests regarding confidential business information ("CBI")

To request confidential treatment for CBI contained in an IUCLID entity, document, section, row or field, including any attachment provided thereunder:

- i. set the **CBI flag** by clicking on
 - the confidentiality flag pertaining to the relevant entity, document, section, row or field



- and the drop-down menu selecting the option "**CBI –[confidential business information]**".



As a general rule, always select the most specific confidentiality flag. For example, if you wish to submit a confidentiality request regarding molecular and structural information in the reference substance, do not use the confidentiality flag related in the IUCLID document where the reference substance is *referenced*, i.e. the **secondary source**.

Set values X

CBI
 EU: PPP

Reference substance
 Metabolite C

Typical concentration
None

Concentration range ? ^ ? ^

v

<=

v

press Esc to close

Remarks
Dummy data

Instead, you should use the confidential flag available for this specific information in the **primary source**, i.e. the reference substance entity.

None
 None

UUID: b9ee1a81-1f00-49bd-b0b2-48756852518f

Reference substance name*
Metabolite C

IUPAC name
None

Description
None

Inventory

Inventory number
None

No inventory information available - Justification
None

CAS number
None

CAS name
None

Synonyms

Synonyms + New item 📁 Import file v

#	Identifier	Identity	Remarks	Actions

Molecular and structural information CBI None

Molecular formula
None

Molecular weight
None

Do not submit a confidentiality request for fields which do not have the UNLESS_CONF rule as this will have no impact on the filtering applied for dossier publication.

- ii. and insert a **justification** for each confidentiality request in compliance with the standards set out in the Practical Arrangements. Note that you should not use the “*Insert existing templates*” function, since the available template is not currently tailored to the requirements applicable to dossiers submitted under the EU legal framework governing pesticides.

Justification ? v

~~A Insert existing templates~~

0/32768

Instead, please fill in the justification field in line with the requirements set out in EFSA's [Practical Arrangements concerning transparency and confidentiality](#). You can find further details on the interpretation of the provisions in EFSA's Practical Arrangements in the [Question and Answers document](#) prepared by EFSA.

Where a confidentiality flag covers multiple fields or attachments in an IUCLID entity, document, section or row you are expected to insert a **separate justification** in the text box for each individual field/attachment containing information for which you request confidential treatment. In practice, this may imply that you have to insert several separate justifications in the justification text box of the confidentiality flag. If the information claimed confidential concerns the same subject, e.g. percentage value of constituent xyz in the active substance, you may insert a single justification in the justification text box with regard to all fields/attachments covering the same item of information. However, this does not absolve you from the requirement to **clearly identify** each field or attachment, including the exact page, paragraph and line or part thereof, as appropriate, containing information covered by the same justification, see the template justification below. Where the same item of information is provided in different sections or documents in the dossier **each confidentiality flag must be set (to allow automated filtering)** and a complete justification must be provided in the justification text box. In this case the completed justification template text can be reused.

Template justification (note that those parts of the template marked in **green** indicate the action needed from applicants to complete the justification)

I. Identification of the relevant item: The item claimed confidential can be found in the field(s) [indicate the IUCLID path of the field(s) and, in case of attachment(s), also the file name of each attachment, where the information considered confidential is located. For open text fields, also add a reference to the exact paragraph, line and part thereof, as appropriate, where the piece of information claimed confidential can be found. For attachments, also add a reference to the exact page, paragraph and line and part thereof, as appropriate, where the piece of information claimed confidential is located. Nota bene: as explained above, if you would like to insert only one justification in the justification field with regard to several fields/attachments because they concern the same item of information, e.g. percentage value of constituent xyz in the active substance, you must **clearly identify** each single field or attachment, as explained above, containing information covered by the same justification].

II. Legal basis: [insert a brief and precise description of the item of information considered confidential, e.g. "*the percentage value of constituent xyz of the active substance*" and insert the legal basis under which you would like to request the item of information concerned to be kept confidential, e.g. "*Article 39(2)(d) of Regulation (EC) No 178/2002*"].

III. Rationale for award of confidential status: I hereby declare that the item claimed confidential should be granted confidential status because it meets the following cumulative requirements:

- a)** it is not publicly available;
- b)** it is eligible or worthy legal protection and has not been acquired in an unlawful manner;
- c)** it does not constitute environmental information within the meaning of Article 2(1)(d) of Regulation (EC) No 1367/2006; and
- d)** its disclosure would be liable to cause potential harm to a significant degree because:
 - i.** it would result in financial damage corresponding to at least 5% of my gross annual turnover/earnings, and
 - ii.** the information is not older than 5 years

[provide the rationale for the award of confidential status to the item of information covered by your confidentiality request. **Nota bene:** if you are unable to declare significant harm by reference to the reasons under d) (i) and (ii), other specific and actual reasons may be provided to substantiate why public disclosure may still potentially harm your interests to a significant degree. The rationale for the award of confidential status to the item of information covered by your confidentiality request must be **accurate** and **truthful** reflecting the applicant's good faith in light of applicable legal requirements and guidance documents. Note that the EFSA will perform a **detailed individual examination** of the justification provided and will reject any confidential request supported by a justification that that does not meet all of the cumulative requirements set out in Article 10 of EFSA's Practical Arrangements concerning transparency and confidentiality. Moreover, EFSA reserves its right for any action, as appropriate, to address instances where incorrect or inaccurate information was provided wilfully or negligently].

Examples of compliant¹⁶ justifications

A. Justification regarding the same subject contained in several fields subject to the same confidentiality flag

Set Flags

Confidentiality ?

CBI

X

Justification ?

Insert existing templates

I. Identification of the relevant item: The item claimed confidential can be found in the fields "FLEXIBLE_RECORD.SubstanceComposition.Constituents.Constituents.0.ProportionTypical", "FLEXIBLE_RECORD.SubstanceComposition.Constituents.Constituents.0.Concentration" and "FLEXIBLE_RECORD.SubstanceComposition.Constituents.Constituents.0.Remarks" (third paragraph, line 2-3).

II. Legal basis: The item claimed confidential consists in the percentage values specifying the concentration of the constituent in the active substance and is considered to fall within the scope of Article 39(2)(d) of Regulation (EC) No 178/2002.

III. Rationale for award of confidential status: I hereby declare that the item claimed confidential should be granted confidential status because it meets the following cumulative requirements: a) it is not publicly available, b) it is eligible or worthy legal protection and has not been acquired in an unlawful manner, c) it does not constitute environmental information within the meaning of Article 2(1)(d) of Regulation (EC) No 1367/2006 and d) its disclosure would be liable to cause potential harm to a significant degree because (i) it would result in financial damage corresponding to at least 5% of my gross annual turnover and (ii) the information is not older than 5 years.

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B. Justification regarding different items of information contained in several fields and attachments, including literature reference, subject to the same confidentiality flag

¹⁶ The term "compliant" is used in a procedural sense here having regard to the requirement to provide a "verifiable justification" as reflected in Article 9(4)(b) of EFSA's practical arrangements concerning transparency and confidentiality and Article 5(2)(b) of EFSA's practical arrangements concerning confidentiality in accordance with Article 7(3) and 16 of Regulation (EC) No 1107/2009, whichever is applicable.

Confidentiality ?

CBI

X

Justification ?

Insert existing templates

1)

I. Identification of the relevant item: The item claimed confidential can be found in the field "ENDPOINT_STUDY_RECORD.AnalyticalMethods.MaterialsAndMethods.TestMaterials.SpecificDetailsOnTestMaterialUsedForTheStudyConfidential" (paragraph 2, last line) and in two study reports referenced in this endpoint study record as literature references, (i) the study report "XYZ1", on page 14, paragraph 5, line 3-5 (until the end of the sentence) and (ii) the study report "XYZ2" on page 2, figure 1 and page 6, table 2).

II. Legal basis: The item claimed confidential consists in information concerning detailed contractual arrangements between a producer and the applicant and is considered to fall within the scope of Article 39(2)(b) of Regulation (EC) No 178/2002.

III. Rationale for award of confidential status: I hereby declare that the item claimed confidential should be granted confidential status because it meets the following cumulative requirements: a) it is not publicly available, b) it is eligible or worthy legal protection and has not been acquired in an unlawful manner, c) it does not constitute environmental information within the meaning of Article 2(1)(d) of Regulation (EC) No 1367/2006 and d) its disclosure would be liable to cause potential harm to a significant degree because (i) it would result in financial damage corresponding to at least 5% of my gross annual turnover and (ii) the information is not older than 5 years.

2)

I. Identification of the relevant item: The item claimed confidential can be found in the fields "ENDPOINT_STUDY_RECORD.AnalyticalMethods.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables.OtherInformation" (table 2),

"ENDPOINT_STUDY_RECORD.AnalyticalMethods.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables.OtherInformation" (figure 1) and

"ENDPOINT_STUDY_RECORD.AnalyticalMethods.OverallRemarksAttachments.AttachedBackgroundMaterial.0.AttachedDocument" (attached file "Background doc XYZ1", page 5, paragraph 6, line 3-6 and attached file "Background doc XYZ2", page 7, paragraph 5, line 5-8 and paragraph 7, line 1-3).

II. Legal basis: The item claimed confidential consists in the percentage values specifying the concentration of the constituent in the active substance and is considered to fall within the scope of Article 39(2)(d) of Regulation (EC) No 178/2002.

III. Rationale for award of confidential status: I hereby declare that the item claimed confidential should be granted confidential status because it meets the following cumulative requirements: a) it is not publicly available, b) it is eligible or worthy legal protection and has not been acquired in an unlawful manner, c) it does not constitute environmental information within the meaning of Article 2(1)(d) of Regulation (EC) No 1367/2006, including in particular Article 6(1) thereof and d) its disclosure would be liable to cause potential harm to a significant degree because (i) it would result in financial damage corresponding to at least 5% of my gross annual turnover and (ii) the information is not older than 5 years.

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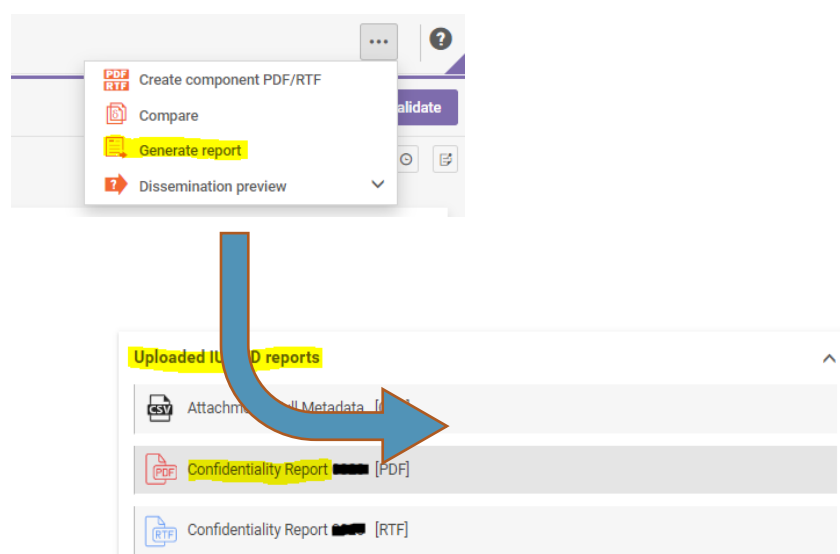
Before submitting your dossier, EFSA urges you to verify that your justification is fully readable and understandable. The justification field is a simple free text field which does not recognise most formatting options (e.g. underlining, putting text in bold or italics), in particular table structures. Therefore, applicants are strongly advised against copy-pasting information from tables, including, e.g., word or excel tables, into the IUCLID justification field.

In principle, only the justification box can be used to support your confidentiality request. This means that confidentiality requests must be adapted to the justification box and, to the extent possible, to the character limit.

It is only in **exceptional circumstances** where the number of requests and their justification is so long that it cannot fit in the character limit that an attachment can be used to ensure the part of the justification exceeding the character limit may be provided. Note that the use of an attachment is not acceptable, if the length of the justification is compatible with the character limit or is due to the unnecessary repetition of the same text or of quotation of text from relevant legal acts EFSA has already access to.

If in these exceptional cases, an attachment is provided to complement the justification provided in the justification box, it must be provided as a confidential document in the field "*AttachedConfidentialDocument*" under the IUCLID summary, record or section containing the field or attachment to which the confidentiality justification relates. The text in the justification box must also expressly refer to the attachment, with the name of the attachment and the field where it can be found.

To verify all your confidentiality requests, you can generate the IUCLID report "*Confidentiality report*" under "*Uploaded IUCLID reports*":



The Confidentiality report allows the applicant to identify:

- i. the IUCLID sub-sections and/or fields where a confidentiality flag has been set (with an hyperlink), and
- ii. the corresponding justification provided.

CORRECT SUBMISSION OF ATTACHMENTS IN IUCLID

For each attachment submitted there must *always* be a public version uploaded under the field "*Attached(Sanitised)DocumentsForPublication*". If no confidentiality request is submitted on the attachment, no other version of the attachment than the public version needs to be submitted. However, if a confidentiality request is made on the attachment, the applicant must *also* upload a confidential version of the attachment under the field reserved for confidential attachments "*AttachedConfidentialDocument*".

with all information claimed confidential boxed or earmarked (but *not blackened*) in the confidential attachment. Moreover, in that case, content- and layout-wise, the public version of your attachment must be fully identical with the confidential version, save for information that is duly blackened in line with your confidentiality request(s).

For published literature where *copyright is not owned for reproduction the original publication should be provided in the "AttachedConfidentialDocument"* field and a bibliographic citation provided in the "Attached(Sanitised)DocumentsForPublication"

To verify whether you have submitted your attachments correctly, you are recommended to generate the IUCLID Attachment report for dataset or dossier



List of Attachments for datasets only [CSV]



List of Attachments for dossiers only [CSV]

RIGHT TO BE HEARD AND MEANS OF REVIEW

Applicants have several opportunities to participate in the decision-making process regarding confidentiality requests made on their renewal dossiers and to put forward their views and observations, namely:

- a. prior to the adoption of a decision rejecting the applicant's confidentiality request in part or in full, by being consulted on the draft decision;
- b. after the adoption of a confidentiality decision, by making use of the possibility of submitting a confirmatory application;
- c. after the adoption of a decision on a confirmatory application, by having the possibility of bringing an action for annulment against the decision on the confirmatory application pursuant to Article 263 of the Treaty on the Functioning of the European Union.¹⁷

A comprehensive description of applicable procedures and provisions is available in EFSA's [Practical Arrangements concerning transparency and confidentiality](#)¹⁸.

Note: An addendum to this manual may be published with further details on the treatment of Personal Data after approval by the PSN IUCLID subgroup. In the interim period the CBI feature can be used to indicate the presence of personal data.

To insert (a) confidentiality request(s) regarding personal data (PD), we encourage you to use the below template PD request(s)¹⁹ depending on the applicable scenario(s). Copy-paste the applicable template(s) into the justification box and supplement it/them with specific information, as appropriate. **Scenario 1, applicable to information classified as personal data "by its very nature"**: the information concerned by the confidentiality request qualifies as personal data within the meaning of Article 3(1) of

¹⁷ Consolidated version of the Treaty on the Functioning of the European Union. OJ C 326, 26.10.2012, p. 47–390.

¹⁸ See *supra* note 21.

¹⁹ Note that a revised version of the template PD requests may be published as part of the Addendum in keeping with the technical solution deployed for PD requests.

Regulation (EU) 2018/1725 by its very nature (this applies, for instance, to the name of the author of an unpublished study report, personal contact details, handwritten signatures etc.).

I would like to request confidential treatment for information contained in or related to study report with report number NNNN (YYYY) titled "XYZ1" / document (YYYY) titled "XYZ1" [please provide the particulars of the study report/document concerned allowing EFSA to identify it] that qualifies as personal data within the meaning of Article 3(1) of Regulation (EU) 2018/1725 by its very nature.

I. Category of personal data: The information concerned covers the following information in an unpublished document:

a) name(s) of (a) natural person(s) other than those referred to in Article 39e(1) of Regulation (EC) No 178/2002; and/or

b) (an) address(es) of (a) natural person(s); and/or

c) handwritten signature(s); and/or

d) personal contact details.

[select whichever of the options among option a), b), c) and/or d) that is applicable and copy-paste it into the justification field. If you select option d) further specify whether it concerns (an) email address(es), (a) direct phone number(s) and/or (a) fax line(s) of (a) natural person(s)].

II. Identification of the personal data:

[indicate for each page the exact paragraph(s) and line(s) or part(s), as appropriate, where the personal data in question is/are located. In that context always specify the category of the personal data, as per those categories selected under I.].

Example of correct PD request under scenario 1

Confidentiality ?

CBI

X

Justification ?

A. Insert existing templates

I would like to request confidential treatment for information in the study report with report number 0119298 (1999) titled "Magnitude of residues of active substance xyz in or on wheat in France (North)" that qualifies as personal data within the meaning of Article 3(1) of Regulation (EU) 2018/1725 by its very nature.

I. Category of personal data: The information concerned covers the following information in an unpublished document:

- a) names of natural persons other than those referred to in Article 39e(1) of Regulation (EC) No 178/2002; and
- c) handwritten signatures.

II. Identification of the personal data:

- Page 6: name of natural persons other than those referred to in Article 39e(1) of Regulation (EC) No 178/2002 (paragraph 6, line 2);
- Page 8: name of natural persons other than those referred to in Article 39e(1) of Regulation (EC) No 178/2002 (footnote 7);
- Page 9: handwritten signature (after 5th paragraph);
- Page 12: handwritten signature (after 6th paragraph);
- Page 14: names of natural persons other than those referred to in Article 39e(1) of Regulation (EC) No 178/2002 (paragraph 6, line 2 and paragraph 7, line 3);
- Page 23: handwritten signature (after 9th paragraph).

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Scenario 2, applicable to more specific information belonging to the concept of personal data:

the information concerned by the confidentiality request constitutes personal data within the meaning of Article 3(1) of Regulation (EU) 2018/1725 in light of the specific circumstances pertaining to that information (names and addresses of test facilities, GPS coordinates of trial sites etc.).

I would like to request confidential treatment for information contained in or related to study report with report number NNNN (YYYY) titled "XYZZ" / document (YYYY) titled "XYZZ" [please provide the particulars of the study report/document concerned allowing EFSA to identify it] which qualifies as personal data within the meaning of Article 3(1) of Regulation (EU) 2018/1725 in light of the specific circumstances pertaining to that information.

I. Nature of information: The information concerned covers [indicate the type of information concerned, e.g. name and address of a test facility] in an unpublished document.

II. Identification of the information: [indicate for each page the exact paragraph(s) and line(s) or part(s), as appropriate, where the information in question is/are located. In that context always specify the type of information concerned, e.g. name and address of a test facility].

III. Specific circumstances: The information concerned must be qualified as personal data due to the specific circumstance(s) pertaining to that information disclosure of which would enable the identification of (a) natural person(s). The specific circumstance(s) consist(s) in [provide a description of specific circumstances pertaining to the information which would allow EFSA to confirm that the information concerned constitutes personal data within the meaning of Article 3(1) of Regulation (EU) 2018/1725. If you refer to different types of information under I., add a specific description for each type of information as listed under I. If there are different instances pertaining to the same type of information, e.g. name and address of test facility A and name and address of test facility B, start with the instance mentioned first in the study report/document concerned without mentioning actual personal data].

Example of correct PD request under Scenario 2

Confidentiality ⓘ

CBI

Justification ⓘ

Insert existing templates

I would like to request confidential treatment for information contained in the study report with report number 298119 (2003) titled "Magnitude of residues of active substance xyz in or on rotational crops in Germany (North)" which qualifies as personal data within the meaning of Article 3(1) of Regulation (EU) 2018/1725 in light of the specific circumstances pertaining to that information.

I. Nature of personal data: The information concerned covers the name and address of two trial sites and the GPS coordinates of a trial site in an unpublished document.

II. Identification of the personal data:

- Page 6: name and address of first trial site (last paragraph, line 5);
- Page 7: name and address of second trial site (after last paragraph);
- Page 8: GPS coordinates of second trial site (footnote 2);
- Page 21: name and address of second trial site (after paragraph 5);
- Page 23: GPS coordinates of second trial site (footnote 29).

III. Specific circumstances: The information concerned must be qualified as personal data due to the specific circumstances pertaining to that information disclosure of which would enable the identification of natural persons.

- 1) As for the name and address of the first trial site mentioned in the study report, the specific circumstance consists in the limited size of the undertaking (<5 employees) which made the trial site available. Disclosure of the name and address of the trial site would therefore be such as to allow for the identification of natural persons employed in the undertaking administering the trial site.
- 2) Concerning the name and address of second trial site mentioned in the study report, the specific circumstance likewise consists in the fact that the trial site pertains to a private residence (farmhouse). Disclosure of the name and address of the trial site would therefore be such as to allow for the identification of natural persons inhabiting that private residence.
- 3) Regarding the GPS coordinates, the explanations referred to under 1) and 2) are applicable by analogy.

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Note: An addendum to this manual may be published with further details on the treatment of Personal Data. In the interim period the CBI feature can be used to indicate the presence of personal data as indicated above.

Dossier Header: EU PPP MRL Application

Purpose:

The dossier header contains administrative data and information about the type and purpose of the application. Information in the dossier header is used by IUCLID tools to process the dossier, for example different validation assistant scenarios could be applied depending of the selection of the purpose of the application. This information is also used in automated e-mail notifications.

Please note that all information in the dossier header (including attachments) is published by default. Confidential data/attachments should be provided elsewhere in the dossier as appropriate.

DOSSIER.EU_PPP_MAXIMUM_RESIDUE_LEVELS - v2.1			
Field name	Instructions	Data Type	Field path
Dossier template		Header 1	DOSSIER.EU_PPP_MAXIMUM_RESIDUE_LEVEL S.DossierTemplate
Name		Read-only	DOSSIER.EU_PPP_MAXIMUM_RESIDUE_LEVEL S.DossierTemplate.Name
Version		Read-only	DOSSIER.EU_PPP_MAXIMUM_RESIDUE_LEVEL S.DossierTemplate.Version
Dossier name (given by user)	Short name for the dossier (this should be maintained in all versions). Refer to the active substance name in the text (e.g. "MRL application for <i>active substance</i> in <i>commoditie(s)</i> " or "Import tolerance for <i>active substance</i> in <i>commoditie(s)</i> ").	Text	DOSSIER.EU_PPP_MAXIMUM_RESIDUE_LEVEL S.DossierTemplate.NameGivenByUser
Dossier subject	System information	Read-only	DOSSIER.EU_PPP_MAXIMUM_RESIDUE_LEVEL S.DossierSubject

Submitting legal entity	System information	Read-only	DOSSIER.EU_PPP_MAXIMUM_RESIDUE_LEVEL S.DossierSubject.SubmittingLegalEntity
Dossier creation date/time	System information	Read-only	DOSSIER.EU_PPP_MAXIMUM_RESIDUE_LEVEL S.DossierSubject.DossierCreationDateTime
Dossier submission remark	The EFSA question number if allocated can be reported in this field. e.g. EFSA-Q-2021-00475. In case of re-submission, clarify the reason for the update (e.g. new data reported).	Text area	DOSSIER.EU_PPP_MAXIMUM_RESIDUE_LEVEL S.DossierSubject.DossierSubmissionRemark
Used in category		Read-only	DOSSIER.EU_PPP_MAXIMUM_RESIDUE_LEVEL S.DossierSubject.UsedInCategory
MRL application		Header 1	DOSSIER.EU_PPP_MAXIMUM_RESIDUE_LEVEL S.MRLApplication
Dossier specific information		Header 2	DOSSIER.EU_PPP_MAXIMUM_RESIDUE_LEVEL S.MRLApplication.DossierSpecificInformation
European reference number	Contains the unique number to identify all version of a dossier submitted under a regulatory action. From the 1 May it will be possible to generate	Text	DOSSIER.EU_PPP_MAXIMUM_RESIDUE_LEVEL S.MRLApplication.DossierSpecificInformation.EURReferenceNumber

	<p>the UUID within the IUCLID application.</p> <p>Prior to this, a UUID can be generated using this website https://www.uuidgenerator.net/ and pasted into this field.</p>		
Purpose of the application	<p>Select at least one purpose of the application and add (optional) remarks. Remarks can be used to specify the following:</p> <ul style="list-style-type: none"> - If "set specific maximum residue level(s) (changing current EU MRL listed in Annex II or III of Regulation (EC) No 396/2005" is selected: the reason for lowering/increasing the current MRL (e.g. new GAP, new data, monitoring data) - If "delete maximum residue level(s)" is selected: the reason for deleting the current MRL (e.g. consumer intake concern) - If "amend existing residue definition" is selected: the reason for amending the current monitoring RD (e.g. new metabolism studies, new data on analytical methods) - For all the other selections: any useful information that would 	Multi select closed list with remarks (2000)	DOSSIER.EU_PPP_MAXIMUM_RESIDUE_LEVEL S.MRLApplication.DossierSpecificInformation.Purpose

	explain the context of the application (optional)		
Evaluating Member State (EMS)	<p>Indicate the member state assessing the dossier</p> <p>For import tolerance specify in the remark field if the evaluating Member State (EMS) is also the reporting Member State (RMS). If the EMS is not the RMS, please explain why.</p> <p>If the application is not for import tolerance, the rationale for the choice of the EMS may be explained in the remark field below the selection (optional).</p>	Closed list with remarks (2000)	DOSSIER.EU_PPP_MAXIMUM_RESIDUE_LEVEL S.MRLApplication.DossierSpecificInformation.EMS
Applicant(s) is/are	Category of applicant, more than one category can apply. If the applicant represents the minor use association, indicate this in the remark field below the selection.	Multi select closed list with remarks (2000)	DOSSIER.EU_PPP_MAXIMUM_RESIDUE_LEVEL S.MRLApplication.DossierSpecificInformation.Applicant
Data requirements used to assess the dossier	Indicate the data requirements applied to assess the dossier and indicate in the remark field the rationale for this approach.	Closed list with remarks (2000)	DOSSIER.EU_PPP_MAXIMUM_RESIDUE_LEVEL S.MRLApplication.DossierSpecificInformation.DataRequirements
Notification of studies		Header 1	DOSSIER.EU_PPP_MAXIMUM_RESIDUE_LEVEL S.NotificationOfStudies

Pre-application identifiers	List pre-application identifiers which have been issued for the application	Text	DOSSIER.EU_PPP_MAXIMUM_RESIDUE_LEVEL S.NotificationOfStudies. PreApplicationId
NoS ID	List all Notification of Studies identifiers which are present in the database linked to the Pre-application identifiers (see above) but are not included in the dossier.	Text	DOSSIER.EU_PPP_MAXIMUM_RESIDUE_LEVEL S.NotificationOfStudies. StudiesReqJustification. NoSID
Justification	Justification for the absence of the NoS ID in the dossier	Multi-line text	DOSSIER.EU_PPP_MAXIMUM_RESIDUE_LEVEL S.NotificationOfStudies. StudiesReqJustification. Justification
Attached information		Header 2	DOSSIER.EU_PPP_MAXIMUM_RESIDUE_LEVEL S.NotificationOfStudies. AttachedInformation
Attachment			DOSSIER.EU_PPP_MAXIMUM_RESIDUE_LEVEL S.NotificationOfStudies .AttachedInformation.A ttachment
Attachment	Attached administrative documents to support the application. Documents with confidential or personal information should not be attached here (e.g. letters). Remarks are used to indicate the topic/reason for	Single file attachment	DOSSIER.EU_PPP_MAXIMUM_RESIDUE_LEVEL S.NotificationOfStudies .AttachedInformation.A ttachment.Attachment

	<p>including the attachment</p> <p>The Summary and Evaluation document can also be used for including attachments in the dossier. This is recommended as sanitised and original documents can be uploaded together.</p> <p>Scientific information should be uploaded into documents in the Table of Contents of the dossier</p>		
Remarks	Specify the motivation and the nature of the attachment.	Text area	DOSSIER.EU_PPP_MAXIMUM_RESIDUE_LEVEL S.NotificationOfStudies .AttachedInformation.Attachment.Remarks
Attachment			
Other submission related information		Header 1	DOSSIER.EU_PPP_MAXIMUM_RESIDUE_LEVEL S.OtherSubmissionRelatedInformation
Active substance application dossier is submitted simultaneously?	Check box to Indicate whether the MRL application is a part of the active substance approval/renewal of approval dossier.	Check box	DOSSIER.EU_PPP_MAXIMUM_RESIDUE_LEVEL S.OtherSubmissionRelatedInformation.PartOfActiveSubstanceAppl
Submission number of the active substance dossier	If the box above is checked, the European Reference Number of the related active substance approval/renewal of approval dossier must be provided.	Text	DOSSIER.EU_PPP_MAXIMUM_RESIDUE_LEVEL S.OtherSubmissionRelatedInformation.SubmissionNumber

Links to support material:

[GUIDANCE DOCUMENT ON THE INTERPRETATION OF THE TRANSITIONAL MEASURES FOR THE DATA REQUIREMENTS FOR CHEMICAL ACTIVE SUBSTANCES AND PLANT PROTECTION PRODUCTS ACCORDING TO REGULATION \(EU\) No 283/2013 AND REGULATION \(EU\) No 284/2013](#)

1. Identity of the product / active substance information

1.1 Identity of the product

Purpose:

This document covers the data requirements:

Applicant and contact person

Trade name or proposed trade name and producer's development code number of the plant protection product if appropriate

Mixture v.6.4 (Final)			
Name	Instructions	Data Type	Field Path
Mixture/Product name	This must be completed; this information is also included in the dossier header as 'Dossier subject'	Multi-line text	MIXTURE.MixtureName
Public name	Public name of the mixture	Multi-line text	MIXTURE.PublicName
Other identifiers	All former and current trade names and proposed trade names and development code numbers of the plant protection product/preparation shall be provided. Flags can be used to indicate if the trade name is confidential		MIXTURE.OtherNames
Confidential		Confidentiality	MIXTURE.OtherNames. Protection
Name type		Open list	MIXTURE.OtherNames. NameType
Name		Multi-line text	MIXTURE.OtherNames. Name
Country		Multi select open list	MIXTURE.OtherNames. Country

Remarks		Text area	MIXTURE.OtherNames. Remarks
Other identifiers			
Legal entity flags		Confidentiality	MIXTURE.OwnerLegalE ntityProtection
Legal entity owner	This must be completed; this information is also included in the dossier header as 'Submitting Legal Entity'. When submitting a dossier through the Submission Portal the same legal entity should be used, 3 third party consultants may do this as foreign entities. For task forces, the lead applicant can act as the legal entity. Links the dossier to the Legal entity of the dossier owner.	Entity reference field	MIXTURE.OwnerLegalE ntity
Third party flags	Option to link to the legal entity of a third party	Confidentiality	MIXTURE.ThirdPartyPro tection
Third party		Entity reference field	MIXTURE.ThirdParty
Contact persons	Link to the relevant Contact entity . The primary contact point for the dossier should be provided, name, position, telephone and e-mail address		MIXTURE.ContactPerso ns
Person flags		Confidentiality	MIXTURE.ContactPerso ns.DataProtection
Person	See Legal Entity (including contact person)	Entity reference field	MIXTURE.ContactPerso ns.ContactPerson
Contact persons			
Role in the supply chain	Check 'Manufacturer' to indicate the applicant is the Producer of the plant protection product	Header 1	MIXTURE.RoleInSupply Chain
Role flags		Confidentiality	MIXTURE.RoleInSupply Chain.RoleProtection
Manufacturer		Check box	MIXTURE.RoleInSupply Chain.Manufacturer

Importer		Check box	MIXTURE.RoleInSupplyChain.Importer
Only representative		Check box	MIXTURE.RoleInSupplyChain.OnlyRepresentative
Downstream user		Check box	MIXTURE.RoleInSupplyChain.DownstreamUser

Links to support materials:

[Legal entity](#)

1.2 Product composition / active substance information

Purpose

This document covers the data requirements:

Detailed quantitative and qualitative information on the composition of the plant protection product/preparation

Product formulation type and function of component

This document is used to link the active substance dataset (and if relevant the other substance dataset) to the Mixture/product.

FLEXIBLE_RECORD.MixtureComposition – v.7.1 (Final)			
Name	Instructions	Data Type	Field Path
Administrative data		Header 1	FLEXIBLE_RECORD.MixtureComposition.AdministrativeData
	See Confidentiality Requests Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	Confidentiality	FLEXIBLE_RECORD.MixtureComposition.AdministrativeData.DataProtection
General information		Header 1	FLEXIBLE_RECORD.MixtureComposition.GeneralInformation
Mixture/product name	Name of formulation/preparation reported. In case of multiple formulations more than one document can be completed. Linking to reference substances rather than substances is recommended for the additional documents unless a new component which requires a dataset is included.	Text	FLEXIBLE_RECORD.MixtureComposition.GeneralInformation.Name
Trade names			FLEXIBLE_RECORD.MixtureComposition.GeneralInformation.TradeNames

Country		Multi select open list	FLEXIBLE_RECORD. MixtureComposition. GeneralInformation. TradeNames.Country
Trade name	Trade name of formulation/preparation reported	Multi-line text	FLEXIBLE_RECORD. MixtureComposition. GeneralInformation. TradeNames.TradeN ame
Trade names			
Brief description	Additional information on the formulation/preparation can be added here	Text	FLEXIBLE_RECORD. MixtureComposition. GeneralInformation. Description
Formulation type	Select the formulation type according the international coding system for pesticides from the scroll down list	Multi select open list	FLEXIBLE_RECORD. MixtureComposition. GeneralInformation. FormulationType
Components		Header 1	FLEXIBLE_RECORD. MixtureComposition. Components
			FLEXIBLE_RECORD. MixtureComposition. Components.Compo nents
Component flag	See Confidentiality Requests Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	Confidentiality	FLEXIBLE_RECORD. MixtureComposition. Components.Compo nents.DataProtection
Name	<p>Link to a 'reference substance' or 'substance'.</p> <p>Select 'substance' for the active substance/micro-organism and relevant impurities. This creates a dataset for each component of this type.</p> <p>Link to 'reference substance' for other components e.g. safeners, synergists, co-formulants, by- products, culture medium etc. If a component of the mixture is confidential it is important that the confidentiality flag of the reference substance entity is also set to CBI to ensure substance identifiers are not shown in the mixture composition document.</p>	Entity reference field	FLEXIBLE_RECORD. MixtureComposition. Components.Compo nents.Reference

	the formulation/preparation which cannot be provided in the other fields		Components.Components.Remarks
Substance of concern	The additional check boxes in this table are not relevant for European Plant Protection Products	Check box	FLEXIBLE_RECORD.MixtureComposition.Components.Components.SubstanceOfConcern
Generic component identifier (GCI)	Not relevant for EU PPP	Check box	FLEXIBLE_RECORD.MixtureComposition.Components.Components.Gci
Interchangeable component group (ICG)	Not relevant for EU PPP	Check box	FLEXIBLE_RECORD.MixtureComposition.Components.Components.Icg
Standard formula (SF) component	Not relevant for EU PPP	Check box	FLEXIBLE_RECORD.MixtureComposition.Components.Components.Sfc
Substance generated in situ (from one or more precursors, at the place of use)		Check box	FLEXIBLE_RECORD.MixtureComposition.Components.Components.SubstanceGeneratedInSitu

Links to support material:

[Catalogue of pesticide formulation types and international coding system](#)

1.2.1 Information on metabolites

Purpose:

Any information on potentially harmful effects of metabolites on human and animal health, the environment or on groundwater shall be included in the dossier.

Chemical name in accordance with IUPAC and CA nomenclature, CAS-number EC number, molecular and structural formula, molar mass shall be reported.

FLEXIBLE_SUMMARY.Metabolites v2.1 (Final)			
Name	Instructions	Data type	Field path
Metabolites information		Header 1	FLEXIBLE_SUMMARY.Metabolites.MetabolitesInfo

Metabolites information overview	<p>Description of the metabolites included in the dossier.</p> <p>For microorganisms in cases where other strains belonging to the same microbial species are known to produce metabolites with unacceptable effects on human health and/or the environment, this should be described here.</p>	Rich text area	FLEXIBLE_SUMMARY.Metabolites.MetabolitesInfo.MetabolitesInfoOverview
Parent of metabolites	<p>Link to the parent of the metabolites in the 'List of metabolites'.</p> <p>If more than one active substance is included in the dossier mixture composition, then parent of the metabolites must be reported</p> <p>If the metabolite is secondary or tertiary, then the parent of the metabolites must be reported</p> <p>The link should be made to the reference substance of the parent</p>	Entity reference field	FLEXIBLE_SUMMARY.Metabolites.MetabolitesInfo.ParentOfMetabolites

List of metabolites		Header 1	FLEXIBLE_SUMMARY.Metabolites.ListMetabolites
Metabolites	See Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants		FLEXIBLE_SUMMARY.Metabolites.ListMetabolites.Metabolites
		Confidentiality	FLEXIBLE_SUMMARY.Metabolites.ListMetabolites.Metabolites.DataProtection
Link to metabolite dataset	<p>A metabolite dataset is required where further studies have been performed using a metabolite as the test material. The link must be made using a substance to create a dataset. In the dataset linked to the substance endpoint study records and endpoint summaries can be completed in the relevant sections e.g. Toxicological and metabolism studies, Fate and behavior in the environment, Ecotoxicological studies. The Table of Contents for a metabolite is the 'Other substance' dataset</p> <p>Where a metabolite is detected and reported in an endpoint study record and the test material is the active substance only a link</p>	Entity reference field	FLEXIBLE_SUMMARY.Metabolites.ListMetabolites.Metabolites.LinkMetaboliteDataset

	<p>to a reference substance is required.</p> <p>In both cases the IUPAC and CA nomenclature, CAS-number EC number, molecular and structural formula, molar mass should be reported in the reference substance document. SMILES and InChi are recommended.</p> <p>Any metabolites included in this document must be reported in the results of in at least one endpoint study record where the test material is the active substance</p>		
Remarks	<p>Further information on the inclusion of the metabolite in document can be included e.g. 'found in lysimeter studies at annual average concentrations exceed 0.1 µg/L in the leachate' or 'metabolite included in residue definition for environmental monitoring'</p>	Multi-line text	FLEXIBLE_SUMMARY.Metabolites.ListMetabolites.Metabolites.Remarks
Metabolites			
Additional information	Discussion (Header 1) – common block	Header 1	FLEXIBLE_SUMMARY.Metabolites.Discussion

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Links to support material:

[Scientific Opinion on Evaluation of the Toxicological Relevance of Pesticide Metabolites for Dietary Risk Assessment](#)

2. Good agricultural practices (GAP)

Purpose

The Good Agricultural Practice (GAP) describes the intended or registered safe use of plant protection products, according to Article 3(2)(a) of Regulation (EC) No 396/2005. The different fields required to define the use of the plant protection product unambiguously are listed in Table 4.

The IUCLID GAP form implements the following data requirements:

- Details of intended use
- Application rate
- Method of application
- Number and timing of applications and duration of protection
- Necessary waiting periods or other precautions to avoid phytotoxic effects on succeeding crops

If you click on the red plus sign next to the header 'x Good agricultural practices (GAP)' you can create a new GAP. A name will be assigned automatically to the GAP, containing as default name 'Good agricultural practices (GAP)' followed by a dot and three numbers.

Please note that separate GAP documents need to be created, if the GAPs differ in one or more of the parameters. For some fields multiple options from a picklist can be selected. Please read carefully below the instructions to see whether in a given case a separate GAP document needs to be created or whether it is appropriate to describe the different use options in one form.

FLEXIBLE_RECORD.GAP – v. 2.1		
Name	Instructions	Field Path
Administrative data	The general rules on confidentiality requests apply in setting the flags Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	FLEXIBLE_RECORD.GAP.AdministrativeDataSummary
Product	This field is mandatory. Click on the red plus sign to link the GAP to an existing mixture composition (see Introduction).	FLEXIBLE_RECORD.GAP.AdministrativeDataSummary.Product

	<p>If no mixture dossier or dataset is available in the inventory, create first a new one and add a mixture composition.</p> <p>In general, the GAP has to be completed for the target a.s., i.e. the a.s. for which the approval/renewal of the approval is requested or for which the MRL application is submitted.</p> <p>If the product contains a second (non-target) a.s., it is not required to provide a separate GAP form for the second a.s.</p>	
Description of key information	<p>The free text field can be used to give a short explanation/description of the GAP. This information is not mandatory.</p> <p>For GAPs that involve different application methods at different growth stages (e.g. drench application at sowing followed by foliar application at a later growth stage), the GAP should be split in separate GAPs (in the example the first GAP being the drench application, the second the foliar use). In this field, the GAPs belonging to a sequential application should be labelled (e.g. GAP 1 of 2, GAP 2 of 2). The field should also be used to label representative uses (relevant for applications on the approval or the renewal of the approval). For existing uses (D2 document), indicate "authorised use" in this field; otherwise the document will be interpreted as for an intended use (D1).</p>	FLEXIBLE_RECORD. GAP.KeyInformation
Purpose of the GAP		FLEXIBLE_RECORD. GAP.KeyInformation .PurposeOfTheGAP
Active substance / microorganism / basic substance applications	Select the term that describes the purpose of the GAP. Not relevant for EU PPP MRL applications.	FLEXIBLE_RECORD. GAP.KeyInformation .PurposeOfTheGAP. ActiveSubstanceMicroorganismBasicSubstanceApplications
MRL applications	Select the term that describes the purpose of the GAP. Only relevant for EU PPP MRL applications.	FLEXIBLE_RECORD. GAP.KeyInformation .PurposeOfTheGAP. MRLApplications
Crop information		FLEXIBLE_RECORD. GAP.KeyInformation .CropInformation
Crop/treated object	<p>Information on the crop/treated object is mandatory. A picklist is implemented to describe the crop or object to be treated with the product.</p> <p>The picklist is based on EPPO codes which have been enhanced with additional information to make them more user friendly/self-explanatory. The extended EPPO codes cover the following types of information:</p> <ul style="list-style-type: none"> the first 5 digits are the EPPO code (see EPPO Plant Protection Thesaurus at http://eppt.eppo.org) (e.g. PIBSX), followed by the scientific name of the crop (PIBSX Pisum sativum); in brackets, the crop name in English is reported (PIBSX Pisum sativum (English pea)); 	FLEXIBLE_RECORD. GAP.KeyInformation .CropInformation.Crop

- for the most important crops, the corresponding food code of the MRL food classification is reported after a dash (code of Annex I of Regulation (EC) No 396/2005). For some crops, more than one food code is applicable (e.g. PIBSX *Pisum sativum* (English pea) - 0260030, 0260040, 0300030).

In the current version of IUCLID, the link with the food codes of the MRL legislation has been established only for codes listed in Part A of Annex I of Regulation (EC) No 396/2005; food codes listed in Part B of Annex I to, the connection to the crop code has not yet been implemented (the link will be included in the next release of IUCLID). Please note that not for all codes all four name elements are available.

To find the codes for the crop/object, the user can either use the hierarchy search tool which requests to choose between crops or treated products.

Alternatively, a text string (e.g. the EPPO code, the scientific name) can be directly entered in the search window, resulting in a subset of matching options.


In the hierarchy tool, the user should first select between the two highest hierarchy levels 'crops' or 'treated product'. Treated products is relevant only for post-harvest uses and for uses on non-crop objects (e.g. treatment of railways).

As a next step, a text string (EPPO code, scientific name, name of the crop in English or the food code of the MRL legislation) can be inserted. EPPO codes matching with the search term are displayed in yellow, and the user should select the relevant one.

For post-harvest treatment of food products, two EPPO codes are available (HARFO and HARPO) which were combined with all food codes (Part A) of Annex I of Regulation (EC) No 396/2005:

- If the treatment with the product is intended on the fresh harvested product (e.g. oranges), the code combining HARFO and the respective food code should be selected (e.g. 3HARFO – Oranges – 011020).
- For GAPs describing a use on a processed harvested product (e.g. raisins), the code HARPO in combination with the food code should be used (e.g. 3HARPO – Table grapes – 0151010).

In general, codes for crop groups should not be selected. Instead the EPPO codes for the individual crops should be chosen. A multiple selection of crop codes is allowed, only if all parameters of the GAP are identical for all crops selected. If the GAPs differ for the individual crops in one or several fields, a separate GAP form needs to be completed. To facilitate the work to complete separate GAP forms, an existing GAP can be copied and modified for the respective parameters (see 1.3.6).

	<p>Further remarks on the crop/treated product can be reported in a free text field, which is created when the user clicks on the symbol  .</p> <p>Remarks are necessary to specify whether food or feed has been in contact with the plant protection product indirectly if one of the following codes for treated product has been selected:</p> <table><tr><td>3IRRWO</td><td>irrigation water (treatment of)</td></tr><tr><td>BULBO</td><td>bulbs, tubers, corms (treatment of)</td></tr><tr><td>PLABO</td><td>plant base (treatment of)</td></tr><tr><td>SEEDO</td><td>seeds (treatment of)</td></tr><tr><td>WOUNO</td><td>wounds (treatment of)</td></tr></table>	3IRRWO	irrigation water (treatment of)	BULBO	bulbs, tubers, corms (treatment of)	PLABO	plant base (treatment of)	SEEDO	seeds (treatment of)	WOUNO	wounds (treatment of)	
3IRRWO	irrigation water (treatment of)											
BULBO	bulbs, tubers, corms (treatment of)											
PLABO	plant base (treatment of)											
SEEDO	seeds (treatment of)											
WOUNO	wounds (treatment of)											
Genetical modification of crop	<p>If relevant, describe variety of genetically modified crops on which the use of the product is intended to be used or authorised.</p>	FLEXIBLE_RECORD. GAP.KeyInformation .CropInformation.Ge neticalModification										
Crop destination(s)	<p>The field is not mandatory. Please select the relevant EPPO code for crop destination. Multiple selection is allowed (e.g. grown for animal consumption (3ANICD) and grown for human consumption (3HCOND)). In remarks field more details on the crop destination can be described. See also EPPO code list https://gd.eppo.int/PPPUse/3CRODK</p>	FLEXIBLE_RECORD. GAP.KeyInformation .CropInformation.Cr opDestination										
Authorisation zone	<p>Please select the relevant Authorisation zone from the picklist. The assignment of countries to the different zones for the authorisation of products can be found in Annex I of Regulation (EC) No 1107/2009. Please note that multiple selection of codes is not allowed. Information on the authorisation zone is not mandatory if at least one country has been selected in the field 'Country or territory'. If no information is provided in 'Country or territory' and in 'Authorisation zone', it is assumed that the GAP is relevant for all EU zones.</p>	FLEXIBLE_RECORD. GAP.KeyInformation .CropInformation.Au thorisationZone										
MRL zone	<p>Select the MRL zone in which the GAP is intended. The assignment of the individual European countries to the zones can be found in the guidance document SANTE/2019/12752 (https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_mrl_guidelines_app-d.pdf) (or a subsequent revision of this document).</p>	FLEXIBLE_RECORD. GAP.KeyInformation .CropInformation.Mr lZone										
Country or territory	<p>Select the country or the territory related to the GAP. The selection of more than one country is possible if the same GAP applies.</p>	FLEXIBLE_RECORD. GAP.KeyInformation										

		.CropInformation.CountryOrTerritory
Crop location (F/G/I)	<p>This data element is mandatory for GAPs that refer to crops (children codes listed under crops and children codes of '3HARVO harvested crops (treatment of)'. For other GAPs the field should remain empty.</p> <p>The available picklist contains EPPO codes with detailed descriptions of the cases.</p> <p>I: Code to be used for crops grown or stored in closed walk-in buildings. This code includes for example mushroom houses and structures for witloof chicory or rhubarb forcing.</p> <p>G: A walk-in, static, closed place of crops production with a usually translucent outer shell, which allows controlled exchange of material and energy with the surroundings and prevents release of products into the environment.</p> <p>F: Fields and other structures which do not prevent release of products into the environment.</p> <p>For crops grown outdoor (F), more details can be reported using the more specific subcodes. The detailed description of the subcodes is provided in the picklist.</p>	FLEXIBLE_RECORD. GAP.KeyInformation. CropInformation.CropLocation
Target organisms	Select 'New item' and compile the block consisting of 'Scientific name', 'Common name', 'Development stage of target pest' and 'Development stage of target plant'. See detailed descriptions below.	FLEXIBLE_RECORD. GAP.PestDiseaseTreated.TargetOrganisms
Scientific name	<p>Select the appropriate code and scientific name from picklist. The picklist is based on the EPPO list (https://gd.eppo.int/taxon/).</p> <p>At least one target organism needs to be defined in a GAP. It is possible to select more than one target organism, if the GAP parameters are identical for the different target organisms.</p> <p>If the target organism is not listed, select 'other' and specify.</p> <p>If a scientific name is not relevant or not known, select 'no data'.</p> <p>Any remarks can be entered in the supplementary remarks field, for instance any code for target organism if required according to a programme-specific guidance. If so, indicate the type of coding system in parentheses, e.g. 'I.1.1.1 (EU BPD)'.</p> <p>Please make sure that the scientific name entered in this field matches with the organism described in the field 'Common name'.</p>	FLEXIBLE_RECORD. GAP.PestDiseaseTreated.TargetOrganisms.ScientificName
Common name	Please add the common name of the target organism in this field that matches with the Scientific name.	FLEXIBLE_RECORD. GAP.PestDiseaseTreated.TargetOrganisms.CommonName
Development stage of target pest	For insecticide and fungicide uses, indicate the developmental stage of the target organism/pest (e.g. development stage of the insect or of the disease for	FLEXIBLE_RECORD. GAP.PestDiseaseTreated.TargetOrganisms

	<p>diseases caused by fungi).</p> <p>If no appropriate description is available in the list, select 'other:' and specify the development stage in the remarks.</p> <p>If the development stage is not known or not further specified, select 'not specified'.</p> <p>If the development stage is not relevant/applicable, leave field empty.</p> <p>Multiple selection of terms is allowed.</p>	ms.DevelopmentStagePest																
Development stage of target plant	<p>For herbicide uses, indicate the developmental stage of the target plant.</p> <p>In the picklist BBCH codes have been implemented. Although these codes have been developed for describing the development stages of crops, they can be used in analogy for the target plants.</p> <p>Any remarks can be entered in the supplementary remarks field, for instance an alternative description of the developmental stage which is not available in the picklist.</p>	FLEXIBLE_RECORD.GAP.PestDiseaseTreated.TargetOrganisms.DevelopmentStagePlant																
Major/minor use	<p>Select the applicable code from the picklist. Minor use according to Art. 51 of Regulation (EC) No 1107/2009 should be flagged as 'minor use'.</p> <p>Other EU uses are to be considered as major use (combination of crop/target organism).</p> <p>Please note that GAPs need to be split in separate documents/GAP forms, if the different crops selected in the field 'crops/treated object' would require different the flags (e.g. not all crops are major crops).</p> <p>The field is not relevant for uses in third countries (e.g. import tolerances).</p>	FLEXIBLE_RECORD.GAP.PestDiseaseTreated.MajorMinorUse																
Application target	<p>The target to be treated can be selected from a picklist. The following terms are implemented:</p> <table><tr><th>Picklist value</th><th>Description</th></tr><tr><td>Foliage/Plant</td><td>Application to a plant or the leaves of a plant.</td></tr><tr><td>Seed / Seed Pieces</td><td>Application to a small object produced by a plant from which a new plant can grow.</td></tr><tr><td>Propagation Stock</td><td>Application to a specimens of a plant, used for breeding by natural processes from the parent stock.</td></tr><tr><td>Root/Bulb</td><td>Applications (such as dip applications) to a rootball (the compact mass of roots), or bulb (a part of plants that functions as a food storage during dormancy).</td></tr><tr><td>Bark</td><td>Application to or into the tough, protective outer sheath of the trunk, branches, and twigs of a tree or woody shrub.</td></tr><tr><td>Stump / cut stem</td><td>Application to the recently cut of a tree or woody shrub (excludes cut flowers).</td></tr><tr><td>Containerized plant</td><td>Application to a plant and soil grown in a movable container.</td></tr></table>	Picklist value	Description	Foliage/Plant	Application to a plant or the leaves of a plant.	Seed / Seed Pieces	Application to a small object produced by a plant from which a new plant can grow.	Propagation Stock	Application to a specimens of a plant, used for breeding by natural processes from the parent stock.	Root/Bulb	Applications (such as dip applications) to a rootball (the compact mass of roots), or bulb (a part of plants that functions as a food storage during dormancy).	Bark	Application to or into the tough, protective outer sheath of the trunk, branches, and twigs of a tree or woody shrub.	Stump / cut stem	Application to the recently cut of a tree or woody shrub (excludes cut flowers).	Containerized plant	Application to a plant and soil grown in a movable container.	FLEXIBLE_RECORD.GAP.PestDiseaseTreated.ApplicationDetails.ApplicationTarget
Picklist value	Description																	
Foliage/Plant	Application to a plant or the leaves of a plant.																	
Seed / Seed Pieces	Application to a small object produced by a plant from which a new plant can grow.																	
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Stump / cut stem	Application to the recently cut of a tree or woody shrub (excludes cut flowers).																	
Containerized plant	Application to a plant and soil grown in a movable container.																	

	Agricultural Commodity	Post-harvest application to an agricultural product that can be bought and sold (<i>e.g.</i> , treatment to grain, fibre, cut flowers, packaged animal feed, <i>etc.</i>).
	Soil (surface)	Application to the ground in which plants can grow.
	Soil (subsurface)	Application below the ground, or immediately incorporated.
	Water	Application to water in systems, pools, pipes, tanks or other containers, or bodies of water, such as lakes, ponds, bays, estuaries, oceans, reservoirs.
	Air	Application directed to a space, rather than a specific target. Examples of these types of applications include foggers, mosquitocides, ozone generators, knock-down insecticides, etc. This does not include aerial broadcast applications over a crop because the target is the crop, not the air over the crop.
	Surface	Application to the interior and/or exterior boundaries of an inanimate object. Examples of these types of applications include boat hulls, countertops, hives, nests, etc.
	Non-porous Surface	Surfaces where liquids will not absorb such as ceramic, porcelain, glass, metal, plastic/vinyl, rubber, stainless steel.
	Porous Surface	Surfaces where a liquid is likely to absorb such as fabric, drywall, composition board surfaces, paint films and surfaces, plaster surfaces, and wood.
	other	
Please select the most appropriate treatment target.		
Method of application	<p>Information on the application method is mandatory.</p> <p>Select the treatment/application method relevant for the GAP. The picklist is based on the EPPO list (https://gd.eppo.int/taxon/).</p> <p>If no EPPO code is available to describe the method of application, select 'other:' from the picklist and describe the method of application in the remarks. Examples for methods of application with no EPPO codes are listed below:</p> <ul style="list-style-type: none"> - bait treatment - basal bark treatment - dabbing/rubbing - [local treatment] - incorporation into compost - material incorporation or impregnation - [no class] 	<p>FLEXIBLE_RECORD.</p> <p>GAP.PestDiseaseTreated.ApplicationDetails.ApplicationMethod</p>

	<ul style="list-style-type: none"> - paint - [local treatment] - paste guns for volatile substances - pressure treatment - prune/wound treatment - [local treatment] - soil bed solarization <p>The remarks field can be also used to provide further details on the EPPO code selected to describe the method of application.</p> <p>Examples for further specification of some EPPO codes are listed below:</p> <p>Circulating water application (3CWATM)</p> <ul style="list-style-type: none"> - hydroponic/aquaponic water treatment <p>Fogging (3FOGGM)</p> <ul style="list-style-type: none"> - mechanical fogging - thermal fogging <p>Fumigating (3FUMIM)</p> <ul style="list-style-type: none"> - fumigation: enclosed spaces - fumigation: vacuum chamber - gassing <p>Injecting (3INJEM)</p> <ul style="list-style-type: none"> - stem injection <p>Placing (3PLACM)</p> <ul style="list-style-type: none"> - doseable matrix dispensers for volatile substances - retrievable active dispensers for volatile substances - retrievable passive dispensers for volatile substances - non retrievable active dispensers for volatile substances - non retrievable passive dispensers for volatile substances <p>Spraying (3SPRYM):</p> <ul style="list-style-type: none"> - air assisted broadcast spraying - high volume spraying - low volume spraying - ultra low volume spraying - application in overhead irrigation water - banded spraying - spot treatment (spraying) <p>Spreading (3SPRDM)</p> <ul style="list-style-type: none"> - granules application in row - granules application overall <p>If different application methods are foreseen on a crop (e.g. seed treatment followed by foliar broadcast), two uses should be described as separate GAPs, including in the remarks that the two GAPs are combined.</p>	
Application equipment	Select the types of application equipment used. This information is used in the operator and worker exposure scenarios	FLEXIBLE_RECORD. GAP.PestDiseaseTreated.ApplicationDetails.ApplicationEquipment
Growth stage and season	Click on 'New item' and compile the block of fields that comprises the following fields: Growth stage of crop (first application), Growth stage of crop (last application), Treatment season.	FLEXIBLE_RECORD. GAP.PestDiseaseTreated.ApplicationDetails.GrowthStageAndSeason

	<p>If the GAP foresees treatments at different treatment windows (e.g. first treatment window before flowering, second treatment window after flowering), the block can be repeated.</p> <p>Information on the growth stage is mandatory if the GAP refers to a crop; if the GAP refers to treatment of non-crop objects (children of 3NOCFO), it is not required; if the GAP refers to treatment of harvested crops (children codes of 3HARVO), BBCH 99 should be entered; if the GAP refers to children codes of 3CRPAO (treatment of crop parts), it is not required.</p> <p>If number of applications is greater than 1, the information on the growth stage needs to be reported for the first and the last application. Treatment season is not mandatory.</p>	
Growth stage of crop (first application)	<p>This field is intended to describe the growth stage of the crop at the first treatment with the product. The picklist offers the BBCH codes which describe the phenomenologically similar growth stages of all mono- and dicotyledonous plant species (source: BBCH Monograph edited by Uwe Meier, Julius Kühn-Institut, 2018, https://www.julius-kuehn.de/media/Veroeffentlichungen/bbch%20epaper%20en/page.pdf).</p> <p>Select the growth stage of the crop at first application. If a treatment is foreseen at one specified growth stage, select the BBCH code only in this field (Growth stage of crop (first application)).</p> <p>For a range, also select the relevant BBCH code in the field 'Growth stage of crop (last application)'.</p> <p>If necessary, more details on the treatment timing shall be reported in remarks (e.g. a description of the timing/growth stage at the application to specify more detailed the timing of the application (e.g. pre-plant, before transplant, etc.).</p> <p>The letters in bracket after the description of the crop development show to which plant group the respective definition refers. (D = Dicotyledons, M = Monocotyledons, G = Gramineae, P = Perennial plants, V = Development from vegetative parts or propagated organs).</p> <p>Please note that BBCH codes 71 to 79 is not used, if the main fruit growth happens in principal growth stage 8.</p>	FLEXIBLE_RECORD. GAP.PestDiseaseTreated.ApplicationDetails.GrowthStageAndSeason.GrowthStageCropFirst
Growth stage of crop (last application)	<p>Please select from the picklist the growth stage of crop at last application. See above (Growth stage of crop (first application)) for further details.</p>	FLEXIBLE_RECORD. GAP.PestDiseaseTreated.ApplicationDetails.GrowthStageAndSeason.GrowthStageCropLast
Treatment season	<p>For autumn/winter sown crops, report whether the treatment is foreseen in autumn/winter or in spring/summer. Multiple selection is allowed. If necessary,</p>	FLEXIBLE_RECORD. GAP.PestDiseaseTreated.ApplicationDetails.GrowthStageAn

	any other restrictions for the treatment season can be reported in the remarks field, selecting the option 'other:'	dSeason.Treatment Season
Number of applications (range)	Information on the number of applications is mandatory. Report the number of applications (e.g. 1 – 3). If only one treatment is foreseen, report '1' in the lower numeric field.	FLEXIBLE_RECORD. GAP.PestDiseaseTreated.ApplicationDetails.ApplicationsRange
Re-treatment interval (in days)	Enter the interval between treatments (re-treatment interval); if relevant, a range for minimum interval and maximum interval between treatments, expressed in days, can be reported.	FLEXIBLE_RECORD. GAP.PestDiseaseTreated.ApplicationDetails.RetreatmentInterval
Application rate per treatment (product) – range	Mandatory information. For reporting the application rate, follow the recommendations on dose expression for products (EPPO General Standard PPI/239(3)). Enter the numeric value in the first numeric field corresponding the lower application rate (for the formulation) per treatment. Use the second numeric field to report the upper application rate per treatment. Select the most appropriate unit to express the application rate. For applications on crops, the application rate should preferably be expressed as application rate per hectare. See also below application rate per treatment for target a.s. (range).	FLEXIBLE_RECORD. GAP.PestDiseaseTreated.ApplicationDetails.ApplicationRatePerTreatment
Remarks on application rate	Any further explanations related to the application rate can be provided in this field. For 3-dimensional crops, the application rate expressed on leaf wall area can be reported in addition to the application rate reported per hectare.	FLEXIBLE_RECORD. GAP.PestDiseaseTreated.ApplicationDetails.RemarksOnApplicationRate
Water amount per treatment / spray volume	For products applied after dilution with water, the minimum and maximum amount of water used in spray application (spray volume) should be reported.	FLEXIBLE_RECORD. GAP.PestDiseaseTreated.ApplicationDetails.WaterAmountPerTreatment
Concentration of formulation in dilution	For products applied after dilution with water, report the concentration of the formulation in the solution.	FLEXIBLE_RECORD. GAP.PestDiseaseTreated.ApplicationDetails.ConcentrationFormulationDilution
Safener/ synergist/ adjuvant added	Is a safener/synergist/adjuvant intended to be added to the tank mix? If yes, the information on the type and the amount of safener/synergist/adjuvant is mandatory. Please indicate whether the addition of the safener/synergist/adjuvant is mandatory or whether it is only recommended.	FLEXIBLE_RECORD. GAP.PestDiseaseTreated.ApplicationDetails.SafenerSynergistAdjuvant

	Indicate the safener/synergist/additive type, the name and the amount added to the tank mix (volume (%)). See also EPPO standard PP1/291(1) .	
Application rate per treatment for target a.s. (range)	<p>It is mandatory to report the application rate for the target a.s.</p> <p>The field is intended to specify the application rate for the target active substance (i.e. the a.s. defined in the active substance dataset (EU PPP Active substance information) of the IUCLID dossier).</p> <p>For reporting the application rate, follow the recommendations on dose expression for products (EPPO General Standard PPI/239(3)).</p> <p>Enter the numeric value in the first numeric field corresponding the lower application rate per treatment.</p> <p>Use the second numeric field to report the upper application rate per treatment.</p> <p>If the formulation contains a variant of the active substance (e.g. an ester), the application rate should be expressed for the a.s. (not for the variant!).</p> <p>Example for a variant: the formulation contains quizalofop-P-terfuryl which is a variant of the a.s quizalofop-P. In the field defining the application rate for the target a.s. the application rate should be expressed as quizalofop-P. The factor to recalculate the application rate of quizalofop-P-terfuryl (molecular weight 428.9) to quizalofop-P (molecular weight 344.7) is derived as the ratio of the molecular weight ($344.7/428.9=0.804$).</p>	FLEXIBLE_RECORD. GAP.PestDiseaseTreated.ApplicationDetails.ApplicationRateForTarget
Maximum annual application rate (a.s.)	If restrictions need to be defined for the annual application rate (in case of crops which have more than one harvest per season), please report the maximum annual application rate for the active substance. The application rate should be reported for the a.s. (not the variant).	FLEXIBLE_RECORD. GAP.PestDiseaseTreated.ApplicationDetails.SeasonalApplication
Non-target a.s.		FLEXIBLE_RECORD. GAP.PestDiseaseTreated.ApplicationDetails.NonTargetAS
Non-target a.s.	Select non-target active substance	FLEXIBLE_RECORD. GAP.PestDiseaseTreated.ApplicationDetails.NonTargetAS.NonTargetAS
Application rate per treatment for other a.s. (range)	This field is intended to specify the application rate for other active substance.	FLEXIBLE_RECORD. GAP.PestDiseaseTreated.ApplicationDetails.NonTargetAS.A

	For reporting the application rate, follow the recommendations on dose expression for products (EPPO General Standard PPI/239(3)).	pplicationRatePerTreatmentForOtherAS Range
Maximum annual application rate for other a.s.	If restrictions need to be defined for the annual application rate (in case of crops which have more than one harvest per season), please report the maximum annual application rate for other active substance. The application rate should be reported for the a.s. (not the variant).	FLEXIBLE_RECORD. GAP.PestDiseaseTreated.ApplicationDetails.NonTargetAS.MaximumAnnualApplicationRateForOtherAS
Treatment window (for dispensers)	For dispensers or similar application forms, the duration of treatment window needs to be reported.	FLEXIBLE_RECORD. GAP.PestDiseaseTreated.ApplicationDetails.TreatmentWindowDispensers
Seeding rate	Field relevant for seed treatments only. Enter the seeding rate: For crops where the seeds are usually sold by number of units (e.g. sugar beet, maize, sunflower), the seeding rate should be expressed as unit/ha (unit is usually 100.000 individual kernel). For seeds sold by weight (e.g. cereals the seeding rate is normally expressed in kg or g seeds /ha or m ² . If 'other:' is selected as unit, describe the seeding rate unit in the additional field.	FLEXIBLE_RECORD. GAP.PestDiseaseTreated.ApplicationDetails.MaxSeedingRate
Planting density	The field is not mandatory. Describe the planting density (number of plants per ha or m ²).	FLEXIBLE_RECORD. GAP.PestDiseaseTreated.ApplicationDetails.PlantingDensity
Pre-harvest interval	Mandatory field. Specify the minimum pre-harvest interval (PHI) in days (i.e. the minimum time between the last treatment of a crop and the harvest). This field should also be used to describe the time between post-harvest treatment of a food/feed item and the placement on the market. Enter a single numeric value. The qualifier '>' can be used together with a PHI to describe treatments at early development stages of the crop where the PHI cannot be specified more accurately. 'Not applicable' can be selected where the pesticide is applied to empty storage rooms, or for treatment of fields after harvest. In case 'not applicable' is selected, further clarifications need to be provided in the field 'additional information'.	FLEXIBLE_RECORD. GAP.PestDiseaseTreated.ApplicationDetails.PreharvestInterval
Re-entry period livestock	The field is not mandatory. This field should be used to describe the minimum re-entry period (hours/days) for livestock, i.e. the time that needs to elapse before animals may enter treated pastures.	FLEXIBLE_RECORD. GAP.PestDiseaseTreated.ApplicationDetails.ReentryPeriodLivestock

Withholding period animal feed	The field is not mandatory. This field is intended to define the minimum time (in days) between harvest of a feed crop and the use of the feed.	FLEXIBLE_RECORD. GAP.PestDiseaseTreated.ApplicationDetails.WithholdingPeriod
Re-entry period	The field is not mandatory. Describe the minimum re-entry period (in days or hours) for workers in the field/room treated with pesticide, in order to safeguard human health. If no re-entry period is defined/required, select 'not applicable'.	FLEXIBLE_RECORD. GAP.PestDiseaseTreated.ApplicationDetails.ReentryPeriod
Waiting period handling treated product	The field is not mandatory. This field is intended to describe the minimum waiting periods (hours/days) that need to be respected between treatment and handling of treated products (e.g. handling of products after fumigation).	FLEXIBLE_RECORD. GAP.PestDiseaseTreated.ApplicationDetails.WaitingPeriod
Ventilation practices	The field is not mandatory. If relevant, please describe the ventilation practices to be carried out after indoor treatments, to safeguard human health.	FLEXIBLE_RECORD. GAP.PestDiseaseTreated.ApplicationDetails.VentilationPractices
Plant-back interval	The field is not mandatory. If relevant, please describe the plant-back interval (expressed as days) that has to be respected (e.g. in case of crop failure) before the planting of succeeding crops is allowed.	FLEXIBLE_RECORD. GAP.PestDiseaseTreated.ApplicationDetails.PlantbackInterval
Restrictions	The field is not mandatory. If relevant, please report any relevant restrictions that would have an impact on the risk assessment e.g.: <ul style="list-style-type: none"> - geographical restrictions, - restriction related to use of other a.s., - maximum number of applications per season for a.s. belonging to the same group (e.g. dithiocarbamates, triazoles), - restrictions for rotational crops, - PPE, - buffer zones, - temperature range at application, - soil incorporation depth and time, - restricted soil type, - restriction to crops grown in artificial substrate, - restriction to be used only in crops grown in hydroponic systems, - restriction to crops grown in pots/no connection to natural soil, - restrictions to be used in crops up to a certain crop height, - minimum percent soil organic matter, - restrictions to protect pollinators, - restriction regarding application equipment. 	FLEXIBLE_RECORD. GAP.PestDiseaseTreated.ApplicationDetails.Restrictions

Type of user	The field is not mandatory. Please select one or several terms from the picklist (professional/non-professional/other:). If other is selected, please provide more details in the remark field.	FLEXIBLE_RECORD. GAP.PestDiseaseTreated.ApplicationDetails.TypeOfUser
Additional information	Any relevant information on the GAP that cannot be reported in any of the data fields above should be entered in this field.	FLEXIBLE_RECORD. GAP.AdditionalInformation

EU PPP MRL application - active substance information

1. Identity of the active substance and applicant

1.1 Identity of the active substance and applicant

Purpose:

This document facilitates the creation of a substance dataset when completing a mixture/product dossier. It also links to a reference substance in a mixture composition document. This document should be completed for active substance and relevant metabolites and impurities

Note: if there are no studies for a component of mixture link directly to a reference substance.

Substance – v.8.1 (Final)			
Name	Instructions	Type	Field Path
Substance name	The International Organization for Standardization (ISO) common name, or proposed ISO common name	Multi-line text	SUBSTANCE.ChemicalName
Public name	Public name of the active substance	Multi-line text	SUBSTANCE.PublicName
Other substance identifiers	Code numbers used to identify the active substance, during development work, shall be reported. For each code number reported, the material to which it relates, the period for which it was used should be reported in the Remarks field The Member States or other countries in which it was used and is being used, should be reported in the Country field		SUBSTANCE.OtherNames
Flags	See confidentiality	Confidentiality	SUBSTANCE.OtherNames.DataProtection
Identifier		Open list	SUBSTANCE.OtherNames.NameType
Identity		Multi-line text	SUBSTANCE.OtherNames.Name
Country		Multi select open list	SUBSTANCE.OtherNames.Country
Relation		Open list	SUBSTANCE.OtherNames.Relation
Remarks		Text area	SUBSTANCE.OtherNames.Remarks
Other substance identifiers			

Legal entity flags		Confidentiality	SUBSTANCE.OwnerLegalEntityProtection
Legal entity	Include the name of the legal entity i.e. Company name for the applicant	Entity reference field	SUBSTANCE.OwnerLegalEntity
Third party flags		Confidentiality	SUBSTANCE.ThirdPartyProtection
Third party	Option to link to the legal entity of a third party. This is to be filled in by consultants if they are working on the dossier.	Entity reference field	SUBSTANCE.ThirdParty
Contact persons	Contact entity		SUBSTANCE.ContactPersons
Person flags		Confidentiality	SUBSTANCE.ContactPersons.DataProtection
Person		Entity reference field	SUBSTANCE.ContactPersons.ContactPerson
Contact persons			
Identification of substance		Header 1	SUBSTANCE.ReferenceSubstance
Reference substance flags		Confidentiality	SUBSTANCE.ReferenceSubstance.Protection
Reference substance	Link to the reference substance Reference substance v.6.4 (Final)	Entity reference field	SUBSTANCE.ReferenceSubstance.ReferenceSubstance
Type of substance		Header 1	SUBSTANCE.TypeOfSubstance
Type of substance	For Microorganism dossiers 'microorganism or toxin produced by microorganism' must be selected. The other types can be used for chemicals	Open list	SUBSTANCE.TypeOfSubstance.Composition
Origin	Picklist to indicate class of active substance e.g organic or inorganic	Open list	SUBSTANCE.TypeOfSubstance.Origin
Role in the supply chain	Check 'Manufacturer' to indicate the applicant is the Producer of the active substance	Header 1	SUBSTANCE.RoleInSupplyChain
Role flags		Confidentiality	SUBSTANCE.RoleInSupplyChain.RoleProtection
Manufacturer		Check box	SUBSTANCE.RoleInSupplyChain.Manufacturer
Importer		Check box	SUBSTANCE.RoleInSupplyChain.Importer
Only representative		Check box	SUBSTANCE.RoleInSupplyChain.OnlyRepresentative

Downstream user		Check box	SUBSTANCE.RoleInSupplyChain.DownstreamUser
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Links to support materials

[Legal entity](#)

[ISO/TC 81](#)

1.8 Method of manufacture (synthesis pathway) of the active substance

Purpose:

To describe the method of manufacture (synthesis pathway) of the active substance. For each manufacture plant, describe, the purity of the starting materials, chemical pathways and identity of impurities present in the final product. and identity of impurities present in the final product.

FLEXIBLE_RECORD.Manufacturer_EU_PPP – v.2.2 (Final)			
Name	Instructions	Type	Field Path
Administrative data		Header 1	FLEXIBLE_RECORD.Manufacturer_EU_PPP.AdministrativeDataSummary
	See Confidentiality of dossiers Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	Confidentiality	FLEXIBLE_RECORD.Manufacturer_EU_PPP.AdministrativeDataSummary.DataProtection
Related compositions	Link to one or more compositions of the substance can be made which will then display the corresponding name(s). This link enables to transparently identify which composition of the substance is relevant for which use during its life cycle (from manufacture to service life).	Endpoint reference list	FLEXIBLE_RECORD.Manufacturer_EU_PPP.AdministrativeDataSummary.RelatedCompositions
Description of key information	Describe the manufacturing process	Header 1	FLEXIBLE_RECORD.Manufacturer_EU_PPP.Key Information

	<p>e.g. chemical pathways involved.</p> <p>Where the required information is provided for a pilot plant production system, that information shall again be provided once industrial scale production methods and procedures have stabilised. Where available, industrial scale data shall be provided before approval under Regulation (EC) No 1107/2009. Where data on industrial scale production are not available, a justification shall be provided.</p>		
	This text will be published.	Rich text area	FLEXIBLE_RECORD.Manufacturer_EU_PPP.KeyInformation.field4764
Additional information	State the manufacturing plant if separate documents are provided for each manufacturing plant	Header 1	FLEXIBLE_RECORD.Manufacturer_EU_PPP.AdditionalInformation
	This text will be published.	Rich text area	FLEXIBLE_RECORD.Manufacturer_EU_PPP.AdditionalInformation.field7821
Grounds for confidential file	<p>Select one or more of the following grounds for confidentiality to justify the claim</p> <p>Article 63(2)(a) of Regulation (EC) No 1107/2009 (making reference to Article 39 of Regulation (EC) No 178/2002)</p> <p>the manufacturing or production process, including the method and innovative aspects thereof, as well as</p>	Multi select open list with remarks (32000)	FLEXIBLE_RECORD.Manufacturer_EU_PPP.AdditionalInformation.GroundsForConfidentialFile

	<p>other technical and industrial specifications inherent to that process or method, except for information which is relevant to the assessment of safety; commercial links between a producer or importer and the applicant or the authorisation holder, where applicable; commercial information revealing sourcing, market shares or business strategy of the applicant</p> <p>quantitative composition of the subject matter of the request, except for information which is relevant to the assessment of safety</p> <p>Article 63(2)(b) of Regulation (EC) No 1107/2009</p> <p>the specification of impurity of the active substance and the related methods of analysis for impurities in the active substance as manufactured, except for the impurities that are considered to be toxicologically, ecotoxicologically or environmentally relevant and the related methods of analysis for such impurities</p>		
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	<p>Article 63(2)(c) of Regulation (EC) No 1107/2009</p> <p>results of production batches of the active substance including impurities</p> <p>Article 63(2)(d) of Regulation (EC) No 1107/2009</p> <p>information on the complete composition of a plant protection product</p> <p>Article 39e (2) of Regulation (EC) No 178/2002</p> <p>personal data (names and addresses) of individuals involved in testing on vertebrate studies or in obtaining toxicological information</p> <p>Article 39e (3) of Regulation (EC) No 178/2002</p> <p>other personal data (names, addresses, signatures etc.)</p>		
Justification	<p>Enter a justification supporting your confidentiality request(s) concerning fields/attachments forming part of this record thereby making use of the justification template made available to you by means of this Manual. Note that this field should not be used for</p>	Text area	<p>FLEXIBLE_RECORD.Manufacturer_EU_PPP.AdditionalInformation.Justification</p>

	justifications supporting confidentiality request(s) made in other IUCLID records/summaries or (sub-)sections thereof.		
Conditions	<p>Select condition/s that apply to the confidentiality claim</p> <p>No public availability: the document, information or data for which confidentiality status is requested is not publicly available or is known only to a limited number of persons;</p> <p>Potential harm: the public disclosure of the document, information or data for which confidentiality status is requested may potentially harm the interests of the applicant to a significant degree and that the harm that may be caused is of a significance corresponding at least to 5% of their total gross turnover for legal persons, or earnings for natural persons, in the year preceding that of the submission of the confidentiality request. If the harm is quantified as not reaching this percentage, or the applicant is unable to calculate its impact on their turnover/earnings, the applicant should provide a specific</p>	Multi select open list with remarks (32000)	FLEXIBLE_RECORD.Manufacturer_EU_PPP.AdditionalInformation.Conditions

	<p>reason in the form of a free text in the respective Justification box on why they consider that any public disclosure would potentially harm their interests to a significant degree.</p> <p>Worthiness of legal protection: the document, information or data for which confidentiality treatment is requested is eligible for legal protection in the form of the award of the confidentiality status.</p> <p>No environmental information: the document, information or data for which confidentiality status is requested does not fall under the definition of "environmental information" pursuant to Article 2(1)(d) of Regulation (EC) No 1367/2006.</p> <p>Novelty: the document, information or data for which confidentiality status is requested has not been finalised in the form submitted to EFSA more than five years prior to the submission of the confidentiality request. If the document, information or data deemed to be awarded confidential status is older than five years, the applicant</p>		
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	shall provide a specific reason in the form of a free text in the respective Justification on why public disclosure of that information would still potentially harm its interests to a significant degree.		
Document J	<p>The original file only needs to be attached here if the non-confidential file uploaded under "Attached (sanitised) documents for publication" contains redactions. If a file is uploaded under this field, (a) confidentiality claim(s) must be submitted for each part of the file considered confidential and the information claimed confidential must be clearly boxed or earmarked consistently with the redactions applied in the corresponding non-confidential file. This file will not be published.</p> <p>The filled-in "IUCLID templates for PPP Risk Assessment - Template 1.1 - Template for presentation the assessment for the equivalence of batches" (https://doi.org/10.5281/zenodo.4557366) shall be included in Document J. The relevant IUCLID documents should be completed. However</p>	Single file attachment	FLEXIBLE_RECORD.Manufacturer_EU_PPP.AdditionalInformation.DocumentJ

	<p>Document J can contain the information previously included in this document to ensure a complete assessment for an interim period until all sections are available in the 'Working contexts' with appropriate confidentiality management.</p> <p>For this reason analytical methods for impurities which are not toxicologically relevant should be reported in Doc J.</p>		
Sanitised Document J	<p>Document J must be uploaded here in its public (non-confidential) version. The public version will be published once the dossier has been considered valid/admissible. All elements therein claimed confidential should be sanitised. Save for the elements blackened, if applicable, content and layout-wise the public version must be fully identical with the confidential version. Upon conclusion of the confidentiality assessment, if applicable, a revised public version removing the redactions relating to confidentiality requests that were rejected in part or in full must be uploaded here.</p>	Single file attachment	FLEXIBLE_RECORD.Manufacturer_EU_PPP.AdditionalInformation.SanitisedDocumentJ
Attached background material	Additional background material can be uploaded here, use		FLEXIBLE_RECORD.Manufacturer_EU_PPP.Add

	<p>remarks to indicate the contents of the uploaded files</p> <p>The original file only needs to be attached here if the non-confidential file uploaded under "Attached (sanitised) documents for publication" contains redactions. If a file is uploaded under this field (a) confidentiality claim(s) must be submitted for each part of the file considered confidential and the information claimed confidential must be clearly boxed or earmarked consistently with the redactions applied in the corresponding non-confidential file. This file will not be published.</p>		<p>itionalInformation.AttachedBackgroundMaterial</p>
<p>Attached confidential document</p>	<p>Upload supporting material (e.g. Excel files) as described in regulatory guidance. Click the upload icon. As appropriate, enter any additional information, e.g. language. The file name is displayed after uploading the document.</p> <p>The original file only needs to be attached here if the non-confidential file uploaded under "Attached (sanitised) documents for publication" contains redactions. If a file is uploaded under this field (a) confidentiality claim(s) must be</p>	<p>Single file attachment</p>	<p>FLEXIBLE_RECORD.Manufacturer_EU_PPP.AdditionalInformation.AttachedBackgroundMaterial.AttachedDocument</p>

	submitted for each part of the file considered confidential and the information claimed confidential must be clearly boxed or earmarked consistently with the redactions applied in the corresponding non-confidential file. This file will not be published.		
Remarks	As appropriate, include remarks, e.g. a short description of the content of the attached document if the file name is not self-explanatory.	Text	FLEXIBLE_RECORD.Manufacturer_EU_PPP.AdditionalInformation.AttachedBackgroundMaterial.Remarks
Attached background material			
Attached (sanitised) documents for publication	<p>A non-confidential version of any submitted background material must be uploaded here. These will be published once the dossier has been considered valid/admissible. All elements therein claimed confidential should be sanitised. Save for the elements blackened, if applicable, content and layout-wise the public version must be fully identical with the confidential version.</p> <p>Upon conclusion of the confidentiality assessment, if applicable, a revised non-confidential version removing the redactions relating to confidentiality requests that were rejected in part or in</p>	Attachments list	FLEXIBLE_RECORD.Manufacturer_EU_PPP.AdditionalInformation.AttachedSanitisedDocsForPublication

	full must be uploaded here.		
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Links to support materials:

Transparency Regulation: Practical Arrangements

<https://www.efsa.europa.eu/en/corporate/pub/tr-practical-arrangements>

1.9 Specification of purity of the active substance in g/kg

Purpose

The minimum content in g/kg of pure active substance in the manufactured material used for production of plant protection products, shall be reported. A justification shall be provided for the minimum content proposed in the specification; this shall include a statistical analysis of the data on at least five representative batches, as referred to in point 1.11. Additional supporting data may be provided to further justify the technical specification.

Where the required information is provided for a pilot plant production system, that information shall again be provided once industrial scale production methods and procedures have stabilized. Where available, industrial scale data shall be provided before approval under Regulation (EC) No 1107/2009. Where data on industrial scale production are not available, a justification shall be provided.

For microorganisms; the identity and maximum content of all contaminating micro-organisms, expressed in the appropriate unit, must be reported, where relevant detailed information on all components such as condensates, culture medium, etc. must be provided, identity and content should also be reported for impurities and additives

If the active substance is manufactured as technical concentrate (TK), the minimum and maximum content of the pure active substance shall be given, along with its content in the theoretical dry weight material.

If the active substance is a mixture of isomers, the ratio or the ratio range of the content of isomers shall be provided. The relative biological activity of each isomer, both in terms of efficacy and toxicity, shall be reported.


For plant extracts, a different approach may be taken if adequately justified.

FLEXIBLE_RECORD.SubstanceComposition v.7.4 (Final)			
Name	Instructions	Data type	Field path
General Information	To report the analytical profile of batches a substance composition document should be completed for each batch	Header 1	FLEXIBLE_RECORD.SubstanceComposition.GeneralInformation
Name	Indicate a name representative of the composition.	Text	FLEXIBLE_RECORD.SubstanceComposition.GeneralInformation.Name
Type of composition	Select the type of composition as appropriate. - A 'legal entity composition of the substance' refers to a composition specific to the party carrying out the application/notification/registration.	Open list	FLEXIBLE_RECORD.SubstanceComposition.GeneralInformation.TypeOfComposition
State / form	Indicate the physical state and form of the composition. The picklist is not exhaustive, but aims to reflect states and forms that may influence the properties of the substance. If none of pre-defined picklist items appropriately describe your composition, select 'other:'. A text field is then activated next to the list field in which you can enter the state and form of the composition. If multiple options apply, please create a separate composition for each.	Open list	FLEXIBLE_RECORD.SubstanceComposition.GeneralInformation.StateForm

Description	Include in this field, as appropriate, additional information on the composition. For a complex substance, the description should enable the understanding of the process that led to the particular composition. Free-text templates are available to support the user in providing a suitable description.	Text template	FLEXIBLE_RECORD.SubstanceComposition.GeneralInformation.DescriptionOfComposition
Justification for deviations	Provide in this field, if relevant, the justification for deviating from agreed conventions when reporting the composition. Such deviations can for example relate to the definitions of substance types (e.g. mono-constituent substance), or the level to which a composition has been described in terms of separate constituents, impurities and additives. Consult any programme-specific guidance on how to use this field.	Text area	FLEXIBLE_RECORD.SubstanceComposition.GeneralInformation.JustificationForDeviations
Attached description / justification	Attach in this table supporting information to describe the composition, e.g. schematics for relevant chemical reactions or process steps that take place in the generation of the composition.		FLEXIBLE_RECORD.SubstanceComposition.GeneralInformation.AttachedDescription
Attached document	Upload a file by clicking the upload icon. Documents with confidential material should not be uploaded in this field.	Single file attachment	FLEXIBLE_RECORD.SubstanceComposition.GeneralInformation.AttachedDescription.AttachedDocument
Remarks	Provide information about the contents of the attached document.	Text	FLEXIBLE_RECORD.SubstanceComposition.GeneralInformation.AttachedDescription.Remarks
Attached description / justification			
Related composition(s)		Header 2	FLEXIBLE_RECORD.SubstanceComposition.GeneralInformation.RelatedCompositions
Related composition	Use this field, where relevant, to link compositions of the type 'legal entity composition of the substance' to other compositions in the same dataset. Typically, this field is used to link a legal entity composition to the boundary composition that encompasses that legal entity composition. The field is active only for compositions of the type 'legal entity composition of the substance' to prevent multiple links between the same compositions. Related compositions in other datasets or dossiers should be referred to textually in the field 'Reference to related composition(s)'.	Endpoint reference list	FLEXIBLE_RECORD.SubstanceComposition.GeneralInformation.RelatedCompositions.RelatedComposition

Reference to related composition(s)	Use this field, where relevant, to refer compositions of the type 'legal entity composition of the substance' to compositions in other datasets. Typically, this field is used to provide a textual reference from a legal entity composition to the boundary composition that encompasses the legal entity composition, when the boundary composition is provided in another dataset. The field is active only for compositions of the type 'legal entity composition of the substance' to prevent multiple referencing between the same compositions. Related compositions located in the same dataset should be linked in the field 'Related composition'.	Multi-line text	FLEXIBLE_RECORD.SubstanceComposition.GeneralInformation.RelatedCompositions.ReferenceToRelatedCompositions
Degree of purity		Header 1	FLEXIBLE_RECORD.SubstanceComposition.DegreeOfPurity
	Set confidentiality and regulatory programme flags.	Confidentiality	FLEXIBLE_RECORD.SubstanceComposition.DegreeOfPurity.DataProtection
	Indicate the degree of purity; give the purity with the upper and lower limit for typical commercial batches of the substance. For providing only a single numeric value; enter the value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='.	Range with open list (Decimal)	FLEXIBLE_RECORD.SubstanceComposition.DegreeOfPurity.Purity
Constituents	This part is a repeatable block subsection enabling to provide detail on all constituents of a specific composition of the substance. Click the Plus button to open the repeatable block. If the composition contains more than one constituent, add a new block to describe each constituent.	Header 1	FLEXIBLE_RECORD.SubstanceComposition.Constituents
			FLEXIBLE_RECORD.SubstanceComposition.Constituents.Constituents
	Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	Confidentiality	FLEXIBLE_RECORD.SubstanceComposition.Constituents.Constituents.DataProtection
Reference substance	Assign here the reference substance that identifies the constituent. Click the Arrow button to access a linked reference substance and modify it as appropriate. Click the Link button to link/change the reference substance. If the desired reference substance is not present in your database, click the New button at the bottom of the Query window and insert the information of the reference substance in the available fields. For further	Entity reference field	FLEXIBLE_RECORD.SubstanceComposition.Constituents.Constituents.ReferenceSubstance

	<p>information on reference substances, see chapter 10 of 'Functionalities of IUCLID', in the left pane of the Help system window.</p> <p>Where relevant detailed information on all components such as condensates, culture medium, etc. must be provided</p>		
Typical concentration	<p>Indicate the typical concentration of the constituent in the selected composition of the substance.</p> <p>Note: scientific notation can be used, 5e7= 500000000\</p> <p>For technical specifications this field must be completed</p>	Half-bounded with open list (Decimal)	FLEXIBLE_RECORD.SubstanceComposition.Constituents.Constituents.ProportionTypical
Concentration range	<p>Indicate the concentration range of the constituent the selected composition of the substance. If only providing a single numeric value:</p> <ul style="list-style-type: none"> -Enter the value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.' -Use the second numeric field if the qualifier is '<' or '<='. 	Range with open list (Decimal)	FLEXIBLE_RECORD.SubstanceComposition.Constituents.Concentration
Remarks	Provide additional information about the constituent, as relevant.	Text area	FLEXIBLE_RECORD.SubstanceComposition.Constituents.Remarks
Impurities	<p>This part is a repeatable block subsection enabling to provide detail on all impurities of a specific composition of the substance. Click the Plus button to open the repeatable block. If the composition contains more than one impurity, add a new block to describe each impurity.</p>	Header 1	FLEXIBLE_RECORD.SubstanceComposition.Impurities
			FLEXIBLE_RECORD.SubstanceComposition.Impurities.Impurities
	<p>Set confidentiality and regulatory programme flags.</p> <p>Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants</p>	Confidentiality	FLEXIBLE_RECORD.SubstanceComposition.Impurities.Impurities.DataProtection
Reference substance	<p>Assign here the reference substance that identifies the impurity. Click the Arrow button to access a linked reference substance and modify it as appropriate. Click the Link button to link/change the reference substance. If the desired reference substance is not present in your database, click the New button at the bottom of the Query window and insert the information of the reference substance in the available fields. For further</p>	Entity reference field	FLEXIBLE_RECORD.SubstanceComposition.Impurities.ReferenceSubstance

	information on reference substances, see chapter 10 of 'Functionalities of IUCLID', in the left pane of the Help system window.		
Typical concentration	Indicate the typical concentration of the impurity in the selected composition of the substance. Ensure to follow regulatory guidance on what constitutes an impurity. For technical specifications this field must be completed	Half-bounded with open list (Decimal)	FLEXIBLE_RECORD.SubstanceComposition.Impurities.Impurities.ProportionTypical
Concentration range	Indicate the concentration range of the impurity the selected composition of the substance. If only providing a single numeric value: -Enter the value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.' -Use the second numeric field if the qualifier is '<' or '<='.	Range with open list (Decimal)	FLEXIBLE_RECORD.SubstanceComposition.Impurities.Impurities.Concentration
Remarks	Provide additional information about the impurity, as relevant.	Text area	FLEXIBLE_RECORD.SubstanceComposition.Impurities.Impurities.Remarks
This impurity is considered relevant for the classification and labelling of the substance	Select the checkbox to indicate that the impurity has an impact on the classification and labelling of the substance.	Checkbox	FLEXIBLE_RECORD.SubstanceComposition.Impurities.Impurities.RelevantForClassificationLabeling
Additives	This part is a repeatable block subsection enabling to provide detail on all additives of a specific composition of the substance. Click the Plus button  to open the repeatable block. If the composition contains more than one additive, add a new block to describe each additive.	Header 1	FLEXIBLE_RECORD.SubstanceComposition.Additives
			FLEXIBLE_RECORD.SubstanceComposition.Additives.Additives
	Set confidentiality and regulatory programme flags. Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	Confidentiality	FLEXIBLE_RECORD.SubstanceComposition.Additives.Additives.DataProtection
Reference substance	Assign here the reference substance that identifies the additive. Click the Arrow button to access a linked reference substance and modify it as appropriate. Click the Link button to link/change the reference substance. If the desired reference substance is not present in	Entity reference field	FLEXIBLE_RECORD.SubstanceComposition.Additives.Additives.ReferenceSubstance

	your database, click the New button at the bottom of the Query window and insert the information of the reference substance in the available fields. For further information on reference substances, see chapter 10 of 'Functionalities of IUCLID', in the left pane of the Help system window.		
Typical concentration	Indicate the typical concentration of the additive in the selected composition of the substance. For technical specifications this field must be completed	Half-bounded with open list (Decimal)	FLEXIBLE_RECORD.SubstanceComposition.Additives.Additives.ProportionTypical
Concentration range	Indicate the concentration range of the additive the selected composition of the substance. If only providing a single numeric value: -Enter the value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.' -Use the second numeric field if the qualifier is '<' or '<='.	Range with open list (Decimal)	FLEXIBLE_RECORD.SubstanceComposition.Additives.Additives.Concentration
Function	Indicate the function of the additive in the composition of the substance. Ensure to follow regulatory guidance on what constitutes an additive.	Open list	FLEXIBLE_RECORD.SubstanceComposition.Additives.Additives.Function
Details of function in composition	Provide further information related to the function of the additive in the composition of the substance. In particular, if selecting a less specific entry in the previous 'Function' field, it is recommended to include more details on the function in this field.	Text area	FLEXIBLE_RECORD.SubstanceComposition.Additives.Additives.DetailsOfFunctionInComposition
Remarks	Provide additional information about the additive, as relevant.	Text area	FLEXIBLE_RECORD.SubstanceComposition.Additives.Additives.Remarks
This additive is considered relevant for the classification and labelling of the substance	Select the checkbox to indicate that the additive has an impact on the classification and labelling of the substance.	Checkbox	FLEXIBLE_RECORD.SubstanceComposition.Additives.Additives.RelevantForClassificationLabelling
Characterisation of nanoforms	This section is not relevant for pesticides	Header 1	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms
Characterisation of polymers	This section is not relevant for pesticides	Header 1	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfPolymers

2. Physical and chemical properties of the active substance – Endpoint summary

Purpose

Summary information of to the most relevant study(ies) from which the key value for chemical safety assessment is extrapolated. Provide only the most relevant details for:

- Appearance
- Flammability (state purity)
- Explosive properties (state purity)
- Oxidizing properties (state purity)
- Solubility in water
- Partition coefficient

(according to (Regulation (EU) N° 283/2013, Annex Part A, point 2)

ENDPOINT_SUMMARY.PhysicalChemicalProperties – v.5.0 (Final)			
Name	Instructions	Data Type	Field Path
Administrative data	See Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.PhysicalChemicalProperties.AdministrativeDataSummary
Additional information	See Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.PhysicalChemicalProperties.Discussion

2.5 Solubility in water – Endpoint summary

Purpose:

Summary information of to the most relevant study(ies) from which the key value for chemical safety assessment is extrapolated. Provide only the most relevant details, which could be the structural formula, vapour pressure, dissociation constant and hydrolysis as a function of pH.

(COMMISSION REGULATION (EC) No 440/2008)

ENDPOINT_SUMMARY.WaterSolubility – v.5.0 (Final)			
Name	Instructions	Type	Field Path
Administrative data	Administrative data summary – common block Description of key information: Report Information to support solubility in water for example: <ul style="list-style-type: none"> - the structural formula - vapour pressure - dissociation constant - temperature - purity and pH 	Header 1	ENDPOINT_SUMMARY.WaterSolubility.AdministrativeDataSummary

Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.Water Solubility.KeyValueForChemicalSafetyAssessment
Water solubility	Report solubility in water in mg or g/L	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.Water Solubility.KeyValueForChemicalSafetyAssessment.WaterSolubility
at the temperature of		Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.Water Solubility.KeyValueForChemicalSafetyAssessment.TemperatureOf
Additional information	Discussion(Header 1) – common block Provide additional information related to the endpoint, for example: <ul style="list-style-type: none"> - information on the potential data gaps - relevance of the results for the risk assessment - the rationale for the choice of the key study(ies) and the choice for the key value that characterises the endpoint - the rationale for any user-derived values for the sake of transparency -the possible reasons for differentiating results when several studies were identified to be relevant for the assessment. If there is no additional information to be reported this field may be left empty.	Header 1	ENDPOINT_SUMMARY.Water Solubility.Discussion

2.5 Solubility in water – Endpoint study record

Purpose:

The water solubility of purified active substances under atmospheric pressure shall be determined and a value reported for 20 °C. These water solubility determinations shall be made in the neutral range (that is to say in distilled water in equilibrium with atmospheric carbon dioxide). If the pKa is between 2 and 12, water solubility shall also be determined in the acidic range (pH 4 to 5) and in the alkaline range (pH 9 to 10). Where the stability of the active substance in aqueous media is such that water solubility cannot be determined, a justification based on test data shall be provided.

(COMMISSION REGULATION (EU) No 283/2013)

ENDPOINT_STUDY_RECORD.WaterSolubility– v.5.0 (Final)			
Name	Instructions	Type	Field Path

Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.WaterSolubility.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.WaterSolubility.DataSource
Materials and methods	Material and methods – common block Guideline: OECD 105.	Header 1	ENDPOINT_STUDY_RECORD.WaterSolubility.MaterialsAndMethods
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.WaterSolubility.MaterialsAndMethods.TestMaterials
Study design		Header 2	ENDPOINT_STUDY_RECORD.WaterSolubility.MaterialsAndMethods.StudyDesign
Analytical method	Reference to the Analytical Method endpoint study record describing the method can be included in the remarks. In the supplementary remarks field, provide method validation. As appropriate attach all relevant chromatograms.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.WaterSolubility.MaterialsAndMethods.StudyDesign.AnalyticalMethod
Details on methods	Provide details on the methods including analytical method, method validation data and all relevant chromatograms (attach as appropriate) particularly if no guideline was used. If the test substance appears 'insoluble' in water, provide the detection limit of the analytical method. Also provide the purity of water used. If an estimation method was used (to be indicated in field 'Test result type') state the equation(s) applied to calculate the water solubility.	Text area	ENDPOINT_STUDY_RECORD.WaterSolubility.MaterialsAndMethods.StudyDesign.DetailsOnMethods
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.WaterSolubility.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.WaterSolubility.ResultsAndDiscussion
Water solubility	Enter mean water solubility or range if reported so and indicate the temperature and pH conditions in the respective subfields. If necessary, copy this block of fields for each temperature and pH conditions at which		ENDPOINT_STUDY_RECORD.WaterSolubility.ResultsAndDiscussion.WaterSolubility

	the water solubility was determined. If the pH value was measured with another test substance concentration than the given water solubility concentration, specify the concentration with unit in field 'Details on remarks'.		
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.WaterSolubility.ResultsAndDiscussion.WaterSolubility.KeyResult
Water solubility	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.WaterSolubility.ResultsAndDiscussion.WaterSolubility.Solubility
Conc. based on	Indicate whether the concentration is based on the test material (test mat.), active ingredient (act. ingr.), or element. As appropriate the measured / addressed fraction can be specified for either of these entities by selecting the relevant item, e.g. 'element (dissolved fraction)' or 'test mat. (total fraction)'. Further information can be given in the supplementary remarks field, e.g. for specifying the type of fraction if it is not clear per se from the test material specification. Select 'not specified' if the effect concentration type is not known.	Open list with remarks	ENDPOINT_STUDY_RECORD.WaterSolubility.ResultsAndDiscussion.WaterSolubility.ConcBasedOn
Loading of aqueous phase	Indicate the loading, i.e. concentration of massive forms and/or powders introduced into the aqueous medium. Select from drop-down list.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.WaterSolubility.ResultsAndDiscussion.WaterSolubility.LoadingOfAqueousPhase
Incubation duration	Specify the time until equilibrium was reached in the test.	Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.WaterSolubility.ResultsAndDiscussion.WaterSolubility.IncubationDuration
Temp.	Enter numeric value and unit.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.WaterSolubility.ResultsAndDiscussion.WaterSolubility.Temp
pH	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a	Range (Decimal)	ENDPOINT_STUDY_RECORD.WaterSolubility.ResultsAndDiscussion

	range use both numeric fields together with the appropriate qualifier(s) if applicable.		ssion.WaterSolubility.Ph
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any remarks by selecting 'other:'.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.WaterSolubility.ResultsAndDiscussion.WaterSolubility.RemarksOnResults
Water solubility			
Solubility of metal ions in aqueous media	If the concentration of dissolved metal ions in aqueous media was tested in a transformation / dissolution test, indicate the type of test and the concentrations measured after a distinct incubation period, together with the loading, element analysed and test conditions (temperature, pH and oxygen) in the respective subfields. If necessary, copy this block of fields for different test runs, conditions or several metals released in the case of multi-metallic (e.g. UVCB) substances.		ENDPOINT_STUDY_RECORD.WaterSolubility.ResultsAndDiscussion.SolubilityOfMetalIonsInAqueousMedia
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.WaterSolubility.ResultsAndDiscussion.SolubilityOfMetalIonsInAqueousMedia.KeyResult
Type of test	Select from drop-down list.	Open list with remarks	ENDPOINT_STUDY_RECORD.WaterSolubility.ResultsAndDiscussion.SolubilityOfMetalIonsInAqueousMedia.TypeOfTest
Mean dissolved conc.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.WaterSolubility.ResultsAndDiscussion.SolubilityOfMetalIonsInAqueousMedia.MeanDissolvedConc
Element analysed	Specify the element analysed.	Multi-line text	ENDPOINT_STUDY_RECORD.WaterSolubility.ResultsAndDiscussion.SolubilityOfMetalIonsInAqueousMedia.ElementAnalysed
Loading of aqueous phase	Indicate the loading, i.e. concentration of massive forms and/or powders introduced into the aqueous medium. Select from drop-down list.	Unit measure with Open List	ENDPOINT_STUDY_RECORD.WaterSolubility.ResultsAndDiscussion.SolubilityOfMetalIonsInAqueousMed

		(Decimal)	ia.LoadingOfAqueousPhase
Incubation duration	Specify the duration of incubation for the loading applied. Select from drop-down list.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.WaterSolubility.ResultsAndDiscussion.SolubilityOfMetalIonsInAqueousMedia.IncubationDuration
Test conditions	Briefly describe the temperature, pH, oxygen conditions and time interval to determine the concentrations of dissolved metal ions in the water.	Multi-line text	ENDPOINT_STUDY_RECORD.WaterSolubility.ResultsAndDiscussion.SolubilityOfMetalIonsInAqueousMedia.TestConditions
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any remarks by selecting 'other:'.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.WaterSolubility.ResultsAndDiscussion.SolubilityOfMetalIonsInAqueousMedia.RemarksOnResults
Solubility of metal ions in aqueous media			
Details on results		Text area	ENDPOINT_STUDY_RECORD.WaterSolubility.ResultsAndDiscussion.DetailsOnResults
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.WaterSolubility.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.WaterSolubility.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.WaterSolubility.ApplicantSummaryAndConclusion

2.7 Partition coefficient n-octanol/water– Endpoint summary

Purpose:

Summary information of to the most relevant study(ies) from which the key value for chemical safety assessment is extrapolated. Provide only the most relevant details, which could be:

- the results of the preliminary estimation
- all information relevant for the interpretation of the results, especially with regard to impurities and physical state of the substance;
- POW values and their mean for each set of test conditions and the overall mean (if there is the suggestion of concentration dependence of the partition coefficient, this should be noted);
- the standard deviation of individual POW values about their mean;
- the overall mean expressed as its logarithm to base 10;
- the theoretical POW when it has been calculated or when the measured value is above 104 .

(OECD Test No. 107: Partition Coefficient (n-octanol/water): Shake Flask Method)

ENDPOINT_SUMMARY.PartitionCoefficient – v.5.0 (Final)			
Name	Instructions	Type	Field Path
Administrative data	Administrative data summary – common block Description of key information: Report Information to support the partition coefficient, for example state: temperature, pH and purity	Header 1	ENDPOINT_SUMMARY.PartitionCoefficient.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.PartitionCoefficient.KeyValueForChemicalSafetyAssessment
Log Kow (Log Pow)		Decimal	ENDPOINT_SUMMARY.PartitionCoefficient.KeyValueForChemicalSafetyAssessment.LowKow
at the temperature of		Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.PartitionCoefficient.KeyValueForChemicalSafetyAssessment.TemperatureOf
Additional information	Discussion(Header 1) – common block	Header 1	ENDPOINT_SUMMARY.PartitionCoefficient.Discussion

2.7 Partition coefficient n-octanol/water– Endpoint study record

Purpose:

The n-octanol/water partition coefficient (Kow or log Pow) of purified active substance and of all components of the residue definition for risk assessment shall be determined and reported for 20 °C or 25 °C. The effect of pH (4 to 10) shall be investigated when the active substance has a pKa value between 2 and 12.

ENDPOINT_STUDY_RECORD.Partition – v.6.3 (Final)			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.Partition.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.Partition.DataSource
Materials and methods	Material and methods – common block Guideline: Select the applicable test guideline, e.g. OECD 117 Method A.8 Partition coefficient (Annex to Regulation (EC) No 440/2008). For surface active compounds method A.8 can be applicable if no problems occur (e.g. phase separations). The HPLC method described in Method A.8 is not applicable to surface active compounds.	Header 1	ENDPOINT_STUDY_RECORD.Partition.MaterialsAndMethods
Partition coefficient type	Indicate the type of partition coefficient, normally 'octanol-water'. Select 'other:' and specify as appropriate. Note: Data on the Henry's law constant (air - water partition) should be entered in the	Open list	ENDPOINT_STUDY_RECORD.Partition.MaterialsAndMethods.PartitionCoefficientType

	respective chapter; data on Kd values (e.g., partition / distribution coefficients for soil or sediment) should be recorded in chapters 'Adsorption / desorption' or 'Other distribution data'.		
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.Partition.MaterialsAndMethods.TestMaterials
Study design		Header 2	ENDPOINT_STUDY_RECORD.Partition.MaterialsAndMethods.StudyDesign
Analytical method	Reference to the Analytical Method endpoint study record describing the method can be included in the remarks. In the supplementary remarks field, provide method validation. As appropriate attach all relevant chromatograms.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.Partition.MaterialsAndMethods.StudyDesign.AnalyticalMethod
Details on methods	Provide details on the methods. If an estimation method was used (to be indicated in field 'Test result type') state the equation(s) applied to calculate the value. For experimental studies, use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.Partition.MaterialsAndMethods.StudyDesign.DetailsOnMethods
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.Partition.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables

Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.Partition.ResultsAndDiscussion
Partition coefficient	Enter overall mean partition coefficient or lower and upper value in case of range determined at the temperature and pH conditions indicated in the respective subfields. Copy this block of fields for each temperature and pH conditions at which the partition coefficient was determined or for indicating both Pow and log Pow values.		ENDPOINT_STUDY_RECORD.Partition.ResultsAndDiscussion.Partcoeff
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.Partition.ResultsAndDiscussion.Partcoeff.KeyResult
Type	Indicate if Pow or log Pow is given.	Closed list	ENDPOINT_STUDY_RECORD.Partition.ResultsAndDiscussion.Partcoeff.Type
Partition coefficient	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.Partition.ResultsAndDiscussion.Partcoeff.Partition
Temp.	Enter numeric value and unit.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.Partition.ResultsAndDiscussion.Partcoeff.Temp
pH	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric	Range (Decimal)	ENDPOINT_STUDY_RECORD.Partition.ResultsAndDiscussion.Partcoeff.Ph

	field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.		
Remarks on result	<p>This field can be used for:</p> <ul style="list-style-type: none"> - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any remarks by selecting 'other:'. 	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.Partition.ResultsAndDiscussion.Partcoeff.RemarksOnResults
Partition coefficient			
Details on results	<p>Give any further relevant information. As appropriate include table(s) with raw data in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').</p> <p>If requested by the regulatory programme, also attach a chart of relation and fitted regression equation (which includes a correlation coefficient) in field 'Attached background material'.</p>	Text area	ENDPOINT_STUDY_RECORD.Partition.ResultsAndDiscussion.DetailsOnResults

Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.Partition.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.Partition.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.Partition.ApplicantSummaryAndConclusion

3. Further information on the active substance

Purpose:

This document covers the following endpoints:

- Function
- Effects on harmful organisms / Information of target organisms
- Mode of action
- Information on (possible) occurrence of resistance development and appropriate management strategies
-

ENDPOINT_SUMMARY.EffectivenessAgainstTargetOrganism - v5.0			
Name	Instructions	Type	Field Path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.EffectivenessAgainstTargetOrganisms.AdministrativeDataSummary
	Use the Confidentiality flag and/or the Regulatory purpose flag to filter out data in subsequent operations such as exporting, printing or dossier creation. A justification is required when the confidentiality flag is set. Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	Confidentiality	ENDPOINT_SUMMARY.EffectivenessAgainstTargetOrganisms.AdministrativeDataSummary.DataProtection
Additional information	Discussion (Header 1) – common block	Header 1	ENDPOINT_SUMMARY.EffectivenessAgainstTargetOrganisms.Discussion

3.2 Effects on harmful organisms, function, mode of action and possible resistance – Endpoint study record

Purpose:

This document covers the following endpoints:

- Function
- Effects on harmful organisms / Information of target organisms
- Mode of action
- Information on (possible) occurrence of resistance development and appropriate management strategies

ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms v.8.2			
Name	Instructions	Data type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.AdministrativeData
General information		Header 1	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation
Background information	Use this field to include any background information, if required, or any relevant introductory remark. Leave field empty if not applicable. Do not include information for which specific fields are provided. PURPOSE OF THIS TEMPLATE: This template can be used for recording general information on the effectiveness of an active substance, a plant protection product or a biocidal product, together with its active substances (as required by the relevant legislation). For products, efficacy studies should be reported using the corresponding template 'Efficacy data'. For active substances, the effectiveness achieved or claimed should be	Multi-line text	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.BackgroundInformation

	<p>briefly described in this template. If required or sensible such description can be supported by including summary table(s) which give an overview of relevant efficacy studies performed with a product or products. As appropriate, the general information can be provided in one record or in several individual records. For instance, one record may be sensible if several target organisms, but same function and product type are addressed. Separate records may be sensible for addressing different types of target organisms and functions. Note that this template focuses primarily on biocides. If used for other than this purpose additional pieces of information may have to be added in several fields. Consult the programme-specific guidance on the details to be included.</p>		
Pest / target organisms to be controlled		Header 2	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.PestTargetOrganismsToBeControlled
Target organisms	Specify the target organism(s) to be controlled. Repeat this block of fields as		ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.PestT

	necessary. Due to the great number of possible target organisms this picklist is not exhaustive. If the species name is not listed, choose an appropriate superior term (e.g. 'Acaridae:') and specify by entering free text in the related field. If organism is not listed at all, choose 'other:' and enter the name or several names in a row in the related text field.		targetOrganismsToBeControlled.TargetOrganisms
Scientific name	Select appropriate scientific name from picklist. If not listed, select 'other' and specify. If not given/known, select 'no data'. See also instructions on this block of fields. Any remarks can be entered in the supplementary remarks field, for instance any code for target organism if required so according to programme-specific guidance. If so, indicate the type of coding system in parentheses,. If scientific name is not available in the picklist, select "other" and refer to EPPO lists available at https://gd.eppo.int/	Open list with remarks	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.PestTargetOrganismsToBeControlled.TargetOrganisms.ScientificName
Common name	Select appropriate common name from picklist. If not listed, select 'other' and specify. If not given/known, select 'no data'. See also instructions on this block of fields. Any remarks can be	Open list with remarks	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.PestTargetOrganismsToBeControlled.TargetOrganisms.CommonName

	entered in the supplementary remarks field. EPPO codes for common name relevant to plant protection products can be retrieved at https://gd.eppo.int/ .		
Developmental stage of target pest	Indicate the developmental stage of the target organism. If not listed, select 'other' and specify. If not given/known, select 'no data'. If not applicable, leave field empty. Any remarks can be entered in the supplementary remarks field, for instance any code for the developmental stage if required so according to programme-specific guidance. If so, indicate the type of coding system in parentheses.	Open list with remarks	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.PestTargetOrganismsToBeControlled.TargetOrganisms.DevelopmentalStage
Developmental stage of target plant	Indicate the developmental stage of the target organism. If not listed, select 'other' and specify. If not given/known, select 'no data'. If not applicable, leave field empty.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.PestTargetOrganismsToBeControlled.TargetOrganisms.DevelopmentalStageOfTargetPlant
Target organisms			
Products, organisms or objects to be protected / under study		Header 2	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.ProductsOrganismsOrObjectsToBeProtectedUnderStudy
Organisms (to be protected) or treated materials	Describe and specify the organism(s) or materials(s) / object(s) to be protected, e.g. human, pets, farm animals, fur- and wool-bearing animals,	Multi-line text	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.ProductsOrganismsOrObjectsToBeProtectedUnderStudy.OrganismsToBeProtectedOrTreatedMaterials

	plants, plant products, seeds, storage goods, drinking water, hard surface material , porous surface.		
Information on intended use and application		Header 2	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.InformationOnIntendedUseAndApplication
Function addressed	Indicate the function of the substance. Multiple selection is possible for indicating additional functions provided they relate to the same product type indicated in the next field. However, it may be sensible or required according to legislation-specific guidance to use separate records for each function. Any remarks can be entered in the supplementary remarks field, for instance any code for the function if required so according to programme-specific guidance. If so, indicate the type of coding system in parentheses.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.InformationOnIntendedUseAndApplication.FunctionAddressed
Product type	Indicate the product type in which the active substance is intended to be included or which is envisaged for the product. In case of multiple product types use separate records for each of them. Note that only product types related to EU BPD are listed. For other legislations, choose 'other:' and specify in the related text field.	Open list	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.InformationOnIntendedUseAndApplication.ProductType

Field of use envisaged / User	<p>If the use conditions are fully described in a GAP document in the dossier, it is sufficient to make reference to the GAP document which describes the use. IUCLID document name and UUID.</p> <p>If this is provided additional information on the use of the product already described in the GAP document does not need to be provided</p>	Text area	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.InformationOnIntendedUseAndApplication.FieldOfUseEnvisagedUser
Information on application of product		Header 2	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.InformationOnApplicationOfProduct
Method of application	<p>For the product, indicate the method of application. Multiple selection is possible for indicating more than one method. If not listed, select 'other' and specify.</p> <p>Any remarks can be entered in the supplementary remarks field, for instance any code for the method of application if required so according to programme-specific</p>	Multi select open list with remarks (2000)	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.InformationOnApplicationOfProduct.MethodOfApplication

	<p>guidance. If so, indicate the type of coding system in parentheses, e.g. 'VII.1 (EU BPD)'. Reference to use description document is sufficient.</p> <p>Alternatively, see Field of use envisaged / User</p>		
Details on application	See Field of use envisaged / User	Text template	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.InformationOnApplicationOfProduct.DetailsOnApplication
General information on effectiveness		Header 2	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.GeneralInformationOnEffectiveness
Effects on target organisms	<p>The effects on the target organisms required for the claimed efficacy should be described and specified if possible for each use and method of application if these have different effects, including any effect-concentration dependencies or the possible existence of a threshold concentration of the active substance. Refer to the instructions given in the relevant guidance documents (e.g. EU BPD TNsG, SANCO and EPPO</p>	Text area	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.GeneralInformationOnEffectiveness.EffectsOnTargetOrganisms

	<p>standards).</p> <p>In case of a submission of an active substance the effectiveness achieved or claimed should be briefly described. If required or sensible such description can be supported by including summary table(s) which give an overview of relevant efficacy studies performed with a product or products. Upload predefined table(s) in the rich text field 'Overall remarks'. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1'). To show possible differences, the use, i.e. product type and method of application of the product(s) envisaged should also be given. For products, efficacy studies should be reported using the corresponding template 'Efficacy data'.</p>		
Mode of action	<p>Indicate the principles of the mode of action for the function indicated in above field, e.g. 'acute toxin: contact poison'. If not</p>	Open list with remarks	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.GeneralInformationOnEffectiveness.ModeAction

	<p>listed, select 'other' and specify.</p> <p>Any remarks can be entered in the supplementary remarks field, for instance any code for the mode of action if required so according to programme-specific guidance. If so, indicate the type of coding system in parentheses, e.g. 'III.1.2 (EU BPD)'.</p> <p>For plant protection products mode of action, FRAC, HRAC and IRAC codes can be reported.</p>		
Details on mode of action	<p>For the function indicated in above field, indicate the principles of the mode of action; e.g. 'contact poison' or 'stomach poison'.</p> <p>Briefly describe the biochemical and physiological mechanisms, e.g. 'cholinesterase inhibition' and the biochemical pathway and specify any time delay between application and effect.</p> <p>Use the freetext template as appropriate (delete/add elements).</p> <p>For further instructions refer to the relevant guidance documents</p>	Text template	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.GeneralInformationOnEffectiveness.DetailsOnModeOfAction
(Possible) Occurrence of resistance	<p>Indicate whether resistance can possibly develop including cross-resistance. As appropriate include an appraisal of the</p>	Text area	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.GeneralInformationOnEffectiv

	information gained from the efficacy studies.		ness.PossibleOccurrenceOfResistance
Management strategies to avoid resistance	Describe any appropriate management strategies towards the minimization of the development of resistance.	Text area	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.GeneralInformationOnEffectiveness.ManagementStrategiesToAvoidResistance
Any other known limitations and management strategies	As applicable describe any other known limitations and relevant management strategies towards them.	Text area	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.GeneralInformationOnEffectiveness.AnyOtherKnownLimitationsAndManagementStrategies
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.ResultsAndDiscussion
Details on results		Text area	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.ResultsAndDiscussion.DetailsOnResults
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.ApplicantSummaryAndConclusion

Links to support material:

EPPO (2017) EPPO Global Database. Database available online: <https://gd.eppo.int>

EPPO database on PP1 standards <https://pp1.eppo.int/>

4. Analytical methods - Endpoint summary

Purpose

Summary information of to the most relevant study(ies) from which the key value for safety assessment is extrapolated. Provide only the most relevant details, which could be: recovery, selectivity (specificity), calibration, precision (repeatability, reproducibility), limit of detection (LOD), and limit of quantitation (LOQ).

([http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono\(2007\)17&doclanguage=en](http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2007)17&doclanguage=en))

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ENDPOINT_SUMMARY.AnalyticalMethods – v.3.0 (Final)			
Name	Instructions	Data Type	Field Path
Administrative data	Administrative data summary – common block Description of key information: Provide an assessment of the suitability of the proposed methods for monitoring and enforcement. Note Further information on residue definitions and LOQs can be provided in Proposed residue definitions document and Proposed maximum residue levels document in the Residues Section	Header 1	ENDPOINT_SUMMARY.AnalyticalMethods.AdministrativeDataSummary
Additional information	Discussion (Header 1) – common block Attached (sanitised) documents for publication: The file "Template 4.1 - Template for the overview table for analytical methods for risk assessment" (https://doi.org/10.5281/zenodo.4556992) shall be uploaded here.	Header 1	ENDPOINT_SUMMARY.AnalyticalMethods.Discussion

Links to support documents

OECD (2007). Guidance Document on Pesticide Residue Analytical Methods. Environment, Health and Safety Publications. Series on Testing and Assessment No. 72 and Series on Pesticides No. 39. (ENV/JM/MONO(2007)17)

[http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono\(2007\)17&doclanguage=en](http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2007)17&doclanguage=en)

EU guidance document for generating and reporting methods of analysis in support of pre-registration data requirements (SANCO/3029/99).

https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_res_pre-reg-cont-monitor.pdf

EU guidance document on analytical methods for the determination of residues (Post-registration monitoring and control) (SANCO/825/00 rev. 8.1, 2010)

https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_res_post-reg-cont-monitor.pdf

Technical Guideline on the Evaluation of Extraction Efficiency of Residue Analytical Methods (SANTE/2017/10632)

https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_mrl_guidelines_wrkdoc_2017-10632.pdf

4. Analytical Methods - Endpoint study record

Purpose:

The provisions of this Section cover analytical methods used for the generation of pre-approval data and required for post-approval control and monitoring purposes. Descriptions of methods shall be provided and include details of equipment, materials and conditions used. On request, the following shall be provided: (a) analytical standards of the purified active substance; (b) samples of the active substance as manufactured; (c) analytical standards of relevant metabolites and all other components included in all monitoring residue definitions; (d) samples of reference substances for the relevant impurities. Where possible, the standards referred to in points (a) and (c) shall be made commercially available and, on request, the distributing company shall be named.

It is recommended to use the cross-reference feature in endpoint study records to cross link to a specific analytical method endpoint study record used in the study.

ENDPOINT_STUDY_RECORD.AnalyticalMethods – v7.2 (Final)			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.AnalyticalMethods.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.AnalyticalMethods.DataSource
Reference	Literature reference	Literature reference	ENDPOINT_STUDY_RECORD.AnalyticalMethods.DataSource.Reference

		ence list	
Background		Header 1	ENDPOINT_STUDY_REC ORD.AnalyticalMethods. Background
Background information	<p>Use this field to include any background information, if required, or any relevant introductory remarks on the study summary. Leave field empty if not applicable. Do not include information for which specific fields are provided. For instance, include any background information on the test substance in fields on 'Test materials'.</p> <p>PURPOSE OF THIS TEMPLATE:</p> <p>This template can be used for summarising analytical methods for determining a given substance in various matrices. Depending on the requirements of the relevant legislation, methods for the following matrices may have to be recorded: soil, sediment, suspended particulates, air, water (including drinking water), animal and human body fluids and tissues, plants, plant products, food and feedingstuffs, formulated product, other.</p>	Multi-line text	ENDPOINT_STUDY_REC ORD.AnalyticalMethods. Background.Background Information
Materials and methods	<p>Material and methods – common block</p> <p>Guideline: Select the applicable test guideline, e.g. EU guidance document on analytical methods for the analysis of technical material and preparation (SANCO/3030/99 rev. 4)</p> <p>Residues:</p> <p>EU guidance document on pesticide analytical methods for risk assessment and post-approval control and monitoring purposes (SANTE/2020/12830, Rev.1)</p> <p>EU guidance document on analytical methods for the determination of residues (Post-registration monitoring and control) (SANCO/825/00 rev. 8.1, 2010)</p> <p>EU guidance document for generating and reporting methods of analysis in support of pre-registration data requirements (SANCO/3029/99 rev. 4).</p> <p>OECD (2007). Guidance Document on Pesticide Residue Analytical Methods. Environment, Health and Safety Publications. Series on Testing and Assessment No. 72 and Series on Pesticides No. 39.</p> <p>SANCO/825/00 Guidance document on pesticide residue analytical methods</p>	Header 1	ENDPOINT_STUDY_REC ORD.AnalyticalMethods. MaterialsAndMethods
Matrix / medium	<p>Indicate the medium (e.g. plants, high oil content, egg, soil, groundwater) for which the analytical method is described. In the supplementary remarks field, you can add explanations as appropriate.</p> <p>Note: The picklist is not descriptive as to whether analytical methods have to be submitted for each of</p>	Multi select open list with	ENDPOINT_STUDY_REC ORD.AnalyticalMethods. MaterialsAndMethods.M atrixMedium

	the matrices provided in the picklist. If the methods for several matrices can be summarised in one record, you can copy this field for indicating the respective matrices.	remarks	
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.AnalyticalMethods.MaterialsAndMethods.TestMaterials
Principles of analytical methods		Header 2	ENDPOINT_STUDY_RECORD.AnalyticalMethods.MaterialsAndMethods.PrinciplesOfAnalyticalMethods
Instrument / detector	<p>Indicate the instrument / detector used for the quantitative analysis including the type of detector, e.g. 'HPLC-UV'. Multiple selection is possible if more than one method needs to be specified. Give any further details in field 'Details on analytical data collection method'.</p> <p>Note: If a residue analytical method is recorded, the instrument/detector used for the so-called data collection or data-gathering method should be specified here. Data collection method is the analytical method used to collect quantitative residue data by analysing the analyte(s) in the matrices. This method can be identical with or differ from the so-called enforcement method which has to be recorded under the heading 'Enforcement method (if applicable)'. Enforcement method is a validated analytical method which can be applied by the regulatory agency for enforcing the proposed tolerance, i.e. maximum residue limits (MRL) for pesticides.</p>	Multiple selection open list	ENDPOINT_STUDY_RECORD.AnalyticalMethods.MaterialsAndMethods.PrinciplesOfAnalyticalMethods.InstrumentDetector
Details on analytical method	<p>Briefly describe further details on the principles of the method used to detect the analytes (to be specified, e.g. 'parent compound', 'parent and transformation products' or 'transformation product:') in matrices. Use freetext template and delete/add elements as appropriate. For example, add specific parameters in the case of inorganic chemicals. As an option you may include an excerpt from the study report.</p> <p>Note: If a residue analytical method is recorded, the details for the so-called data collection or data-gathering method should be specified here. As to the terms 'data collection method' and 'enforcement method' see help text for field 'Instrument / detector'. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.</p>	Text template	ENDPOINT_STUDY_RECORD.AnalyticalMethods.MaterialsAndMethods.PrinciplesOfAnalyticalMethods.DetailsOnAnalyticalMethod
Enforcement method (if		Header 2	ENDPOINT_STUDY_RECORD.AnalyticalMethods.MaterialsAndMethods.En

applicable)			forcementMethodIfApplicable
Instrument / detector for enforcement method	If no enforcement method is proposed or required, ignore this field. An enforcement method is a validated analytical method which can be applied by the regulatory agency for enforcing the proposed tolerance, i.e. maximum residue limits (MRL) for pesticides. If such a method is proposed indicate the instrument / detector used in the enforcement method. Multiple selection is possible if more than one method needs to be specified. Give any further details in field 'Details on data enforcement method'.	Multi select open list	ENDPOINT_STUDY_RECORD.AnalyticalMethods.MaterialsAndMethods.EnforcementMethodIfApplicable.InstrumentDetectorForEnforcementMethod
Details on enforcement method	'Briefly describe further details on the principles of the method used to detect the analytes (to be specified, e.g. "parent compound", "parent and transformation products" or "transformation product:") in matrices. Use freetext template and delete/add elements as appropriate. For example, add specific parameters in the case of inorganic chemicals. As an option you may include an excerpt from the study report. Note: If a residue analytical method is recorded, the details for the so-called data collection or data-gathering method should be specified here. As to the terms "data collection method" and "enforcement method" see help text for field "Instrument / detector". Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.AnalyticalMethods.MaterialsAndMethods.EnforcementMethodIfApplicable.DetailsOnEnforcementMethod
Confirmatory method (if applicable)		Header 2	ENDPOINT_STUDY_RECORD.AnalyticalMethods.MaterialsAndMethods.ConfirmatoryMethodIfApplicable
Instrument / detector for confirmatory method	'If not applicable, ignore this field. If a confirmatory method was used (i.e. applying techniques to demonstrate specificity in case the original method is not highly specific), indicate the instrument / detector used. Note: Not all picklist items may be relevant for a confirmatory technique. Multiple selection is possible if more than one method needs to be specified. Give any further details in field "Details on data confirmatory method".'	Multi select open list	ENDPOINT_STUDY_RECORD.AnalyticalMethods.MaterialsAndMethods.ConfirmatoryMethodIfApplicable.InstrumentDetectorForConfirmatoryMethod
Details on confirmatory method	Briefly describe further details on the principles of the confirmatory method if any. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Multi-line text	ENDPOINT_STUDY_RECORD.AnalyticalMethods.MaterialsAndMethods.ConfirmatoryMethodIfApplicable.DetailsOnConfirmatoryMethod

Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_REC ORD.AnalyticalMethods. MaterialsAndMethods.An yOtherInformationOnMa terialsAndMethodsInclTa bles
Results and discussion		Header 1	ENDPOINT_STUDY_REC ORD.AnalyticalMethods. ResultsAndDiscussion
Recovery results and characteristics of analytical method		Header 2	ENDPOINT_STUDY_REC ORD.AnalyticalMethods. ResultsAndDiscussion.R ecoveryResultsAndChara cteristicsOfAnalyticalMet hod
Recovery results	Indicate the compound (analyte) addressed (e.g. 'parent compound', 'parent and transformation products' or 'transformation product:'). Report the recovery rates at each level (e.g. at spiking level 1, spiking level 2 etc.) at the limit of quantification and give the mean % recovery and the relative standard deviation in % including the number of recovery studies. Include a brief evaluation of the repeatability of the method (e.g. 'These values demonstrate that the method has satisfactory repeatability.') Use freetext template and delete/add elements as appropriate, or include a table (particularly for comprehensive data) in rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1'). Note: Specific tables may be required.	Text template	ENDPOINT_STUDY_REC ORD.AnalyticalMethods. ResultsAndDiscussion.R ecoveryResultsAndChara cteristicsOfAnalyticalMet hod.RecoveryResults
Characteristics of analytical method	For each compound (analyte) addressed (to be specified, e.g. 'parent compound', 'parent and transformation products' or 'transformation product:'), report both the limit of quantitation (LOQ) and limit of detection (LOD), and the criteria used to determine the LOD or LOQ, i.e., the lowest fortification/spiking level or S/N ratio. Use freetext template, delete/add elements and edit text set in [...] as appropriate, or include a table (particularly for comprehensive data) in rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1'). If	Text template	ENDPOINT_STUDY_REC ORD.AnalyticalMethods. ResultsAndDiscussion.R ecoveryResultsAndChara cteristicsOfAnalyticalMet hod.CharacteristicsOfAn alyticalMethod

	<p>a residue analytical method is recorded, the details for the so-called data collection or data-gathering method should be specified here. As to the terms 'data collection method' and 'enforcement method' see help text for field 'Instrument / detector'.</p> <p>Provide information on extractability studies.</p> <p>Note: Specific tables may be required.</p>		
Results using enforcement method (if applicable)		Header 2	ENDPOINT_STUDY_REC ORD.AnalyticalMethods. ResultsAndDiscussion.R resultsUsingEnforcement Method
Recovery results (enforcement method)	<p>If not applicable, ignore this field. If an enforcement method is proposed which is different from the analytical method described as general analytical method (or 'data-gathering method' in residue analysis), indicate the compound (analyte) addressed (e.g. 'parent compound', 'parent and transformation products' or 'transformation product:'). Report the recovery rates at each level (e.g. at spiking level 1, spiking level 2 etc.) at the limit of quantification and give the mean % recovery and the relative standard deviation in % including the number of recovery studies. Include a brief evaluation of the repeatability of the method (e.g. 'These values demonstrate that the method has satisfactory repeatability.')</p> <p>Use freetext template and delete/add elements as appropriate, or include a table (particularly for comprehensive data) in rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').</p> <p>Note: Specific tables may be required.</p>	Text template	ENDPOINT_STUDY_REC ORD.AnalyticalMethods. ResultsAndDiscussion.R resultsUsingEnforcement Method.RecoveryResults
Characteristics of enforcement method	<p>If not applicable, ignore this field. If an enforcement method is proposed which is different from the analytical method described as general analytical method (or 'data-gathering method' in residue analysis), report both the limit of quantitation (LOQ) and limit of detection (LOD), and the criteria used to determine the LOD or LOQ, i.e., the lowest fortification/spiking level or S/N ratio for each compound (analyte) addressed (to be specified, e.g. 'parent compound', 'parent and transformation products' or 'transformation product:').</p> <p>Use freetext template, delete/add elements and edit text set in [...] as appropriate, or include a table (particularly for comprehensive data) in rich text field 'Any other information on results incl. tables'. Upload</p>	Text template	ENDPOINT_STUDY_REC ORD.AnalyticalMethods. ResultsAndDiscussion.R resultsUsingEnforcement Method.CharacteristicsOf EnforcementMethod

	predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1'). Note: Specific tables may be required.		
Independent laboratory validation (if applicable)	If not applicable, ignore this field. If applicable (as for enforcement methods), discuss the independent laboratory validation (ILV) in terms of whether or not it was conducted according to guideline specifications. Discuss any method modifications that may impact the analyses of the residues (e.g., altered LOQ) that are suggested by the independent laboratory. Alternatively, include a table (particularly for comprehensive data) in rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1'). Note: Specific tables may be required.	Header 2	ENDPOINT_STUDY_RECORD.AnalyticalMethods.ResultsAndDiscussion.IndependentLaboratoryValidation
Independent laboratory validation	If not applicable, ignore this field. If applicable (as for enforcement methods), discuss the independent laboratory validation (ILV) in terms of whether or not it was conducted according to guideline specifications. Discuss any method modifications that may impact the analyses of the residues (e.g., altered LOQ) that are suggested by the independent laboratory. Alternatively, include a table (particularly for comprehensive data) in rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1'). Note: Specific tables may be required.	Multi-line text	ENDPOINT_STUDY_RECORD.AnalyticalMethods.ResultsAndDiscussion.IndependentLaboratoryValidation.IndependentLaboratoryValidation
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.AnalyticalMethods.ResultsAndDiscussion.AnyOtherInformationOnResultsIncTables
Overall remarks, attachments	Overall remarks, attachments – common block Further information on extractability can be uploaded in the attachment fields.	Header 1	ENDPOINT_STUDY_RECORD.AnalyticalMethods.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.AnalyticalMethods.ApplicantSummaryAndConclusion

Links to support material:

OECD GUIDANCE DOCUMENT ON PESTICIDE RESIDUE ANALYTICAL METHODS

[http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono\(2007\)17&doclang=eng](http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2007)17&doclang=eng)

Technical Active Substance and Plant protection products: Guidance for generating and reporting methods of analysis in support of pre- and post-registration data requirements for Annex (Section 4) of Regulation (EU) No 283/2013 and Annex (Section 5) of Regulation (EU) No 284/2013.

https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_phys-chem-ana_3030.pdf

[Guidance document on analytical quality control and method validation procedures for pesticide residues analysis in food and feed](#) - SANTE/12682/2019 - 1 January 2020

[Technical Guideline on the Evaluation of Extraction Efficiency of Residue Analytical Methods](#) – SANTE 2017/10632 rev.3, 22 November 2017

Principles of analytical methods

Instrument / detector

✓ HPLC-UV

Details on analytical method

Method REM 138.12

Homogenized plant samples are extracted with acetonitrile. Fatty coextracts are removed by partitioning into hexane. The analytes are cleaned up subsequently by solid phase extraction on a C-18 cartridge, reextraction into hexane-diethyl ether and a second solid phase extraction step on a silica cartridge. Active substance is eluted in a fraction and determined by HPLC on a 2-column switching system with UV-detection.

Results and discussion

Recovery results and characteristics of analytical method

Recovery results

Please refer to the table below for more details.

Characteristics of analytical method

COMPOUND (ANALYTE): Active substance

- Equipment ID: HPLC-UV
- Limit of quantitation (LOQ): 0.02 mg/kg for grain, 0.1 mg/kg for straw and green plant material
- Accuracy / precision: all mean recoveries of the individual fortifications levels as well as the overall mean recoveries are within the range of 70 - 110%
- Repeatability: all the relative standard deviations are less than 20%
- Linearity: not reported
- Specificity: The control chromatograms generally have no peaks above the chromatographic background and the spiked sample chromatograms contain only the analyte peak of interest.

5. Toxicological and metabolism studies on the active substance

Introduction

For EU pesticides, when compiling the dossier for active substances the applicant should consult programme-specific guidance under Commission Communication on list of test methods and guidance documents for active substances available at [https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:52013XC0403\(02\)](https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:52013XC0403(02)) [Commission Communication in the framework of the implementation of Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market Text with EEA relevance]

It is expected that under MRL application the applicant will submit *in vivo* toxicological studies mainly by the oral route of exposure, relevant for consumer exposure. Therefore, under the MRL application the applicant is not expected to fill in data fields relevant for other routes of exposure such as inhalation and dermal exposure.

It is important than when presenting the results in tabular format for mammalian toxicology studies the applicant follows the recommendations of the IUCLID templates for PPP Risk Assessment - Template 5.1 - Template for presentation of results in tabular format for mammalian toxicology studies. [<http://doi.org/10.5281/zenodo.4557274>].

In cases that there are not specific study records fit for purposes please consider the use of the study record for intermediate effects if the aim of the study is mechanistic or the study record for other toxicological studies if the aim is not mechanistic (e.g. hazard identification), both under 5.8.

In cases QSARs are submitted please also attached in the respective study record a summary assessment report of a QSAR. See IUCLID templates for PPP Risk Assessment - Template 5.2 - Summary assessment report of a QSAR and example. [<http://doi.org/10.5281/zenodo.4557311>].

The following templates should be used when compiling documents in this section:

Template name and link	Information
Template 5.1 Template for presentation of results in tabular format for mammalian toxicology studies	This word file contains the template for presentation of results in tabular format for mammalian toxicology studies, replacing the appendix F of the EFSA administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances (EFSA, 2019). The template shall be used when compiling tables in the “ Any other information on results incl. tables ” field in the relevant endpoint study record(s) .
Template 5.2 Template for a summary assessment report of a QSAR	The word file contains the template for a summary assessment report of a QSARs. The filled-in template shall be uploaded in Attached (sanitised) documents for publication in the relevant endpoint study record(s) .

Template 5.3 Template for a summary table integrating experimental evidence on genotoxicity for metabolites	This word file contains the template for a summary table integrating experimental evidence on genotoxicity for metabolites. The filled template shall be uploaded in Attached (sanitised) documents for publication under 5.4 Genotoxicity testing (endpoint summary) or alternatively the template shall be used when compiling tables in the “ Description of key information ” field in the 5.4 Genotoxicity testing Section (endpoint summary).
Template 5.4 Template for a summary table on the assessment of the toxicological profile of metabolites	This word file contains the template for a summary table on the assessment of the toxicological profile of metabolites. The filled in template shall be uploaded in Attached (sanitised) documents for publication under 5.8 Other toxicological studies - Endpoint summary.

5. Toxicological and metabolism studies on the active substance – Flexible record

Purpose

To report Health-based guidance values than under the pesticides peer review are called toxicological reference values. These are the Acceptable operator exposure level (AOEL), Acceptable daily intake (ADI), Acute reference dose (ARfD) and Acute Acceptable operator Exposure Level (AAOEL) values derived for the active substance or metabolite (if applicable).

FLEXIBLE_SUMMARY.ToxRefValues – v2.1 (Final)			
Name	Instructions	Type	Field Path
Administrative data	Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	Header 1	FLEXIBLE_SUMMARY.ToxRefValues.AdministrativeDataSummary
		Confidentiality	FLEXIBLE_SUMMARY.ToxRefValues.AdministrativeDataSummary.DataProtection
Description of key information		Header 1	FLEXIBLE_SUMMARY.ToxRefValues.KeyInformation
	Rational for the derivation of the reference values reported below, plus specific information which should be considered when	Rich text area	FLEXIBLE_SUMMARY.ToxRefValues.KeyInformation.KeyInformation

	assessing the reported values.		
Human health hazard characteristics		Header 1	FLEXIBLE_SUMMARY.T oxRefValues.HumanHea lthHazardCharacteristics
AOEL (Acceptable operator exposure level)		Header 2	FLEXIBLE_SUMMARY.T oxRefValues.HumanHea lthHazardCharacteristics .AcceptableOperatorExp osureLevel
Not allocated	Check the box if an AOEL is not necessary for the application	Check box	FLEXIBLE_SUMMARY.T oxRefValues.HumanHea lthHazardCharacteristics .AcceptableOperatorExp osureLevel.NoAllocated
Justification	Justification for the non-derivation of an AOEL	Text	FLEXIBLE_SUMMARY.T oxRefValues.HumanHea lthHazardCharacteristics .AcceptableOperatorExp osureLevel.Justification
AOEL	Report the AOEL value and select the relevant units	Unit measure with Closed List (Decimal)	FLEXIBLE_SUMMARY.T oxRefValues.HumanHea lthHazardCharacteristics .AcceptableOperatorExp osureLevel.Aoel
Study retained	Type of study used to derive the AOEL (species and duration)	Multi select open list with remarks	FLEXIBLE_SUMMARY.T oxRefValues.HumanHea lthHazardCharacteristics .AcceptableOperatorExp osureLevel.StudyRetain ed
Route of original study	Route of exposure in the study used to derive the AOEL	Closed list	FLEXIBLE_SUMMARY.T oxRefValues.HumanHea lthHazardCharacteristics .AcceptableOperatorExp osureLevel.RouteOfOrig inalStudy
Oral absorption value (%)	Oral absorption value derived from the toxicokinetic studies expressed as a percentage	Decimal	FLEXIBLE_SUMMARY.T oxRefValues.HumanHea lthHazardCharacteristics .AcceptableOperatorExp osureLevel.OralAbsorpti on
Overall uncertainty factor (UF)	The overall assessment factor is the product of all the assessment factors used. The default UF is 100 (10 for intraspecies differences and 10 for	Text	FLEXIBLE_SUMMARY.T oxRefValues.HumanHea lthHazardCharacteristics .AcceptableOperatorExp osureLevel.OverallUnce rtainty

	interspecies differences).		
Justification of the overall UF	<p>Justification for the uncertainty factor applied considering intra/inter species extrapolation.</p> <p>Please detail if additional UF are applied e.g.:</p> <ul style="list-style-type: none"> - UF for dose response relationship i.e. consideration should be given to the uncertainties in the dose descriptor as the surrogate for the true no-adverse-effect-level. For instance, in case the starting point for AOEL derivation is a LOAEL instead of a NOAEL, the uncertainty factor should be between 2 and 10. However, by using the BMD approach instead of NOAEL/LOAEL approach there would be not need to apply an additional UF in this case. - UF for differences in duration of exposure i.e. need to be considered taking into account that, in general, the experimental dose descriptor will decrease with increasing exposure times and that other and more serious adverse effects may appear with increasing exposure times. - UF for the quality of the whole database i.e. may be applied to compensate for the 	Multi-line text	<p>FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcceptableOperatorExposureLevel.JustificationOverallUf</p>

	<p>potential remaining uncertainties during AAOEL derivation. In that case, it should be considered issues related to completeness and consistency of the available data and issues related to reliability of alternative data if those have been used.</p> <p>e.g. In case some studies are missing, additional UF can be added.</p> <p>- UF for remaining uncertainties. In that case, the assessment factor should where relevant be applied and justified on a case-by-case basis.</p>		
Dose descriptor starting point	Critical endpoint value, type (e.g. NOAEL, BMDL05), value and units	Open list	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcceptableOperatorExposureLevel.DoseDescriptorStartingPoint
		Unit measure with Closed List (Decimal)	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcceptableOperatorExposureLevel.field8204
Justification and comments	Provide additional information related to the derivation of this specific toxicological reference value.	Rich text area	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcceptableOperatorExposureLevel.JustificationAndComments
ADI (Acceptable daily intake)		Header 2	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcceptableDailyIntake
Not allocated	Check the box if an ADI is not necessary for the application	Check box	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcceptableDailyIntake.NoAllocated

Justification	Justification for the non-derivation of an ADI	Text	FLEXIBLE_SUMMARY.T oxRefValues.HumanHealthHazardCharacteristics. AcceptableDailyIntake. Justification
ADI	Report the ADI value and select the relevant units	Unit measure with Closed List (Decimal)	FLEXIBLE_SUMMARY.T oxRefValues.HumanHealthHazardCharacteristics. AcceptableDailyIntake. Adi
Study retained	Type of study used to derive the ADI (species and duration)	Multi select open list with remarks	FLEXIBLE_SUMMARY.T oxRefValues.HumanHealthHazardCharacteristics. AcceptableDailyIntake. StudyRetained
Route of original study	Route of exposure in the study used to derive the ADI. It should be by default: oral.	Closed list	FLEXIBLE_SUMMARY.T oxRefValues.HumanHealthHazardCharacteristics. AcceptableDailyIntake. RouteOfOriginalStudy
Overall uncertainty factor (UF)	<p>The overall assessment factor is the product of all the assessment factors used.</p> <p>The default UF is 100 (10 for intraspecies differences and 10 for interspecies differences).</p> <p>Please detail if additional UF are applied e.g.:</p> <ul style="list-style-type: none"> - UF for dose response relationship i.e. consideration should be given to the uncertainties in the dose descriptor as the surrogate for the true no-adverse-effect-level. For instance, in case the starting point for AOEL derivation is a LOAEL instead of a NOAEL, the uncertainty factor should be between 2 and 10. 	Text	FLEXIBLE_SUMMARY.T oxRefValues.HumanHealthHazardCharacteristics. AcceptableDailyIntake. OverallUncertainty

	<p>- UF for differences in duration of exposure i.e. need to be considered taking into account that, in general, the experimental NOAEL will decrease with increasing exposure times and that other and more serious adverse effects may appear with increasing exposure times.</p> <p>- UF for the quality of the whole database i.e. may be applied to compensate for the potential remaining uncertainties during AOEL derivation. In that case, it should be considered issues related to completeness and consistency of the available data and issues related to reliability of alternative data if those have been used.</p> <p>e.g. In case some studies are missing, additional UF can be added.</p> <p>- UF for remaining uncertainties. In that case, the assessment factor should where relevant be applied and justified on a case-by-case basis.</p>		
Justification of the overall UF	Justification for the uncertainty factor applied considering intra/inter species extrapolation	Multi-line text	FLEXIBLE_SUMMARY.T oxRefValues.HumanHealthHazardCharacteristics .AcceptableDailyIntake. JustificationOverallUf

Dose descriptor starting point	Critical endpoint value, type (e.g. NOAEL, BMDL05), value and units	Open list	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcceptableDailyIntake.DoseDescriptorStartingPoint
		Unit measure with Closed List (Decimal)	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcceptableDailyIntake.field8204
Justification and comments	Provide additional information related to the derivation of this specific toxicological reference value.	Rich text area	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcceptableDailyIntake.JustificationAndComments
ARfD (Acute reference dose)		Header 2	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcuteReferenceDose
Not allocated	Check the box if an ARfD is not necessary for the application	Check box	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcuteReferenceDose.NoAllocated
Justification	Justification for the non-derivation of an ARfD	Text	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcuteReferenceDose.Justification
ARfD	Report the ARfD value and select the relevant units	Unit measure with Closed List (Decimal)	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcuteReferenceDose.Arfd
Study retained	Type of study used to derive the ARfD (species and duration)	Multi select open list with remarks	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcuteReferenceDose.StudyRetained
Route of original study	Route of exposure in the study used to derive the ARfD. It should be by default: oral.	Closed list	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcuteReferenceDose.RouteOfOriginalStudy
Overall uncertainty factor (UF)	The overall assessment factor is the product of all the assessment factors used.	Text	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcuteReferenceDose.OverallUncertainty

	The default UF is 100 (10 for intraspecies differences and 10 for interspecies differences).		
Justification of the overall UF	<p>Please detail if additional UF are applied e.g.:</p> <ul style="list-style-type: none"> - UF for dose response relationship i.e. consideration should be given to the uncertainties in the dose descriptor as the surrogate for the true no-adverse-effect-level. For instance, in case the starting point for ARfD derivation is a LOAEL instead of a NOAEL, the uncertainty factor should be between 2 and 10. However, by using the BMD approach instead of NOAEL/LOAEL approach there would be not need to apply an additional UF in this case. - UF for differences in duration of exposure i.e. need to be considered taking into account that, in general, the experimental dose descriptor will decrease with increasing exposure times and that other and more serious adverse effects may appear with increasing exposure times. - UF for the quality of the whole database i.e. may be applied to compensate for the potential remaining uncertainties during 	Multi-line text	FLEXIBLE_SUMMARY.T oxRefValues.HumanHea lthHazardCharacteristics .AcuteReferenceDose.J ustificationOverallUf

	<p>ARfD derivation. In that case, it should be considered issues related to completeness and consistency of the available data and issues related to reliability of alternative data if those have been used.</p> <p>e.g. In case some studies are missing, additional UF can be added.</p> <p>- UF for remaining uncertainties. In that case, the assessment factor should where relevant be applied and justified on a case-by-case basis.</p> <p>Justification for the uncertainty factor applied considering intra/inter species extrapolation</p>		
Dose descriptor starting point	Critical endpoint value, type (e.g. NOAEL, BMDL05), value and units	Open list	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcuteReferenceDose.DoseDescriptorStartingPoint
		Unit measure with Closed List (Decimal)	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcuteReferenceDose.field8204
Justification and comments	Provide additional information related to the derivation of this specific toxicological reference value.	Rich text area	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcuteReferenceDose.JustificationAndComments
AAOEL (Acute acceptable operator exposure level)		Header 2	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcuteAcceptableOperatorExposureLevel

Not allocated	Select the box if an AAOEL is not necessary for the application. It should be ticked for each toxicological reference value.	Check box	FLEXIBLE_SUMMARY.T oxRefValues.HumanHealthHazardCharacteristics .AcuteAcceptableOperatorExposureLevel.NoAllocated
Justification	Justification for the non-derivation of an AAOEL	Text	FLEXIBLE_SUMMARY.T oxRefValues.HumanHealthHazardCharacteristics .AcuteAcceptableOperatorExposureLevel.Justification
AAOEL	Report the AOEL and if they are available select the relevant units.	Unit measure with Closed List (Decimal)	FLEXIBLE_SUMMARY.T oxRefValues.HumanHealthHazardCharacteristics .AcuteAcceptableOperatorExposureLevel.Aaoel
Study retained	Type of study used to derive the AAOEL (species and duration)	Multi select open list with remarks	FLEXIBLE_SUMMARY.T oxRefValues.HumanHealthHazardCharacteristics .AcuteAcceptableOperatorExposureLevel.StudyRetained
Route of original study	Route of exposure in the study used to derive the AAOEL	Closed list	FLEXIBLE_SUMMARY.T oxRefValues.HumanHealthHazardCharacteristics .AcuteAcceptableOperatorExposureLevel.RouteOfOriginalStudy
Oral absorption value (%)	Oral absorption value derived from the toxicokinetic studies expressed as a percentage	Decimal	FLEXIBLE_SUMMARY.T oxRefValues.HumanHealthHazardCharacteristics .AcuteAcceptableOperatorExposureLevel.OralAbsorption
Overall uncertainty factor (UF)	The overall assessment factor is the product of all the assessment factors used. The default UF is 100 (10 for intraspecies differences and 10 for interspecies differences).	Text	FLEXIBLE_SUMMARY.T oxRefValues.HumanHealthHazardCharacteristics .AcuteAcceptableOperatorExposureLevel.OverallUncertainty
Justification of the overall UF	Justification for the uncertainty factor applied considering	Multi-line text	FLEXIBLE_SUMMARY.T oxRefValues.HumanHealthHazardCharacteristics .AcuteAcceptableOperator

	<p>intra/inter species extrapolation.</p> <p>Please detail if additional UF are applied e.g.:</p> <ul style="list-style-type: none"> - UF for dose response relationship i.e. consideration should be given to the uncertainties in the dose descriptor as the surrogate for the true no-adverse-effect-level. <p>For instance, in case the starting point for AAOEL derivation is a LOAEL instead of a NOAEL, the uncertainty factor should be between 2 and 10. However, by using the BMD approach instead of NOAEL/LOAEL approach there would be not need to apply an additional UF in this case.</p> <ul style="list-style-type: none"> - UF for differences in duration of exposure i.e. need to be considered taking into account that, in general, the experimental dose descriptor will decrease with increasing exposure times and that other and more serious adverse effects may appear with increasing exposure times. - UF for the quality of the whole database i.e. 		<p>orExposureLevel.JustificationOverallUf</p>
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	<p>may be applied to compensate for the potential remaining uncertainties during AAOEL derivation. In that case, it should be considered issues related to completeness and consistency of the available data and issues related to reliability of alternative data if those have been used.</p> <p>e.g. In case some studies are missing, additional UF can be added.</p> <p>- UF for remaining uncertainties. In that case, the assessment factor should where relevant be applied and justified on a case-by-case basis.</p>		
Dose descriptor starting point	Critical endpoint value, type (e.g. NOAEL, BMDL05), value and units	Open list	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcuteAcceptableOperatorExposureLevel.DoseDescriptorStartingPoint
		Unit measure with Closed List (Decimal)	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcuteAcceptableOperatorExposureLevel.field8204
Justification and comments	Provide additional information related to the derivation of this specific toxicological reference value.	Rich text area	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcuteAcceptableOperatorExposureLevel.JustificationAndComments
Additional information	Discussion (Header 1) – common block	Header 1	FLEXIBLE_SUMMARY.ToxRefValues.Discussion

Links to support materials:

OECD (2010) "Guidance for the Derivation of an Acute Reference Dose" OECD Series on testing and assessment, No. 124, 08-Jun-2010

[http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono\(2010\)15&doclanguage=en](http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2010)15&doclanguage=en)

Guidance for the setting of an acute reference dose (ARfD)

https://ec.europa.eu/food/system/files/2016-10/pesticides_ppp_app-proc_guide_tox_acute-ref-dose.pdf

Guidance for the setting and application of acceptable operator exposure levels (AOELS)

https://ec.europa.eu/food/system/files/2016-10/pesticides_ppp_app-proc_guide_tox_accpt-exp-levs-2006.pdf

Guidance on selected default values to be used by the EFSA Scientific Committee, Scientific Panels and Units in the absence of actual measured data

<https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2012.2579>

Update: use of the benchmark dose approach in risk assessment

<https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2017.4658>

ADI (Acceptable daily intake)

☐ Not allocated

Justification

None

ADI

0.36 mg/kg bw/day

Study retained

✓ 2-year, rat

Route of original study

oral

Overall uncertainty factor (UF)

100

Justification of the overall UF

None

Dose descriptor starting point

NOAEL

36 mg/kg bw/day

Justification and comments

Mild anemia (rat & mouse), adrenal medullar
hyperplasia (male rat), thyroid hyperplasia (rat)

5.1 Studies on absorption, distribution, metabolism and excretion in mammals - Endpoint Summary

Purpose:

Provide summary information of the most relevant study(-ies) from which the key value for chemical assessment is extrapolated. Provide only the most relevant details (according to Absorption, distribution, metabolism and excretion (toxicokinetics):

- Rate and extent of oral absorption/systemic bioavailability
- Toxicokinetics (C_{max}, T_{max}, Plasma T_{1/2})
- Distribution (indicate which organs have the highest levels)
- Rate and extent of excretion
- Provide statement on comparative in vitro metabolism interspecies differences between human and test species.

The document should contain the information needed to be reported according to the list of end points for ADME (SANCO/12592/2012-rev. 2, 22 March 2019).

Absorption, distribution, metabolism and excretion (toxicokinetics) (Regulation (EU) N° 283/2013, Annex Part A, point 5.1)

PBPK modelling including results, if available, should be summarised under this section. Modeling codes and results can be uploaded as attachments.

ENDPOINT_SUMMARY.Toxicokinetics - v5.0 (Final)			
Name	Instructions	Type	Field Path
Administrative data	Administrative data summary – common block <u>Study name / type:</u> Provide the link to the most relevant study(ies) from which the key value for chemical safety assessment is extrapolated. Currently comparative in vitro metabolism studies should be reported under 5.8 Other toxicological studies (ENDPOINT_STUDY_RECORD.AdditionalToxicologicalInformation - v.6.3). <u>Description of key information:</u> Provide a brief description of toxicity studies and effects. The information provided for absorption,	Header 1	ENDPOINT_SUMMARY.Toxicokinetics.AdministrativeDataSummary

	<p>distribution, metabolism and excretion, or observations based on physicochemical properties should be described.</p> <p>The interpretation of the result should be done considering:</p> <ul style="list-style-type: none"> - a discussion on potential data gaps, - the relevance of the results for the risk assessment (e.g. the extent to which the results from an animal study are relevant for human health). 		
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.Toxicokinetics.KeyValue
Bioaccumulation potential	<p>This information is usually based on physicochemical properties (e.g. log Kow, molecular structure and molecular weight) and on metabolism.</p> <p>The rationale for the indicated value should be explained in the "Description of key information" field.</p>	Closed list	ENDPOINT_SUMMARY.Toxicokinetics.KeyValue.Bioaccumulation
Absorption rate - oral (%)	<p>This information can be obtained experimentally or generated considering physicochemical properties (e.g. water solubility, log Kow, molecular structure, molecular weight)</p>	Decimal	ENDPOINT_SUMMARY.Toxicokinetics.KeyValue.AbsorptionOral
Absorption rate - dermal (%)		Decimal	ENDPOINT_SUMMARY.Toxicokinetics.KeyValue.AbsorptionDerm
Absorption rate - inhalation (%)	<p>This information can be obtained experimentally or generated considering physicochemical properties (e.g. water</p>	Decimal	ENDPOINT_SUMMARY.Toxicokinetics.KeyValue.AbsorptionInhal

	solubility, log Kow, molecular structure, molecular weight)		
Additional information	Discussion(Header 1) – common block Provide additional information related to the endpoint, for example: Rate and extent of oral absorption/systemic bioavailability; Toxicokinetics (Cmax, Tmax, Plasma T1/2; for parent and metabolites if available); Distribution (indicate which organs have highest levels); Rate and extent of excretion; In vitro metabolism (mention key findings, especially human:test species comparison); Toxicologically relevant compounds	Header 1	ENDPOINT_SUMMARY.Toxicokinetics.Discussion

5.1 Studies on absorption, distribution, metabolism and excretion in mammals - Endpoint study record

Purpose:

Provide information on Absorption, distribution, metabolism and excretion (ADME) properties.

Currently comparative in vitro metabolism studies should be reported under “[5.8 Other toxicological studies](#)” (ENDPOINT_STUDY_RECORD.AdditionalToxicologicalInformation - v.6.3 (Final) [September 2020])

Specific considerations for the reporting of metabolism studies in IUCLID:

An endpoint study record should be created for each metabolism study, filling out the standard fields of the template. In addition, metabolism studies should be entered via the DER-composer (part of the Metapath software package).

ENDPOINT_STUDY_RECORD.BasicToxicokinetics - v.8.4 (Final)			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.AdministrativeData

Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.DataSource
Reference	<p>Indicate the bibliographic reference of the study report or publication the study summary is based on. Select item from 'Literature Reference' database or create 'New Reference'.</p> <p>If you entered in the study in the DER composer, the XML-files created with the DER-composer should be attached in the LITERATURE object, to which reference is made here. These XML-files shall contain all the data fields on material and methods and on results and discussions that were not directly reported in the present study record.</p> <p>In the field "attached documents", please use the function "select files" and attach here each XML-file associated to study referred to in this LITERATURE OBJECT.</p> <p>If you did not enter yourself the study in the DER composer because the XML-files linked to this study record are already in the list of "DER-composer XML-files" available to the Regulatory Authorities, the attachment of the XML-files is not mandatory. In such a case, please simply report the "MAP-number(s)" or the XML-file(s) in the field "other study identifier(s)" to help the Regulatory Authority identifying the corresponding XML-file(s) in the database.</p>	Literature reference list	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.DataSource.Reference
Materials and methods	<p>Material and methods – common block</p> <p>Applicable test guideline: According to the provisions in Article 62(1) of Regulation (EC) No 1107/2009, in vivo methods can only be used where alternative methods are not suitable Method B.36 Toxicokinetics (Annex to Regulation (EC) No 440/2008). OECD Test Guideline 417: Toxicokinetics (* Communication from the Commission in the framework of the implementation of Commission Regulation (EU) No 283/2013 of 1 March 2013)</p> <p>Guideline: Guideline: Method B.36 Toxicokinetics (Annex to Regulation (EC) No 440/2008).</p>	Header 1	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.MaterialsAndMethods

	OECD Test Guideline 417: Toxicokinetics		
Objective of study	Indicate the purpose of the study. The field is repeatable. Select the respective toxicokinetic aspect(s) investigated. Multiple selection is possible. If not listed, select 'other' and specify.	Multi select open list	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.MaterialsAndMethods.ObjectiveOfStudyPick
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.MaterialsAndMethods.TestMaterials
Radiolabelling	Indicate if labelled or non-labelled test material was used. Details on labelled material to be described in field 'Details on test material'. In the supplementary remarks field, any further explanations can be provided, e.g. for indicating that both labelled and unlabelled substances were used.	Open list with remarks	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.MaterialsAndMethods.TestMaterials.Radiolabelling
Test animals	Test animals (OHT: Repeated dose toxicity) – common block Sex: If different sexes were used in multiple test runs recorded in the same record, select 'male/female' and differentiate in field 'Doses / concentrations'.	Header 2	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.MaterialsAndMethods.TestAnimals
Administration / exposure		Header 2	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.MaterialsAndMethods.AdministrationExposure
Route of administration	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.MaterialsAndMethods.AdministrationExposure.RouteOfAdministration
Vehicle	Select 'unchanged (no vehicle)' if none was used or select vehicle used if any. If not available from picklist, select 'other' and specify. Further information can be given in the supplementary remarks field. Note that some of the vehicles provided in this list are used for specific routes of administration only.	Open list with remarks	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.MaterialsAndMethods.AdministrationExposure.Vehicle
Details on exposure	Select freetext template for the respective type of study and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.MaterialsAndMethods.AdministrationExposure.DetailsOnExposure
Duration and frequency of	Indicate duration and frequency of application, e.g. 'single application' or	Multi-line text	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.MaterialsAndMetho

treatment / exposure	'multiple application: 14 days, 2 doses per day, 5 days per week'.		ds.AdministrationExposure.DurationAndFrequencyOfTreatmentExposure
Doses / concentrations	Indicate the dose or concentration levels applied and the basis of quantity used. Copy this block of fields for each numeric value and to record values on a different basis, i.e. mg/kg bw/day (nominal), mg/kg bw/day (actual dose received), mg/kg diet ,mg/L drinking water, mg/kg bw (total dose), ppm if applicable. Conversion of the dose / conc. values to the relevant unit used for the effect levels may be required.		ENDPOINT_STUDY_RECORD.BasicToxicokinetics.MaterialsAndMethods.AdministrationExposure.DosesConcentrations
Dose / conc.	Enter numeric value.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.DoseConc
Remarks	Enter any remarks related to dose / concentration values / pilot study / main study.	Multi-line text	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.Remarks
Doses / concentrations			
No. of animals per sex per dose / concentration	Enter value or specify according to dose if different number of animals per dose / concentration, e.g. '4 in each dose / concentration group with single application; 2 f and 4 m in multiple application group'. In case of a robust study summary, include animal numbers per sex in table on animal assignment.	Multi-line text	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.MaterialsAndMethods.AdministrationExposure.NoOfAnimalsPerSexPerDose
Control animals	Indicate whether and what type of concurrent control groups were used. Multiple selection is possible. If not listed, select 'other' and specify.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.MaterialsAndMethods.AdministrationExposure.ControlAnimals
Positive control reference chemical	Indicate if a positive control was used and if appropriate indicate purity, Lot/batch No.	Multi-line text	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.MaterialsAndMethods.AdministrationExposure.PositiveControl
Details on study design	Include further details on the study design including a brief description on dose selection and animal assignment rationale if appropriate. Briefly describe the results from range-finding or other studies used as basis for dose selection. More comprehensive	Text template	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.MaterialsAndMethods.AdministrationExposure.DetailsOnStudyDesign

	<p>details may be attached. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.</p>		
Details on dosing and sampling	<p>Include details on dosing and sampling. Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from the study report.</p>	Text template	ENDPOINT_STUDY_RE CORD.BasicToxicokinet ics.MaterialsAndMetho ds.AdministrationExpos ure.DetailsOnDosingAn dSampling
Statistics	<p>List parameters that were analysed by which statistical methods, computer programme used.</p>	Multi-line text	ENDPOINT_STUDY_RE CORD.BasicToxicokinet ics.MaterialsAndMetho ds.AdministrationExpos ure.Statistics
Any other information on materials and methods incl. tables	<p>Any other information on materials and methods incl. tables - (H2) – common block</p>	Header 2	ENDPOINT_STUDY_RE CORD.BasicToxicokinet ics.MaterialsAndMetho ds.AnyOtherInformatio nOnMaterialsAndMetho dsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RE CORD.BasicToxicokinet ics.ResultsAndDiscussio n
Preliminary studies	<p>Briefly describe the results of preliminary / pilot study or studies if any.</p>	Text area	ENDPOINT_STUDY_RE CORD.BasicToxicokinet ics.ResultsAndDiscussio n.PreliminaryStudies
Main ADME results	<p>Briefly describe the most relevant results with regard to absorption, distribution, metabolism, excretion and any other aspects related to toxicokinetics. Further details can be given in the below fields 'Details on absorption', 'Details on distribution in tissues', 'Details on excretion' and/or 'Any other information on results incl. tables'.</p> <p>If required, copy block of fields to include several parameters.</p> <p>Absorption: Include degree of absorption in %. In case of a robust study summary, include a function relating excretion of radioactivity (in urine, feces, etc.) to sampling time.</p> <p>Distribution: For each treatment group / study design or combined groups, describe levels of radioactivity measured at given time points in</p>		ENDPOINT_STUDY_RE CORD.BasicToxicokinet ics.ResultsAndDiscussio n.MainAdmeResults

	<p>tissues/organs.</p> <p>Excretion: For each treatment group / study design or combined groups, describe levels of radioactivity measured at given time points in tissues and excreta including total recovery.</p> <p>Material balance: Indicate mass balance of study.</p> <p>Metabolism including clearance: describe any decrease of the test chemical concentration from the incubation vial measured to determine the clearance in vitro.</p>		
Type	Select either 'absorption', 'distribution', 'metabolism', 'excretion' or 'other:' from drop-down list.	Open list	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion.MainAdmeResults.Type
Results	Briefly describe the most relevant results.	Text	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion.MainAdmeResults.Results
Main ADME results			
Toxicokinetic / pharmacokinetic studies		Header 2	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion.PharmacokineticStudies
Details on absorption	In case of a robust study summary, describe further details on absorption. As appropriate include a detailed table in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Note: Specific tables may be required.	Text area	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion.PharmacokineticStudies.DetailsOnAbsorption
Details on distribution in tissues	In case of a robust study summary, describe further details on distribution including organs with highest levels. As appropriate include a detailed table in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Note: Specific tables may be required.	Text area	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion.PharmacokineticStudies.DetailsOnDistribution
Transfer into organs	Indicate the transfer of the radiolabelled test substance into organs. Copy this block of		ENDPOINT_STUDY_RECORD.BasicToxicokinetic

	fields for each transfer type and/or different test runs if applicable.		ics.ResultsAndDiscussion.PharmacokineticStudies.TransferIntoOrgans
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion.PharmacokineticStudies.TransferIntoOrgans.KeyResult
Test no.	Select a consecutive test number from drop-down list if more than one test runs are reported.	Closed list	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion.PharmacokineticStudies.TransferIntoOrgans.TestNo
Transfer type	Select type of transfer (e.g. 'blood/brain transfer') from picklist.	Open list with remarks	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion.PharmacokineticStudies.TransferIntoOrgans.TransferType
Observation	Select the qualitative description (e.g. 'distinct transfer') that characterises the observed transfer of radiolabelled test substance into the brain or spinal cord or into the placenta and on the secretion of radioactivity via the gastric mucosa, respectively. As appropriate, include quantitative data and/or any explanations in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion.PharmacokineticStudies.TransferIntoOrgans.Observation
Transfer into organs			
Details on excretion	In case of a robust study summary, describe further details on excretion. As appropriate include a detailed table in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Note: Specific tables may be required.	Text area	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion.PharmacokineticStudies.DetailsOnExcretion
Toxicokinetic parameters	Select toxicokinetic parameter from picklist and enter the corresponding value(s) with unit in the related text field. Examples: (i) Half-life 1st: 23.4 hrs (male, single administration study); (ii) C(time): 88 µg/l at 40 hrs Copy this block of fields for each parameter. If multiple test runs are recorded, enter test numbers in subfield 'Test No.'.		ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion.PharmacokineticStudies.ToxicokineticParameters
Key result	Set this flag for identifying the key information which is of potential relevance for	Check box	ENDPOINT_STUDY_RECORD.BasicToxicokinetics

	hazard/risk assessment or classification purpose.		ics.ResultsAndDiscussion.PharmacokineticStudies.ToxicokineticParameters.KeyResult
Test no.	Select a consecutive test number from drop-down list if more than one test runs are reported.	Closed list	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion.PharmacokineticStudies.ToxicokineticParameters.TestNo
Toxicokinetic parameters	Select parameter from drop-down list. Explanations: - AUC: Area under the plasma (blood) level vs. time curve from zero up to a certain measured time point (specify the time); Cmax: Maximum (peak) concentration; C(time): Maximum concentration at a specified time after administration of a given dose; Tmax: Time to reach peak or maximum concentration following administration	Open list with remarks	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion.PharmacokineticStudies.ToxicokineticParameters
Toxicokinetic parameters			
Metabolite characterisation studies		Header 2	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion.MetaboliteCharacterisationStudies
Metabolites identified	Indicate whether metabolites were identified.	Closed list with remarks	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion.MetaboliteCharacterisationStudies.MetabolitesIdentified
Details on metabolites	List the metabolites identified, include percent of radioactive dose given, where they were identified, when, if applicable, how they were identified, if applicable, how much parent was present in the excreta. In case of a robust study summary, also include a detailed table in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). When available, include summary of metabolic pathways and attach figures in field 'Attached background material'. Mention which are major vs. minor pathways. Attach the submitter's postulated pathway as a	Text area	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion.MetaboliteCharacterisationStudies.DetailsOnMetabolites

	figure. Note: Specific tables may be required.		
Enzymatic activity		Header 2	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion.EnzymaticActivity
Enzymatic activity measured	Indicate the results of any enzymatic activity measured (induction, inhibition or biotransformation of test material). Identify enzyme(s) involved, rate of activity, time points measured, data from individual vials, time point for each independent run, calculated clearance and summary statistics, and method used to follow the activity. Specify whether measurements were done in vivo or in vitro, in main study or supplemental approach.	Text area	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion.EnzymaticActivity.EnzymaticActivityMeasured
Bioaccessibility (or Bioavailability)		Header 2	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion.Bioaccessibility
Bioaccessibility (or Bioavailability) testing results	Indicate the results of the bio-accessibility (or bio-availability) tests, if applicable.	Text area	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion.Bioaccessibility.BioaccessibilityTestingResults
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion.AnyOtherInformationOnResultsIncTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ApplicantSummaryAndConclusion

Links to support material:

Test guideline: Communication from the Commission in the framework of the implementation of Commission Regulation (EU) No 283/2013 of 1 March 2013

Please find specific instructions on who to structure the results of mammalian toxicology metabolism studies under the following link:

<https://www.efsa.europa.eu/en/applications/pesticides/tools>

5.2 Acute toxicity – Endpoint Summary

Purpose

Chemical (Active and Product): Provide summary information of the most relevant study(-ies) from which the key value for chemical assessment is extrapolated. Provide only the most relevant details (according to Acute toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.2):

- Rat LD50 oral
- Rat LD50 dermal
- Rat LC50 inhalation

Microorganism (Active and Product): Provide summary information of the most relevant study(-ies) in which the relative hazards associated with the different routes of exposure have been investigated in test mammals. The information generated through acute toxicity, pathogenicity and infectiveness testing is of particular value in assessing hazards likely to arise in accident situations and consumer risks due to exposure to possible residues.

All signs of infection and/or pathogenicity and a clearance assessment should be included.

The document should contain the information needed to be reported according to the list of end points for acute oral, dermal and inhalation toxicity (SANCO/12592/2012-rev. 2, 22 March 2019).

ENDPOINT_SUMMARY.AcuteToxicity- v.6.2 (Final)			
Name	Instructions	Type	Field Path
Administrative data	Administrative data summary – common block Description of key information: Provide a brief description of toxicity studies and effects.	Header 1	ENDPOINT_SUMMARY.AcuteToxicity.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.AcuteToxicity.KeyValueForChemicalSafetyAssessment
Acute toxicity: via oral route		Header 2	ENDPOINT_SUMMARY.AcuteToxicity.KeyValueForChemicalSafetyAssessment.AcuteToxicityViaOralRoute
Link to relevant study records	Endpoint summary block for relevant study record The following factors, among others, should be taken into account when the robust study summary is selected: quality of the study (e.g. Klimisch score,	Header 3	ENDPOINT_SUMMARY.AcuteToxicity.KeyValueForChemicalSafetyAssessment.AcuteToxicityViaOralRoute.LinkToRelevantStudyRecords

	duration of the study, whether or not the study is GLP.		
Endpoint conclusion	Endpoint conclusion block (quality of database) Note: In case of acute studies with micro-organisms, less severe but still adverse effects are also considered during the assessment. Dose descriptor: LD50 should usually be chosen. However, if the acute toxicity was established by determining the discriminating dose, that should be chosen.	Header 3	ENDPOINT_SUMMARY.AcuteToxicity.KeyValueForChemicalSafetyAssessment.AcuteToxicityViaOralRoute.EndpointConclusion
Acute toxicity: via inhalation route		Header 2	ENDPOINT_SUMMARY.AcuteToxicity.KeyValueForChemicalSafetyAssessment.AcuteToxicityViaInhalationRoute
Link to relevant study records	Endpoint summary block for relevant study record The following factors, among others, should be taken into account when the robust study summary is selected: quality of the study (e.g. Klimisch score), duration of the study, whether or not the study is GLP.	Header 3	ENDPOINT_SUMMARY.AcuteToxicity.KeyValueForChemicalSafetyAssessment.AcuteToxicityViaInhalationRoute.LinkToRelevantStudyRecords
Endpoint conclusion	Note: In case of acute studies with micro-organisms, less severe but still adverse effects are also considered during the assessment. Dose descriptor: LC50 should usually be chosen. However, if the acute toxicity was established by determining the discriminating	Header 3	ENDPOINT_SUMMARY.AcuteToxicity.KeyValueForChemicalSafetyAssessment.AcuteToxicityViaInhalationRoute.EndpointConclusion

	concentration, that should be chosen.		
Physical form	Indicate in what physical form the test material was administered.	Open list	ENDPOINT_SUMMARY.AcuteToxicity.KeyValueForChemicalSafetyAssessment.AcuteToxicityViaInhalationRoute.EndpointConclusion.PhysicalForm
Acute toxicity: via dermal route		Header 2	ENDPOINT_SUMMARY.AcuteToxicity.KeyValueForChemicalSafetyAssessment.AcuteToxicityViaDermalRoute
Link to relevant study records	Endpoint summary block for relevant study record The following factors, among others, should be taken into account when the robust study summary is selected: quality of the study (e.g. Klimisch score, duration of the study, whether or not the study is GLP)	Header 3	ENDPOINT_SUMMARY.AcuteToxicity.KeyValueForChemicalSafetyAssessment.AcuteToxicityViaDermalRoute.LinkToRelevantStudyRecords
Endpoint conclusion	Endpoint conclusion block (quality of database) Note: In case of acute studies with micro-organisms, less severe but still adverse effects are also considered during the assessment. Dose descriptor: LD50 should usually be chosen. However, if the acute toxicity was established by determining the discriminating dose, that should be chosen.	Header 3	ENDPOINT_SUMMARY.AcuteToxicity.KeyValueForChemicalSafetyAssessment.AcuteToxicityViaDermalRoute.EndpointConclusion
Additional information	Discussion (Header 1) – common block Provide additional information related to the endpoint, for example: Rat LD50 oral	Header 1	ENDPOINT_SUMMARY.AcuteToxicity.Discussion

	Rat LC50 inhalation Rat LD50 intraperitoneal/subcutaneous		
Justification for classification or non-classification	Not relevant for micro-organisms.	Header 1	ENDPOINT_SUMMARY.AcuteToxicity.JustificationForClassificationOrNoClassification

5.2.1 Oral (includes acute oral toxicity to mammals)– Endpoint study record

Purpose:

Chemical Active: The acute oral toxicity of the active substance shall always be reported.

Chemical Product: A test for acute oral toxicity shall be carried out, unless the applicant can justify an alternative approach under Regulation (EC) No 1272/2008. In the latter case, acute oral toxicity of all components shall be provided or reliably predicted with a validated method. Consideration shall be given to the possible effects of components on the toxic potential of the total mixture.

Microorganism Active: The acute oral toxicity study should permit the identification of effects following a single exposure to the microorganism, including an assessment of toxicity, pathogenicity and infectiveness, and evaluation of the clearance of the microorganism.

Microorganism Product: An acute oral test with the plant protection product shall always be carried only if the applicant cannot justify an alternative approach under Regulation (EC) No 1272/2008.

ENDPOINT_STUDY_RECORD.AcuteToxicityOral - v.9.2 (Final)			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.DataSource
Materials and methods	Material and methods – common block Applicable test guideline: Method B.1 bis Acute oral toxicity - fixed dose procedure (Annex to Regulation (EC) No 440/2008). Method B.1 tris Acute oral toxicity - Acute toxic class method (Annex to Regulation (EC) No 440/2008).	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.MaterialsAndMethods

	<p>OECD Test Guideline 420: Acute oral toxicity: fixed dose procedure</p> <p>OECD Test Guideline 423: Acute oral toxicity: acute toxic class method</p> <p>OECD Test Guideline 425: Acute oral toxicity: up-and-down procedure</p> <p>Microbial Pesticide Test Guidelines: OPPTS 885.3050 Acute Oral Toxicity/Pathogenicity</p> <p>Are relevant for this endpoint Information on the version and date of the guideline used and/or any other specifics can be entered in the next field 'Version / remarks'.</p>		
Test type	<p>If possible, indicate whether the acute toxic class method, fixed dose procedure, up-and-down procedure or standard acute method was used. The latter method should not be used any more. However, it may apply to existing studies. If neither of these test types applies, either leave field empty or use 'other:'.</p> <p>Note: This field may be redundant with the information given in field 'Guideline',but is considered useful for searching reasons.</p>	Open list	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.MaterialsAndMethods.TestType
Limit test	Indicate if the experiment was a limit test.	Closed list	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.MaterialsAndMethods.LimitTest
Test material	Test material	Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.MaterialsAndMethods.TestMaterials
Test animals	<p>Test animals (OHT: Repeated dose toxicity)</p> <p>Species Select name of species. If not available from picklist, select 'other' and specify.</p> <p>NOTE: Human data should be reported in an appropriate subsection of section 'Basic information'</p> <p>It can be useful to document, in the section on acute toxicity, that human data are provided by creating a record and referring to the human data in field 'Cross-reference'. This could be relevant if lack of animal experiments is defended by the availability of data on experience with human exposure.</p>	Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.MaterialsAndMethods.TestAnimals
Administration / exposure		Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.MaterialsAndMethods.AdministrationExposure
Route of administration	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.MaterialsAnd

			Methods.Administrati onExposure.RouteOf Administration
Vehicle	Select 'unchanged (no vehicle)' if none was used or select vehicle used if any. If not available from picklist, select 'other' and specify. Further information can be given in the supplementary remarks field. Note that some of the vehicles provided in this list are used for specific routes of administration only.	Open list with remarks	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.MaterialsAndMethods.Administrati onExposure.Vehicle
Details on oral exposure	Indicate details of oral exposure. Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from the study report.	Text template	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.MaterialsAndMethods.Administrati onExposure.DetailsO nOralExposure
Doses	Include the doses including unit administered to the test animals (in CFU/ml or CFU/kg bw). As appropriate include notes in parentheses, e.g. '(male)'.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.MaterialsAndMethods.Administrati onExposure.Doses
No. of animals per sex per dose	Enter value or specify according to dose if different number of animals per dose, e.g. '10 (controls), 5 (in dose groups)'. For robust study summaries or as requested by the regulatory programme, also include a detailed table on the animal assignment in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Note: Specific tables may be required.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.MaterialsAndMethods.Administrati onExposure.NoOfAni malsPerSexPerDose
Control animals	Indicate whether concurrent control group was used.	Open list with remarks	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.MaterialsAndMethods.Administrati onExposure.ControlA nimals
Details on study design	Include any further details on the study design, i.e. observation period, frequency of observations/weighing, necropsy of survivors and other examinations performed. Use freetext template and delete/add elements as appropriate.	Text template	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.MaterialsAndMethods.Administrati onExposure.DetailsO nStudyDesign
Statistics	Indicate the method of calculating the LD50 or other.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.MaterialsAndMethods.Administrati onExposure.Statistics

Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block Verification that each enumeration method is sufficiently sensitive to serve as a useful quantitative assay, for the micro-organism in tissues, organs, and body fluids	Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion
Preliminary study	Summarise evidence of toxicity and mortality of any preliminary sighting study.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion.Preliminary
Effect levels	Provide the LD50 with confidence limits if available and/or other effect levels reported. Copy this field block for each effect level. If both sexes were tested at each dose level, then the combined effect level should be stated. Where there are significant differences in response between the sexes, include the effect levels for both. If the test was conducted according to the fixed dose procedure, include the discriminating dose, i.e. the highest out of the four fixed dose levels which can be administered without causing compound-related mortality (including human kills). If no LD50 or other endpoint available from picklist is reported, but only a dose level, specify this dose using 'other' and indicate the effects observed in subfield 'Remarks on result'.		ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion.EffectLevels
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion.EffectLevels.KeyResult
Sex	Select from drop-down list.	Closed list	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion.EffectLevels.Sex
Dose descriptor	Select the relevant dose descriptor from drop-down list, i.e. the exposure level that corresponds to a quantified level of effects. If a fixed dose procedure was used, select 'discriminating dose', i.e the dose causing evident toxicity but not mortality. With the up-and-down procedure an 'approximate LD50' may be derived. Where no value could be achieved based on the	Open list with remarks	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion.EffectLevels.Endpoint

	method and boundaries used, the upper or lower dose level for the relevant dose descriptor can be reported as appropriate with relevant qualifier, e.g. LD50 >10 or LD50 <10. An additional explanation may be given in field 'Remarks on result', e.g. 'not determinable due to absence of adverse toxic effects'.		
Effect level	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion.EffectLevels.EffectLevel
Based on	Indicate whether the concentration is based on the test material (test mat.), active ingredient (act. ingr.) or element. As appropriate the measured / addressed fraction can be specified for either of these entities by selecting the relevant item, e.g. 'element (dissolved fraction)' or 'test mat. (total fraction)'. Further information can be given in the supplementary remarks field, e.g. for specifying the type of fraction if it is not clear per se from the test material specification. Select 'not specified' if the effect concentration type is not known.	Open list with remarks	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion.EffectLevels.BasedOn
95% CL	For robust study summaries or as requested by the regulatory programme, provide the 95% confidence limits if available. Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion.EffectLevels.cl
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion.EffectLevels.RemarksOnResults
Effect levels			
Mortality	In the case of a fixed dose study, summarise evidence of toxicity and mortality of any preliminary sighting study at the fixed doses administered.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion.Mortality
Clinical signs	Briefly describe significant effects found, including the numbers of animals showing signs, time of onset, duration of the major clinical signs	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion.ClinicalSigns

	and time when most animals recovered. Do not dwell on effects that are most likely due to agonal death. Focus on any important findings, i.e. compound-related or suspected related effects. In case particular effects are considered control-related e.g. because of abnormal control values, this should be specifically addressed. Note if there was a reference point (e.g. NOAELs) for clinical findings. If the fixed dose method was used, indicate if animals appeared to recover completely and state if there were no obvious substance-related signs of toxicity.		tyOral.ResultsAndDiscussion.ClinicalSigns
Body weight	Briefly describe whether animals gained or lost weight. . Indicate if body weight loss was greater than 10%.	PickListWithRemarks2000	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion.BodyWeight
Gross pathology	Briefly describe whether there were any treatment related effects. Do not stress effects due to agonal death.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion.GrossPathology
Other findings	The following should be reported for studies with micro-organisms: - Clearance estimates (numeration of the micro-organism/toxin in the relevant tissues/organs/body fluids at different time points) - Infectivity/persistence findings (numeration and findings in affected organs/tissues, if any)	Text template	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion.OtherFindings
Any other information on results incl. tables)	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block Attached document: Detailed results in the different dose groups can be reported in Appendix F format either as an attachment and in the 'Any other information on results incl. tables'	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ApplicantSummaryAndConclusion

Results and discussion

Preliminary study
None

Effect levels + New item 🔥 Import file ▼

#	Key result	Sex	Dose descriptor	Effect level	Based on	95% CL	Remarks on result	Actions
1	<input type="checkbox"/>	male/female	LD50	1829 mg/kg bw	test mat.	None	None	
2	<input checked="" type="checkbox"/>	male	LD50	1392 mg/kg bw	test mat.	None	None	
3	<input type="checkbox"/>	female	LD50	2271 mg/kg bw	test mat.	None	other:	

Mortality
No mortality was recorded in either sex at 500 mg/kg bw. At 2000 mg/kg bw 4/5 males and 1/5 females were found dead at days 8 and 9 of the observation period. At 5000 mg/kg bw all the animals died during the first two days after treatment with the exception of one male that died on the ninth day

Clinical signs
✓ other: The following symptoms were reported: dyspnea, exophthalmos and hunched body position. In addition; sedation was reported on the sixth day after treatment in the animals that received 2000 mg/kg bw. Sedation was also reported from the days of administrati

Body weight
None

Gross pathology
The autopsy of the animals received 500 mg/kg bw and the survivors of the 2000 mg/kg bw dose group did not show any treatment related changes. Dilatation, hemorrhage or liquid content of the intestinal tract were reported in the 4 dead males and one female at 2000 mg/kg bw and in one male and one female at 5000 mg/kg bw. Reddish or discolored lungs with oedema were seen in 4 males and 1 female at 2000 mg/kg bw and in 4 males and 3 females at 5000 mg/kg bw. Soft liver was reported in one male and one female at 2000 mg/kg bw. Thymic hemorrhage was reported in four males and four females at the highest dose.

5.2.2 Dermal – Endpoint study record

Purpose

Chemical Active: The acute dermal toxicity of the active substance shall be reported unless waiving is scientifically justified (for example where oral LD50 (2) is greater than 2 000 mg/kg). Both local and systemic effects shall be investigated.

Chemical Product: A test for dermal toxicity shall be carried out on a case by case basis, unless the applicant can justify an alternative approach under Regulation (EC) No 1272/2008. In the latter case, acute dermal toxicity of all components shall be provided or reliably predicted with a validated method. Consideration shall be given to the possible effects of components on the toxic potential of the total mixture.

Microorganism Product: An acute percutaneous test with the plant protection product shall be conducted only if the applicant cannot justify an alternative approach under Regulation (EC) No 1272/2008, where applicable.

Findings of severe skin irritation (Grade 4 erythema or oedema) in the dermal study shall be used instead of performing a specific irritation study.

ENDPOINT_STUDY_RECORD.AcuteToxicityDermal - v.8.4 (Final)			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.DataSource
Materials and methods	Material and methods – common block Applicable test guideline:	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.MaterialsAndMethods

	<ul style="list-style-type: none"> - Method B.3 Acute toxicity (dermal) (Annex to Regulation (EC) No 440/2008). - OECD Test Guideline 402: Acute Dermal Toxicity 		
Test type	<p>If possible, indicate whether the fixed dose procedure or standard acute method was used. The latter method should not be used any more. However, it may apply to existing studies.</p> <p>If neither of these test types applies, either leave field empty or use 'other:'.</p> <p>Note: This field may be redundant with the information given in field 'Guideline', but is considered useful for searching reasons.</p>	Open list	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.MaterialsAndMethods.TestType
Limit test	Indicate if the experiment was a limit test.	Closed list	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.MaterialsAndMethods.LimitTest
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.MaterialsAndMethods.TestMaterials
Test animals	<p>Test animals (OHT: Repeated dose toxicity)</p> <p>Species:</p> <p>NOTE: Human data should be reported in an appropriate subsection of section 'Exposure related observations', particularly subsection 'Direct observations: clinical cases, poisoning incidents and other'.</p> <p>It can be useful to document, in the section on acute toxicity, that human data are provided by creating a record and referring to the human data in field 'Cross-reference'. This could be relevant if lack of animal experiments is defended by the availability of data on experience with human exposure.</p> <p>Sex: Testing in one sex (usually females) is generally considered sufficient. Provide rationale for use of males (if applicable), in field 'Details on test animals and environment conditions'.</p>	Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.MaterialsAndMethods.TestAnimals
Administration / exposure		Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.MaterialsAndMethods.AdministrationExposure
Type of coverage	Select type of coverage used. For robust study summaries specify the area of application in field 'Details on dermal exposure'.	Open list	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.MaterialsAnd

			Methods.Administrati onExposure.TypeOfC overage
Vehicle	Select 'unchanged (no vehicle)' if none was used or select vehicle used if any. If not available from picklist, select 'other' and specify. Further information can be given in the supplementary remarks field. Note that some of the vehicles provided in this list are used for specific routes of administration only.	Open list with remarks	ENDPOINT_STUDY_R ECORD.AcuteToxicity Dermal.MaterialsAnd Methods.Administrati onExposure.Vehicle
Details on dermal exposure	Indicate details of exposure. Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from the study report.	Text template	ENDPOINT_STUDY_R ECORD.AcuteToxicity Dermal.MaterialsAnd Methods.Administrati onExposure.DetailsO nDermalExposure
Duration of exposure	Indicate total duration of exposure in hours, e.g. '4 hrs'.	Multi-line text	ENDPOINT_STUDY_R ECORD.AcuteToxicity Dermal.MaterialsAnd Methods.Administrati onExposure.Duration OfExposure
Doses	Include the doses including unit administered to the test animals, e.g. 50, 200, 1000 and 2000 mg/kg bw', or mention the doses after '- other:'. As appropriate include notes in parentheses, e.g. '(male)'. For a robust study summary also indicate the analytical concentrations of the test substance in the vehicle in the results table (see field 'Mortality').	Text template	ENDPOINT_STUDY_R ECORD.AcuteToxicity Dermal.MaterialsAnd Methods.Administrati onExposure.Doses
No. of animals per sex per dose	Enter value or specify according to dose if different number of animals per dose, e.g. '10 (controls), 5 (in dose groups)'. For robust study summaries or as requested by the regulatory programme, also include a detailed table on the animal assignment in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Note: Specific tables may be required.	Multi-line text	ENDPOINT_STUDY_R ECORD.AcuteToxicity Dermal.MaterialsAnd Methods.Administrati onExposure.NoOfAni malsPerSexPerDose
Control animals	Indicate whether and what type of concurrent control groups were used or select 'not required' if applicable.	Open list with remarks	ENDPOINT_STUDY_R ECORD.AcuteToxicity Dermal.MaterialsAnd Methods.Administrati onExposure.ControlA nimals

Details on study design	Include any further details on the study design, i.e. observation period, frequency of observations/weighing, necropsy of survivors and other examinations performed. Use freetext template and delete/add elements as appropriate. If TG 402 (9 October 2017) was used, see flowchart for the testing procedure in its Annex 2.	Text template	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.MaterialsAndMethods.AdministrationExposure.DetailsOnStudyDesign
Statistics	Indicate the method of calculating the LD50 or other, if applicable.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.MaterialsAndMethods.AdministrationExposure.Statistics
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.ResultsAndDiscussion
Preliminary study	Summarise evidence of toxicity and mortality of any preliminary sighting study.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.ResultsAndDiscussion.Preliminary
Effect levels			ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.ResultsAndDiscussion.EffectLevels
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.ResultsAndDiscussion.EffectLevels.KeyResult
Sex	Select from drop-down list.	Closed list	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.ResultsAndDiscussion.EffectLevels.Sex
Dose descriptor	Select the relevant dose descriptor from drop-down list, i.e. the exposure level that corresponds to a quantified level of effects. If a fixed dose procedure was used, select 'discriminating dose', i.e the dose causing evident toxicity but not mortality. With the up-and-down procedure an 'approximate LD50' may be derived. Where no value could be achieved based on the method and boundaries	Open list with remarks	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.ResultsAndDiscussion.EffectLevels.Endpoint

	used, the upper or lower dose level for the relevant dose descriptor can be reported as appropriate with relevant qualifier, e.g. LD50 >10 mg/kg bw or LD50 <10 mg/kg bw. An additional explanation may be given in field 'Remarks on result', e.g. 'not determinable due to absence of adverse toxic effects'.		
Effect level	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable. For GHS classification, see 'Interpretation of results' under section 'Applicant's summary conclusion' below.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORDER.AcuteToxicityDermal.ResultsAndDiscussion.EffectLevels.EffectLevel
Based on	Indicate whether the concentration is based on the test material (test mat.), active ingredient (act. ingr.) or element. As appropriate the measured / addressed fraction can be specified for either of these entities by selecting the relevant item, e.g. 'element (dissolved fraction)' or 'test mat. (total fraction)'. Further information can be given in the supplementary remarks field, e.g. for specifying the type of fraction if it is not clear per se from the test material specification. Select 'not specified' if the effect concentration type is not known.	Open list with remarks	ENDPOINT_STUDY_RECORDER.AcuteToxicityDermal.ResultsAndDiscussion.EffectLevels.BasedOn
95% CL	For robust study summaries or as requested by the regulatory programme, provide the 95% confidence limits if available. Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORDER.AcuteToxicityDermal.ResultsAndDiscussion.EffectLevels.cl
Remarks on result	This field can be used for: - giving a qualitative description of results where required and in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORDER.AcuteToxicityDermal.ResultsAndDiscussion.EffectLevels.RemarksOnResults
Effect levels			
Mortality	Include raw data on mortality and evident toxicity for each sex and approximate time of deaths. As appropriate include a detailed table	Multi-line text	ENDPOINT_STUDY_RECORDER.AcuteToxicity

	<p>in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1').</p> <p>If the fixed dose method was used, tabulate the evidence of toxicity and mortality (number of animals) for each sex and dose group. 'Evidence of toxicity' describes clear signs of toxicity following administration of test substance, which should be such that an increase in the exposure concentration can be expected to result in the development of severe toxic signs and probable mortality. Note: Specific tables may be required.</p>		Dermal.ResultsAndDiscussion.Mortality
Clinical signs	<p>Briefly describe significant effects found, including the numbers of animals showing signs, time of onset, duration of the major clinical signs and time when most animals recovered. Distinguish between effects at the site of application (local) and systemic effects. Do not dwell on effects that are most likely due to agonal death. Focus on any important findings, i.e. compound-related or suspected related effects. In case particular effects are considered control-related e.g. because of abnormal control values, this should be specifically addressed. Note if there was a reference point (e.g. NOAELs) for clinical findings.</p>	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.ResultsAndDiscussion.ClinicalSigns
Body weight	Briefly describe whether animals gained or lost weight.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.ResultsAndDiscussion.BodyWeight
Gross pathology	Briefly describe whether there were any treatment related effects. Do not stress effects due to agonal death.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.ResultsAndDiscussion.GrossPathology
Other findings	Report results related to pathogenicity, infectiveness or clearance in studies with micro-organisms	Text template	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.ResultsAndDiscussion.OtherFindings
Any other information on results incl. tables)	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables

Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.ApplicantSummaryAndConclusion

5.2.3 Inhalation – Endpoint study record

Purpose:

Chemical: The acute inhalation toxicity of the active substance shall be reported where any of the following apply:

- the active substance has a vapour pressure $> 1 \times 10^{-2}$ Pa at 20 °C;
- the active substance is a powder containing a significant proportion of particles of a diameter $< 50 \mu\text{m}$ ($> 1\%$ on weight basis);
- the active substance is included in products that are powders or are applied by spraying.

The head/nose only exposure shall be used, unless whole body exposure can be justified.

Microorganism Active: The acute toxicity study by inhalation should permit the identification of effects following a single exposure to the microorganism, including an assessment of toxicity, pathogenicity and infectiveness, and evaluation of the clearance of the microorganism.

Microorganism Product: The acute inhalation toxicity study must be carried out where the plant protection product:

- is used with fogging equipment,
- is an aerosol,
- is a powder containing a significant proportion of particles of diameter < 50 micrometre ($> 1\%$ on a weight basis),
- is to be applied from aircraft in cases where inhalation exposure is relevant,
- is to be applied in a manner which generates a significant proportion of particles or droplets of diameter < 50 micrometre ($> 1\%$ on a weight basis),
- contains a volatile component at greater than 10%.

ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation - v.9.4 (Final)			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.DataSource
Materials and methods	Material and methods – common block Applicable test guideline: Microbial Pesticide Test Guidelines: OPPTS 885.3150 Acute Pulmonary Toxicity/Pathogenicity Are relevant for this endpoint	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMethods

Test type	If possible, indicate which method was used in the study. If neither of these test types applies, either leave field empty or use 'other':. Note: This field may be redundant with the information given in field 'Guideline', but is considered useful for searching reasons.	Open list	ENDPOINT_STUDY_REC ORD.AcuteToxicityInhal ation.MaterialsAndMeth ods.TestType
Limit test	Indicate if the experiment was a limit test.	Closed list	ENDPOINT_STUDY_REC ORD.AcuteToxicityInhal ation.MaterialsAndMeth ods.LimitTest
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_REC ORD.AcuteToxicityInhal ation.MaterialsAndMeth ods.TestMaterials
Test animals	Select name of species. If not available from picklist, select 'other' and specify. NOTE: Human data should be reported in an appropriate subsection of section 'Basic information'. It can be useful to document, in the section on acute toxicity, that human data are provided by creating a record and referring to the human data in field 'Cross-reference'. This could be relevant if lack of animal experiments is defended by the availability of data on experience with human exposure. Sex: Provide rationale for use of females (if applicable), in field 'Details on test animals and environment conditions'.	Header 2	ENDPOINT_STUDY_REC ORD.AcuteToxicityInhal ation.MaterialsAndMeth ods.TestAnimals
Administration / exposure		Header 2	ENDPOINT_STUDY_REC ORD.AcuteToxicityInhal ation.MaterialsAndMeth ods.AdministrationExpos ure
Route of administration	Specify the route of administration by indicating in what physical form the test material was administered. In case of intratracheal administration, specify it under 'Type of inhalation'.	Open list	ENDPOINT_STUDY_REC ORD.AcuteToxicityInhal ation.MaterialsAndMeth ods.AdministrationExpos ure.RouteOfAdministrati on
Type of inhalation exposure	Indicate type of inhalation exposure, e.g. 'nose only'. Any remarks can be entered in the supplementary remarks subfield. In case of intratracheal administration, select other and report this in the 'remarks' field.	Open list with remarks	ENDPOINT_STUDY_REC ORD.AcuteToxicityInhal ation.MaterialsAndMeth ods.AdministrationExpos ure.TypeOfInhalationEx posure
Vehicle	Select the vehicle used. If not available from picklist, select 'other'.	Open list with remarks	ENDPOINT_STUDY_REC ORD.AcuteToxicityInhal ation.MaterialsAndMeth

			ods.AdministrationExposure.Vehicle
Mass median aerodynamic diameter (MMAD)	Specify the particle size distribution in terms of mass median aerodynamic diameter (MMAD). Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMethods.AdministrationExposure.MassMedianAerodynamicDiameter
Geometric standard deviation (GSD)	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable. This field can be used for giving an additional information by selecting 'other:' or selecting a pre-defined reason why no numeric value is provided, e.g. 'not measured/tested' or 'not determinable' and entering free text explanation in the supplementary remarks field.	Range (Decimal)	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMethods.AdministrationExposure.GeometricStandardDeviation
Remark on MMAD/GSD	Enter any remarks related to the mass median aerodynamic diameter.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMethods.AdministrationExposure.RemarksOnMMAD
Details on inhalation exposure	Indicate details of inhalation exposure. Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt (i.e. diagram as pdf/jpeg etc.) from the study report.	Text template	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMethods.AdministrationExposure.DetailsOnInhalationExposure
Analytical verification of test atmosphere concentrations	Indicate whether the test atmosphere concentrations and the particle size were analytically verified. For robust study summaries or as requested by the regulatory programme, include a short description on the method of analysis in the supplementary remarks field. State whether the analytical data indicated that the difference between nominal and actual concentrations was acceptable. If any problems occurred, then they should be reported in more detail. If this could have affected the veracity or conclusions	Closed list with remarks	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMethods.AdministrationExposure.AnalyticalVerificationOfTestAtmosphereConcentrations

	of the study, discuss this in field 'Rationale for reliability incl. deficiencies'.		
Duration of exposure	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with closed list (Decimal)	ENDPOINT_STUDY_REC ORD.AcuteToxicityInhalation.MaterialsAndMethods.AdministrationExposure.DurationOfExposure
Remarks on duration	Enter any remarks related to the recorded value as appropriate.	Text	ENDPOINT_STUDY_REC ORD.AcuteToxicityInhalation.MaterialsAndMethods.AdministrationExposure.RemarksOnDuration
Concentrations	<p>Provide rationale for the selection of the starting concentration.</p> <p>Include the nominal concentrations the test animals were exposed to, e.g. '100, 500, 2500 and 20000 ppmV(gas)' or '0.5, 2.0, 10, 20 mg/L air (dust/mist)'.</p> <p>For micro-organisms (CFU/L air or some other units should be used)</p> <p>As appropriate include notes in parentheses, e.g. '(male)'.</p> <p>For robust study summaries, also provide the analytical concentrations in the results table (see field 'Mortality').</p>	Multi-line text	ENDPOINT_STUDY_REC ORD.AcuteToxicityInhalation.MaterialsAndMethods.AdministrationExposure.Concentrations
No. of animals per sex per dose	<p>Enter number or state numbers for different groups if varying, e.g. '10 (controls), 5 (in test groups)'.</p> <p>For robust study summaries or as requested by the regulatory programme, also include a detailed table on the animal assignment in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) if available and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1').</p> <p>Note: Specific tables may be required.</p>	Multi-line text	ENDPOINT_STUDY_REC ORD.AcuteToxicityInhalation.MaterialsAndMethods.AdministrationExposure.NoOfAnimalsPerSexPerDose
Control animals	Indicate whether concurrent control group was used.	Open list with remarks	ENDPOINT_STUDY_REC ORD.AcuteToxicityInhalation.MaterialsAndMethods.AdministrationExposure.ControlAnimals
Details on study design	Include any further details on the study design, i.e. observation period, frequency of observations/weighing, necropsy of survivors and other examinations	Text template	ENDPOINT_STUDY_REC ORD.AcuteToxicityInhalation.MaterialsAndMethods.AdministrationExposure

	performed. Use freetext template and delete/add elements as appropriate.		ure.DetailsOnStudyDesign
Statistics	Indicate the method of calculating the category. LC50 or other, if applicable.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMethods.AdministrationExposure.Statistics
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block Information on the test atmosphere characteristics can be provided e.g. Nominal concentration and Temperature For microorganisms: Verification that each enumeration method is sufficiently sensitive to serve as a useful quantitative assay for the MPCA tissues, organs, and body fluids should be reported	Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion
Preliminary study	Summarise evidence of toxicity and mortality of any preliminary sighting study (if performed).	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion.Preliminary
Effect levels	Provide the LC50 with confidence limits if available and/or other effect levels reported. Copy this field block for each effect level. If both sexes were tested at each dose level, then the combined effect level should be stated. Where there are significant differences in response between the sexes, include the effect levels for both. If no LC50 or other endpoint available from picklist is reported, but only a concentration level, specify this concentration using 'other' and indicate the effects observed in subfield 'Remarks on result'.		ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion.EffectLevels
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment.	Check box	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion.EffectLevels.KeyResult
Sex	Select from drop-down list.	Closed list	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion.EffectLevels.Sex

Dose descriptor	<p>Select the relevant dose descriptor from drop-down list, i.e. the exposure level that corresponds to a quantified level of effects. If a fixed dose concentration was used, select 'discriminating conc.', i.e the dose causing evident toxicity but not mortality. Where no value could be achieved based on the method and boundaries used, the upper or lower dose level for the relevant dose descriptor can be reported as appropriate with relevant qualifier, e.g. LC50 >10 mg/m³ air or LC50 <10 mg/m³ air.</p> <p>For micro-organisms (CFU/L air or some other units should be used)</p> <p>An additional explanation may be given in field 'Remarks on result', e.g. 'not determinable due to absence of adverse toxic effects'.</p>	Open list with remarks	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion.EffectLevels.Endpoint
Effect level	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion.EffectLevels.EffectLevel
Based on	<p>Indicate whether the concentration is based on the test material (test mat.), active ingredient (act. ingr.) or element. As appropriate the measured / addressed fraction can be specified for either of these entities by selecting the relevant item, e.g. 'element (dissolved fraction)' or 'test mat. (total fraction)'. Further information can be given in the supplementary remarks field, e.g. for specifying the type of fraction if it is not clear per se from the test material specification.</p> <p>Select 'not specified' if the effect concentration type is not known.</p>	Open list with remarks	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion.EffectLevels.BasedOn
95% CL	<p>For robust study summaries or as requested by the regulatory programme, provide the 95% confidence limits if relevant available.</p> <p>Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together</p>	Range (Decimal)	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion.EffectLevels.cl

	with the appropriate qualifier(s) if applicable.		
Exp. duration	Enter numeric value. If exposure cannot be described by a single (integer) number, calculate hours and minutes reported to a decimal number, preferably based on the unit 'h (hour)', e.g. 4.15 h for 4 h, 9 min.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_REC ORD.AcuteToxicityInhalation.ResultsAndDiscussion.EffectLevels.ExposureDuration
Remarks on result	This field can be used for: - giving a qualitative description of results where required and in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_REC ORD.AcuteToxicityInhalation.ResultsAndDiscussion.EffectLevels.RemarksOnResults
Effect levels			
Mortality	Summarise evidence of toxicity and mortality of any preliminary sighting study.	Multi-line text	ENDPOINT_STUDY_REC ORD.AcuteToxicityInhalation.ResultsAndDiscussion.Mortality
Clinical signs	Choose the corresponding clinical sign and briefly describe significant effects found, including the numbers of animals showing signs, time of onset, duration of the major clinical signs and time when most animals recovered. (For non TG 433 inhalation studies, do not dwell on effects that are most likely due to agonal death.) Focus on any important findings, i.e. compound-related or suspected related effects. In case particular effects are considered control-related e.g. because of abnormal control values, this should be specifically addressed. If another clinical sign should be reported, choose option – other: and mention the sign as contained in the comprehensive Clinical sign lexicon provided as Table 2 in the publication by Sewell F. et al. (2015), "A global initiative to refine acute inhalation studies through the use of 'evident toxicity' as an endpoint: Towards adoption of the Fixed Concentration Procedure", Regul Toxicol Pharmacol, Vol. 73, pp. 770-779. Note if there was a reference point (e.g. NOAELs) for clinical findings.	Open list with remarks	ENDPOINT_STUDY_REC ORD.AcuteToxicityInhalation.ResultsAndDiscussion.ClinicalSigns

Body weight	Briefly describe whether animals gained or lost weight. Indicate if body weight loss was greater than 10%.	Text template	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion.BodyWeight
Gross pathology	Briefly describe whether there were any treatment related effects. Do not stress effects due to agonal death.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion.GrossPathology
Other findings	For microorganism studies report results related to: - Clearance estimates, notably in the lungs (numeration of the micro-organism/toxin in the relevant tissues/organs/body fluids at different time points) - Infectivity/persistence findings (numeration of micro-organism and findings in affected organs/tissues, if any	Text template	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion.OtherFindings
Any other information on results incl. tables)	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ApplicantSummaryAndConclusion
Executive summary		Rich text area	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ApplicantSummaryAndConclusion.ExecutiveSummary

5.2.4 Irritation – Endpoint summary

Purpose

Chemical and Microorganism: Indicate whether Skin irritation, Eye irritation is observed.

The document should contain the information needed to be reported according to the list of end points for skin and eye irritation (SANCO/12592/2012-rev. 2, 22 March 2019).

ENDPOINT_SUMMARY.IrritationCorrosion - v.5.0 (Final)			
Name	Instructions	Type	Field Path

Administrative data	Administrative data summary – common block Description of key information: Provide a brief description of irritation studies and effects	Header 1	ENDPOINT_SUMMARY.IrritationCorrosion.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.IrritationCorrosion.KeyValueForChemicalSafetyAssessment
Skin irritation / corrosion		Header 2	ENDPOINT_SUMMARY.IrritationCorrosion.KeyValueForChemicalSafetyAssessment.SkinIrritationCorrosion
Link to relevant study records	Endpoint summary block for relevant study record The following factors, among others, should be taken into account when the robust study summary is selected: quality of the study (e.g. Klimisch score, duration of the study, whether or not the study is GLP.	Header 3	ENDPOINT_SUMMARY.IrritationCorrosion.KeyValueForChemicalSafetyAssessment.SkinIrritationCorrosion.LinkToRelevantStudyRecords
Endpoint conclusion		Header 3	ENDPOINT_SUMMARY.IrritationCorrosion.KeyValueForChemicalSafetyAssessment.SkinIrritationCorrosion.EndpointConclusion
Endpoint conclusion	“Adverse effect observed (irritating)” should be chosen if the substance meets the classification criteria for skin irritation (Category 2). “Adverse effect observed (corrosive)” should be chosen if the substance meets the classification criteria for skin corrosion (Categories 1A, 1B or 1C). “No adverse effect	Closed list	ENDPOINT_SUMMARY.IrritationCorrosion.KeyValueForChemicalSafetyAssessment.SkinIrritationCorrosion.EndpointConclusion.EndpointConclusion

	observed (not irritating)” should be chosen if the substance does not meet the criteria for classification. If “No study available” is chosen, a justification needs to be provided.		
Eye irritation		Header 2	ENDPOINT_SUMMARY.IrritationCorrosion.KeyValueForChemicalSafetyAssessment.EyeRespirationIrritation
Link to relevant study records	Endpoint summary block for relevant study record The following factors, among others, should be taken into account when the robust study summary is selected: quality of the study (e.g. Klimisch score, duration of the study, whether or not the study is GLP.	Header 3	ENDPOINT_SUMMARY.IrritationCorrosion.KeyValueForChemicalSafetyAssessment.EyeRespirationIrritation.LinkToRelevantStudyRecords
Endpoint conclusion		Header 3	ENDPOINT_SUMMARY.IrritationCorrosion.KeyValueForChemicalSafetyAssessment.EyeRespirationIrritation.EndpointConclusion
Endpoint conclusion	“Adverse effect observed (irritating)” should be chosen if the substance meets the classification criteria for eye irritation (Category 2). “Adverse effect observed (irreversible damage)” should be chosen if the substance meets the classification criteria for irreversible effects on the eye (Category 1). “No adverse effect observed (not irritating)” should be chosen if the substance	Closed list	ENDPOINT_SUMMARY.IrritationCorrosion.KeyValueForChemicalSafetyAssessment.EyeRespirationIrritation.EndpointConclusion.EndpointConclusion

	does not meet the criteria for classification. If "No study available" is chosen, a justification needs to be provided.		
Respiratory irritation		Header 2	ENDPOINT_SUMMARY.IrritationCorrosion.KeyValueForChemicalSafetyAssessment.RespiratoryIrritation
Endpoint conclusion		Header 3	ENDPOINT_SUMMARY.IrritationCorrosion.KeyValueForChemicalSafetyAssessment.RespiratoryIrritation.EndpointConclusion
Endpoint conclusion	"Adverse effect observed (irritating)" should be chosen if the substance is found to cause respiratory irritation. "Adverse effect observed (irreversible damage)" should be chosen if the substance does not cause respiratory irritation. "No study available" should be chosen if there is no data to conclude on respiratory irritation.	Closed list	ENDPOINT_SUMMARY.IrritationCorrosion.KeyValueForChemicalSafetyAssessment.RespiratoryIrritation.EndpointConclusion.EndpointConclusion
Additional information	Discussion (Header 1) – common block Provide additional information related to the endpoint, for example: skin/eye irritant or non-irritant	Header 1	ENDPOINT_SUMMARY.IrritationCorrosion.Discussion
Justification for classification or non-classification		Header 1	ENDPOINT_SUMMARY.IrritationCorrosion.JustificationForClassificationOrNonClassification
	The available information should be compared against the classification criteria and the reasons for fulfilling or not fulfilling	Rich text area	ENDPOINT_SUMMARY.IrritationCorrosion.JustificationForClassificationOrNonClassification.Remarks

	the classification criteria should be presented.		
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5.2.4.1 Skin Irritation – Endpoint study record

Purpose

Chemical (Active): Provide information on the potential for skin irritancy of the active substance including, where relevant, the potential reversibility of the effects observed.

Before undertaking in vivo studies for corrosion/irritation of the active substance, a weight-of-evidence analysis shall be performed on the existing relevant data. Where insufficient data are available, they can be developed through application of sequential testing.

The testing strategy shall follow a tiered approach: (1) the assessment of dermal corrosivity using a validated in vitro test method; (2) the assessment of dermal irritation using a validated in vitro test method (such as human reconstituted skin models); (3) an initial in vivo dermal irritation study using one animal, and where no adverse effects are noted; (4) confirmatory testing using one or two additional animals.

Chemical (Product): The skin irritancy of the plant protection product shall be reported based on the tiered approach, unless the applicant can justify an alternative approach under Regulation (EC) No 1272/2008, for which skin irritation properties of all components shall be provided or reliably predicted with a validated method.

Microorganism (Product): The skin irritancy of the plant protection product, including the potential reversibility of the effects observed, must always be determined where the co-formulants are not expected to be skin irritant or the microorganism is shown not to be skin irritant or where it is likely, as indicated in the test guideline, that severe skin effects can be excluded.

ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion - v.8.3 (Final)			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.DataSource
Materials and methods	Material and methods – common block Applicable test guideline: Method B.4 Acute toxicity: dermal irritation/corrosion (Annex to Regulation (EC) No 440/2008). OECD TG 430 / Method B.40 In vitro skin corrosion: transcutaneous electrical resistance test (TER) (Annex to Regulation (EC) No 440/2008).	Header 1	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods

	<p>OECD TG 431 / Method B.40 bis In vitro skin corrosion: human skin model test (Annex to Regulation (EC) No 440/2008).</p> <p>OECD Test Guideline 404: Acute Dermal Irritation/Corrosion</p> <p>OECD Test Guideline 431: In vitro Skin Corrosion: Human Skin Model Test</p> <p>OECD Test Guideline 430: In vitro Skin Corrosion: Transcutaneous Electrical Resistance Test</p> <p>OECD Test Guideline 435: In vitro Membrane Barrier Test Method for Skin Corrosion</p> <p>OECD Test Guideline 439: In vitro Skin Irritation: Reconstructed Human Epidermis Test Method</p> <p>OECD TG 439 / Method B.46 In vitro skin irritation: reconstructed human epidermis model test (Annex III of Regulation (EC) No 761/2009 (7).</p>		
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.TestMaterials
In vitro test system		Header 2	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.InVitroTestSystem
Test system	Select as appropriate. If not available from picklist, select 'other:' and specify. Further information can be given in the supplementary remarks field. Use of other than the test systems recommended by the test guidelines is to be considered as deviation from guideline and should be noted and justified in the field "Test guideline - Deviations".	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.InVitroTestSystem.TestSystem
Source species	Select as appropriate. Indicate the species used as source of the in vitro test system. If not available from picklist, select 'other:' and specify.	Open list	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.InVitroTestSystem.SourceSpecies
Cell type	For in vitro tests, e.g. according to OECD Guidelines 431 and 439, indicate the cell type used to construct the in vitro test system. If not available from picklist, select 'other:' and specify.	Open list	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.InVitroTestSystem.CellType
Cell source	For in vitro tests, e.g. according to OECD Guidelines 431 and 439, indicate the source of the cells used to	Open list	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAnd

	construct the in vitro test system. If not available from picklist, select 'other:' and specify.		Methods.InVitroTestSystem.CellSource
Source strain	For in vitro tests, e.g. according to OECD Guideline 430, indicate the strain used as source of the test system. If not available from picklist, select 'other:' and specify. Use of other than the strain recommended by the test guideline is to be considered as deviation from guideline and should be noted and justified in the respective fields.	Open list	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.InVitroTestSystem.SourceStrain
Details on animal used as source of test system	For in vitro tests, e.g. according to OECD Guideline 430, give details on the animal used as source of the skin discs. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Explanations: - Diet: Describe type of diet (e.g. conventional laboratory diet / caloric restriction) and whether it was provided ad libitum. - Water: Describe type (e.g. drinking water) and whether it was provided ad libitum.	Text template	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.InVitroTestSystem.DetailsOnAnimalUsedAsSourceOfTestSystem
Justification for test system used	Provide a justification for the test system used	Multi-line text	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.InVitroTestSystem.JustificationForTestSystemUsed
Vehicle	Select 'unchanged (no vehicle)' if none was used or select vehicle used if any. Further information can be given in the supplementary remarks field	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.InVitroTestSystem.Vehicle
Details on test system	For in vitro tests, e.g. according to OECD Guidelines 430, 431, 435 or 439, indicate details on the test system used including test conditions. Select freetext template for the respective type of study (i.e. Transcutaneous electrical resistance test (TER) (e.g OECD TG 430) or Artificial membrane barrier test method (e.g OECD TG 435) or Human skin model test (e.g OECD TG 431) or Reconstructed human epidermis test method) (e.g OECD TG 439)) and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Explanations: - SKIN DISC PREPARATION (if Transcutaneous electrical resistance test): Summarise the procedure used to prepare the skin discs and, for each animal skin used as source for skin discs, indicate the electrical resistances obtained with two of the isolated skin discs before testing (should be $\geq 10 \text{ k}\Omega$)	Text template	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.InVitroTestSystem.DetailsOnTestSystem

	<p>- RECONSTRUCTED HUMAN EPIDERMIS (RHE) TISSUE: For human skin model tests, e.g. according to OECD Guidelines 431 and 439, indicate the Reconstructed human Epidermis (RhE) tissue model used, batch number(s) used, the production date, the shipping date, the delivery date, and the date of initiation of testing.</p> <p>- TEMPERATURE USED FOR TEST SYSTEM: Indicate the temperature used during treatment / exposure (e.g. room temperature, 25°C, 37°C, etc). If more than one temperature was used, indicate the different sequential temperatures used and the exact exposure time at each temperature.</p> <p>- REMOVAL OF TEST MATERIAL AND CONTROLS: Indicate the volume (if applicable) and number of washing steps used to remove the test item from the test system after treatment / exposure. Indicate if any observable damage was induced by the washing procedure. Indicate any modification to the validated SOP introduced in the washing procedure.</p> <p>- FUNCTIONAL MODEL CONDITIONS WITH REFERENCE TO HISTORICAL DATA (if human skin model test): Provide details on viability (negative control OD values of each tissue batch in comparison to historical acceptability ranges); barrier function (for each tissue batch, indicate the IC50 obtained with 18 h treatment with SDS or the ET50 obtained with treatment with 1% Triton X-100 in comparison to historical acceptability ranges); morphology (number and type of viable epithelial cell layers (basal layer, stratum spinosum, stratum granulosum) and the approximate number of layers of the stratum corneum, as assessed by histological examination); contamination (indicate if the tissue batches used were free of contamination by bacteria, viruses, mycoplasma or fungi, reproducibility (indicate the reproducibility of the negative and positive controls over time)</p> <p>- PREDICTION MODEL / DECISION CRITERIA: Describe and justify the prediction model / decision criteria used to derive the corrosion/irritation classification</p>		
Control samples	<p>Indicate whether and what type of concurrent control groups were used or select 'not required' if applicable. In the supplementary remarks field, specify the name of the control substance and other identifiers (e.g. CAS number, the physical state, lot/batch No. including expiration date, purity and any other relevant information.</p> <p>Multiple selection is possible if more than one type of control was used, e.g. a concurrent positive control, a concurrent negative control, non-specific colour controls and non-specific MTT reduction controls.</p>	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.InVitroTestSystem.ControlSamples

Amount/ concentration applied	Give the amount(s) of substance / controls applied (volume or weight with unit) and the concentration of the substance, controls and vehicle (if used) in the test solution. Specify if different doses were applied. Use freetext template and delete/add elements as appropriate.	Text template	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.InVitoTestSystem.AmountConcentrationApplied
Duration of treatment / exposure	Indicate length of time test material was in contact with test system, e.g. '3 min. ' or '4 hours'. Also indicate if different exposure time periods were applied in different tests of this study.	Multi -line text	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.InVitoTestSystem.DurationOfTreatmentExposure
Duration of post- treatment incubation (if applicable)	Indicate length of post-treatment incubation period as applicable.	Multi -line text	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.InVitoTestSystem.DurationOfPostTreatmentIncubationIfApplicable
Number of replicates	Indicate the number of replicate tissues/skin discs used in each treatment / exposure and control groups.	Multi -line text	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.InVitoTestSystem.NumberOfReplicates
Test animals	Test animals (OHT: Repeated dose toxicity) Species: For in vitro tests, indicate the species used as source of the test system. If not available from picklist, select 'other' and specify. Use of other than the species recommended by the test guideline is to be considered as deviation from guideline and should be noted and justified in the respective fields NOTE: Human data should be reported in an appropriate subsection of section 'Exposure related observations', particularly subsection 'Direct observations: clinical cases, poisoning incidents and other'. It can be useful to document, in section 'Skin irritation / corrosion', that human data are provided by creating a record and referring to the human data in field 'Cross-reference'. This could be relevant if lack of animal experiments is defended by the availability of data on experience with human exposure.	Header 2	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.TestAnimals
Test system		Header 2	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.TestSystem
Type of coverage	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.TestSystem.TypeOfCoverage

Preparation of test site	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.TestSystem.PreparationOfTestSite
Vehicle	Select 'unchanged (no vehicle)' if none was used or select vehicle used if any. Further information can be given in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.TestSystem.Vehicle
Controls	Indicate whether and what type of concurrent control groups were used or select 'not required' if applicable. In the supplementary remarks field, specify the name of the control substance and other identifiers (e.g. CAS number, the physical state, lot/batch No. including expiration date, purity and any other relevant information). Multiple selection is possible if more than one type of control was used, e.g. a concurrent positive control and a concurrent negative control.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.TestSystem.Controls
Amount / concentration applied	Give the amount(s) of substance applied (volume or weight with unit) and the concentration of the substance and vehicle (if used) in the test solution. Specify if different doses were applied. Use freetext template and delete/add elements as appropriate.	Text template	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.TestSystem.AmountConcentrationApplied
Duration of treatment / exposure	Indicate length of time test material was in contact with test animal, including unit, e.g. '4 hours'. Also indicate if different exposure time periods were applied in different tests of this study.	Multi-line text	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.TestSystem.DurationOfTreatmentExposure
Observation period	Indicate length of observation period.	Multi-line text	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.TestSystem.ObservationPeriod
Number of animals	Indicate number of animals used.	Multi-line text	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.TestSystem.NumberOfAnimals
Details on study design	For in vivo tests, e.g. according to OECD Guideline 404, give details on study design. Describe the method of calculation of maximum average score given in the results table used (if applicable). Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.TestSystem.DetailsOnStudyDesign
Any other	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.SkinIrritationC

information on materials and methods incl. tables			orrosion.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion
In vitro		Header 2	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVitro
Results	<p>Indicate the overall irritation / corrosion results for the test substance in terms of tissue viability, transcutaneous electrical resistance, penetration time or other. Copy this block of fields as appropriate.</p> <p>In case of a robust study summary or as requested by the regulatory programme, also provide the raw data of the results (including means and standard deviations) for the test material and all controls used in the field "Irritant/corrosive response data" and/or upload a table in the field "Any other information on results incl. tables".</p> <p>(Q)SAR results can be reported under the appropriate heading, i.e. 'In vitro' or 'In vivo', depending on the applicability domain of the model behind and based on what kind of data the model was mainly validated. At least the field 'Remarks on result' should be completed by entering the adequate qualitative description of the prediction.</p> <p>Note that a separate field "Interpretation of results" is provided in the section "APPLICANT'S SUMMARY AND CONCLUSION" for indicating a classification based on the study results.</p>		ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVitro.Results
Irritation / corrosion parameter	Select type of parameter from picklist, if applicable. Further details can be given in the supplementary remarks field, e.g. "based on optical density measurement".	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVitro.Results.IrritationCorrosionParameter
Run / experiment	<p>Indicate the run / experiment the measurement relates to, if more than one run / experiment was performed and the length of time the test material was in contact with the test system, if different exposure time periods were applied in different test runs of this study.</p> <p>Examples: Run 1 (duration of exposure: 2 hours); Run 1, replicate 1 (duration of exposure: 2 hours), Mean of three runs with two replicates each.</p>	Text	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVitro.Results.RunExperiment

Value	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVitro.Results.Value
Vehicle controls validity	Indicate whether test(s) with vehicle control(s) (i.e. without test substance, with/without solvent) is/are valid. Relevant remarks can be given in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVitro.Results.VehicleControlsValid
Negative controls validity	Indicate whether test with negative control(s) is valid, i.e. substance(s) with known lack of irritation/corrosion in the test conducted. Relevant remarks can be given in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVitro.Results.NegativeControlsValid
Positive controls validity	Indicate whether test with positive control(s) is valid, i.e. substance(s) with known irritation/corrosion in the test conducted. Relevant remarks can be given in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVitro.Results.PositiveControlsValid
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVitro.Results.RemarksOnResults
Results			
Other effects / acceptance of results	Use freetext template and delete/add elements as appropriate. Provide the following information as appropriate: - OTHER EFFECTS: Describe any other observed effects (e.g. visible damage on test system, no visible damage on test system, direct-MTT reduction, colour interference with MTT, etc). Discuss the applicability of the test method to test colorants and/or direct MTT-reducers in reference to the %NSC and/or %NSMTT values reported in the block of fields above. - DEMONSTRATION OF TECHNICAL PROFICIENCY: If required according to the test guideline, indicate if and when technical proficiency has been demonstrated using the proficiency chemicals listed in the guideline used. Upload table(s) with data for each individual proficiency chemical in the rich text field 'Any other information on results incl. tables'. - ACCEPTANCE OF RESULTS: Demonstrate that the assay acceptance criteria (for negative control, positive control, and variability	Text template	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVitro.OtherEffectsAcceptanceOfResults

	<p>between replicate measurements) were met in reference to historical ranges. Indicate the range of historical values if different from the ones indicated in the relevant test guideline.</p> <p>Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.</p>		
In vivo		Header 2	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVivo
Results	<p>For in vivo test results, provide individual time point scores per animal and mean scores. If reported or required by the relevant legislation, indicate overall irritation / corrosion results in terms of an Overall irritation score, Primary dermal irritation index or other (specify). Copy this block of fields as appropriate. (Q)SAR results can be reported under the appropriate heading, i.e. 'In vitro' or 'In vivo', depending on the applicability domain of the model behind and based on what kind of data the model was mainly validated. At least the field 'Remarks on result' should be completed by entering the adequate qualitative description of the prediction.</p> <p>In case of a robust study summary or as requested by the regulatory programme, also provide the raw data of the results (including means and standard deviations) for the test material and all controls used in the field "Irritant/corrosive response data" and/or upload a table in the field "Any other information on results incl. tables".</p> <p>Note that a separate field "Interpretation of results" is provided in the section "APPLICANT'S SUMMARY AND CONCLUSION" for indicating a classification based on the study results.</p>		ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVivo.Results
Irritation parameter	Select type of parameter from picklist. Further details can be given in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVivo.Results.Parameter
Basis	Indicate if the score is the mean of all scoring results for the parameter selected on the preceding subfield or based on individual animals, e.g. animal #1. Option 'animal:' allows to enter text/numbers in the related supplementary remarks field, e.g. 'animal: #1, 2 and 3').	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVivo.Results.Basis
Time point	Indicate the time point(s) the score relates to by selecting the appropriate value from the picklist, e.g. '24' or '24/48/72 h' (if the same score applies), and in the following field, the unit.	Open list	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVivo.Results.TimePoint
Score	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the	Range	ENDPOINT_STUDY_RECORD.SkinIrritationC

	second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	(Decimal)	corrosion.ResultsAndDiscussion.InVivo.Results.Score
Max. score	Provide the numeric value of the total possible score depending on the scale used.	Decimal	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVivo.Results.Scale
Reversibility	Indicate whether the irritation was reversible or not. As appropriate use supplementary remarks field linked to the picklist item selected for indicating average time for (non-)reversibility.	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVivo.Results.Reversibility
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:' An explanation should be provided when there was a need to humanely sacrifice animals in pain or showing signs of severe and enduring distress.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVivo.Results.RemarksOnResults
Results			
Irritant / corrosive response data	For robust study summaries or as requested by the regulatory programme, tabulate the raw data for each individual animal at each observation time up to removal of each animal from the test (unless these data are given in above block of fields 'Irritation / corrosion results'). Upload predefined table(s) if any in the rich text field 'Any other information on results incl. tables' or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). In field "Details on study design (in vivo)", describe the method of calculation used. Note: Specific tables may be required.	Text area	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVivo.IrritationCorrosionResponseData
Other effects	Use freetext template and delete/add elements as appropriate. For in vivo tests, e.g. according to OECD Guideline 404, describe any other adverse local (e.g. defatting of skin) and systemic effects in addition to dermal irritation or corrosion.	Text template	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVivo.OtherEffects
Any other information on results	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables

incl. tables			
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ApplicantSummaryAndConclusion

5.2.4.2 Eye Irritation – Endpoint study record

Purpose

Chemical: The eye irritancy of the active substance shall always be tested, except where it is likely that severe effects on the eyes may be produced based on criteria listed in the test methods. The results of the study shall provide the potential of eye irritancy of the active substance including, where relevant, the potential reversibility of the effects observed. Before undertaking in vivo studies for eye corrosion/irritation of the active substance, a weight-of-evidence analysis shall be performed on the existing relevant data.

Where available data are considered insufficient, further data may be developed through application of sequential testing. The testing strategy shall follow a tiered approach:

- (1) the use of an in vitro dermal irritation/corrosion test to predict eye irritation/corrosion;
- (2) the performance of a validated or accepted in vitro eye irritation study to identify severe eye irritants/corrosives (such as Bovine Corneal Opacity and Permeability (BCOP) assay, Isolated Chicken Eye (ICE) assay, Isolated Rabbit Eye (IRE) assay, Hen's Egg Test - Chorio-Allantoic Membrane assay (HET-CAM)), and where negative results are obtained, the assessment of eye irritation using an in vitro test method for identification of non irritants or irritants, and where not available;
- (3) an initial in vivo eye irritation study using one animal, and where no adverse effects are noted;
- (4) confirmatory testing using one or two additional animals.

Microorganism (product): The test will provide the potential for eye irritation of the plant protection product, including the potential reversibility of the effects observed. The eye irritancy of the plant protection product must be determined, where the co-formulants are suspected to be eye irritant, except where the microorganism is eye irritant or where it is likely, as indicated in the test guideline, that severe effects on the eyes may be produced.

ENDPOINT_STUDY_RECORD.EyeIrritation - v.8.3 (Final)			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.EyeIrritation.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.EyeIrritation.DataSource
Materials and methods	Material and methods – common block Applicable test guideline:	Header 1	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMethods

	<p>Method B.5 Acute toxicity: eye irritation/corrosion OECD 405</p> <p>OECD 437</p> <p>OECD 438</p> <p>Method B.47 Bovine corneal opacity and permeability test method for identifying ocular corrosives and severe irritants (</p> <p>Method B.48 Isolated chicken eye test method for identifying ocular corrosives and severe irritants</p>		
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMethods.TestMaterials
Test animals / tissue source		Header 2	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMethods.TestAnimals
Species	<p>Select as appropriate. For in vitro / ex vivo tests, indicate the species used as source of the test system. If not available from picklist, select 'other' and specify.</p> <p>Use of other than the species recommended by the test guideline is to be considered as deviation from guideline and should be noted and justified in the respective fields</p> <p>NOTE: Human data should be reported in an appropriate subsection of section 'Exposure related observations', particularly subsection 'Direct observations: clinical cases, poisoning incidents and other'.</p> <p>It can be useful to document, in section 'Irritation / corrosion', that human data are provided by creating a record and referring to the human data in block 'Cross-reference'. This could be relevant if lack of animal experiments is defended by the availability of data on experience with human exposure.</p>	Open list	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMethods.TestAnimals.Species
Strain	Select strain as appropriate. If not available from picklist, select 'other' and specify.	Open list with remarks	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMethods.TestAnimals.Strain
Details on test animals or tissues and environmental conditions	<p>Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Explanations:</p> <ul style="list-style-type: none"> - Diet: Describe type of diet (e.g. conventional laboratory diet / caloric restriction) and whether it 	Text template	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMethods.TestAnimals.OrganismDetails

	<p>was provided ad libitum.</p> <ul style="list-style-type: none"> - Water: Describe type (e.g. drinking water) and whether it was provided ad libitum. - Food quality and water quality: provide analytical information on the nutrient and dietary contaminant levels. Similarly provide analytical information on the drinking water used in the study. - IN-LIFE DATES: If required, specify the in-life dates (i.e. the phase of a study following treatment in which the test system is alive/growing). 		
Test system		Header 2	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMethods.TestSystem
Vehicle	Select 'unchanged (no vehicle)' if none was used or select vehicle used if any. Further information can be given in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMethods.TestSystem.Vehicle
Controls	<p>Indicate whether and what type of concurrent control groups were used or select 'not required' if applicable.</p> <p>In the supplementary remarks field, specify the name of the control substance and other identifiers (e.g. CAS number, the physical state, lot/batch No. including expiration date, purity and any other relevant information).</p> <p>Multiple selection is possible if more than one type of control was used, e.g. a concurrent positive control and a concurrent negative control.</p>	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMethods.TestSystem.Controls
Amount / concentration applied	Give the amount(s) of substance / controls applied (volume or weight with unit) and the concentration of the substance, controls and vehicle (if used) in the test solution. Specify if different doses were applied. Use freetext template and delete/add elements as appropriate.	Text template	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMethods.TestSystem.AmountConcentrationApplied
Duration of treatment / exposure	Indicate length of time test material was in contact with animal/cell/tissue including unit, e.g. '4 hours'. Also indicate if different exposure time periods were applied in different tests of this study.	Multi-line text	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMethods.TestSystem.DurationOfTreatmentExposure
Observation period (in vivo)	Indicate length of observation period.	Multi-line text	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMethods.TestSystem.ObservationPeriod
Duration of post- treatment incubation (in vitro)	Indicate length of post-treatment incubation period as appropriate.	Multi-line text	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMethods.TestSystem.Dur

			ationOfPostTreatmentIncubationInVitro
Number of animals or in vitro replicates	Indicate number of animals used (if in vivo) or, in the case of in vitro tests, the number of replicate tissues used in each treatment / exposure and control group.	Multi-line text	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMethods.TestSystem.NumberOfAnimals
Details on study design	Select freetext template for the respective type of study (i.e. In vivo test method, In vitro test method (BCOP) or In vitro test method (ICE) and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMethods.TestSystem.DetailsOnStudyDesign
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion
In vitro		Header 2	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVitro
Results	<p>Indicate the overall irritation / corrosion results for the test substance in terms of the relevant endpoints examined (e.g. cornea opacity score) and the overall irritation / corrosion results (specify as appropriate). Copy this block of fields for reporting several scores, e.g. means of individual replicates.</p> <p>In case of a robust study summary or as requested by the regulatory programme, also provide the raw data of the results (including means and standard deviations) for the test material and all controls used in the field "Irritant/corrosive response data" and/or upload a table in the field "Any other information on results incl. tables".</p> <p>(Q)SAR results can be reported under the appropriate heading, i.e. 'In vitro' or 'in vivo', depending on the applicability domain of the model behind and based on what kind of data the model was mainly validated. At least the field 'Remarks on result' should be completed by entering the adequate qualitative description of the prediction. Note that a separate field "Interpretation of results" is provided in the section "APPLICANT'S SUMMARY AND CONCLUSION" for indicating a classification based on the study results.</p>		ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVitro.ResultsOfExVivoInVitroStudy

Irritation parameter	Select type of parameter from picklist, if applicable. Further details can be given in the supplementary remarks field. For instance, in the case of morphological effects, specify if and to what severity pitting of corneal epithelial cells, loosening of epithelium, roughening of the corneal surface and sticking of the test substance to the cornea occurred.	Open list with remarks	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVitro.ResultsOfExVivoInVitroStudy.IrritationParameter
Run / experiment	Indicate the run / experiment the measurement relates to, if more than one run / experiment was performed and the length of time the test material was in contact with the test system, if different exposure time periods were applied in different test runs of this study. Examples: Run 1 (duration of exposure: 10 min.); Run 1, replicate 1 (duration of exposure: 10 min.), Mean of three runs with two replicates each.	Text	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVitro.ResultsOfExVivoInVitroStudy.RunExperiment
Value	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVitro.ResultsOfExVivoInVitroStudy.Value
Vehicle controls validity	Indicate whether test(s) with vehicle control(s) (i.e. vehicle only without test substance) is/are valid. Relevant remarks can be given in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVitro.ResultsOfExVivoInVitroStudy.VehicleControlsValid
Negative controls validity	Indicate whether test with negative control(s) demonstrated lack of irritation/corrosion of the known non-irritant/non-corrosive substance, and/or that the negative control falls within the acceptance criteria range as described in the TG. Relevant remarks can be given in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVitro.ResultsOfExVivoInVitroStudy.NegativeControlsValid
Positive controls validity	Indicate whether test with positive control(s) demonstrated irritation/corrosive effects of the known irritant/corrosive substance and/or that positive control results fall within the acceptance criteria as described in the TG. Relevant remarks can be given in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVitro.ResultsOfExVivoInVitroStudy.PositiveControlsValid
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVitro.ResultsOfExVivoInVitroStudy.RemarksOnResult
Results			

Other effects / acceptance of results	<p>Select freetext template and delete/add elements as appropriate. Provide the following information as appropriate:</p> <ul style="list-style-type: none"> - OTHER EFFECTS: Describe any other observed effects (e.g. visible damage on test system) - DEMONSTRATION OF TECHNICAL PROFICIENCY: If required according to the test guideline, indicate if and when technical proficiency has been demonstrated using the proficiency chemicals listed in the guideline used. Upload table(s) with data for each individual proficiency chemical in the rich text field 'Any other information on results incl. tables'. - ACCEPTANCE OF RESULTS: Demonstrate that the assay acceptance criteria (for negative and positive control) were met in reference to historical ranges. Indicate the range of historical values if different from the ones indicated in the relevant test guideline. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. 	Text template	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVitro.OtherEffectsAcceptanceOfResults
In vivo		Header 2	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVivo
Results	<p>Indicate the scores of the relevant endpoints examined (e.g. cornea opacity score) and the overall irritation / corrosion results (specify as appropriate). In subfield "Basis of irritation parameter" indicate if the score is an average value (i.e. mean), or for a give animal, or other. Copy this block of fields for reporting several scores, e.g. means or for individual animals.</p> <p>In case of a robust study summary or as requested by the regulatory programme, also provide the raw data of the results (including means and standard deviations) for the test material and all controls used in the field "Irritant/corrosive response data" and/or upload a table in the field "Any other information on results incl. tables".</p> <p>(Q)SAR results can be reported under the appropriate heading, i.e. 'In vitro' or 'in vivo', depending on the applicability domain of the model behind and based on what kind of data the model was mainly validated. At least the field 'Remarks on result' should be completed by entering the adequate qualitative description of the prediction. Note that a separate field "Interpretation of results" is provided in the section "APPLICANT'S SUMMARY AND CONCLUSION" for indicating a classification based on the study results.</p>		ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVivo.IrritationCorrosionResults

Irritation parameter	Select type of parameter from picklist. Further details can be given in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVivo.IrritationCorrosionResults.Parameter
Basis	Indicate if the score is the mean of all scoring results for the parameter selected on the preceding subfield or based on individual animals, e.g. animal #1. Option 'animal:' allows to enter text/numbers in the related supplementary remarks field, e.g. 'animal: #1, 2 and 3').	Open list with remarks	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVivo.IrritationCorrosionResults.Basis
Time point	Indicate the time point(s) the score relates to by selecting the appropriate value from the picklist, e.g. '24' or '24/48/72 h' (if the same score applies), and in the following field, the unit.	Open list	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVivo.IrritationCorrosionResults.TimePoint
Score	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVivo.IrritationCorrosionResults.Score
Max. score	Provide the numeric value of the total possible score depending on the scale used.	Decimal	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVivo.IrritationCorrosionResults.Scale
Reversibility	Indicate whether the irritation was reversible or not. As appropriate use supplementary remarks field linked to the picklist item selected for indicating average time for (non-)reversibility.	Open list with remarks	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVivo.IrritationCorrosionResults.Reversibility
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:'.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVivo.IrritationCorrosionResults.RemarksOnResults
Results			
Irritant / corrosive response data	For robust study summaries or as requested by the regulatory programme, tabulate the raw data for each individual animal at each observation time (unless these data are given in above block of fields 'Irritation / corrosion results'). Upload predefined or other appropriate table(s) if available and tailor	Text area	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVivo.IrritationCorrosionResponseData

	it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Describe the method of calculation of maximum average score given in the results table. Note: Specific tables may be required.		
Other effects	Select freetext template and delete/add elements as appropriate. Describe any other relevant results including lesions and clinical observations, ophthalmoscopic and histopathological findings, effects of rinsing or washing if applicable.	Text template	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVivo.OtherEffects
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.EyeIrritation.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.EyeIrritation.ApplicantSummaryAndConclusion

5.2.5 Skin sensitisation – Endpoint Summary

Purpose:

Chemical (Active) - Microorganism (Product): Provide summary information of the most relevant study(ies) from which the key value for active substance assessment is extrapolated. Provide only the most relevant details e.g. Sensitising (state method, e.g. LLNA) related to the potential of the chemical active or microorganism product to provoke sensitisation.

Microorganism (Active): The available methods for testing dermal sensitisation are not suitable for testing microorganisms, and there are no validated test methods for sensitisation by inhalation.

As a consequence, all microorganisms will be labelled as potential sensitisers, unless the applicant wants to demonstrate the non-sensitising potential by submitting data. Therefore, this data requirement should be regarded as optional, on a provisional basis.

The document should contain the information needed to be reported according to the list of end points for skin sensitisation (SANCO/12592/2012-rev. 2, 22 March 2019).

ENDPOINT_SUMMARY.Sensitisation - v.4.0 (Final)			
Name	Instructions	Type	Field Path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.Sensitisation.AdministrativeDataSummary

	Description of key information: Provide a brief description of the study and the potential of the micro-organism to provoke sensitisation reactions.		
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.Sensitisation.KeyValueForChemicalSafetyAssessment
Skin sensitisation		Header 2	ENDPOINT_SUMMARY.Sensitisation.KeyValueForChemicalSafetyAssessment.SkinSensitisation
Link to relevant study records	Endpoint summary block for relevant study record The following factors, among others, should be taken into account when the robust study summary is selected: quality of the study (e.g. Klimisch score, duration of the study, whether or not the study is GLP.	Header 3	ENDPOINT_SUMMARY.Sensitisation.KeyValueForChemicalSafetyAssessment.SkinSensitisation.LinkToRelevantStudyRecords
Endpoint conclusion		Header 3	ENDPOINT_SUMMARY.Sensitisation.KeyValueForChemicalSafetyAssessment.SkinSensitisation.EndpointConclusion
Endpoint conclusion	"Adverse effect observed (sensitising)" should be chosen if the micro-organism shows effects of skin sensitisation . "No adverse effect observed (not sensitising)" should be chosen if the substance does not show effects of skin sensitisation. If "No study available" is chosen, a justification needs to be provided.	Closed list	ENDPOINT_SUMMARY.Sensitisation.KeyValueForChemicalSafetyAssessment.SkinSensitisation.EndpointConclusion.EndpointConclusion
Additional information	Provide additional information related to the endpoint, for example:	Rich text area	ENDPOINT_SUMMARY.Sensitisation.KeyValueForChemicalSafetyAssessment.SkinSensitisation.

	<ul style="list-style-type: none"> - relevance of the results for the risk assessment - the rationale for the choice of the key study(ies) and the choice for the key value that characterises the endpoint - the rationale for any user-derived values for the sake of transparency -the possible reasons for differentiating results when several studies were identified to be relevant for the assessment. <p>If there is no additional information to be reported this field may be left empty.</p>		EndpointConclusion.AdditionalInformation
Respiratory sensitisation		Header 2	ENDPOINT_SUMMARY.Sensitisation.KeyValueForChemicalSafetyAssessment.RespiratorySensitisation
Link to relevant study records	Endpoint summary block for relevant study record The following factors, among others, should be taken into account when the robust study summary is selected: quality of the study (e.g. Klimisch score, duration of the study, whether or not the study is GLP.	Header 3	ENDPOINT_SUMMARY.Sensitisation.KeyValueForChemicalSafetyAssessment.RespiratorySensitisation.LinkToRelevantStudyRecords
Endpoint conclusion		Header 3	ENDPOINT_SUMMARY.Sensitisation.KeyValueForChemicalSafetyAssessment.RespiratorySensitisation.EndpointConclusion
Endpoint conclusion	"Adverse effect observed (sensitising)" should be chosen if the micro-organism shows effects of respiratory	Closed list	ENDPOINT_SUMMARY.Sensitisation.KeyValueForChemicalSafetyAssessment.RespiratorySensitisation

	sensitisation. "No adverse effect observed (not sensitising)" should be chosen if the substance does not show effects of respiratory sensitisation. If "No study available" is chosen, a justification needs to be provided.		sation.EndpointConclusion.EndpointConclusion
Additional information	Provide additional information related to the endpoint, for example: sensitising (state source of evidence, e.g. type of study, clinical data, etc)	Rich text area	ENDPOINT_SUMMARY.Sensitisation.KeyValueForChemicalSafetyAssessment.RespiratorySensitisation.EndpointConclusion.AdditionalInformation
Justification for classification or non-classification		Header 1	ENDPOINT_SUMMARY.Sensitisation.JustificationForClassificationOrNonClassification
	The available information should be compared against the classification criteria and the reasons for fulfilling or not fulfilling the classification criteria should be presented.	Rich text area	ENDPOINT_SUMMARY.Sensitisation.JustificationForClassificationOrNonClassification.Remarks

5.2.5 Skin sensitisation – Endpoint Study record

Purpose:

Chemical (Active): Provide sufficient information to assess the potential of the active substance to provoke skin sensitisation reactions. The study shall always be carried out, except where the active substance is a known sensitiser. The local lymph node assay (LLNA) shall be used, including where appropriate the reduced variant of the assay. In case the LLNA cannot be conducted, a justification shall be provided and the Guinea Pig Maximisation Test shall be performed. Where a guinea pig assay (Maximisation or Buehler), meeting OECD guidelines and providing a clear result, is available, further testing shall not be carried out for animal welfare reasons. Since an active substance identified as a skin sensitiser can potentially induce hypersensitivity reaction, potential respiratory sensitisation should be taken into account when appropriate tests are available or when there are indications of respiratory sensitisation effects. Note: the sections of this document to be completed are dependent on the endpoint selected

Chemical (Product): The skin sensitisation test shall be carried out unless the active substances or co-formulants are known to have sensitising properties or the applicant can justify an alternative approach under Regulation (EC) No 1272/2008. In the latter case, skin sensitisation properties of all components shall be provided or reliably predicted with a validated method. Consideration shall be given to the possible effects of components on the sensitising potential of the total mixture.

Microorganisms (Active): Provide sufficient information to assess the potential of the microorganism to provoke sensitisation reactions by inhalation as well as with dermal exposure. A maximised test has to be performed.

Microorganism (Product): The test will provide sufficient information to assess the potential of the plant protection product to provoke skin sensitisation reactions. The test must be carried out where the co-formulants are suspected to have skin sensitising properties, except where the microorganism(s) or the co-formulants are known to have skin sensitising properties.

ENDPOINT_STUDY_RECORD.SkinSensitisation - v.10.5 (Final)			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.SkinSensitisation.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.SkinSensitisation.DataSource
Materials and methods	Material and methods – common block Applicable test guideline: OECD 406 Method B.42 Skin sensitisation: Local lymph node assay (Annex to Regulation (EC) No 440/2008). Method B.6 Skin sensitisation (Annex to Regulation (EC) No 440/2008). OECD 429 OECD 442A + 442B.	Header 1	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods
Type of study	Select type of study as appropriate. If another than the LLNA test system was used, a justification may be required in the following field.	Open list	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.TypeOfStudy
Justification for non-LLNA method	Provide a justification for the use of another than the LLNA test system (if in vivo), if the relevant legislation so requires. For instance it could be argued that the LLNA method was not available yet by the time the study was conducted or that the LLNA test is not suitable for that substance or that an appropriate guinea pig maximisation test is available which would not justify conducting an additional LLNA due to animal welfare. Refer to the relevant legislation-specific guidance document.	Multi-line text	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.JustificationForNonLLNA Method
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.SkinSensitisation.

			MaterialsAndMethods.TestMaterials
In vitro test system		Header 2	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVitoTestSystem
Details of test system	If standard cell lines not used, please select 'other:' and specify in the freetext field exact details of the cell line used.	Open list	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVitoTestSystem.DetailsTestSystem
Details on the study design	<p>PREPARATION OF TEST SOLUTIONS: describe how test solutions were prepared to obtain suitable concentration including specific substance details on the materials used (EC/CAS, purity, treatment of the material) etc. If stable dispersion is not obtained and the test solution is still used, add an explanation why this is not considered to affect the validity of the study.</p> <p>DOSE RANGE FINDING ASSAY: describe the highest concentration used for the dose range finding assay and how appropriate doses were selected taking solubility and cytotoxicity into account. Specify which solvents were used and finally selected and how cytotoxicity assessment was performed.</p> <p>APPLICATION OF THE TEST CHEMICAL AND CONTROL SUBSTANCES: describe the application of test chemical and control substance exposure conditions in detail.</p> <p>SEEDING AND INCUBATION: describe the seeding and incubation conditions and whether precipitation was noted.</p> <p>MEASUREMENT OF CELL SURFACE EXPRESSION/LUCIFERASE ACTIVITY: describe the steps taken to ensure the suitability of the cell surface marker expression/luciferase activity measurements for the test chemical, including solvents used</p> <p>LUCIFERASE ACTIVITY MEASUREMENTS: describe the steps taken to ensure the suitability of the luciferase activity measurements for the test chemical, including solvents used</p> <p>DATA EVALUATION: report the cytotoxicity measurements taken and the prediction model to be used.</p>	Text template	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVitoTestSystem.DetailsOnStudyDesign

Vehicle / solvent control	Select the vehicle/solvent as appropriate. If not available from the picklist, select 'other:' and provide detailed justification for not using a standard vehicle/solvent.	Open list	ENDPOINT_STUDY_RE CORD.SkinSensitisation. MaterialsAndMethods.In VitroTestSystem.Vehicle SolventControl
Negative control	Select the negative control as appropriate. If no negative control required (Keratinosens), select 'not applicable'. If not available from the picklist, select 'other:' and provide detailed justification for not using a standard vehicle/solvent.	Open list	ENDPOINT_STUDY_RE CORD.SkinSensitisation. MaterialsAndMethods.In VitroTestSystem.Negati veControl
Positive control	Select the positive control as appropriate. If not available from the picklist, select 'other:' and provide detailed justification for not using a standard positive control.	Open list	ENDPOINT_STUDY_RE CORD.SkinSensitisation. MaterialsAndMethods.In VitroTestSystem.Positiv eControl
In chemico test system		Header 2	ENDPOINT_STUDY_RE CORD.SkinSensitisation. MaterialsAndMethods.In ChemicoTestSystem
Details of test system	Indicate the purity of the peptides used in the 'remarks' field. If standard peptides are not used, please select 'other:' and specify in the freetext field the exact details of the peptide used and supporting information on the scientific validity of their use.	Multi select open list with remarks	ENDPOINT_STUDY_RE CORD.SkinSensitisation. MaterialsAndMethods.In ChemicoTestSystem.De tailsTestSystem
Details on the study design	PREPARATION OF TEST SOLUTIONS: describe how test solutions were prepared to obtain suitable concentration including specific substance details on the materials used (EC/CAS, purity, treatment of the material) etc. INCUBATION: describe the incubation conditions and whether precipitation was noted. PREPARATION OF THE HPLC: describe the steps taken to ensure the suitability of the HPLC for the test chemical, including solvents used DATA EVALUATION: report the UV wavelength used for peptide/derivative detection.	Text template	ENDPOINT_STUDY_RE CORD.SkinSensitisation. MaterialsAndMethods.In ChemicoTestSystem.De tailsOnStudyDesign
Vehicle / solvent	Select the vehicle/solvent as appropriate. If not available from the picklist, select 'other:' and provide detailed justification for not using a standard vehicle/solvent.	Open list	ENDPOINT_STUDY_RE CORD.SkinSensitisation. MaterialsAndMethods.In ChemicoTestSystem.Ve hicleSolvent
Positive control	Select the positive control as appropriate. If not available from the picklist, select 'other:' and provide detailed justification for not using a standard positive control.	Open list	ENDPOINT_STUDY_RE CORD.SkinSensitisation. MaterialsAndMethods.In

			ChemicoTestSystem.PositiveControl
In vivo test system		Header 2	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem
Test animals		Header 3	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.TestAnimals
Species	Select as appropriate. For in vitro tests, indicate the species used as source of the test system. If not available from picklist, select 'other' and specify. NOTE: Human data should be reported in an appropriate subsection of section 'Exposure related observations', particularly subsection 'Sensitisation data'. It can be useful to document, in section 'Skin sensitisation', that human data are provided by creating a record and referring to the human data in field 'Cross-reference'. This could be relevant if lack of animal experiments is defended by the availability of data on experience with human exposure.	Open list	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.TestAnimals.Species
Strain	Select strain as appropriate. If not available from picklist, select 'other' and specify. In the supplementary remarks field, also specify the substrain if not specified by picklist item. Provide rationale for choice of strain and substrain if deviating from the ones recommended by the test guideline used.	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.TestAnimals.Strain
Sex	Select as appropriate. If females were used, indicate in field "Details on test animals and environmental conditions" whether nulliparous and non-pregnant.	Closed list	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.TestAnimals.Sex
Details on test animals and environmental conditions	Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Explanations: - Diet: Describe type of diet (e.g. conventional laboratory diet / caloric restriction) and whether it was provided ad libitum. - Water: Describe type (e.g. drinking water) and whether it was provided ad libitum.	Text template	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.TestAnimals.DetailsOnTestAnimalsAndEnvironmentalConditions

	- IN-LIFE DATES: If required, specify the in-life dates (i.e. the phase of a study following treatment in which the test system is alive/growing).		
Study design: in vivo (non-LLNA)		Header 3	ENDPOINT_STUDY_RE CORD.SkinSensitisation. MaterialsAndMethods.In VivoTestSystem.StudyD esignInVivoNonLLNA
Induction	Record the vehicle, test substance concentrations used for induction exposure(s), the total amount of substance applied and the day(s) and duration of the induction. Copy this block of fields as appropriate.		ENDPOINT_STUDY_RE CORD.SkinSensitisation. MaterialsAndMethods.In VivoTestSystem.StudyD esignInVivoNonLLNA.In duction
Route	Indicate the route of induction exposure.	Open list	ENDPOINT_STUDY_RE CORD.SkinSensitisation. MaterialsAndMethods.In VivoTestSystem.StudyD esignInVivoNonLLNA.In duction.Route
Vehicle	Select 'unchanged (no vehicle)' if none was used or select vehicle used if any. Further information can be given in the supplementary remarks field. If the vehicle used is not from the list provided in the test guideline, a rationale should be provided.	Open list with remarks	ENDPOINT_STUDY_RE CORD.SkinSensitisation. MaterialsAndMethods.In VivoTestSystem.StudyD esignInVivoNonLLNA.In duction.Vehicle
Concentration / amount	Provide the test substance concentrations used for induction exposures and the total amount of substance applied (i.e. undiluted, %, % active substance, FCA, mg, g). Provide justification for dose selection (including results from pre-screen test, if conducted).	Multi-line text	ENDPOINT_STUDY_RE CORD.SkinSensitisation. MaterialsAndMethods.In VivoTestSystem.StudyD esignInVivoNonLLNA.In duction.ConcentrationA mount
Day(s)/duration	Indicate the day number(s) on which the induction took place and as appropriate the duration (e.g. day 5-7 and day 6-8).	Text	ENDPOINT_STUDY_RE CORD.SkinSensitisation. MaterialsAndMethods.In VivoTestSystem.StudyD esignInVivoNonLLNA.In duction.DaySDuration
Adequacy of induction	Indicate if the test concentration used for the induction exposure was well-tolerated systemically and the highest to cause mild-to-moderate skin irritation, or if the highest technically applicable concentration used. If the substance is a non-irritant, indicate in field 'Details on study design' the appropriate pre-treatment applied for causing local irritation.	Open list	ENDPOINT_STUDY_RE CORD.SkinSensitisation. MaterialsAndMethods.In VivoTestSystem.StudyD esignInVivoNonLLNA.In duction.AdequacyOfInd uction
Induction			
Challenge	Record the vehicle, test substance concentrations used for challenge		ENDPOINT_STUDY_RE CORD.SkinSensitisation.

	exposure(s), the total amount of substance applied and the day(s) and duration of challenge. Copy this block of fields as appropriate. Consecutive numbers can be entered in the subfield "No." for indicating multiple challenges.		MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoNonLLNA.Challenge
No.	For indicating multiple challenges or rechallenge select a consecutive number from drop-down list.	Closed list	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoNonLLNA.Challenge.No
Route	Indicate the route of challenge exposure.	Open list	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoNonLLNA.Challenge.Route
Vehicle	Select 'unchanged (no vehicle)' if none was used or select vehicle used if any. Further information can be given in the supplementary remarks field. If the vehicle used is not from the list provided in the test guideline, a rationale should be provided.	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoNonLLNA.Challenge.Vehicle
Concentration / amount	Provide the test substance concentrations used for challenge exposures and the total amount of substance applied (i.e. undiluted, %, % active substance, FCA, mg, g). Provide justification for dose selection (including results from pre-screen test, if conducted).	Multi-line text	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoNonLLNA.Challenge.ConcentrationAmount
Day(s)/duration	Indicate the day number(s) on which the induction took place and as appropriate the duration (e.g. day 5-7 and day 6-8).	Text	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoNonLLNA.Challenge.DaySDuration
Adequacy of challenge	Indicate if the test concentration used for the challenge exposure was the highest non-irritation dose.	Open list	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoNonLLNA.Challenge.AdequacyOfChallenge
Challenge			
No. of animals per dose	Provide number of animals per dose or range if different numbers were used, e.g. '10 (controls), 10-20 (in test groups)'.	Multi-line text	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoNonLLNA.NoOfAnimalsPerDose

Details on study design	<p>For in vivo non-LLNA sensitisation tests, describe any range finding tests (pilot study) and for the main study the induction and challenge procedures including the type of information given in the freetext template. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.</p> <p>Example for Freund's Complete Adjuvant (FCA) test (partly adopted from OECD 406):</p> <ul style="list-style-type: none"> - A. INDUCTION EXPOSURE - No. of exposures: 5 - Exposure period: - - Test groups: TS in FCA - Control group: FCA only - Site: R flank - Frequency of applications: every 2nd day - Duration: 0-8 d - Concentrations: same throughout B. CHALLENGE EXPOSURE - No. of exposures: 2 - Day(s) of challenge: 22 & 35 - Exposure period: - - Test groups: TS - Control group: TS - Site: L flank - Concentrations: 4 different - Evaluation (hr after challenge): 24, 48, 72 	Text template	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoNonLLNA.DetailsOnStudyDesign
Challenge controls	Discuss the use of a challenge (i.e. naive) control group: number and sex of animals, dose for challenge application.	Multi-line text	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoNonLLNA.ChallengeControls
Positive control substance(s)	Indicate if positive control substance(s) was/were used. If yes, describe the positive control(s) in supplementary field as appropriate. If no, describe any periodic or historic positive control(s).	Closed list with remarks	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoNonLLNA.PositiveControlSubstances
Study design: in vivo (LLNA)		Header 3	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoLLNA
Vehicle	Select 'unchanged (no vehicle)' if none was used or select vehicle used if any. Further information can be given in the supplementary remarks field. If the vehicle used is not from the list provided in the test guideline, a rationale must be provided.	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoLLNA.Vehicle

Concentration	Describe dose selection, i.e. at least 3 consecutive concentrations (100%, 50%, 25% 10%, 5%, 2.5%, 1%, 0.5% etc.) of the test substance. Adequate scientific rationale should accompany the selection of the concentration series used.	Multi-line text	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoLLNA.Concentration
No. of animals per dose	Provide number of animals per dose or range if different numbers were used.	Multi-line text	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoLLNA.NoOfAnimalsPerDose
Details on study design	<p>For LLNA, LLNA:DA or LLNA:BrdU-ELISA, describe details on materials and methods as indicated in the freetext template. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.</p> <ul style="list-style-type: none"> - Details on radio isotope: to be included in field 'Details on test material' - RANGE FINDING TESTS: Briefly describe compound solubility, irritation and lymph node proliferation response if significant. - PRE-SCREEN TESTS: Briefly describe compound solubility, irritation, systemic toxicity (changes in: nervous system function, behaviour, respiratory patterns, food and water consumption), ear thickness measurements, erythema scores (0-3 on any day of measurement). <p>MAIN STUDY</p> <ul style="list-style-type: none"> - ANIMAL ASSIGNMENT AND TREATMENT: Indicate name of test method used. Comment on criteria used to consider a positive response. - TREATMENT PREPARATION AND ADMINISTRATION: Describe dose preparation and administration. (e.g. for LLNA:BrdU-ELISA 25 µl of compound x was applied to the entire dorsal surface of each ear of each mouse. The application was repeated on days 2 and 3). On day 5 an injection of 0.5 ml (5mg/mouse) of BrdU (10 mg/ml) solution was made intraperitoneally for each experimental mouse. Twenty-four hours later, the draining auricular lymph node of each ear was excised into PBS (indicate individual animal approach or pooled animal approach). A single cell suspension of lymph node cells 	Text template	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoLLNA.DetailsOnStudyDesign

	was prepared from each mouse (describe method of cell suspension).		
Positive control substance(s)	Indicate the positive control substance(s) used and give additional remarks in supplementary field as appropriate, e.g. the concentration used. Multiple selection is possible. If not listed, select 'other' and specify.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoLLNA.PositiveControlSubstances
Statistics	Provide the statistical procedures employed (e.g., linear regression analysis or William's test to assess dose-response trends; Dunnett's test to make pairwise comparisons).	Multi-line text	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoLLNA.Statistics
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion
Positive control results	Discuss the positive control results and demonstrate that the laboratory has the capability to identify positive dermal sensitizers.	Multi-line text	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.PositiveControlResults
In vitro / in chemico		Header 2	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.InVitoInChemico
Results	Indicate the test results. Copy this block of fields as appropriate. In case of a robust study summary or as requested by the regulatory programme, also provide the raw data of the results (including means and standard deviations) for the test material and all controls used in the field "Any other information on results incl. tables". (Q)SAR results can be reported under the appropriate heading, i.e. 'In vitro / in chemico', 'In vivo (non-LLNA)' or 'In vivo (LLNA)', depending on the applicability domain of the model behind and based on what kind of data the model was mainly validated. At least the field 'Remarks on result' should be completed by entering the adequate qualitative description of the prediction. Note that a separate field "Interpretation of results" is provided in the section		ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.InVitoInChemico.Results

	"APPLICANT'S SUMMARY AND CONCLUSION" for indicating a classification based on the study results.		
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RESULT.SkinSensitisation.ResultsAndDiscussion.InVitoInChemico.Results.KeyResult
Group		Open list	ENDPOINT_STUDY_RESULT.SkinSensitisation.ResultsAndDiscussion.InVitoInChemico.Results.Group
Run / experiment	Indicate the run / experiment the measurement relates to.	Open list	ENDPOINT_STUDY_RESULT.SkinSensitisation.ResultsAndDiscussion.InVitoInChemico.Results.RunExperiment
Parameter	Select type of parameter from picklist, if applicable. Further details can be given in the supplementary remarks field. Please include EC150 and EC200 values, if those can be calculated.	Open list with remarks	ENDPOINT_STUDY_RESULT.SkinSensitisation.ResultsAndDiscussion.InVitoInChemico.Results.Parameter
Value	Indicate also the unit of measurement e.g. µM, mM, µg/ml, mg/ml etc.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RESULT.SkinSensitisation.ResultsAndDiscussion.InVitoInChemico.Results.Value
At concentration		Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RESULT.SkinSensitisation.ResultsAndDiscussion.InVitoInChemico.Results.AtConcentration
Cell viability		Text area	ENDPOINT_STUDY_RESULT.SkinSensitisation.ResultsAndDiscussion.InVitoInChemico.Results.CellViability
Vehicle controls validity	Indicate whether test(s) with vehicle control(s) (i.e. without test substance, with/without solvent) is/are valid. Relevant remarks can be given in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RESULT.SkinSensitisation.ResultsAndDiscussion.InVitoInChemico.Results.VehicleControlsValid
Negative controls validity	Indicate whether test with negative control(s) is valid, i.e. substance(s) with known lack of irritation/corrosion in the test conducted. Relevant remarks can be given in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RESULT.SkinSensitisation.ResultsAndDiscussion.InVitoInChemico.Results.NegativeControlsValid
Positive controls validity	Indicate whether test with positive control(s) is valid, i.e. substance(s) with known irritation/corrosion in the test	Open list with remarks	ENDPOINT_STUDY_RESULT.SkinSensitisation.ResultsAndDiscussion.I

	conducted. Relevant remarks can be given in the supplementary remarks field.		nVItroInChemico.Results.PositiveControlsValid
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.I nVItroInChemico.Results.RemarksOnResults
Results			
Outcome of the prediction model	For DPRA, the mean peptide % depletion values have been specified for each reactivity group in the test guideline for each prediction model.	Open list	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.I nVItroInChemico.PredictionModelOutcome
Other effects / acceptance of results	Use freetext template and delete/add elements as appropriate. Provide the following information as appropriate: - OTHER EFFECTS: Describe any other observed effects (e.g. visible damage on test system) - DEMONSTRATION OF TECHNICAL PROFICIENCY: If required according to the test guideline, indicate if and when technical proficiency has been demonstrated using the proficiency chemicals listed in the guideline used. Upload table(s) with data for each individual proficiency chemical in the rich text field 'Any other information on results incl. tables'. - ACCEPTANCE OF RESULTS: Demonstrate that the assay acceptance criteria (for negative control, positive control, and variability between replicate measurements) were met in reference to historical ranges. Indicate the range of historical values if different from the ones indicated in the relevant test guideline. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.I nVItroInChemico.Other EffectsAcceptanceOfResults
In vivo (non-LLNA)		Header 2	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.T

			raditionalSensitisationTest
Results	Record the results of in vivo non-LLNA tests at the different readings for each test or control group used. Copy this block of fields as appropriate. Present the scores from the challenge responses in a table. (Q)SAR results can be reported under the appropriate heading, i.e. 'In vitro / in chemico', 'In vivo (non-LLNA)' or 'In vivo (LLNA)', depending on the applicability domain of the model behind and based on what kind of data the model was mainly validated. At least the field 'Remarks on result' should be completed by entering the adequate qualitative description of the prediction.		ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.TraditionalSensitisationTest.ResultsOfTest
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.TraditionalSensitisationTest.ResultsOfTest.KeyResult
Reading	Select from drop-down list.	Open list	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.TraditionalSensitisationTest.ResultsOfTest.Reading
Hours after challenge	Enter numeric value.	Decimal	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.TraditionalSensitisationTest.ResultsOfTest.HoursAfterChallenge
Group	Select from drop-down list.	Open list	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.TraditionalSensitisationTest.ResultsOfTest.Group
Dose level	If more than one concentration was tested at challenge, specify the concentration(s) the reading refers to, e.g. '0.15 g of a 10% aqueous solution'. Several dose levels can be given if the results reported in this block of fields is the same for all challenge groups, e.g. '0.15 or 0.3 g of a 10% aqueous solution'.	Text	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.TraditionalSensitisationTest.ResultsOfTest.DoseLevel
No. with + reactions	Enter numeric value.	Integer	ENDPOINT_STUDY_RECORD.SkinSensitisation.

			ResultsAndDiscussion.TraditionalSensitisationTest.ResultsOfTest.NoWithReactions
Total no. in group	Enter numeric value.	Integer	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.TraditionalSensitisationTest.ResultsOfTest.TotalNoInGroup
Clinical observations	Briefly describe relevant clinical observations.	Text	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.TraditionalSensitisationTest.ResultsOfTest.ClinicalObservations
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.TraditionalSensitisationTest.ResultsOfTest.RemarksOnResults
Results			
In vivo (LLNA)		Header 2	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.InVivoLLNA
Results	Indicate the cell proliferation results for the test substance, i.e. either ATP (measured adenosine triphosphate content of lymphocytes) or BrdU (measured 5-bromo-2-deoxyuridine content in DNA of lymphocytes) or DPM (incorporated radioactivity as disintegrations per minute) or other. Copy this block of fields as appropriate. (Q)SAR results can be reported under the appropriate heading, i.e. 'In vitro / in chemico', 'In vivo (non-LLNA)' or 'In vivo (LLNA)', depending on the applicability domain of the model behind and based on what kind of data the model was mainly validated. At least the field 'Remarks on result' should be completed by entering the adequate qualitative description of the prediction. In case of a robust study summary or as requested by the regulatory		ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.InVivoLLNA.Results

	programme, also provide the raw data of the results (including means and standard deviations) for the test material and all controls used in the field "Cellular proliferation data / Observations" and/or upload a table in the field "Any other information on results incl. tables". Note that a separate field "Interpretation of results" is provided in the section "APPLICANT'S SUMMARY AND CONCLUSION" for indicating a classification based on the study results.		
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RESULT.SkinSensitisation.ResultsAndDiscussion.InVivoLLNA.Results.Key Result
Parameter	Select type of parameter from picklist, if applicable, i.e. either SI (stimulation index) or EC3 (estimated concentration of a test substance needed to produce a stimulation index of three) or ECt (estimated concentration of a test substance needed to produce a stimulation index that is indicative of a positive response) or other (specify). Further details can be given in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RESULT.SkinSensitisation.ResultsAndDiscussion.InVivoLLNA.Results.Parameter
Value	Provide the numeric value or a range of values if reported so. Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RESULT.SkinSensitisation.ResultsAndDiscussion.InVivoLLNA.Results.Value
Variability	Indicate the standard deviation or other appropriate measure of variability that takes into account the inter-animal variability in both the test substance and control groups when using the individual animal approach.	Text	ENDPOINT_STUDY_RESULT.SkinSensitisation.ResultsAndDiscussion.InVivoLLNA.Results.Variability
Test group / Remarks	Indicate the concentration of the test material, the run / experiment number the calculated value relates to and any other relevant information. Examples: Exp. 1 (0%); Exp. 1 (0.5%); Exp. 1 (1%), etc. or Mean of three runs (0%), etc.	Text	ENDPOINT_STUDY_RESULT.SkinSensitisation.ResultsAndDiscussion.InVivoLLNA.Results.Test GroupRemarks
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting	Open list with remarks (2000)	ENDPOINT_STUDY_RESULT.SkinSensitisation.ResultsAndDiscussion.InVivoLLNA.Results.RemarksOnResults

	'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'		
Results			
Cellular proliferation data / Observations	For robust study summaries or as requested by the regulatory programme, tabulate the raw data (unless these data are given in above block of fields 'Stimulation index / EC value') and indicate any relevant observations. Use freetext template and delete/add elements as appropriate. Alternatively or in addition refer to appropriate table(s), which were uploaded in the rich text field 'Any other information on results incl. tables'. Use predefined table if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them (e.g. '... see Table 1'). Provide the results of cellular proliferation measurements (DPM values for conventional LLNA or ATP content values for LLNA: DA or BrdU content values for LLNA: BrdU-ELISA). Comment on dose-response trends and comparisons with the vehicle control group. Give statistical comparisons of group mean measurements compared to control. Indicate whether results are from the individual animals or pooled. Indicate whether the overall result is positive or negative. Note: Specific tables may be required.	Text template	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.InVivoLLNA.CellularProliferationDataObservations
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.SkinSensitisation.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.SkinSensitisation.ApplicantSummaryAndConclusion

5.2.6 Phototoxicity – Endpoint Summary

Purpose:

State if 'not required' or 'not phototoxic/probably phototoxic/phototoxic'

The document should contain the information needed to be reported according to the list of end points for phototoxicity (SANCO/12592/2012-rev. 2, 22 March 2019).

Acute toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.2)

ENDPOINT_SUMMARY.Phototoxicity - v.1.2 (Final)			
Name	Instructions	Type	Field Path
Administrative data	Administrative data summary – common block Description of key information: Provide a brief description of the phototoxicity studies and effects.	Header 1	ENDPOINT_SUMMARY.Phototoxicity.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.Phototoxicity.KeyValueCsa
Results		Open list	ENDPOINT_SUMMARY.Phototoxicity.KeyValueCsa.Results
Additional information	Discussion(Header 1) – common block Provide additional information related to the endpoint, for example: state 'not required' or 'not phototoxic/probably phototoxic/phototoxic'	Header 1	ENDPOINT_SUMMARY.Phototoxicity.Discussion

5.2.6 Phototoxicity – Endpoint Study record

Purpose:

The study shall provide information on the potential of certain active substances to induce cytotoxicity in combination with light, for example active substances that are phototoxic in vivo after systemic exposure and distribution to the skin, as well as active substances that act as photo-irritants after dermal application. A positive result shall be taken into account when considering potential human exposure. The in vitro study shall be required where the active substance absorbs electromagnetic radiation in the range 290- 700 nm and is liable to reach the eyes or light-exposed areas of skin, either by direct contact or through systemic distribution. If the Ultraviolet/visible molar extinction/absorption coefficient of the active substance is less than $10 \text{ L} \times \text{mol}^{-1} \times \text{cm}^{-1}$, no toxicity testing is required.

ENDPOINT_STUDY_RECORD.PhototoxicityVitro - v.1.5 (Final)			
Name	Instructions	Type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.PhototoxicityVitro.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.PhototoxicityVitro.DataSource
Materials and methods	Material and methods – common block Type of study: Indicate whether an in vitro 3T3 NRU phototoxicity test or a reactive oxygen species (ROS) assay was performed. Applicable test guideline: OECD 432, OECD 101, Method B.41 In vitro 3T3 NRU phototoxicity test '.	Header 1	ENDPOINT_STUDY_RECORD.PhototoxicityVitro.MaterialsAndMethods
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.PhototoxicityVitro.MaterialsAndMethods.TestMaterials
Test system		Header 2	ENDPOINT_STUDY_RECORD.PhototoxicityVitro.MaterialsAndMethods.TestSystem
Species / strain	Indicate the species and tester strain(s) used in the type of study indicated in the respective field above. Copy this field block for each tester strain.		ENDPOINT_STUDY_RECORD.PhototoxicityVitro.MaterialsAndMethods.TestSystem.SpeciesStrain
Species / strain / cell type	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list with remarks	ENDPOINT_STUDY_RECORD.PhototoxicityVitro.MaterialsAndMethods.TestSystem.SpeciesStrain.SpeciesStrainCell
Details on mammalian cell	For robust study summaries, describe relevant details on cell cultures if applicable.	Text template	ENDPOINT_STUDY_RECORD.Phototoxicity

type (if applicable)	Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.		Vitro.MaterialsAndMethods.TestSystem.SpeciesStrain.MammalianCellDetails
Species / strain			
Controls	Indicate whether vehicle, true negative and/or positive controls were tested.		ENDPOINT_STUDY_RECORD.Phototoxicity Vitro.MaterialsAndMethods.TestSystem.Controls
Negative solvent / vehicle controls	Indicate whether solvent / vehicle controls (i.e. consisting of solvent or vehicle alone, without test substance, and otherwise treated in the same way as the treatment groups) were tested. Any explanations can be given in the supplementary remarks field. In particular, indicate the concentration (and/or volume) of vehicle added.	Open list with remarks	ENDPOINT_STUDY_RECORD.Phototoxicity Vitro.MaterialsAndMethods.TestSystem.Controls.NegativeControls
Positive controls	Indicate whether positive controls (i.e. substances with known genotoxicity) were tested. If so, indicate what substance(s) was/were used as positive control(s) in field "Positive control substance".	Open list with remarks	ENDPOINT_STUDY_RECORD.Phototoxicity Vitro.MaterialsAndMethods.TestSystem.Controls.PositiveControls
Positive control substance	<p>If applicable, indicate which substance(s) was/were used as positive control(s). Multiple items can be selected.</p> <p>If other than the reference substance(s) specified in the test guidelines was/were used, include a brief justification.</p> <p>Final concentration, conditions and durations of treatment and recovery periods.</p> <p>Note that the list of substances provided is not exhaustive.</p>	Open list with remarks	ENDPOINT_STUDY_RECORD.Phototoxicity Vitro.MaterialsAndMethods.TestSystem.Controls.PositiveControlSubstance
Remarks	Enter any remarks related to the recorded controls as appropriate.	Text	ENDPOINT_STUDY_RECORD.Phototoxicity Vitro.MaterialsAndMethods.TestSystem.Controls.Remarks
Controls			
Details on test system and experimental conditions	Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.Phototoxicity Vitro.MaterialsAndMethods.TestSystem.ExperimentalConditions

Vehicle	Indicate whether vehicle was used to emulsify or mix the experimental test material to enhance its solubility. If yes, specify in field 'Details on test solution'.	Closed list with remarks	ENDPOINT_STUDY_RECORD.Phototoxicity Vitro.MaterialsAndMethods.TestSystem.Vehicle
Vehicle / solvent	<p>Indicate whether and which vehicle(s)/solvent(s) was/were used or state 'none' or 'no data' as applicable. Indicate if different vehicle/ solvent were used for tests with and without metabolic activation.</p> <p>Provide the percentage or volume of vehicle/solvent in the medium (e.g. 'DMSO (1% or 0.1 ml per 10 ml medium') and a justification for the choice of solvent/vehicle.</p> <p>Also indicate whether vehicle (or negative) controls (i.e. consisting of culture medium or medium with solvent or vehicle alone) were tested for their compatibility with the test chemical, test system and their lack of genetic toxicity at the concentrations used.</p> <p>Use freetext template and delete/add elements as appropriate. Note that the list of substances provided is not exhaustive.</p>	Text template	ENDPOINT_STUDY_RECORD.Phototoxicity Vitro.MaterialsAndMethods.TestSystem.VehicleSolvent
Evaluation criteria	Describe the evaluation criteria used in the study to judge if a substance is positive, negative or equivocal.	Multi-line text	ENDPOINT_STUDY_RECORD.Phototoxicity Vitro.MaterialsAndMethods.TestSystem.EvaluationCriteria
Statistics	List parameters that were analysed and the statistical methods used; include a statement on the appropriateness of the statistical analyses used. If inappropriate, provide alternative/rationale.	Multi-line text	ENDPOINT_STUDY_RECORD.Phototoxicity Vitro.MaterialsAndMethods.TestSystem.Statistics
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.Phototoxicity Vitro.ResultsAndDiscussion
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.Phototoxicity Vitro.ResultsAndDiscussion.KeyResult
Results	Include the main test results.	Text template	ENDPOINT_STUDY_RECORD.Phototoxicity Vitro.ResultsAndDiscussion.Results
Remarks on result	This field can be used for:	Open list with remarks	ENDPOINT_STUDY_RECORD.Phototoxicity

	<p>- giving a qualitative description of results in addition to or if no numeric value(s) were derived;</p> <p>- giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or</p> <p>- entering any additional information on the effect level by selecting 'other:'</p>		Vitro.ResultsAndDiscussion.RemarksOnResult
Results with reference substance (positive control)	<p>If reference substance(s) was/were tested, indicate whether the results with it/them are valid and provide relevant effect levels and other relevant information.</p> <p>Use freetext template and delete/add elements as appropriate.</p>	Text template	ENDPOINT_STUDY_RECORD.Phototoxicity Vitro.ResultsAndDiscussion.ResultsReferenceSubstance
Reported statistics and error estimates	Indicate the parameters analysed, the statistical method used and the statistical test performed. If probit analysis was used, indicate the intercept and probit slope. As appropriate state any relevant error estimates associated with the determination of concentration-response relationship.	Multi-line text	ENDPOINT_STUDY_RECORD.Phototoxicity Vitro.ResultsAndDiscussion.StatisticsErrorEstimates
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.Phototoxicity Vitro.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.Phototoxicity Vitro.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.Phototoxicity Vitro.ApplicantSummaryAndConclusion

5.2.7 Acute toxicity: Other routes – Endpoint study record

Purpose:

Provide information:

- For human risk assessment additional dermal studies shall be considered on a case by case basis, unless the active substance is a severe irritant.
- For volatile active substances (vapour pressure >10–2 Pascal) expert judgement (for example based on route-specific kinetic data) shall be required to decide whether the short term studies have to be performed by inhalation exposure.

ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes - v.7.3 (Final)			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.DataSource
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.MaterialsAndMethods
Limit test	Indicate if the experiment was a limit test.	Closed list	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.MaterialsAndMethods.LimitTest
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.MaterialsAndMethods.TestMaterials
Test animals	Test animals (OHT: Repeated dose toxicity) – common block Species: NOTE: Human data should be reported in an appropriate subsection of section 'Exposure related observations', particularly subsection 'Direct observations: clinical cases, poisoning incidents and other'. It can be useful to document, in the section on acute toxicity, that human data are provided by creating a record and referring to the human data in field 'Cross-reference'. This could be relevant if lack of animal experiments is defended by the availability of data on experience with human exposure.	Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.MaterialsAndMethods.TestAnimals
Administration / exposure		Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.MaterialsAndMethods.AdministrationExposure
Route of administration	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.MaterialsAndMethods.Administ

			rationExposure.RouteOfAdministration
Vehicle	Select 'unchanged (no vehicle)' if none was used or select vehicle used if any. If not available from picklist, select 'other' and specify. Further information can be given in the supplementary remarks field. Note that some of the vehicles provided in this list are used for specific routes of administration only.	Open list with remarks	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.MaterialsAndMethods.AdministrationExposure.Vehicle
Details on exposure	Briefly describe details of exposure.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.MaterialsAndMethods.AdministrationExposure.DetailsOnExposure
Doses	Include the doses including unit administered to the test animals, '5, 50, 500 and 2000 mg/kg bw'. As appropriate include notes in parentheses, e.g. '(male)'.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.MaterialsAndMethods.AdministrationExposure.Doses
No. of animals per sex per dose	Enter value or specify according to dose if different number of animals per dose, e.g. '10 (controls), 5 (in dose groups)'. For robust study summaries or as requested by the regulatory programme, also include a detailed table on the animal assignment in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Note: Specific tables may be required.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.MaterialsAndMethods.AdministrationExposure.NoOfAnimalsPerSexPerDose
Control animals	Indicate whether concurrent control group was used.	Open list with remarks	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.MaterialsAndMethods.AdministrationExposure.ControlAnimals
Details on study design	Include any further details on the study design, i.e. observation period, frequency of observations/weighing, necropsy of survivors and other examinations performed. Use freetext template and delete/add elements as appropriate.	Text template	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.MaterialsAndMethods.AdministrationExposure.DetailsOnStudyDesign
Statistics	Indicate the method of calculating the LD50 or other.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.MaterialsAndMethods.AdministrationExposure.Statistics

Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.ResultsAndDiscussion
Effect levels	Provide the LD50 with confidence limits if available and/or other effect levels reported. Copy this field block for each effect level. If both sexes were tested at each dose level, then the combined effect level should be stated. If no LD50 or other endpoint available from picklist is reported, but only a dose level, specify this dose using 'other' and indicate the effects observed in subfield 'Remarks on result'.		ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.ResultsAndDiscussion.EffectLevels
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Checkbox	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.ResultsAndDiscussion.EffectLevels.KeyResult
Sex	Select from drop-down list.	Closed list	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.ResultsAndDiscussion.EffectLevels.Sex
Dose descriptor	Select the relevant dose descriptor from drop-down list, i.e. the exposure level that corresponds to a quantified level of effects. Where no value could be achieved based on the method and boundaries used, the upper or lower dose level for the relevant dose descriptor can be reported as appropriate with relevant qualifier, e.g. LD50 >10 mg/kg bw or LD50 <10 mg/kg bw. An additional explanation may be given in field 'Remarks on result', e.g. 'not determinable due to absence of adverse toxic effects'.	Open list with remarks	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.ResultsAndDiscussion.EffectLevels.Endpoint
Effect level	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.ResultsAndDiscussion.EffectLevels.EffectLevel
Based on	Indicate whether the concentration is based on the test material (test mat.), active ingredient (act. ingr.) or element. As appropriate the measured / addressed fraction can be specified for	Open list with	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.ResultsA

	either of these entities by selecting the relevant item, e.g. 'element (dissolved fraction)' or 'test mat. (total fraction)'. Further information can be given in the supplementary remarks field, e.g. for specifying the type of fraction if it is not clear per se from the test material specification. Select 'not specified' if the effect concentration type is not known.	remarks	ndDiscussion.EffectLevels.BasedOn
95% CL	For robust study summaries or as requested by the regulatory programme, provide the 95% confidence limits if available. Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.ResultsAndDiscussion.EffectLevels.cl
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.ResultsAndDiscussion.EffectLevels.RemarksOnResults
Effect levels			
Mortality	Include raw data on mortality and evident toxicity for each sex and approximate time of deaths. As appropriate include a detailed table in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Note: Specific tables may be required.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.ResultsAndDiscussion.Mortality
Clinical signs	Briefly describe significant effects found, including the numbers of animals showing signs, time of onset, duration of the major clinical signs and time when most animals recovered. Do not dwell on effects that are most likely due to agonal death. Focus on any important findings, i.e. compound-related or suspected related effects. In case particular effects are considered control-related e.g. because of abnormal control values, this should be specifically addressed. Note if there was a reference point (e.g. NOAELs) for clinical findings.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.ResultsAndDiscussion.ClinicalSigns
Body weight	Briefly describe whether animals gained or lost weight.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.ResultsAndDiscussion.BodyWeight

Gross pathology	Briefly describe whether there were any treatment related effects. Do not stress effects due to agonal death.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.ResultsAndDiscussion.GrossPathology
Other findings	Report results related to pathogenicity, infectiveness or clearance in studies with micro-organisms	Text template	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.ResultsAndDiscussion.OtherFindings
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.ApplicantSummaryAndConclusion

5.3 Repeated dose toxicity– Endpoint Summary

Purpose:

Chemical (Active): Provide consolidated information across the four routes (oral/inhalation/dermal/other) in both rodent and non-rodent species. The studies, data and information to be provided and evaluated, shall be sufficient to permit the identification of effects following repeated exposure to the active substance, and in particular to further establish, or indicate:

- Target organ / critical effect
- Relevant oral reference point (e.g. NOAELs).
- Relevant dermal reference point (e.g. NOAELs).
- Relevant inhalation reference point (e.g. NOAELs).

Microorganisms (Active): In addition, an estimation of the microorganism clearance in the main organs must be performed. Investigations shall be included for pathogenicity and infectiveness endpoints.

The document should contain the information needed to be reported according to the list of end points for short-term toxicity (SANCO/12592/2012-rev. 2, 22 March 2019).

ENDPOINT_SUMMARY.RepeatedDoseToxicity - v.6.2 (Final)			
Name	Instructions	Type	Field path

Administrative data	Administrative data summary – common block Description of key information: Provide brief description of the toxicity studies and effects.	Header 1	ENDPOINT_SUMMARY.RepeatedDoseToxicity.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment
Toxic effect type	In this field, you should select whether there is a relationship between the exposure concentration and the magnitude of the toxic effect, i.e. dose-dependent, or whether the toxic effect is driven but not modulated by the exposure concentration, i.e. concentration-driven.	Closed list	ENDPOINT_SUMMARY.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.ToxicEffectType
Repeated dose toxicity: via oral route - systemic effects		Header 2	ENDPOINT_SUMMARY.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.RepeatedDoseToxicityViaOralRouteSystemicEffects
Link to relevant study records	Endpoint summary block for relevant study record Study name / type: The study giving rise to the highest concern should be chosen e.g. most sensitive species. The following factors, among others, should be taken into account when the robust study summary is selected: quality of the study (e.g. Klimisch score, duration of the study, whether or not the study is GLP. Available epidemiological data	Header 3	ENDPOINT_SUMMARY.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.RepeatedDoseToxicityViaOralRouteSystemicEffects.LinkToRelevantStudyRecords

	are preferred provided that they are reliable and relevant. However, epidemiological studies should be reported under 5.9.4		
Endpoint conclusion	<p>Endpoint conclusion: "Adverse effect observed" should be chosen if adverse effects were observed at or below the limit dose level. "No adverse effect observed" should be chosen if no adverse effects were observed at or below the limit dose level. If "No study available" is chosen, a justification needs to be provided. If the dossier contains a testing proposal for repeated dose toxicity (90-day study), "No study available (further information necessary)" should be chosen.</p> <p>Dose descriptor: The primary dose descriptor in this endpoint is the NOAEL. In some studies also the BMDL (benchmark dose level). The LOAEL should be used only if NOAEL is not available. If the dose descriptor is expressed in ppm, it should first be converted to ng/kg, µg/kg or mg/kg for the toxin(s) or CFU/kg bw or other relevant unit for the micro-organism.</p>	Header 3	ENDPOINT_SUMMARY. RepeatedDoseToxicity. KeyValueForChemicalSafetyAssessment.RepeatedDoseToxicityViaOralRouteSystemicEffects.EndpointConclusion

	<p>Study duration: The duration of the selected robust study summary.</p> <p>Species: The species reported in the selected robust study summary should be chosen here.</p> <p>The system in which adverse effects were observed should be specified here. If adverse effects were observed in several systems, the target system in which the adverse effects gives rise to highest concern should be selected, i.e. the system that is associated with the dose descriptor.</p> <p>The organ in which adverse effects were observed should be specified here. If adverse effects were observed in several organs, the target system in which the adverse effects gives rise to highest concern should be selected, i.e. the system that is associated with the dose descriptor.</p>		
Repeated dose toxicity: inhalation - systemic effects		Header 2	ENDPOINT_SUMMARY.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.RepeatedDoseToxicityInhalationSystemicEffects
Link to relevant study records	<p>Endpoint summary block for relevant study record</p> <p>The following factors, among others, should be taken into account when the robust study summary is selected:</p>	Header 3	ENDPOINT_SUMMARY.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.RepeatedDoseToxicityInhalationSystemicEffects.LinkToRelevantStudyRecords

	quality of the study (e.g. Klimisch score, duration of the study, whether or not the study is GLP)		
Endpoint conclusion	<p>Endpoint conclusion: "Adverse effect observed" should be chosen if adverse effects were observed at or below the limit dose level. "No adverse effect observed" should be chosen if no adverse effects were observed at or below the limit dose level. If "No study available" is chosen, a justification needs to be provided. If the dossier contains a testing proposal for repeated dose toxicity (90-day study), "No study available (further information necessary)" should be chosen.</p> <p>Dose descriptor: The primary dose descriptor in this endpoint is the NOAEL. In some studies also the BMDL (benchmark dose level). The LOAEL should be used only if NOAEL is not available. If the dose descriptor is expressed in ppm, it should first be converted to ng/kg per day, µg/ kg per day or mg/ kg per day. Study duration: The duration of the selected robust study summary.</p> <p>Species: The species reported in the selected</p>	Header 3	ENDPOINT_SUMMARY. RepeatedDoseToxicity. KeyValueForChemicalSafetyAssessment.RepeatedDoseToxicityInhalationSystemicEffects.EndpointConclusion

	<p>robust study summary should be chosen here.</p> <p>The system in which adverse effects were observed should be specified here. If adverse effects were observed in several systems, the target system in which the adverse effects gives rise to highest concern should be selected, i.e. the system that is associated with the dose descriptor.</p> <p>The organ in which adverse effects were observed should be specified here. If adverse effects were observed in several organs, the target system in which the adverse effects gives rise to highest concern should be selected, i.e. the system that is associated with the dose descriptor.</p>		
Repeated dose toxicity: inhalation - local effects		Header 2	ENDPOINT_SUMMARY.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.RepeatedDoseToxicityInhalationLocalEffects
Link to relevant study records	<p>Endpoint summary block for relevant study record</p> <p>The following factors, among others, should be taken into account when the robust study summary is selected: quality of the study (e.g. Klimisch score, duration of the study, whether or not the study is GLP.</p>	Header 3	ENDPOINT_SUMMARY.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.RepeatedDoseToxicityInhalationLocalEffects.LinkToRelevantStudyRecords

<p>Endpoint conclusion</p>	<p>Endpoint conclusion block (Species version)</p> <p>Endpoint conclusion: "Adverse effect observed" should be chosen if adverse effects were observed at or below the limit dose level. "No adverse effect observed" should be chosen if no adverse effects were observed at or below the limit dose level. If "No study available" is chosen, a justification needs to be provided. If the dossier contains a testing proposal for repeated dose toxicity (90-day study), "No study available (further information necessary)" should be chosen.</p> <p>Dose descriptor: The primary dose descriptor in this endpoint is the NOAEL. In some studies also the BMDL (benchmark dose level). The LOAEL should be used only if NOAEL is not available. If the dose descriptor is expressed in ppm, it should first be converted to ng/kg per day, µg/ kg per day or mg/ kg per day. For the toxin(s) or CFU/kg bw or other relevant unit for the micro-organism. Study duration: The duration of the selected robust study summary.</p>	<p>Header 3</p>	<p>ENDPOINT_SUMMARY.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.RepeatedDoseToxicityInhalationLocalEffects.EndpointConclusion</p>
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	<p>Species: The species reported in the selected robust study summary should be chosen here.</p> <p>The system in which adverse effects were observed should be specified here. If adverse effects were observed in several systems, the target system in which the adverse effects gives rise to highest concern should be selected, i.e. the system that is associated with the dose descriptor.</p> <p>The organ in which adverse effects were observed should be specified here. If adverse effects were observed in several organs, the target system in which the adverse effects gives rise to highest concern should be selected, i.e. the system that is associated with the dose descriptor.</p>		
Repeated dose toxicity: dermal - systemic effects		Header 2	ENDPOINT_SUMMARY.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.RepeatedDoseToxicityDermalSystemicEffects
Link to relevant study records	<p>Endpoint summary block for relevant study record</p> <p>The following factors, among others, should be taken into account when the robust study summary is selected: quality of the study (e.g. Klimisch score, duration of the study,</p>	Header 3	ENDPOINT_SUMMARY.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.RepeatedDoseToxicityDermalSystemicEffects.LinkToRelevantStudyRecords

	whether or not the study is GLP.		
Endpoint conclusion	<p>Endpoint conclusion block (Species version)</p> <p>Endpoint conclusion: "Adverse effect observed" should be chosen if adverse effects were observed at or below the limit dose level. "No adverse effect observed" should be chosen if no adverse effects were observed at or below the limit dose level. If "No study available" is chosen, a justification needs to be provided. If the dossier contains a testing proposal for repeated dose toxicity (90-day study), "No study available (further information necessary)" should be chosen.</p> <p>Dose descriptor: The primary dose descriptor in this endpoint is the NOAEL. In some studies also the BMDL (benchmark dose level). The LOAEL should be used only if NOAEL is not available. If the dose descriptor is expressed in ppm, it should first be converted to ng/kg per day, µg/ kg per day or mg/ kg per day. For the toxin(s) or CFU/kg bw or other relevant unit for the micro-organism.</p>	Header 3	ENDPOINT_SUMMARY. RepeatedDoseToxicity. KeyValueForChemicalSafetyAssessment.RepeatedDoseToxicityDermalSystemicEffects.Endpoint Conclusion

	<p>Study duration: The duration of the selected robust study summary.</p> <p>Species: The species reported in the selected robust study summary should be chosen here.</p> <p>The system in which adverse effects were observed should be specified here. If adverse effects were observed in several systems, the target system in which the adverse effects gives rise to highest concern should be selected, i.e. the system that is associated with the dose descriptor.</p> <p>The organ in which adverse effects were observed should be specified here. If adverse effects were observed in several organs, the target system in which the adverse effects gives rise to highest concern should be selected, i.e. the system that is associated with the dose descriptor.</p>		
Repeated dose toxicity: dermal - local effects		Header 2	ENDPOINT_SUMMARY.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.RepeatedDoseToxicityDermalLocalEffects
Link to relevant study records	<p>Endpoint summary block for relevant study record</p> <p>The following factors, among others, should be taken into account when the robust study summary is selected:</p>	Header 3	ENDPOINT_SUMMARY.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.RepeatedDoseToxicityDermalLocalEffects.LinkToRelevantStudyRecords

	quality of the study (e.g. Klimisch score, duration of the study, whether or not the study is GLP).		
Results		Read-only	ENDPOINT_SUMMARY.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.RepeatedDoseToxicityDermalLocalEffects.LinkToRelevantStudyRecords.Results
Endpoint conclusion	<p>Endpoint conclusion block (Species version)</p> <p>Endpoint conclusion: "Adverse effect observed" should be chosen if adverse effects were observed at or below the limit dose level. "No adverse effect observed" should be chosen if no adverse effects were observed at or below the limit dose level. If "No study available" is chosen, a justification needs to be provided. If the dossier contains a testing proposal for repeated dose toxicity (90-day study), "No study available (further information necessary)" should be chosen.</p> <p>Dose descriptor: The primary dose descriptor in this endpoint is the NOAEL. In some studies also the BMDL (benchmark dose level). The LOAEL should be used only if NOAEL is not available. If the dose descriptor is</p>	Header 3	ENDPOINT_SUMMARY.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.RepeatedDoseToxicityDermalLocalEffects.EndpointConclusion

	<p>expressed in ppm, it should first be converted to ng/kg per day, µg/ kg per day or mg/ kg per day. Study duration: The duration of the selected robust study summary.</p> <p>Species: The species reported in the selected robust study summary should be chosen here.</p> <p>The system in which adverse effects were observed should be specified here. If adverse effects were observed in several systems, the target system in which the adverse effects gives rise to highest concern should be selected, i.e. the system that is associated with the dose descriptor.</p> <p>The organ in which adverse effects were observed should be specified here. If adverse effects were observed in several organs, the target system in which the adverse effects gives rise to highest concern should be selected, i.e. the system that is associated with the dose descriptor.</p>		
Mode of Action Analysis / Human Relevance Framework		Header 2	ENDPOINT_SUMMARY. RepeatedDoseToxicity. KeyValueForChemicalSafetyAssessment.ModeOfActionAnalysisHumanRelevanceFramework
	A discussion about the mode of action and the relevance of the data	Rich text area	ENDPOINT_SUMMARY. RepeatedDoseToxicity. KeyValueForChemicalSa

	for human health should be provided here.		fetyAssessment.ModeOfActionAnalysisHumanRelevanceFramework.ModeOfActionAnalysis
Additional information	Discussion (Header 1) – common block Provide information on short-term toxicity studies in other species that the most sensitive species (described under study name / type, see above). Please provide: -Target organ/toxicity -Relevant dose descriptor (e.g. NOAEL)	Header 1	ENDPOINT_SUMMARY.RepeatedDoseToxicity.Discussion
Justification for classification or non-classification		Header 1	ENDPOINT_SUMMARY.RepeatedDoseToxicity.JustificationForClassificationOrNonClassification
	The available information should be compared against the classification criteria and the reasons for fulfilling or not fulfilling the classification criteria should be presented.	Rich text area	ENDPOINT_SUMMARY.RepeatedDoseToxicity.JustificationForClassificationOrNonClassification.Remarks

5.3.1 Repeated dose toxicity: oral– Endpoint study record

Purpose:

Chemical (Active): Provide data related to the short-term oral toxicity of the active substance to rodents (90-day), usually the rat, a different rodent species shall be justified, and non rodents (90-day toxicity study in dogs), shall always be reported. Where available, 28-day studies shall be reported.

Microorganism (Active): If the information already available is not sufficient to assess human health effects, data related to the short-term toxicity (minimum 28 days) of the microorganism must be reported, providing information on infectiveness, pathogenicity and toxicity. The choice of test species has to be justified. The choice of study length depends on acute toxicity and clearance data. Expert judgement is required to decide what route of administration is preferable.

ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral - v.8.4 (Final)			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxi

			cityOral.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.DataSource
Materials and methods	Material and methods – common block Applicable test guideline: 90 d OECD 408 OECD 409 Method B.26 Sub-chronic oral toxicity test. Method B.27 Sub-chronic oral toxicity test. 28 d OECD 407 Method B.7 Repeated dose (28 d).	Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods
Limit test	Indicate if the experiment was a limit test.	Closed list	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.LimitTest
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.TestMaterials
Test animals	Test animals (OHT: Repeated dose toxicity) – common block	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.TestAnimals
Administration / exposure		Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.AdministrationExposure
Route of administration	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.AdministrationExposure.RouteOfAdministration
Details on route of administration	For robust study summaries or as requested by the regulatory programme, provide details explaining the choice of the oral route and method of administration.	Multi-line text	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.AdministrationExposure.DetailsOnRouteOfAdministration
Vehicle	Select the vehicle used. If not available from picklist, select 'other' and specify. Further information can be given in the supplementary remarks field.	Open list with	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMe

	Note that some of the vehicles provided in this list are used for specific routes of administration only.	remarks	thods.AdministrationExposure.Vehicle
Details on oral exposure	Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.AdministrationExposure.DetailsOnOralExposure
Analytical verification of doses or concentrations	Indicate whether the doses or concentrations were analytically verified.	Closed list with remarks	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.AdministrationExposure.AnalyticalVerificationOfDosesOrConcentrations
Details on analytical verification of doses or concentrations	For robust study summaries or as requested by the regulatory programme, include a short description on the method of analysis. State whether the analytical data indicated that the difference between nominal and actual dosage (if diet is route of administration) or concentrations (for drinking water study) was acceptable. If diet is the route of administration, briefly record when and at what dose levels the dosage analyses were made and include the results (range of values) of (i) Homogeneity analysis, (ii) Stability analysis and (iii) Concentration analysis. If any problems occurred in any of these procedures, then they should be reported in more detail. If this could have affected the veracity or conclusions of the study, discuss this in field 'Rationale for reliability incl. deficiencies'. It may be appropriate to include a cross-reference to another study in which stability analysis was performed and reported. If so, a justification should also be included briefly explaining the rationale of referring to another study.	Text area	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.AdministrationExposure.DetailsOnAnalyticalVerificationOfDosesOrConcentrations
Duration of treatment / exposure	Indicate duration in days, weeks or months, e.g. '104 weeks' or '90 days'.	Multi-line text	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.AdministrationExposure.DurationOfTreatmentExposure
Frequency of treatment	Indicate the frequency of the administration of doses to the test animals (e.g., 'daily, 7 days each week'). Use of non-standard dosing regime (e.g. a five-day per week regime) should be justified.	Multi-line text	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.AdministrationExposure.FrequencyOfTreatment
Doses / concentrations	Indicate the dose or concentration levels applied and the basis of quantity used. Copy this block of fields for each numeric value and to record values on a different		ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMe

	basis, i.e. mg/kg bw/day (nominal), mg/kg bw/day (actual dose received), mg/kg diet ,mg/L drinking water, mg/kg bw (total dose), ppm if applicable. Conversion of the dose / conc. values to the relevant unit used for the effect levels may be required.		thods.AdministrationExposure.DosesConcentrations
Dose / conc.	Enter numeric value.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.DoseConc
Remarks	Enter any remarks related to dose / concentration values.	Multi-line text	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.Remarks
Doses / concentrations			
No. of animals per sex per dose	Enter value or specify according to dose if different number of animals per dose, e.g. '10 in each dose group of main study; 10 f and 5 m in interim sacrifice group'. Also specify number of animals in recovery group if applicable. For robust study summaries or as requested by the regulatory programme, also include a detailed table on the animal assignment in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) if any and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Note: Specific tables may be required.	Multi-line text	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.AdministrationExposure.NoOfAnimalsPerSexPerDose
Control animals	Indicate whether and what type of concurrent control groups were used. Multiple selection is possible. If not listed, select 'other' and specify.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.AdministrationExposure.ControlAnimals
Details on study design	Include any details on the study design including a brief description of the rationale for dose selection (e.g. consideration of known or suspected nonlinearities or inflection points in the dose response, toxicokinetics, precursor lesions, markers of effect, or indicators of the operation of key underlying biological process, key (or suspected) aspects of mode of action, consideration of anticipated human exposure level), animal assignment and selection of satellite groups	Text template	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.AdministrationExposure.DetailsOnStudyDesign

	including the duration of the post-exposure recovery period. As appropriate state study type(s) and briefly describe the results from range-finding or other studies used as basis for dose selection. More comprehensive details may be attached. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.		
Positive control	Indicate if a positive control was used and if necessary indicate purity, Lot/batch No.	Multi-line text	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.AdministrationExposure.PositiveControl
Examinations		Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.Examinations
Observations and examinations performed and frequency	Indicate if and which examinations were performed and the time schedule for those examinations. Also indicate the dose groups that were examined if not all. As appropriate include detailed table(s) in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) if any and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). If other observations (e.g. neurotoxicity, immunotoxicity) are reported in another study summary, include a note in the block 'Cross-reference' and refer to that summary. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.Examinations.ObservationsAndExaminationsPerformedAndFrequency
Sacrifice and pathology	Indicate if and which examinations were performed. Also indicate the dose groups that were examined if not all. Note if not all collected tissues were examined. As appropriate include detailed table(s) in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) if any and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.Examinations.SacrificeAndPathology
Optional endpoint(s)	Describe any other optional endpoint(s).	Text template	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMe

			thods.Examinations.OptionalEndpointS
Other examinations	Describe any other examinations.	Text area	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityOral.MaterialsAndMethods.Examinations.OtherExaminations
Statistics	List parameters that were analysed and the statistical methods used; include a statement that the Reviewer considers the analyses used to be appropriate. If inappropriate, provide alternative/rationale.	Multi-line text	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityOral.MaterialsAndMethods.Examinations.Statistics
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityOral.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityOral.ResultsAndDiscussion
Results of examinations	Results of examinations (OHT: Repeated dose toxicity: oral) – common block	Header 2	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityOral.ResultsAndDiscussion.ResultsOfExaminations
Effect levels	Effect levels (OHT 67-69, 72-74) – common block Dose descriptor: Select the relevant dose descriptor, i.e. the exposure level that corresponds to a quantified level of effects, e.g. NOAEL or LOAEL. If a benchmark dose / concentration was calculated, select appropriate BMD indicator (e.g. 'BMD05' or 'BMD:' and specify in the related text field). If the critical effects at a specific dose or concentration level are reported only, select 'dose. level:' or 'conc. level:' and specify. Where no value could be achieved based on the method and boundaries used, the upper or lower dose level for the relevant dose descriptor can be reported as appropriate with relevant qualifier, e.g. NOAEL >200 mg/kg bw/day or NOAEL <200 mg/kg bw/day. An additional explanation may be given in field 'Remarks on result', e.g. 'not determinable due to absence of adverse toxic effects'.	Header 2	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityOral.ResultsAndDiscussion.EffectLevels
Target system / organ toxicity	Target system (OHT RepDoseTox etc.) - Target system BLOCK -OHT 67-69- 72- 73- 76- 77- common block	Header 2	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityOral.ResultsAndDisc

	Dose response relationship: Flag to indicate if the effects observed and reported in systems and/or organs are in a dose-response manner (monotonic or non-monotonic).		ussion.TargetSystemOrg anToxicity
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxi cityOral.ResultsAndDisc ussion.AnyOtherInforma tionOnResultsIncITables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxi cityOral.OverallRemarks Attachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxi cityOral.ApplicantSumm aryAndConclusion

5.3.2 Repeated dose toxicity: inhalation– Endpoint study record

Purpose:

Chemical (Active): For volatile active substances (vapour pressure >10⁻² Pascal) expert judgement (for example based on route-specific kinetic data) shall be required to decide whether the short term studies have to be performed by inhalation exposure.

Microorganism (Active): Information on the health effects after repeated inhalatory exposure is considered necessary, particularly for the risk assessment of the occupational setting. Repeated exposure might influence the clearance capacity (e.g. resistance) of the host (human). Furthermore, for proper risk assessment the toxicity after repeated exposure to contaminants, growth medium, co-formulants and the microorganism needs to be addressed. It should be kept in mind that the co-formulants in the plant protection product can influence the toxicity and infectiveness of the active

ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation - v.8.5 (Final)			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.DataSource
Materials and methods	Material and methods – common block Applicable test guideline: Microbial Pesticide Test Guidelines: OPPTS 885.3600 Subchronic Toxicity/Pathogenicity Method B8 Repeated dose (28 days) toxicity (inhalation) (Annex to Regulation (EC) No 440/2008) Method B.29 Sub-chronic inhalation toxicity study 90-day repeated inhalation dose study using rodent species (Annex to Regulation (EC) No 440/2008) OECD Test Guideline 412: Subacute inhalation toxicity: 28-day study OECD Test Guideline 413: Subchronic inhalation toxicity: 90-day study Note that the OECD guidelines (and EC) are applicable to toxins if tested in isolation, while only OPPTS is applicable to the micro-organism.	Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods
Limit test	Indicate if the experiment was a limit test.	Closed list	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.LimitTest

Test material	Test material – common block	Header 2	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.TestMaterials
Test animals	Test animals (OHT: Repeated dose toxicity)	Header 2	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.TestAnimals
Administration / exposure		Header 2	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.AdministrationExposure
Route of administration	Specify the route of administration by indicating in what physical form the test material was administered.	Open list	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.AdministrationExposure.RouteOfAdministration
Type of inhalation exposure	Indicate type of inhalation exposure, e.g. 'nose only'. Any remarks can be entered in the supplementary remarks subfield. In case of intratracheal administration, select other and report this in the 'remarks'	Open list with remarks	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.AdministrationExposure.TypeOfInhalationExposure
Vehicle	Select the vehicle used. If not available from picklist, select 'other' and specify.	Open list with remarks	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.AdministrationExposure.Vehicle
Mass median aerodynamic diameter (MMAD)	Specify the particle size distribution in terms of mass median aerodynamic diameter (MMAD). Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.AdministrationExposure.MassMedianAerodynamicDiameter
Geometric standard deviation (GSD)	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Decimal	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.AdministrationExposure.GeometricStandardDeviation
Remarks on MMAD	Enter any remarks related to the mass median aerodynamic diameter.	Multi-line text	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.AdministrationExposure.RemarksOnMMAD
Details on inhalation	Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant	Text template	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityInhalation.MaterialsAn

n exposure	for evaluating this study summary or that are requested by the respective regulatory programme.		dMethods.AdministrationExposure.DetailsOnInhalationExposure
Analytical verification of doses or concentrations	Indicate whether the doses or concentrations were analytically verified.	Close d list with remarks	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.AdministrationExposure.AnalyticalVerificationOfDosesOrConcentrations
Details on analytical verification of doses or concentrations	For robust study summaries or as requested by the regulatory programme, include a short description on the method of analysis. State whether the analytical data indicated that the difference between nominal and actual concentration was acceptable. If any problems occurred in any of these procedures, then they should be reported in more detail. If this could have affected the veracity or conclusions of the study, discuss this in field 'Rationale for reliability incl. deficiencies'. It may be appropriate to include a cross-reference to another study in which stability analysis was performed and reported. If so, a justification should also be included briefly explaining the rationale of referring to another study.	Text area	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.AdministrationExposure.DetailsOnAnalyticalVerificationOfDosesOrConcentrations
Duration of treatment / exposure	Indicate total duration of exposure in days, weeks or months, e.g. '104 weeks', '90 days' or '28 days'.	Multi- line text	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.AdministrationExposure.DurationOfTreatmentExposure
Frequency of treatment	Indicate the frequency of the administration of doses to the test animals (e.g., '6 hours/day, 7 days/week'). Use of non-standard dosing regime (e.g. a five-day per week regime) should be justified.	Multi- line text	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.AdministrationExposure.FrequencyOfTreatment
Doses / concentrations	Indicate the dose or concentration levels applied and the basis of quantity used. Copy this block of fields for each numeric value and to record values on a different basis, e.g. mg/L air (nominal), mg/L air (analytical), ppm if applicable. Conversion of the dose / conc. values to the relevant unit used for the effect levels may be required.		ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.AdministrationExposure.DosesConcentrations
Dose / conc.	Enter numeric value.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.DoseConc

Remarks	Enter any remarks related to dose / concentration values.	Multi-line text	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.Remarks
Doses / concentrations			
No. of animals per sex per dose	Enter value or specify according to test group if different number of animals per group, e.g. '10 in each test group of main study; 10 f and 5 m in interim sacrifice group'. Also specify number of animals in recovery group if applicable. For robust study summaries or as requested by the regulatory programme, also include a detailed table on the animal assignment in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Note: Specific tables may be required.	Multi-line text	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.AdministrationExposure.NoOfAnimalsPerSexPerDose
Control animals	Indicate whether and what type of concurrent control groups were used. Multiple selection is possible. If not listed, select 'other' and specify.	Multi select open list with remarks	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.AdministrationExposure.ControlAnimals
Details on study design	Include any details on the study design including a brief description of the rationale for dose selection, animal assignment and selection of satellite groups including the duration of the post-exposure recovery period. As appropriate state study type(s) and briefly describe the results from range-finding or other studies used as basis for dose selection. More comprehensive details may be attached. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.AdministrationExposure.DetailsOnStudyDesign
Positive control	Indicate if a positive control was used and if necessary indicate purity, Lot/batch No.	Multi-line text	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.AdministrationExposure.PositiveControl
Examinations		Header 2	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.Examinations

Observations and examinations performed and frequency	Indicate if and which examinations were performed and the time schedule for those examinations. Also indicate the dose groups that were examined if not all. As appropriate include detailed table(s) in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) if any and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). If other observations (e.g. neurotoxicity, immunotoxicity) are reported in another study summary, include a note in the block 'Cross-reference' and refer to that summary. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.Examinations.ObservationsAndExaminationsPerformedAndFrequency
Sacrifice and pathology	Indicate if and which examinations were performed. Also indicate the dose groups that were examined if not all. Note if not all collected tissues were examined. As appropriate include detailed table(s) in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.Examinations.SacrificeAndPathology
Other examinations	Describe any other examinations.	Text area	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.Examinations.OtherExaminations
Statistics	List parameters that were analysed and the statistical methods used; include a statement that the Reviewer considers the analyses used to be appropriate. If inappropriate, provide alternative/rationale.	Multi-line text	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.Examinations.Statistics
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block For microorganisms, a verification that each enumeration method is sufficiently sensitive to serve as a useful quantitative assay for the micro-organism in tissues, organs, and body fluids should be reported	Header 2	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and		Header 1	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxic

discussion			ityInhalation.ResultsAndDiscussion
Results of examinations	Results of examinations BLOCK (OHT: Repeated dose toxicity: oral) Details on results: For microorganisms, signs of infection and/or pathogenicity should be reported, as well as microbial enumeration from tissues, organs and body fluids (at different time points) to address infectivity and clearance estimate.	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.ResultsAndDiscussion.ResultsOfExaminations
Effect levels	Dose descriptor: Select the relevant dose descriptor, i.e. the exposure level that corresponds to a quantified level of effects, e.g. NOAEL or LOAEL. If a benchmark dose / concentration was calculated, select appropriate BMD indicator (e.g. 'BMD05' or 'BMD:' and specify in the related text field). If the critical effects at a specific dose or concentration level are reported only, select 'dose. level:' or 'conc. level:' and specify. Where no value could be achieved based on the method and boundaries used, the upper or lower dose level for the relevant dose descriptor can be reported as appropriate with relevant qualifier, e.g. NOAEL >200 mg/kg bw/day or NOAEL <200 mg/kg bw/day. An additional explanation may be given in field 'Remarks on result', e.g. 'not determinable due to absence of adverse toxic effects'.	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.ResultsAndDiscussion.EffectLevels
Target system / organ toxicity	Target system BLOCK (OHT RepDoseTox etc.) Dose response relationship: Flag to indicate if the effects observed and reported in systems and/or organs are in a dose-response manner (monotonic or non-monotonic).	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.ResultsAndDiscussion.TargetSystemOrganToxicity
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.ApplicantSummaryAndConclusion

5.3.3 Repeated dose toxicity: dermal– Endpoint study record

Optional: There is no data requirement for this endpoint, however the endpoint summary record presented below can be used if studies of this type are used to support the risk assessment

Purpose:

Chemical (Active): For human risk assessment additional dermal studies shall be considered on a case by case basis, unless the active substance is a severe irritant.

Microorganism: There is no data requirement for this endpoint, however the endpoint study record presented below can be used if studies of this type are used to support the risk assessment

ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal - v.7.5 (Final)			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.DataSource
Materials and methods	Material and methods – common block Applicable test guideline: OECD 411 (90 d) OECD 410 (28 d) Method B.9 Repeated dose (28 days) Method B.28 Sub-chronic dermal toxicity test: 90-day. Limit test: Indicate if the experiment was a limit test.	Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.MaterialsAndMethods
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.TestMaterials
Test animals	Test animals (OHT: Repeated dose toxicity)	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.TestAnimals
Administration / exposure		Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.AdministrationExposure
Type of coverage	Select type of coverage used. For robust study summaries or as requested by the regulatory programme, specify the area of application in field 'Details on dermal exposure'.	Open list	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.MaterialsAndMe

			thods.AdministrationExposure.TypeOfCoverage
Vehicle	Select 'unchanged (no vehicle)' if none was used or select vehicle used if any. If not available from picklist, select 'other' and specify. Further information can be given in the supplementary remarks field. Note that some of the vehicles provided in this list are used for specific routes of administration only.	Open list with remarks	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.AdministrationExposure.Vehicle
Details on exposure	Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.AdministrationExposure.DetailsOnExposure
Analytical verification of doses or concentrations	Indicate whether the doses or concentrations were analytically verified.	Closed list with remarks	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.AdministrationExposure.AnalyticalVerificationOfDosesOrConcentrations
Details on analytical verification of doses or concentrations	For robust study summaries or as requested by the regulatory programme, include a short description on the method of analysis. State whether the analytical data indicated that the variance between nominal and actual dosage (if diet is route of administration) or concentrations (for drinking water study) was acceptable. If diet is the route of administration, briefly record when and at what dose levels the dosage analyses were made and include the results (range of values) of (i) Homogeneity analysis, (ii) Stability analysis and (iii) Concentration analysis. If any problems occurred in any of these procedures, then they should be reported in more detail. If this could have affected the veracity or conclusions of the study, discuss this in field 'Rationale for reliability incl. deficiencies'. It may be appropriate to include a cross-reference to another study in which stability analysis was performed and reported. If so, a justification should also be included briefly explaining the rationale of referring to another study.	Text area	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.AdministrationExposure.DetailsOnAnalyticalVerificationOfDosesOrConcentrations
Duration of treatment / exposure	Indicate duration in days, weeks or months, e.g. '104 weeks' or '90 days'.	Multi-line text	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.AdministrationExposure.DurationOfTreatmentExposure

Frequency of treatment	Indicate the frequency of the administration of doses to the test animals (e.g., 'daily, 7 days each week'). Use of non-standard dosing regime (e.g. a five-day per week regime) should be justified.	Multi-line text	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.AdministrationExposure.FrequencyOfTreatment
Doses / concentrations	Indicate the dose or concentration levels applied and the basis of quantity used. Copy this block of fields for each numeric value and to record values on a different basis, i.e. mg/kg bw/day (nominal), mg/kg bw/day (actual dose received), mg/kg diet ,mg/L drinking water, mg/kg bw (total dose), ppm if applicable. Conversion of the dose / conc. values to the relevant unit used for the effect levels may be required.		ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.AdministrationExposure.DosesConcentrations
Dose / conc.	Enter numeric value.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.DoseConc
Remarks	Enter any remarks related to dose / concentration values.	Multi-line text	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.Remarks
Doses / concentrations			
No. of animals per sex per dose	Enter value or specify according to dose if different number of animals per dose, e.g. '10 in each dose group of main study; 10 f and 5 m in interim sacrifice group'. Also specify number of animals in recovery group if applicable. For robust study summaries or as requested by the regulatory programme, also include a detailed table on the animal assignment in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Note: Specific tables may be required.	Multi-line text	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.AdministrationExposure.NoOfAnimalsPerSexPerDose
Control animals	Indicate whether and what type of concurrent control groups were used. Multiple selection is possible. If not listed, select 'other' and specify.	Multi select open list with	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.AdministrationExposure.ControlAnimals

		remarks	
Details on study design	<p>Include any details on the study design including a brief description of the rationale for dose selection, animal assignment and selection of satellite groups including the duration of the post-exposure recovery period. As appropriate state study type(s) and briefly describe the results from range-finding or other studies used as basis for dose selection. More comprehensive details may be attached.</p> <p>Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.</p>	Text template	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.AdministrationExposure.DetailsOnStudyDesign
Positive control	Indicate if a positive control was used and if necessary indicate purity, Lot/batch No.	Multi-line text	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.AdministrationExposure.PositiveControl
Examinations		Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.Examinations
Observations and examinations performed and frequency	<p>Indicate if and which examinations were performed and the time schedule for those examinations. Also indicate the dose groups that were examined if not all. As appropriate include detailed table(s) in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1').</p> <p>If other observations (e.g. neurotoxicity, immunotoxicity) are reported in another study summary, include a note in the block 'Cross-reference' and refer to that summary.</p> <p>Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.</p>	Text template	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.Examinations.ObservationsAndExaminationsPerformedAndFrequency
Sacrifice and pathology	Indicate if and which examinations were performed. Also indicate the dose groups that were examined if not all. Note if not all collected tissues were examined. As appropriate include detailed table(s) in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence	Text template	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.Examinations.SacrificeAndPathology

	<p>in which you refer to them in the Remarks text (e.g. '... see Table 1').</p> <p>Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.</p>		
Other examinations	Describe any other examinations.	Text area	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.Examinations.OtherExaminations
Statistics	List parameters that were analysed and the statistical methods used; include a statement that the Reviewer considers the analyses used to be appropriate. If inappropriate, provide alternative/rationale.	Multi-line text	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.Examinations.Statistics
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.ResultsAndDiscussion
Results of examinations	<p>Results of examinations BLOCK (OHT: Repeated dose toxicity: oral)</p> <p>Body weight and weight changes: The effects should be also considered in relation to organ weights.</p> <p>Details on results: For micro-organisms, microbial enumeration in tissues, organs and body fluids (at different time points), and methods uses, and sensitivities and limits of detection (to address infectivity and clearance estimate) should be determined and reported.</p>	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.ResultsAndDiscussion.ResultsOfExaminations
Effect levels	<p>Effect levels BLOCK (OHT 67-69, 72-74)</p> <p>Record the available effect levels for NO(A)EL(s), LO(A)EL(s) and other relevant dose descriptors.</p> <p>Copy this block of fields for entering different effect levels, based on different endpoints and/or separated for each sex.</p> <p>Dose descriptor: Select the relevant dose descriptor, i.e. the exposure level that corresponds to a quantified level of effects, e.g. NOAEL or LOAEL. If a benchmark dose / concentration was calculated, select appropriate BMD indicator (e.g. 'BMD05' or 'BMD:' and</p>	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.ResultsAndDiscussion.EffectLevels

	<p>specify in the related text field). If the critical effects at a specific dose or concentration level are reported only, select 'dose. level:' or 'conc. level:' and specify.</p> <p>Where no value could be achieved based on the method and boundaries used, the upper or lower dose level for the relevant dose descriptor can be reported as appropriate with relevant qualifier, e.g. NOAEL >200 mg/kg bw/day or NOAEL <200 mg/kg bw/day. An additional explanation may be given in field 'Remarks on result', e.g. 'not determinable due to absence of adverse toxic effects'.</p>		
Remarks on result	<p>This field can be used for:</p> <ul style="list-style-type: none"> - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:' 	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.ResultsAndDiscussion.EffectLevels.Efflevel.RemarksOnResults
Target system / organ toxicity	<p>Target system BLOCK (OHT RepDoseTox etc.)</p> <p>Dose response relationship: Flag to indicate if the effects observed and reported in systems and/or organs are in a dose-response manner (monotonic or non-monotonic).</p>	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.ResultsAndDiscussion.TargetSystemOrganToxicity
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.ApplicantSummaryAndConclusion

5.3.4 Repeated dose toxicity: other routes– Endpoint study record

Purpose:

For human risk assessment additional dermal studies shall be considered on a case by case basis, unless the active substance is a severe irritant.

For volatile active substances (vapour pressure >10–2 Pascal) expert judgement (for example based on route-specific kinetic data) shall be required to decide whether the short term studies have to be performed by inhalation exposure.

ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther - v.7.4 (Final)			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.DataSource
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.MaterialsAndMethods
Limit test	Indicate if the experiment was a limit test.	Closed list	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.MaterialsAndMethods.LimitTest
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.MaterialsAndMethods.TestMaterials
Test animals	Test animals (OHT: Repeated dose toxicity) – common block	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.MaterialsAndMethods.TestAnimals
Administration / exposure		Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.MaterialsAndMethods.AdministrationExposure
Route of administration	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.MaterialsAndMethods.AdministrationExposure.RouteOfAdministration
Vehicle	Select 'unchanged (no vehicle)' if none was used or select vehicle used if any. If not available from	Open list	ENDPOINT_STUDY_RECORD.RepeatedDoseToxic

	picklist, select 'other' and specify. Further information can be given in the supplementary remarks field. Note that some of the vehicles provided in this list are used for specific routes of administration only.	with remarks	ityOther.MaterialsAndMethods.AdministrationExposure.Vehicle
Details on exposure	Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text area	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.MaterialsAndMethods.AdministrationExposure.DetailsOnExposure
Analytical verification of doses or concentrations	Indicate whether the doses or concentrations were analytically verified.	Closed list with remarks	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.MaterialsAndMethods.AdministrationExposure.AnalyticalVerificationOfDosesOrConcentrations
Duration of treatment / exposure	Indicate total duration of exposure in days, weeks or months, e.g. '104 weeks' or '90 days'.	Multi-line text	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.MaterialsAndMethods.AdministrationExposure.DurationOfTreatmentExposure
Frequency of treatment	Indicate the frequency of the administration of doses to the test animals (e.g., '8 hours/day, 7 days/week'). Use of non-standard dosing regime (e.g. a five-day per week regime) should be justified.	Multi-line text	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.MaterialsAndMethods.AdministrationExposure.FrequencyOfTreatment
Doses / concentrations	Indicate the dose or concentration levels applied and the basis of quantity used. Copy this block of fields for each numeric value and to record values on a different basis, i.e. mg/kg bw/day (nominal), mg/kg bw/day (actual dose received), mg/kg diet ,mg/L drinking water, mg/kg bw (total dose), ppm if applicable. Conversion of the dose / conc. values to the relevant unit used for the effect levels may be required.		ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.MaterialsAndMethods.AdministrationExposure.DosesConcentrations
Dose / conc.	Enter numeric value.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.DoseConc
Remarks	Enter any remarks related to dose / concentration values.	Multi-line text	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.Remarks

Doses / concentrations			
No. of animals per sex per dose	<p>Enter value or specify according to test group if different number of animals per group, e.g. '10 in each test group of main study; 10 f and 5 m in interim sacrifice group'. Also specify number of animals in recovery group if applicable.</p> <p>For robust study summaries or as requested by the regulatory programme, also include a detailed table on the animal assignment in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1').</p> <p>Note: Specific tables may be required.</p>	Multi-line text	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityOther.MaterialsAndMethods.AdministrationExposure.NoOfAnimalsPerSexPerDose
Control animals	<p>Indicate whether and what type of concurrent control groups were used. Multiple selection is possible. If not listed, select 'other' and specify.</p>	Multi select open list with remarks	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityOther.MaterialsAndMethods.AdministrationExposure.ControlAnimals
Details on study design	<p>Include any details on the study design including a brief description of the rationale for dose selection, animal assignment and selection of satellite groups including the duration of the post-exposure recovery period. As appropriate state study type(s) and briefly describe the results from range-finding or other studies used as basis for dose selection. More comprehensive details may be attached.</p> <p>Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.</p>	Text template	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityOther.MaterialsAndMethods.AdministrationExposure.DetailsOnStudyDesign
Examinations		Header 2	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityOther.MaterialsAndMethods.Examinations
Observations and examinations performed and frequency	<p>Indicate if and which examinations were performed and the time schedule for those examinations. Also indicate the dose groups that were examined if not all. As appropriate include detailed table(s) in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1').</p> <p>If other observations (e.g. neurotoxicity, immunotoxicity) are reported in another study summary, include a note in the block 'Cross-reference'</p>	Text template	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityOther.MaterialsAndMethods.Examinations.ObservationsAndExaminationsPerformedAndFrequency

	and refer to that summary. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.		
Sacrifice and pathology	Indicate if and which examinations were performed. Also indicate the dose groups that were examined if not all. Note if not all collected tissues were examined. As appropriate include detailed table(s) in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityOther.MaterialsAndMethods.Examinations.SacrificeAndPathology
Other examinations	Describe any other examinations.	Text area	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityOther.MaterialsAndMethods.Examinations.OtherExaminations
Statistics	List parameters that were analysed and the statistical methods used; include a statement that the Reviewer considers the analyses used to be appropriate. If inappropriate, provide alternative/rationale.	Multi-line text	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityOther.MaterialsAndMethods.Examinations.Statistics
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityOther.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityOther.ResultsAndDiscussion
Results of examinations	Results of examinations (OHT: Repeated dose toxicity: oral) – common block	Header 2	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityOther.ResultsAndDiscussion.ResultsOfExaminations
Effect levels	Effect levels (OHT 67-69, 72-74) – common block Dose descriptor: Select the relevant dose descriptor, i.e. the exposure level that corresponds to a quantified level of effects, e.g. NOAEL or LOAEL. If a benchmark dose / concentration was calculated, select appropriate BMD indicator (e.g. 'BMD05' or	Header 2	ENDPOINT_STUDY_REC ORD.RepeatedDoseToxicityOther.ResultsAndDiscussion.EffectLevels

	<p>'BMD:' and specify in the related text field). If the critical effects at a specific dose or concentration level are reported only, select 'dose. level:' or 'conc. level:' and specify.</p> <p>Where no value could be achieved based on the method and boundaries used, the upper or lower dose level for the relevant dose descriptor can be reported as appropriate with relevant qualifier, e.g. NOAEL >200 mg/kg bw/day or NOAEL <200 mg/kg bw/day. An additional explanation may be given in field 'Remarks on result', e.g. 'not determinable due to absence of adverse toxic effects'.</p>		
Target system / organ toxicity	<p>Target system (OHT RepDoseTox etc.) - Target system BLOCK -OHT 67-69- 72- 73- 76- 77- common block</p> <p>Record the target system(s) where toxicity was observed that is considered of biological relevance and the specific target organ(s). Copy this block of fields for referring to different target systems, lowest effective dose(s) / concentration(s) and/or treatment relationship, dose response relationship and relevance for humans.</p>	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.ResultsAndDiscussion.TargetSystemOrganToxicity
Critical effects observed	Flag to indicate if critical effects were observed in the study within specific organs or systems.	Closed list	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.ResultsAndDiscussion.TargetSystemOrganToxicity.TargetSystemOrganToxicity.CriticalEffectsObserved
Lowest effective dose / conc.	Enter a numeric value and select the unit in the next field for indicating the lowest dose / concentration with significant and/or severe toxic effects on the target organ(s) affected.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.ResultsAndDiscussion.TargetSystemOrganToxicity.TargetSystemOrganToxicity.LowestEffectiveDoseConc
System	Select any specific system where toxicity was observed that is considered of biological relevance.	Open list	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.ResultsAndDiscussion.TargetSystemOrganToxicity.TargetSystemOrganToxicity.System
Organ	Select from the multiple drop-down list the target organ(s) where toxicity was observed. This field provides context-related picklist values depending on the selection made in the preceding field 'System'.	Multi select open list	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.ResultsAndDiscussion.TargetSystemOrganToxicity.TargetSystemOrganToxicity.Organ

Treatment related	Flag to indicate if the effects in systems and/or organs are treatment related.	Closed list	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.ResultsAndDiscussion.TargetSystemOrganToxicity.TargetSystemOrganToxicity.TreatmentRelated
Dose response relationship	Flag to indicate if the effects observed and reported in systems and/or organs are in a dose-response manner.	Closed list	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.ResultsAndDiscussion.TargetSystemOrganToxicity.TargetSystemOrganToxicity.DoseResponseRelationship
Relevant for humans	Flag to indicate if the effects observed and reported in systems and/or organs on the basis of animal experiments are also relevant for humans. Choose "no" from the picklist if the effects in target system/organ are species specific and not relevant for humans.	Closed list	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.ResultsAndDiscussion.TargetSystemOrganToxicity.TargetSystemOrganToxicity.RelevantForHumans
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.ApplicantSummaryAndConclusion

5.4 Genotoxicity testing – Endpoint Summary

Purpose:

Chemical and Microorganism: State the available in vitro and in vivo studies and the results, as well the overall genotoxic potential. State the photomutagenicity potential, if required.

In the case of metabolites, it is recommended to complete datasets under section 1.4. Where available information on genotoxicity can come from additional sources such as QSAR and read-across there is the need to summarize and integrate all available evidence for genotoxicity in a summary table. For that purpose a template has been created. See IUCLID templates for PPP Risk Assessment - Template 5.3 - Template Summary table integrating experimental evidence on genotoxicity for metabolites. [http://doi.org/10.5281/zenodo.4557333].

The document should contain the information needed to be reported according to the list of end points for genotoxicity (SANCO/12592/2012-rev. 2, 22 March 2019).

Genotoxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.4)

Microorganism: Test on toxins and relevant metabolites shall be performed using the purified chemical, if possible. Studies on the microorganism itself shall be considered depending on expert judgement.

ENDPOINT_SUMMARY.GeneticToxicity - v.5.0 (Final)			
Name	Instructions	Type	Field Path
Administrative data	Administrative data summary – common block Description of key information: Provide a brief description of the genotoxicity studies and effects.	Header 1	ENDPOINT_SUMMARY.GeneticToxicity.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.GeneticToxicity.KeyValueForChemicalSafetyAssessment
Genetic toxicity in vitro		Header 2	ENDPOINT_SUMMARY.GeneticToxicity.KeyValueForChemicalSafetyAssessment.GeneticToxicityInVitro
Link to relevant study records	Endpoint summary block for relevant study record The following factors, among others, should be taken into account when the robust study summary is selected: quality of the study (e.g. Klimisch score), duration of the study,	Header 3	ENDPOINT_SUMMARY.GeneticToxicity.KeyValueForChemicalSafetyAssessment.GeneticToxicityInVitro.LinkToRelevantStudyRecords

	whether or not the study is GLP. Available epidemiological data are preferred provided that they are reliable and relevant.		
Endpoint conclusion		Header 3	ENDPOINT_SUMMARY.GeneticToxicity.KeyValueForChemicalSafetyAssessment.GeneticToxicityInVitro.EndpointConclusion
Endpoint conclusion	"Adverse effect observed (positive)" should be chosen if the outcome of the study was positive. "No adverse effect observed (negative)" should be chosen if the outcome of the study was negative. If "No study available" is chosen, a justification needs to be provided.	Closed list	ENDPOINT_SUMMARY.GeneticToxicity.KeyValueForChemicalSafetyAssessment.GeneticToxicityInVitro.EndpointConclusion.EndpointConclusion
Genetic toxicity in vivo		Header 2	ENDPOINT_SUMMARY.GeneticToxicity.KeyValueForChemicalSafetyAssessment.GeneticToxicityInVivo
Description of key information	Report Information to support the genetic toxicity in vivo.	Header 3	ENDPOINT_SUMMARY.GeneticToxicity.KeyValueForChemicalSafetyAssessment.GeneticToxicityInVivo.DescriptionOfKeyInformation
		Rich text area	ENDPOINT_SUMMARY.GeneticToxicity.KeyValueForChemicalSafetyAssessment.GeneticToxicityInVivo.DescriptionOfKeyInformation.KeyInfo
Link to relevant study records	Endpoint summary block for relevant study record The following factors, among others, should be taken into account when the robust study summary is selected: quality of the study (e.g. Klimisch score),	Header 3	ENDPOINT_SUMMARY.GeneticToxicity.KeyValueForChemicalSafetyAssessment.GeneticToxicityInVivo.LinkToRelevantStudyRecords

	duration of the study, whether or not the study is GLP. Available epidemiological data are preferred provided that they are reliable and relevant.		
Endpoint conclusion		Header 3	ENDPOINT_SUMMARY. GeneticToxicity.KeyValueForChemicalSafetyAssessment.GeneticToxicityInVivo.EndpointConclusion
Endpoint conclusion	"Adverse effect observed (positive)" should be chosen if the outcome of the study was positive. "No adverse effect observed (negative)" should be chosen if the outcome of the study was negative. If "No study available" is chosen, a justification needs to be provided. If the dossier contains a testing proposal for genetic toxicity in vivo, "No study available (further information necessary)" should be chosen.	Closed list	ENDPOINT_SUMMARY. GeneticToxicity.KeyValueForChemicalSafetyAssessment.GeneticToxicityInVivo.EndpointConclusion.EndpointConclusion
Mode of Action Analysis / Human Relevance Framework		Header 2	ENDPOINT_SUMMARY. GeneticToxicity.KeyValueForChemicalSafetyAssessment.MoAHumanRelevanceFramework
	This section is for incorporation of the WHO/IPCS Template Mode of Action Analysis / Human relevance framework at http://echa.europa.eu/web/guest/support/guidance-on-reach-and-clp-implementation/formats . The template is also available in HTML format that can be	Rich text area	ENDPOINT_SUMMARY. GeneticToxicity.KeyValueForChemicalSafetyAssessment.MoAHumanRelevanceFramework.MoA HumanRelevanceFramework

	easily uploaded in this text area where relevant		
Additional information	<p>Discussion (Header 1) – common block</p> <p>Provide additional information related to the endpoint, for example:</p> <ul style="list-style-type: none"> - In vitro studies (state the available in vitro studies and the results), - In vivo studies (state the available in vivo studies and the results) <p>Provide an statement on the photomutagenicity potential: e.g.</p> <ul style="list-style-type: none"> -Not required -Unlikely to be photomutagenic <p>Attached background material: Provide the original version of any document that contains confidential material. For metabolites, please attach the summary table integrating available evidence for genotoxicity on metabolites. See IUCLID templates for PPP Risk Assessment or PPP IUCLID Templates - Template 5.3. Summary table integrating experimental evidence on genotoxicity for metabolites. [http://doi.org/10.5281/zenodo.4557353]</p>	Header 1	ENDPOINT_SUMMARY. GeneticToxicity.Discussion
Justification for classification or non-classification		Header 1	ENDPOINT_SUMMARY. GeneticToxicity.JustificationForClassificationOrNonClassification

	The available information should be compared against the classification criteria and the reasons for fulfilling or not fulfilling the classification criteria should be presented.	Rich text area	ENDPOINT_SUMMARY. GeneticToxicity. JustificationForClassificationOrNonClassification. Remarks
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5.4.1 In vitro studies – Endpoint study record

Purpose:

Chemical (Active): The following in vitro mutagenicity tests shall be performed: bacterial assay for gene mutation, combined test for structural and numerical chromosome aberrations in mammalian cells and test for gene mutation in mammalian cells. However, if gene mutation and clastogenicity/aneuploidy are detected in a battery of tests consisting of Ames and in vitro micronucleus (IVM), no further in vitro testing needs to be conducted. If there are indications of micronucleus formation in an in vitro micronucleus assay further testing with appropriate staining procedures shall be conducted to clarify if there is an aneugenic or clastogenic response. Further investigation of the aneugenic response may be considered to determine whether there is sufficient evidence for a threshold mechanism and threshold concentration for the aneugenic response (particularly for non-disjunction). Active substances which display highly bacteriostatic properties as demonstrated in a range finding test shall be tested in two different in vitro mammalian cell tests for gene mutation. Non performance of the Ames test shall be justified. For active substances bearing structural alerts that have given negative results in the standard test battery, additional testing may be required if the standard tests have not been optimised for these alerts. The choice of additional study or study plan modifications depends on the chemical nature, the known reactivity and the metabolism data on the structurally alerting active substance.

Microorganism (Active): If the microorganism produces secondary metabolites/toxins, then these compounds and any other relevant metabolites in the culture medium must also be tested for genotoxicity. Such tests shall be performed using the purified chemical if possible.

If basic studies do not indicate that toxic metabolites are formed, studies on the microorganism itself shall be considered depending on expert judgement on the relevance and validity of the basic data. In the case of a virus the risk of insertional mutagenesis in mammal cells or the risk of carcinogenicity has to be discussed.

ENDPOINT_STUDY_RECORD.GeneticToxicityVitro - v.9.5 (Final)			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.DataSource
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods

	Applicable test guideline: Method B.13/14 Mutagenicity - reverse mutation test using bacteria Method B.10 Mutagenicity - In vitro mammalian chromosome aberration test Method B.17 – Mutagenicity – In vitro mammalian cell gene mutation test OECD 471 OECD 473 OECD 476 OECD 487		
Type of assay	As appropriate supplement the information provided in field 'Endpoint' and indicate the type of assay used.	Open list	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.TypeOfAssay
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.TestMaterials
Method		Header 2	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method
Target gene	Indicate the target gene (HPRT, XPRT, TK, ATPase, other: specify) only if necessary to characterise the test system.	Multi-line text	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.TargetGene
Species / strain	Indicate the species and tester strain(s) used in the type of study indicated in the respective field above. Copy this field block for each tester strain.		ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.SpeciesStrain
Species / strain / cell type	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list with remarks	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.SpeciesStrain.SpeciesStrain
Details on mammalian cell type (if applicable)	For robust study summaries, describe relevant details on cell cultures if applicable. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.SpeciesStrain.DetailsOnMammalianCellLinesIfApplicable
Additional strain / cell type characteristics	For robust study summaries, indicate additional strain characteristics (e.g. 'DNA-Polymerase-A-deficient') only if necessary to characterise the test system. Otherwise, leave this subfield empty.	Open list with remarks	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.SpeciesStrain.AdditionalStrainCharacteristics
Species / strain			

Cytokinesis block (if used)	If a cytokinesis blocking substance (e.g. cytoB) was used, indicate its identity and its concentration and duration of cell exposure.	Multi-line text	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.CytokinesisBlockIfUsed
Metabolic activation	Indicate whether metabolic activation was applied or not. Select 'not applicable' for mammalian cell lines when no exogenous metabolic system is required.	Closed list	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.MetabolicActivation
Metabolic activation system	For robust study summaries, specify metabolic activation system, if any. Indicate the type and composition of and acceptability criteria for the metabolic activation system used. Alternatively or in addition refer to appropriate table(s), which can be uploaded in the rich text field "Any other information on materials and methods incl. tables". Use predefined table or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Note: Specific tables may be required.	Text template	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.MetabolicActivationSystem
Test concentrations with justification for top dose	Indicate the test concentrations without and with metabolic activation, and for the different treatment harvest schedules. For robust study summaries or as requested by the regulatory programme, include a justification for the maximum dose level used, for instance if maximum recommended concentration for the test, limited by solubility (in solvent and/or culture medium, and presence of precipitates) or cytotoxicity indicating the parameter measured and the targeted level of cytotoxicity, and a detailed table in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) if any. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Note: Specific tables may be required.	Multi-line text	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.TestConcentrationsWithJustificationForTopDose
Vehicle / solvent	Indicate whether and which vehicle(s)/solvent(s) was/were used or state 'none' or 'no data' as applicable. Indicate if different vehicle/ solvent were used for tests with and without metabolic activation. Provide the percentage or volume of vehicle/solvent in the medium (e.g. 'DMSO (1% or 0.1 ml per 10 ml medium') and a justification for the choice of solvent/vehicle. Also indicate whether vehicle (or negative)	Text template	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.Vehicle

	controls (i.e. consisting of culture medium or medium with solvent or vehicle alone) were tested for their compatibility with the test chemical, test system and their lack of genetic toxicity at the concentrations used. Use freetext template and delete/add elements as appropriate. Note that the list of substances provided is not exhaustive.		
Controls	Indicate whether vehicle, true negative and/or positive controls were tested. Repeat this block of fields as necessary, particularly if controls or different substances were used for tests with and without metabolic activation or cytokinesis block. If necessary, indicate so in the supplementary remarks field or in subfield 'Remarks'.		ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.Controls
Untreated negative controls	Indicate whether untreated negative controls (i.e. consisting of culture medium without solvent / vehicle or test substance, and otherwise treated in the same way as the treatment groups) were tested for their compatibility with the test chemical, test system and their lack of genetic toxicity at the concentrations used . Any explanations can be given in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.Controls.NegativeControls
Negative solvent / vehicle controls	Indicate whether solvent / vehicle controls (i.e. consisting of solvent or vehicle alone, without test substance, and otherwise treated in the same way as the treatment groups) were tested. Any explanations can be given in the supplementary remarks field. In particular, indicate the concentration (and/or volume) of vehicle added.	Open list with remarks	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.Controls.SolventControls
True negative controls	Indicate whether true negative control(s) (i.e. substances with known lack of genotoxicity) was/were tested and specify the substance(s) and concentration (and/or volume) in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.Controls.TrueNegativeControls
Positive controls	Indicate whether positive controls (i.e. substances with known genotoxicity) were tested. If so, indicate what substance(s) was/were used as positive control(s) in field "Positive control substance".	Open list with remarks	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.Controls.PositiveControls
Positive control substance	If applicable, indicate which substance(s) was/were used as positive control(s). Multiple items can be selected. If different substances were used for tests with and without metabolic activation or for different tester strains or for the different treatment harvest schedules, include a remark in subfield 'Remarks'.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.Controls.PositiveControlSubstance

	If other than the reference substance(s) specified in the test guidelines was/were used, include a brief justification. Final concentration, conditions and durations of treatment and recovery periods. Note that the list of substances provided is not exhaustive.		
Remarks	Enter any remarks related to the recorded controls as appropriate.	Text	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.Controls.Remarks
Controls			
Details on test system and experimental conditions	Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.DetailsOnTestSystemAndConditions
Rationale for test conditions	Provide the rationale for selection of concentrations and number of cultures, including cytotoxicity data and solubility limitations, if available.	Multi-line text	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.RationaleForTestConditions
Evaluation criteria	Describe the evaluation criteria used in the study to judge if a substance is positive, negative or equivocal.	Multi-line text	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.EvaluationCriteria
Statistics	List parameters that were analysed and the statistical methods used; include a statement on the appropriateness of the statistical analyses used. If inappropriate, provide alternative/rationale.	Multi-line text	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.Statistics
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.ResultsAndDiscussion
Test results	Include the main test results in this block of fields for each tester strain and metabolic activation system used. Multiply this block of fields as often as required. (Note: If only one strain was tested, subfield 'Species/strain' may be left empty.) In case of a robust study summary or as requested by the regulatory programme, also		ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.ResultsAndDiscussion.TestRs

	provide the relevant raw data including statistical analysis and p-values if any, in field 'Additional information on results' and/or refer to detailed tables on the genotoxicity and cytotoxicity results, which can be uploaded in the rich text field 'Any other information on results incl. tables'. Use table numbers in the sequence in which you refer to them (e.g. '... see Table 1'). For instance, results for each strain \pm metabolic activation (e.g. S9 mix) in an Ames test should be tabulated.		
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.ResultsAndDiscussion.TestRs.KeyResult
Species / strain	Indicate the species/strain or cell type tested. Multiply this block of fields for each tester strain.	Open list with remarks	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.ResultsAndDiscussion.TestRs.Organism
Metabolic activation	Indicate whether metabolic activation was applied or not.	Closed list	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.ResultsAndDiscussion.TestRs.MetActivationIndicator
Genotoxicity	Indicate result of the test conducted with the tester strain(s), or cell types and the metabolic activation system specified. If positive or equivocal, include concentration(s) in the supplementary remarks field or representative table. Upload predefined or other appropriate table(s) if any in the rich text field 'Any other information on results incl. tables' and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Note: Specific tables may be required.	Open list with remarks	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.ResultsAndDiscussion.TestRs.Genotoxicity
Cytotoxicity / choice of top concentrations	Indicate whether cytotoxicity was observed. If yes, specify the respective test concentration(s) in the supplementary remarks field and provide details on the cytotoxicity measurement. Alternatively or in addition, use the field 'Any other information on results incl. tables'. If you refer to table(s), use appropriate table numbers (e.g. '... see Table 1'). Note: Specific tables may be required.	Open list with remarks	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.ResultsAndDiscussion.TestRs.Cytotoxicity
Vehicle controls validity	Indicate whether test with vehicle control(s) (i.e. vehicle without test substance,) is valid.	Open list with remarks	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.ResultsAndDiscussion

			ussion.TestRs.VehContrValid
Untreated negative controls validity	Indicate whether test with untreated controls, if applicable (i.e. no vehicle and no test substance) is valid.	Open list with remarks	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.ResultsAndDiscussion.TestRs.NegContrValid
True negative controls validity	Indicate whether test with true negative control(s) (i.e. substances with known lack of genotoxicity) is valid.	Open list with remarks	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.ResultsAndDiscussion.TestRs.TrueNegativeControlsValidity
Positive controls validity	Indicate whether test with positive control(s), i.e. substance(s) with known genotoxicity, is valid.	Open list with remarks	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.ResultsAndDiscussion.TestRs.PosContrValid
Test results			
Additional information on results	Enter any additional information that could be relevant for evaluating this study summary. Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from the study report.	Text template	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.ResultsAndDiscussion.ResultsDetails
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.ResultsAndDiscussion.RemarksOnResults
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.ApplicantSummaryAndConclusion

5.4.2 In vivo studies – Endpoint study record

Purpose:

If all the results of the in vitro studies are negative, at least one in vivo study shall be done with demonstration of exposure to the test tissue (such as cell toxicity or toxicokinetic data), unless valid in vivo micronucleus data are generated within a repeat dose study and the in vivo micronucleus test is the appropriate test to be conducted to address this information requirement.

ENDPOINT_STUDY_RECORD.GeneticToxicityVivo - v.8.4 (Final)			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.DataSource
Materials and methods	Material and methods – common block Applicable test guideline: Method B.12 - Mutagenicity - In vivo mammalian erythrocyte micronucleus test Method B.11 - Mutagenicity – In vivo mammalian bone-marrow chromosome aberration test OECD 474 OECD 475 OECD 486 OECD 488 Method B.39 Unscheduled DNA synthesis (UDS) - Test with mammalian liver cells in vivo In vivo Comet assay.	Header 1	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods
Type of assay	As appropriate supplement the information provided in field 'Endpoint' and indicate the type of assay used.	Open list	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.Studytype
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.TestMaterials

Test animals	Test animals (OHT: Repeated dose toxicity)	Header 2	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.TestAnimals
Administration / exposure		Header 2	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.AdministrationExposure
Route of administration	Select route of administration as appropriate, usually 'oral: gavage'. If another route was used, provide a justification and reasoning in field 'Details on exposure'. In the case of an inhalation study, also specify if 'nose only' or other.	Open list	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.AdministrationExposure.RouteOfAdministration
Vehicle	Indicate whether vehicle(s)/solvent(s) was/were used and specify the substance(s) or state 'none' if no vehicle/solvent was used or 'no data' if not available from the study report or publication. Provide a justification for the choice of solvent/vehicle. Provide further details as appropriate. Use freetext template and delete/add elements as appropriate. Note that the list of substances provided is not exhaustive.	Text template	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.AdministrationExposure.Vehicle
Details on exposure	Select freetext template for the respective type of study and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.AdministrationExposure.DetailsOnExposure
Duration of treatment / exposure	Indicate duration in days, weeks or months, e.g. '5 days' or '10 weeks'.	Multi-line text	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.AdministrationExposure.DurationOfTreatmentExposure
Frequency of treatment	Indicate the frequency of the administration of doses to the test animals (e.g., 'once' or 'daily injections' or '2 doses per day, 7 days per week').	Multi-line text	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.AdministrationExposure.FrequencyOfTreatment
Post exposure period	Indicate observation period (in days, weeks, months) after last exposure to the test material.	Multi-line text	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.AdministrationExposure.PostExposurePeriod

Doses / concentrations	Indicate the dose or concentration levels applied and the basis of quantity used. Copy this block of fields for each numeric value and to record values on a different basis, i.e. mg/kg bw/day (nominal), mg/kg bw/day (actual dose received), mg/kg diet ,mg/L drinking water, mg/kg bw (total dose), ppm if applicable. Conversion of the dose / conc. values to the relevant unit used for the effect levels may be required.		ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.AdministrationExposure.DosesConcentrations
Dose / conc.	Enter numeric value.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.DoseConc
Remarks	Enter any remarks related to dose / concentration values.	Multi-line text	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.Remarks
Doses / concentrations			
No. of animals per sex per dose	Enter value or specify if different number of animals were used per sex and/or dose level or for the pilot, range-finding and main study. For robust study summaries or as requested by the regulatory programme, also include a detailed table on the animal assignment in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Note: Specific tables may be required.	Multi-line text	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.AdministrationExposure.NoOfAnimalsPerSexPerDose
Control animals	Indicate whether and what type of concurrent control groups were used. Multiple selection is possible. If not listed, select 'other' and specify.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.AdministrationExposure.ControlGroup
Positive control(s)	Indicate what substance(s) was/were used as positive control(s) or state 'none' if no positive controls were used or 'no data' if not available from the study report or publication. If other than the reference substance(s) specified in the test	Text template	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.AdministrationExposure.PositiveControls

	<p>guidelines was/were used include a brief justification. Also provide information on the route of administration and doses either under separate headings or in parentheses after the control substance(s) specified.</p> <p>Use freetext template and delete/add elements as appropriate. Note that the list of substances provided is not exhaustive.</p>		
Examinations		Header 2	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.Examinations
Tissues and cell types examined	<p>Indicate tissues and cell types examined including the number of cells analysed per animal. Also note if examinations were not performed with tissues or cells from all animals studied.</p> <p>For robust study summaries or as requested by the regulatory programme, also include a detailed table in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1').</p>	Multi-line text	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.Examinations.TissuesAndCellTypesExamined
Details of tissue and slide preparation	<p>Indicate any relevant details to characterise the test system and test protocol used. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.</p>	Text template	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.Examinations.DetailsOfTissueAndSlidePreparation
Evaluation criteria	<p>Describe the evaluation criteria used in the study to judge if a substance is positive.</p>	Multi-line text	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.Examinations.EvaluationCriteria
Statistics	<p>List parameters that were analysed and the statistical methods used; include a statement that the Reviewer considers the analyses used to be appropriate. If inappropriate, provide alternative/rationale.</p>	Multi-line text	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.Examinations.Statistics
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.AnyOtherInformationOnMaterial

			sAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.ResultsAndDiscussion
Test results	<p>Include the main test results in this block of fields. Multiply this block of fields as often as required, e.g. for recording different results for both sexes used. For robust study summaries or as requested by the regulatory programme, also include a detailed table on the genotoxicity and toxicity results in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1').</p> <p>Note: Specific tables may be required.</p>		ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.ResultsAndDiscussion.TestRs
Key result	This read-only field displays the key results flagged in the corresponding results table(s), if any.	Check box	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.ResultsAndDiscussion.TestRs.KeyResult
Sex	Select from drop-down list.	Closed list	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.ResultsAndDiscussion.TestRs.Sex
Genotoxicity	Indicate if there was evidence of genotoxicity. If result is considered positive or ambiguous, include dose(s) in the supplementary remarks field or representative table, e.g. predefined table or an excerpt from the study report.	Open list with remarks	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.ResultsAndDiscussion.TestRs.Genotoxicity
Toxicity	Indicate whether signs of toxicity were observed or not. If yes, briefly describe the in life animal observations and the effects by dose in the supplementary remarks field (e.g. 'significantly decreased body weight gain in the high dose group'). If necessary include further details in field 'Additional information on results'.	Closed list with remarks	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.ResultsAndDiscussion.TestRs.Toxicity
Vehicle controls validity	Indicate whether test with vehicle control(s) (i.e. without test substance, with/without solvent) is valid.	Open list with remarks	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.ResultsAndDiscussion.TestRs.VehContrValid
Negative controls validity	Indicate whether test with true negative control(s) (i.e. substances with known lack of genotoxicity) is valid.	Open list with remarks	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.ResultsAndDiscussion

			iscussion.TestRs.Neg ContrValid
Positive controls validity	Indicate whether test with positive control(s), i.e. substance(s) with known genotoxicity, is valid.	Open list with remarks	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.ResultsAndDiscussion.TestRs.Pos ContrValid
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.ResultsAndDiscussion.TestRs.RemarksOnResults
Test results			
Additional information on results	Briefly describe the results of results of range-finding study if any. For the definitive study, provide further details on results. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Particularly with comprehensive data, include a table and refer to respective table no. (use predefined table if any). Narrative accompanying such tabular data should address the toxicological significance of the results and not repeat what is presented in the table(s). Note: Depending on the regulatory programme some form of a table may be mandatory.	Text template	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.ResultsAndDiscussion.ResultsDetails
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.ApplicantSu

			SummaryAndConclusion
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5.5 Long-term toxicity and carcinogenicity – Endpoint Summary

Purpose:

Provide summary information of the most relevant study(-ies) from which the key value for chemical assessment is extrapolated. Provide only the most relevant details for both rat and mice species:

- Long-term effects (target organ/critical effect)
- Relevant reference points (e.g. NOAELs) for long-term toxicity.
- Carcinogenicity (target organ, tumour type)
- Relevant reference points (e.g. NOAELs) for carcinogenicity

The document should contain the information needed to be reported according to the list of end points for long-term toxicity and carcinogenicity (SANCO/12592/2012-rev. 2, 22 March 2019).

Long-term toxicity and carcinogenicity (Regulation (EU) N°283/2013, Annex Part A, point 5.5)

ENDPOINT_SUMMARY.Carcinogenicity_EU_PPP - v.5.0 (Final)			
Name	Instructions	Type	Field Path
Administrative data	Administrative data summary – common block Provide a brief description of carcinogenicity studies and effects.	Header 1	ENDPOINT_SUMMARY.Carcinogenicity_EU_PPP.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.Carcinogenicity_EU_PPP.KeyValueForChemicalSafetyAssessment
Long-term toxicity: via oral route		Header 2	ENDPOINT_SUMMARY.Carcinogenicity_EU_PPP.KeyValueForChemicalSafetyAssessment.LongTermToxOral
Link to relevant study records		Header 3	ENDPOINT_SUMMARY.Carcinogenicity_EU_PPP.KeyValueForChemicalSafetyAssessment.LongTermToxOral.RelevantRecords
Study name / type	The study giving rise to the highest concern should be chosen. The following factors,	Endpoint reference list	ENDPOINT_SUMMARY.Carcinogenicity_EU_PPP.KeyValueForChemicalSafetyAssessment.Long

	<p>among others, should be taken into account when the robust study summary is selected: quality of the study (e.g. Klimisch score, duration of the study, whether or not the study is GLP.</p> <p>Available epidemiological data are preferred provided that they are reliable and relevant. However, epidemiological studies should be reported under 5.9.4</p>		TermToxOral.RelevantRecords.StudyNameType
Endpoint conclusion	<p>Endpoint conclusion (Species version) – common block</p> <p>Multiple species can be reported, e.g.: two species, rat and mouse should be reported for pesticides.</p> <p>Endpoint conclusion: “Adverse effect observed” should be chosen if adverse effects were observed at or below the limit dose level.</p> <p>“No adverse effect observed” should be chosen if no adverse effects were observed at or below the limit dose level.</p> <p>If “no study available” is chosen, a justification needs to be provided.</p> <p>If the dossier contains a testing proposal for repeated dose toxicity (e.g. 2-year study), “no</p>		ENDPOINT_SUMMARY.Carcinogenicity_EU_PP.P.KeyValueForChemicalSafetyAssessment.LongTermToxOral.RelevantRecords.EndpointConclusion

	<p>study available (further information necessary)” should be chosen.</p> <p>Dose descriptor: The primary dose descriptor in this endpoint is the NOAEL. In some studies also the BMDL (benchmark dose level).</p> <p>The LOAEL should be used only if NOAEL is not available. If the dose descriptor is expressed in ppm, it should first be converted to ng/kg, µg/kg or mg/ kg.</p> <p>Study duration: Choose the duration of the selected robust study summary: i.e. chronic.</p> <p>Experimental exposure time per week (hours/week): In this field, you should add the experimental exposure conditions in hours per week. This can be done considering the hours per day and the days per week the animals were exposed.</p> <p>Species: The species reported in the selected robust study summary should be chosen here.</p> <p>System: The systems in which adverse effects were observed should be specified here.</p> <p>Organ: The organ in which adverse effects were observed should</p>		
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	be specified here. If adverse effects were observed in several organs, the target system in which the adverse effects gives rise to highest concern should be selected, i.e. the system that is associated with the dose descriptor.		
Endpoint conclusion			
Carcinogenicity: via oral route		Header 2	ENDPOINT_SUMMARY.Carcinogenicity_EU_PP.P.KeyValueForChemicalSafetyAssessment.CarcinogenicityViaOralRoute
Link to relevant study records	The following factors, among others, should be taken into account when the robust study summary is selected: quality of the study (e.g. Klimisch score, duration of the study, whether or not the study is GLP.	Header 3	ENDPOINT_SUMMARY.Carcinogenicity_EU_PP.P.KeyValueForChemicalSafetyAssessment.CarcinogenicityViaOralRoute.LinkToRelevantStudyRecords
Endpoint conclusion	<p>Endpoint conclusion (Species version) – common block</p> <p>Multiple species can be reported, e.g.: two species, rat and mouse should be reported for pesticides.</p> <p>Endpoint conclusion: “Adverse effect observed” should be chosen if the substance was found to be carcinogenic. “No adverse effect observed” should be chosen if the substance was not found to be carcinogenic in the available study(ies). If “No study available” is chosen, a justification needs to be provided.</p>		ENDPOINT_SUMMARY.Carcinogenicity_EU_PP.P.KeyValueForChemicalSafetyAssessment.CarcinogenicityViaOralRoute.LinkToRelevantStudyRecords.EndpointConclusion

	<p>If the dossier contains a testing proposal for carcinogenicity "No study available (further information necessary)" should be chosen.</p> <p>Dose descriptor: The selection of the dose descriptor should only refer to carcinogenic effects.</p> <p>Study duration: Choose the duration of the selected robust study summary. Most of the in vivo carcinogenicity studies are chronic studies.</p> <p>Species: The species reported in the selected robust study summary should be chosen here.</p> <p>System: The systems in which cancer was observed should be specified here.</p> <p>Organ: The organ in which cancer was observed should be specified here. If cancer was observed in several organs, the target organ in which the adverse effects gives rise to highest concern should be selected, i.e. the organ that is associated with the dose descriptor.</p>		
Endpoint conclusion			
Carcinogenicity: via inhalation route		Header 2	ENDPOINT_SUMMARY.Carcinogenicity_EU_PP.P.KeyValueForChemicalSafetyAssessment.CarcinogenicityViaInhalationRoute

Link to relevant study records	The following factors, among others, should be taken into account when the robust study summary is selected: quality of the study (e.g. Klimisch score, duration of the study, whether or not the study is GLP.	Header 3	ENDPOINT_SUMMARY.Carcinogenicity_EU_PP.P.KeyValueForChemicalSafetyAssessment.CarcinogenicityViaInhalationRoute.LinkToRelevantStudyRecords
Endpoint conclusion	<p>Endpoint conclusion (Species version) – common block</p> <p>Endpoint conclusion: “Adverse effect observed” should be chosen if the substance was found to be carcinogenic. “No adverse effect observed” should be chosen if the substance was not found to be carcinogenic in the available study(ies). If “No study available” is chosen, a justification needs to be provided. If the dossier contains a testing proposal for carcinogenicity “No study available (further information necessary)” should be chosen</p> <p>Dose descriptor: The selection of the dose descriptor should only refer to carcinogenic effects.</p> <p>Study duration: Choose the duration of the selected robust study summary. Most of the in vivo carcinogenicity studies are chronic studies.</p> <p>Species: The species reported in the selected</p>	Header 3	ENDPOINT_SUMMARY.Carcinogenicity_EU_PP.P.KeyValueForChemicalSafetyAssessment.CarcinogenicityViaInhalationRoute.EndpointConclusion

	<p>robust study summary should be chosen here</p> <p>System: The system in which cancer was observed should be specified here. If cancer was observed in several systems, the target system in which the adverse effects gives rise to highest concern should be selected, i.e. the system that is associated with the dose descriptor.</p> <p>Organ: The organ in which cancer was observed should be specified here. If cancer was observed in several organs, the target organ in which the adverse effects gives rise to highest concern should be selected, i.e. the organ that is associated with the dose descriptor.</p>		
Carcinogenicity: via dermal route		Header 2	ENDPOINT_SUMMARY.Carcinogenicity_EU_PP.P.KeyValueForChemicalSafetyAssessment.CarcinogenicityViaDermalRoute
Link to relevant study records		Header 3	ENDPOINT_SUMMARY.Carcinogenicity_EU_PP.P.KeyValueForChemicalSafetyAssessment.CarcinogenicityViaDermalRoute.LinkToRelevantStudyRecords
Results		Read-only	ENDPOINT_SUMMARY.Carcinogenicity_EU_PP.P.KeyValueForChemicalSafetyAssessment.CarcinogenicityViaDermalRoute.LinkToRelevantStudyRecords.Results

<p>Endpoint conclusion</p>	<p>Endpoint conclusion (Species version) – common block</p> <p>Endpoint conclusion: “Adverse effect observed” should be chosen if the substance was found to be carcinogenic. “No adverse effect observed” should be chosen if the substance was not found to be carcinogenic in the available study(ies). If “No study available” is chosen, a justification needs to be provided. If the dossier contains a testing proposal for carcinogenicity “No study available (further information necessary)” should be chosen. Dose descriptor: The selection of the dose descriptor should only refer to carcinogenic effects. Study duration: Choose the duration of the selected robust study summary. Most of the in vivo carcinogenicity studies are chronic studies. Species: The species reported in the selected robust study summary should be chosen here. System: The system in which cancer was observed should be specified here. If cancer was observed in several systems, the target system in which the adverse effects gives rise to highest concern should be selected, i.e. the</p>	<p>Header 3</p>	<p>ENDPOINT_SUMMARY.Carcinogenicity_EU_PP P.KeyValueForChemicalSafetyAssessment.CarcinogenicityViaDermalRoute.EndpointConclusion</p>
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	<p>system that is associated with the dose descriptor</p> <p>Organ: The organ in which cancer was observed should be specified here. If cancer was observed in several organs, the target organ in which the adverse effects gives rise to highest concern should be selected, i.e. the organ that is associated with the dose descriptor</p>		
Mode of Action Analysis / Human Relevance Framework		Header 2	ENDPOINT_SUMMARY. Carcinogenicity_EU_PP P.KeyValueForChemical SafetyAssessment.MoA HumanRelevanceFramework
	<p>This section is for incorporation of the WHO/IPCS Template Mode of Action Analysis / Human relevance framework at http://echa.europa.eu/web/guest/support/guidance-on-reach-and-clp-implementation/formats . The template is also available in HTML format that can be easily uploaded in this textarea where relevant</p>	Rich text area	ENDPOINT_SUMMARY. Carcinogenicity_EU_PP P.KeyValueForChemical SafetyAssessment.MoA HumanRelevanceFramework.MoAHumanRelevanceFramework
Additional information	<p>Discussion(Header 1) – common block</p> <p>Provide additional information related to the endpoint, for example:</p> <ul style="list-style-type: none"> -Further description of the critical effects/target organ for long-term toxicity, such as direction of the critical effect: e.g. increased liver weight in rats. 	Header 1	ENDPOINT_SUMMARY. Carcinogenicity_EU_PP P.Discussion

	-Further description of the critical effects/target organ for carcinogenicity, such as tumour type: e.g. adenocarcinoma in rats		
Justification for classification or non-classification		Header 1	ENDPOINT_SUMMARY.Carcinogenicity_EU_PP P.JustificationForClassificationOrNonClassification
	The available information should be compared against the classification criteria and the reasons for fulfilling or not fulfilling the classification criteria should be presented.	Rich text area	ENDPOINT_SUMMARY.Carcinogenicity_EU_PP P.JustificationForClassificationOrNonClassification.JustifClassifCarc

5.5 Long-term toxicity and carcinogenicity – Endpoint Study record

Purpose:

The results of the long-term studies conducted and reported, taken together with other relevant data and information on the active substance, shall be sufficient to permit the identification of effects, following repeated exposure to the active substance, and in particular shall be sufficient to:

- identify adverse effects resulting from long-term exposure to the active substance,
- identify target organs, where relevant,
- establish the dose-response relationship,
- establish the reference point (e.g. NOAELs) and, if necessary, other appropriate reference points.

Correspondingly, the results of the carcinogenicity studies taken together with other relevant data and information on the active substance, shall be sufficient to permit the evaluation of hazards for humans, following repeated exposure to the active substance, and in particular shall be sufficient: (a) to identify carcinogenic effects resulting from long-term exposure to the active substance; 3.4.2013 Official Journal of the European Union L 93/27 EN (b) to establish the species, sex, and organ specificity of tumours induced; (c) to establish the dose-response relationship; (d) where possible, to identify the maximum dose eliciting no carcinogenic effect; (e) where possible, to determine the mode of action and human relevance of any identified carcinogenic response.

ENDPOINT_STUDY_RECORD.Carcinogenicity - v.7.5 (Final)			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.Carcinogenicity.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.Carcinogenicity.DataSource

Materials and methods	Material and methods – common block Applicable test guideline: <ul style="list-style-type: none"> - Method B.32 Carcinogenicity test (Annex to Regulation (EC) No 440/2008). - Method B.33 Combined chronic toxicity/carcinogenicity test (Annex to Regulation (EC) No 440/2008). - OECD Test Guideline 451: Carcinogenicity Studies. OECD Test Guideline 453: Combined Chronic Toxicity/Carcinogenicity Studies. - other 	Header 1	ENDPOINT_STUDY_RECORD.Carcinogenicity.MaterialsAndMethods
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.Carcinogenicity.MaterialsAndMethods.TestMaterials
Test animals	Test animals (OHT: Repeated dose toxicity) – common block	Header 2	ENDPOINT_STUDY_RECORD.Carcinogenicity.MaterialsAndMethods.TestAnimals
Administration / exposure		Header 2	ENDPOINT_STUDY_RECORD.Carcinogenicity.MaterialsAndMethods.AdministrationExposure
Route of administration	Select route of administration as appropriate, usually 'oral: gavage'. If another route was used, provide a justification and reasoning in field 'Details on exposure'. In the case of an inhalation study, also specify if 'nose only' or other.	Open list	ENDPOINT_STUDY_RECORD.Carcinogenicity.MaterialsAndMethods.AdministrationExposure.RouteOfAdministration
Type of inhalation exposure (if applicable)	If route of administration is 'inhalation', indicate type of inhalation exposure, e.g. 'nose only'. Any remarks can be entered in the supplementary remarks subfield.	Open list with remarks	ENDPOINT_STUDY_RECORD.Carcinogenicity.MaterialsAndMethods.AdministrationExposure.TypeOfInhalationExposureIfApplicable
Vehicle	Select the vehicle used. If not available from picklist, select 'other'. Note that some of the vehicles provided in this list are used for specific routes of administration only.	Open list with remarks	ENDPOINT_STUDY_RECORD.Carcinogenicity.MaterialsAndMethods.AdministrationExposure.Vehicle
Mass median aerodynamic diameter (MMAD)	For inhalation studies, specify the mass median aerodynamic diameter (MMAD) of the distribution of particle sizes. Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.Carcinogenicity.MaterialsAndMethods.AdministrationExposure.MassMedianAerodynamicDiameter

	fields together with the appropriate qualifier(s) if applicable.		
Geometric standard deviation (GSD)	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Decimal	ENDPOINT_STUDY_RE CORD.Carcinogenicity. MaterialsAndMethods. AdministrationExposur e.GeometricStandardD eviation
Remarks on MMAD	Enter any remarks related to the mass median aerodynamic diameter.	Multi-line text	ENDPOINT_STUDY_RE CORD.Carcinogenicity. MaterialsAndMethods. AdministrationExposur e.Remarks
Details on exposure	Select freetext template for the respective type of study and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RE CORD.Carcinogenicity. MaterialsAndMethods. AdministrationExposur e.DetailsOnExposure
Analytical verification of doses or concentrations	Indicate whether the doses or concentrations were analytically verified.	Closed list with remarks	ENDPOINT_STUDY_RE CORD.Carcinogenicity. MaterialsAndMethods. AdministrationExposur e.AnalyticalVerification OfDosesOrConcentrati ons
Details on analytical verification of doses or concentrations	<p>For robust study summaries or as requested by the regulatory programme, include a short description on the method of analysis in the supplementary remarks field. If any problems occurred in any of these procedures, then they should be reported in more detail. If this could have affected the veracity or conclusions of the study, discuss this in field 'Rationale for reliability incl. deficiencies'.</p> <p>Further route-dependent information to be included:</p> <p>- For oral studies: State whether the analytical data indicated that the difference between nominal and actual dosage (if diet is route of administration) or concentrations (for drinking water study) was acceptable.</p> <p>If diet is the route of administration, briefly record when and at what dose levels the dosage analyses were made and include the results (range of values) of (i) Homogeneity analysis, (ii) Stability analysis and (iii) Concentration analysis.It may be appropriate</p>	Text area	ENDPOINT_STUDY_RE CORD.Carcinogenicity. MaterialsAndMethods. AdministrationExposur e.DetailsOnAnalyticalV erificationOfDosesOrCo ncentrations

	<p>to include a cross-reference to another study in which stability analysis was performed and reported. If so, a justification should also be included briefly explaining the rationale of referring to another study.</p> <p>- For inhalation studies: State whether the analytical data indicated that the difference between nominal and actual concentrations was acceptable.</p> <p>- For dermal studies: State whether the analytical data indicated that the difference between nominal and actual concentrations of the test substance in the vehicle was acceptable.</p>		
Duration of treatment / exposure	Indicate duration in days, weeks or months, e.g. '104 weeks' or '18 months'.	Multi-line text	ENDPOINT_STUDY_RECORD.Carcinogenicity. MaterialsAndMethods. AdministrationExposure.DurationOfTreatmentExposure
Frequency of treatment	Indicate the frequency of the administration of doses to the test animals (e.g., 'daily, 7 days each week'). Use of non-standard dosing regime (e.g. a five-day per week regime) should be justified.	Multi-line text	ENDPOINT_STUDY_RECORD.Carcinogenicity. MaterialsAndMethods. AdministrationExposure.FrequencyOfTreatment
Post exposure period	Indicate observation period (in days, weeks, months) after last exposure to the test material. Specify, if there are differences for treatment and recovery groups or other individual groups.	Multi-line text	ENDPOINT_STUDY_RECORD.Carcinogenicity. MaterialsAndMethods. AdministrationExposure.PostExposurePeriod
Doses / concentrations	Indicate the dose or concentration levels applied and the basis of quantity used. Copy this block of fields for each numeric value and to record values on a different basis, i.e. mg/kg bw/day (nominal), mg/kg bw/day (actual dose received), mg/kg diet, mg/L drinking water, mg/kg bw (total dose), ppm if applicable. Conversion of the dose / conc. values to the relevant unit used for the effect levels may be required.		ENDPOINT_STUDY_RECORD.Carcinogenicity. MaterialsAndMethods. AdministrationExposure.DosesConcentrations
Dose / conc.	Enter numeric value.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.Carcinogenicity. MaterialsAndMethods. AdministrationExposure.DosesConcentrations.DoseConc
Remarks	Enter any remarks related to dose / concentration values.	Multi-line text	ENDPOINT_STUDY_RECORD.Carcinogenicity. MaterialsAndMethods.

			AdministrationExposure.DosesConcentrations.Remarks
Doses / concentration s			
No. of animals per sex per dose	Enter value or specify according to dose if different number of animals per dose, e.g. '10 in each dose group of main study; 10 f and 5 m in interim sacrifice group'. Also specify number of animals in recovery group if applicable. For robust study summaries or as requested by the regulatory programme, also include a detailed table on the animal assignment in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Note: Specific tables may be required.	Multi-line text	ENDPOINT_STUDY_RECORD.Carcinogenicity.MaterialsAndMethods.AdministrationExposure.NoOfAnimalsPerSexPerDose
Control animals	Indicate whether and what type of concurrent control groups were used. Multiple selection is possible. If not listed, select 'other' and specify.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.Carcinogenicity.MaterialsAndMethods.AdministrationExposure.ControlAnimals
Details on study design	Include any details on the study design including toxicokinetic data if available, a brief description of the rationale for dose selection (e.g. consideration of known or suspected nonlinearities or inflection points in the dose response, toxicokinetics, precursor lesions, markers of effect, or indicators of the operation of key underlying biological process, key (or suspected) aspects of mode of action, consideration of anticipated human exposure level), animal assignment and selection of satellite groups including the duration of the post-exposure recovery period. As appropriate state study type(s) and briefly describe the results from range-finding or other studies used as basis for dose selection. More comprehensive details may be attached. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.Carcinogenicity.MaterialsAndMethods.AdministrationExposure.DetailsOnStudyDesign
Positive control	Indicate if a positive control was used and if necessary indicate purity, Lot/batch No.	Multi-line text	ENDPOINT_STUDY_RECORD.Carcinogenicity.

			MaterialsAndMethods. AdministrationExposur e.PositiveControl
Examinations		Header 2	ENDPOINT_STUDY_RE CORD.Carcinogenicity. MaterialsAndMethods. Examinations
Observations and examinations performed and frequency	<p>Indicate if and which examinations were performed and the time schedule for those examinations. Also indicate the dose groups that were examined if not all. As appropriate include detailed table(s) in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1').</p> <p>If other observations (e.g. neurotoxicity, immunotoxicity) are reported in another study summary, include a note in the block 'Cross-reference' and refer to that summary.</p> <p>Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.</p>	Text template	ENDPOINT_STUDY_RE CORD.Carcinogenicity. MaterialsAndMethods. Examinations.Observat ionsAndExaminationsP erformedAndFrequenc y
Sacrifice and pathology	<p>Indicate if and which examinations were performed. Also indicate the dose groups that were examined if not all. Note if not all collected tissues were examined. As appropriate include detailed table(s) in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1').</p> <p>Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.</p>	Text template	ENDPOINT_STUDY_RE CORD.Carcinogenicity. MaterialsAndMethods. Examinations.Sacrifice AndPathology
Other examinations	Describe any other examinations.	Text area	ENDPOINT_STUDY_RE CORD.Carcinogenicity. MaterialsAndMethods. Examinations.OtherExa minations

Statistics	List parameters that were analysed and the statistical methods used; include a statement that the Reviewer considers the analyses used to be appropriate. If inappropriate, provide alternative/rationale.	Multi-line text	ENDPOINT_STUDY_RE CORD.Carcinogenicity. MaterialsAndMethods. Examinations.Statistics
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RE CORD.Carcinogenicity. MaterialsAndMethods. AnyOtherInformationO nMaterialsAndMethods InclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RE CORD.Carcinogenicity. ResultsAndDiscussion
Results of examinations	Results of examinations (OHT: Repeated dose toxicity: oral) – common block	Header 2	ENDPOINT_STUDY_RE CORD.Carcinogenicity. ResultsAndDiscussion. ResultsOfExaminations
Relevance of carcinogenic effects / potential	Discuss carcinogenic effects / potential, i.e. state if there was (not) a treatment related increase in tumour incidence as compared to controls and specify tumour type if applicable. Indicate if dosing was not considered adequate. Discuss weight of evidence with respect to relevance of tumours observed for human health. This should be in line with information entered under 'Target system / organ toxicity'. Discuss conclusions given in supporting documentation.	Text area	ENDPOINT_STUDY_RE CORD.Carcinogenicity. ResultsAndDiscussion. ResultsOfExaminations .RelevanceOfCarcinoge nicEffectsPotential
Effect levels	Effect levels (OHT 67-69, 72-74) – common block Select the relevant dose descriptor, i.e. the exposure level that corresponds to a quantified level of effects, e.g. NOAEL or LOAEL. If a benchmark dose / concentration was calculated, select appropriate BMD indicator (e.g. 'BMD05' or 'BMD:' and specify in the related text field). If the critical effects at a specific dose or concentration level are reported only, select 'dose. level:' or 'conc. level:' and specify. Where no value could be achieved based on the method and boundaries used, the upper or lower dose level for the relevant dose descriptor can be reported as appropriate with relevant qualifier, e.g. NOAEL >200 mg/kg bw/day or NOAEL <200 mg/kg bw/day. An additional explanation may be given in field 'Remarks on result', e.g. 'not determinable due to absence of adverse toxic effects'.	Header 2	ENDPOINT_STUDY_RE CORD.Carcinogenicity. ResultsAndDiscussion. EffectLevels

Target system / organ toxicity	Target system (OHT RepDoseTox etc.) - Target system BLOCK -OHT 67-69-72- 73- 76- 77- common block	Header 2	ENDPOINT_STUDY_RECORD.Carcinogenicity.ResultsAndDiscussion.TargetSystemOrganToxicity
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.Carcinogenicity.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.Carcinogenicity.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.Carcinogenicity.ApplicantSummaryAndConclusion

5.6 Reproductive toxicity (includes reproduction toxicity to mammals) – Endpoint summary

Purpose:

Provide summary information of the most relevant study(-ies) from which the key value for chemical assessment is extrapolated. Provide only the most relevant details:

Reproduction toxicity

- Reproduction target / critical effect for parental, reproductive and offspring
- Relevant parental reference point (e.g. NOAELs).
- Relevant reproductive reference point (e.g. NOAELs).
- Relevant offspring reference point (e.g. NOAELs).

Developmental toxicity (rats and rabbits)

- Developmental target / critical effect
- Relevant maternal reference point (e.g. NOAELs).
- Relevant developmental reference point (e.g. NOAELs).

The document should contain the information needed to be reported according to the list of end points for reproductive toxicity (SANCO/12592/2012-rev. 2, 22 March 2019).

Reproductive toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.6)

ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP - v1.0 (Final)			
Name	Instructions	Type	Field Path
Administrative data	Administrative data summary – common block Provide a brief description of	Header 1	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.AdministrativeDataSummary

	reproductive toxicity studies and effects.		
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment
Toxic effect type	In this field, you should select whether there is a relationship between the exposure concentration and the magnitude of the toxic effect, i.e. dose-dependent, or whether the toxic effect is driven but not modulated by the exposure concentration, i.e. concentration-driven.	Closed list	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.ToxicEffectType
Effects on reproductive toxicity / fertility		Header 2	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnFertility
Link to relevant study records		Header 3	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnFertility.LinkToRelevantStudyRecords
Effect on fertility-reproductive toxicity: via oral route		Header 3	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnFertility.EffectOnFertilityViaOralRoute
Endpoint conclusion	Endpoint conclusion (Species version) – common block "Adverse effect observed" should be chosen if adverse reproductive effects were observed at or below the limit dose level.	Closed list	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnFertility.EffectOnFertilityViaOralRoute.EndpointConclusion

	<p>"No adverse effect observed" should be chosen if no adverse reproductive effects were observed at or below the limit dose level.</p> <p>If "No study available" is chosen, a justification needs to be provided.</p> <p>The selection of the dose descriptor should only refer for the specific effect on "reproductive toxicity".</p> <p>The study duration of the selected robust study summary should be amongst: Two-generation studies (OECD 416) or extended one-generation studies (OECD 443)". Pre-natal developmental toxicity studies (OECD 414) and screening studies for reproductive toxicity (OECD 421/422) are to be reported as "subacute" studies or as "developmental" studies (e.g. for pesticides).</p> <p>Experimental exposure conditions should be reported in hours per week. This can be done considering the hours per day and the days per week the animals were exposed.</p> <p>The species should be reported in the relative field.</p>		
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Basis for effect level	Indicate the parameter(s) used to establish the given effect level. Multi-selection of different pre-defined values is possible. If none is available, you can select 'other:'. Any explanations can always be entered in the related supplementary text field.	Multi select open list with remarks (32000)	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnFertility.EffectOnFertilityViaOralRoute.BasisForEffectLevel
Remarks on result	<p>This field can be used for:</p> <ul style="list-style-type: none"> - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:'. 	Open list with remarks (2000)	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnFertility.EffectOnFertilityViaOralRoute.RemarksOnResult
Species	The species reported in the selected robust study summary should be chosen here.	Open list	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnFertility.EffectOnFertilityViaOralRoute.Species
Effect on fertility-parental toxicity: via oral route		Header 3	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnFertility.EffectOnParentalToxViaOralRoute

<p>Endpoint conclusion</p>	<p>Endpoint conclusion (Species version) – common block</p> <p>“Adverse effect observed” should be chosen if adverse reproductive effects were observed at or below the limit dose level.</p> <p>“No adverse effect observed” should be chosen if no adverse reproductive effects were observed at or below the limit dose level.</p> <p>If “no study available” is chosen, a justification needs to be provided.</p> <p>The dose descriptor should only refer for the specific effect on “parental toxicity”.</p> <p>The duration of the selected robust study summary, should be: Two-generation studies (OECD 416) or extended one-generation studies (OECD 443) are to be reported as “subchronic” studies or as “multigeneration” studies (e.g. for pesticides). Pre-natal developmental toxicity studies (OECD 414) and screening studies for reproductive toxicity (OECD 421/422) are to be reported as “subacute” studies or as “developmental”</p>	<p>Closed list</p>	<p>ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnFertility.EffectOnParentalToxViaOralRoute.EndpointConclusion</p>
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	<p>studies (e.g. for pesticides).</p> <p>The experimental exposure conditions should be reported in hours per week. This can be done considering the hours per day and the days per week the animals were exposed.</p> <p>The species should be reported in the relative field, usually the rat.</p>		
Basis for effect level	<p>Indicate the parameter(s) used to establish the given effect level. Multi-selection of different pre-defined values is possible. If none is available, you can select 'other:'. Any explanations can always be entered in the related supplementary text field.</p>	Multi select open list with remarks (32000)	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnFertility.EffectOnParentalToxViaOralRoute.BasisForEffectLevel
Remarks on result	<p>This field can be used for:</p> <ul style="list-style-type: none"> - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information 	Open list with remarks (2000)	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnFertility.EffectOnParentalToxViaOralRoute.RemarksOnResult

	on the effect level by selecting 'other:'.		
Effect on fertility-offspring toxicity: via oral route		Header 3	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnFertility.EffectOnFertilityOffspringToxOralRoute
Endpoint conclusion	<p>Endpoint conclusion (Species version) – common block</p> <p>“Adverse effect observed” should be chosen if adverse reproductive effects were observed at or below the limit dose level.</p> <p>“No adverse effect observed” should be chosen if no adverse reproductive effects were observed at or below the limit dose level.</p> <p>If “no study available” is chosen, a justification needs to be provided.</p> <p>The selection of the dose descriptor should only refer for the specific effect on “offspring toxicity”.</p> <p>The duration of the selected robust study summary. Two-generation studies (OECD 416) or extended one-generation studies (OECD 443) are to be reported as “subchronic” studies or as “multigeneration” studies (e.g. for pesticides).</p>	Closed list	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnFertility.EffectOnFertilityOffspringToxOralRoute.EndpointConclusion

	<p>Pre-natal developmental toxicity studies (OECD 414) and screening studies for reproductive toxicity (OECD 421/422) are to be reported as "subacute" studies or as "developmental" studies (e.g. for pesticides). The experimental exposure conditions should be added in hours per week. This can be done considering the hours per day and the days per week the animals were exposed</p> <p>The species reported in the selected robust study summary should be chosen in the relative field, usually the rat.</p>		
Basis for effect level	<p>Indicate the parameter(s) used to establish the given effect level. Multi-selection of different pre-defined values is possible. If none is available, you can select 'other:'. Any explanations can always be entered in the related supplementary text field.</p>	Multi select open list with remarks (32000)	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnFertility.EffectOnFertilityOffspringToxOralRoute.BasisForEffectLevel
Remarks on result	<p>This field can be used for:</p> <ul style="list-style-type: none"> - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric 	Open list with remarks (2000)	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnFertility.EffectOnFertilityOffspringToxOralRoute.RemarksOnResult

	<p>value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or</p> <p>- entering any additional information on the effect level by selecting 'other:'.</p>		
Effect on fertility: via inhalation route		Header 3	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnFertility.EffectOnFertilityViaInhalationRoute
Endpoint conclusion	<p>Endpoint conclusion (Species version) – common block</p> <p>“Adverse effect observed” should be chosen if adverse reproductive effects were observed at or below the limit dose level.</p> <p>“No adverse effect observed” should be chosen if no adverse reproductive effects were observed at or below the limit dose level.</p> <p>If “no study available” is chosen, a justification needs to be provided.</p> <p>The selection of the dose descriptor should only refer for the specific effect on reproduction. Other effects (e.g. maternal toxicity) and dose descriptors should be reported in the section</p>	Closed list	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnFertility.EffectOnFertilityViaInhalationRoute.EndpointConclusion

	<p>"Description of key information.</p> <p>The duration of the selected robust study summary.</p> <p>Two-generation studies (OECD 416) or extended one-generation studies (OECD 443) are to be reported as "subchronic" studies.</p> <p>Pre-natal developmental toxicity studies (OECD 414) and screening studies for reproductive toxicity (OECD 421/422) are to be reported as "subacute" studies.</p> <p>The experimental exposure conditions should be added in hours per week. This can be done considering the hours per day and the days per week the animals were exposed</p> <p>The species reported in the selected robust study summary should be chosen in the relative field, usually the rat.</p>		
Effect on fertility: via dermal route		Header 3	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnFertility.EffectOnFertilityViaDermalRoute
Endpoint conclusion	<p>Endpoint conclusion (Species version) – common block</p> <p>"Adverse effect observed" should be chosen if adverse</p>	Closed list	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnFertility.EffectOnFertilityViaDermal

	<p>reproductive effects were observed at or below the limit dose level.</p> <p>"No adverse effect observed" should be chosen if no adverse reproductive effects were observed at or below the limit dose level.</p> <p>If "no study available" is chosen, a justification needs to be provided.</p> <p>The selection of the dose descriptor should only refer for the specific effect on reproduction. Other effects (e.g. maternal toxicity) and dose descriptors should be reported in the section "Description of key information".</p> <p>The duration of the selected robust study summary, should be: Two-generation studies (OECD 416) and extended one-generation studies (OECD 443) are to be reported as "subchronic" studies. Pre-natal developmental toxicity studies (OECD 414) and screening studies for reproductive toxicity (OECD 421/422) are to be reported as "subacute" studies.</p> <p>The experimental exposure conditions should be added in hours per week. This</p>		Route.EndpointConclusion
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	<p>can be done considering the hours per day and the days per week the animals were exposed</p> <p>The species reported in the selected robust study summary should be chosen in the relative field.</p>		
Additional information		Header 3	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnFertility.AdditionalInformation
	<p>Provide additional information related to the endpoint, for example:</p> <ul style="list-style-type: none"> - information on the potential data gaps - relevance of the results for the risk assessment - the rationale for the choice of the key study(ies) and the choice for the key value that characterises the endpoint - the rationale for any user-derived values for the sake of transparency - the possible reasons for differentiating results when several studies were identified to be relevant for the assessment. <p>If there is no additional information to be reported this field may be left empty.</p>	Rich text area	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnFertility.AdditionalInformation.AdditionalInfo
Effects on developmental toxicity		Header 2	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnDevelopmentalToxicity

Description of key information	Report Information to support the developmental toxicity.	Header 3	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnDevelopmentalToxicity.DescriptionOfKeyInformation
		Rich text area	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnDevelopmentalToxicity.DescriptionOfKeyInformation.KeyInfo
Link to relevant study records		Header 3	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnDevelopmentalToxicity.LinkToRelevantStudyRecords
Effect on developmental toxicity: via oral route		Header 3	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnDevelopmentalToxicity.EffectOnDevelopmentalToxicityViaOralRoute
Developmental toxicity	According to EU data requirements on pesticides at least two developmental toxicity studies should be available, one in rat and one in rabbits. The two species should be reported.		ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnDevelopmentalToxicity.EffectOnDevelopmentalToxicityViaOralRoute.DevTox
Endpoint conclusion	Endpoint conclusion (Species version) – common block "Adverse effect observed" should be chosen if adverse developmental effects were observed at or below the limit dose level. "No adverse effect	Closed list	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnDevelopmentalToxicity.EffectOnDevelopmentalToxicityViaOralRoute.DevTox.EndpointConclusion

	<p>observed" should be chosen if no adverse developmental effects were observed at or below the limit dose level.</p> <p>If "no study available" is chosen, a justification needs to be provided.</p> <p>If the dossier contains a testing proposal for developmental toxicity, "no study available (further information necessary)" should be chosen.</p> <p>The selection of the dose descriptor should only refer for specific effect on maternal toxicity.</p> <p>The duration of the selected robust study summary should be: Pre-natal developmental toxicity studies(OECD 414) is to be reported as "subacute" studies</p> <p>The experimental exposure conditions should be reported in hours per week. This can be done considering the hours per day and the days per week the animals were exposed.</p> <p>The species reported in the selected robust study summary should be chosen in the relative field i.e. rat or rabbits.</p>		
Basis for effect level	Indicate the parameter(s) used to	Multi select open list with remarks (32000)	ENDPOINT_SUMMARY. ToxicityToReproduction

	establish the given effect level. Multi-selection of different pre-defined values is possible. If none is available, you can select 'other:'. Any explanations can always be entered in the related supplementary text field.		_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnDevelopmentalToxicity.EffectOnDevelopmentalToxicityViaOralRoute.DevTox.BasisForEffectLevel
Remarks on result	<p>This field can be used for:</p> <ul style="list-style-type: none"> - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:'. 	Open list with remarks (2000)	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnDevelopmentalToxicity.EffectOnDevelopmentalToxicityViaOralRoute.DevTox.RemarksOnResult
Developmental toxicity			
Effect on developmental toxicity - maternal: via oral route		Header 3	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnDevelopmentalToxicity.EffectOnDevelopmentalToxViaOralRouteMaternal
Maternal toxicity	According to EU data requirements on pesticides at least two developmental toxicity studies should be available, one in rat and one in rabbits. The		ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnDevelopmentalToxicity.EffectOnDevelopmentalToxViaOral

	two species should be reported.		RouteMaternal.Maternal Toxicity
Endpoint conclusion	<p>Endpoint conclusion (Species version) – common block</p> <p>“Adverse effect observed” should be chosen if adverse developmental effects were observed at or below the limit dose level.</p> <p>“No adverse effect observed” should be chosen if no adverse developmental effects were observed at or below the limit dose level.</p> <p>If “no study available” is chosen, a justification needs to be provided.</p> <p>If the dossier contains a testing proposal for developmental toxicity, “no study available (further information necessary)” should be chosen.</p> <p>The selection of the dose descriptor should only refer for the specific effect on developmental toxicity.</p> <p>The duration of the selected robust study summary should be: Pre-natal developmental toxicity studies(OECD 414) is to be reported as "subacute" studies.</p> <p>The experimental exposure conditions</p>	Closed list	<p>RouteMaternal.Maternal Toxicity</p> <p>ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnDevelopmentalToxicity.EffectOnDevelopmentalToxViaOralRouteMaternal.Maternal Toxicity.EndpointConclusion</p>

	<p>should be reported in hours per week. This can be done considering the hours per day and the days per week the animals were exposed.</p> <p>The species reported in the selected robust study summary should be chosen in the relative field i.e. rat or rabbits.</p>		
Basis for effect level	<p>Indicate the parameter(s) used to establish the given effect level. Multi-selection of different pre-defined values is possible. If none is available, you can select 'other:'. Any explanations can always be entered in the related supplementary text field.</p>	Multi select open list with remarks (32000)	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnDevelopmentalToxicity.EffectOnDevelopmentalToxViaOralRouteMaternal.MaternalToxicity.BasisForEffectLevel
Remarks on result	<p>This field can be used for:</p> <ul style="list-style-type: none"> - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:'. 	Open list with remarks (2000)	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnDevelopmentalToxicity.EffectOnDevelopmentalToxViaOralRouteMaternal.MaternalToxicity.RemarksOnResult
Maternal toxicity			

Effect on developmental toxicity: via inhalation route		Header 3	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnDevelopmentalToxicity.EffectOnDevelopmentalToxicityViaInhalationRoute
Endpoint conclusion	<p>Endpoint conclusion (Species version) – common block</p> <p>"Adverse effect observed" should be chosen if adverse reproductive effects were observed at or below the limit dose level.</p> <p>"No adverse effect observed" should be chosen if no adverse reproductive effects were observed at or below the limit dose level.</p> <p>If "No study available" is chosen, a justification needs to be provided.</p> <p>The selection of the dose descriptor should only refer for the specific effect on reproduction. Other effects (e.g. maternal toxicity) and dose descriptors should be reported in the section "Description of key information".</p> <p>The duration of the selected robust study summary should be: Pre-natal developmental toxicity studies(OECD 414) is to be reported as "subacute" studies.</p>	Closed list	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnDevelopmentalToxicity.EffectOnDevelopmentalToxicityViaInhalationRoute.EndpointConclusion

	<p>The experimental exposure conditions should be reported in hours per week. This can be done considering the hours per day and the days per week the animals were exposed.</p> <p>The species reported in the selected robust study summary should be chosen in the relative field i.e. rat or rabbits.</p>		
Effect on developmental toxicity: via dermal route		Header 3	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnDevelopmentalToxicity.EffectOnDevelopmentalToxicityViaDermalRoute
Endpoint conclusion	<p>Endpoint conclusion (Species version) – common block</p> <p>“Adverse effect observed” should be chosen if adverse reproductive effects were observed at or below the limit dose level.</p> <p>“No adverse effect observed” should be chosen if no adverse reproductive effects were observed at or below the limit dose level.</p> <p>If “No study available” is chosen, a justification needs to be provided.</p> <p>The selection of the dose descriptor should only refer for the specific effect on reproduction. Other effects (e.g. maternal</p>	Closed list	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnDevelopmentalToxicity.EffectOnDevelopmentalToxicityViaDermalRoute.EndpointConclusion

	<p>toxicity) and dose descriptors should be reported in the section "Description of key information".</p> <p>The duration of the selected robust study summary should be: Two-generation studies (OECD 416) or extended one-generation studies (OECD 443) are to be reported as "subchronic" studies. Pre-natal developmental toxicity studies (OECD 414) and screening studies for reproductive toxicity (OECD 421/422) are to be reported as "subacute" studies.</p> <p>The experimental exposure conditions should be reported in hours per week. This can be done considering the hours per day and the days per week the animals were exposed.</p> <p>The species reported in the selected robust study summary should be chosen in the relative field.</p>		
Additional information	<p>Provide additional information related to the endpoint, for example:</p> <ul style="list-style-type: none"> - information on the potential data gaps - relevance of the results for the risk assessment - the rationale for the choice of the key study(ies) and the 	Header 3	<p>ENDPOINT_SUMMARY. ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnDevelopmentalToxicity.AdditionalInformation</p>

	<p>choice for the key value that characterises the endpoint</p> <ul style="list-style-type: none"> - the rationale for any user-derived values for the sake of transparency -the possible reasons for differentiating results when several studies were identified to be relevant for the assessment. <p>If there is no additional information to be reported this field may be left empty.</p>		
	Provide any additional information related to the endpoint.	Rich text area	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnDevelopmentalToxicity.AdditionalInformation.AdditionalInfo
Toxicity to reproduction: other studies		Header 2	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.ToxicityToReproductionOnOtherStudies
Description of key information	Report Information to support the toxicity on reproduction.	Header 3	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.ToxicityToReproductionOnOtherStudies.DescriptionOfKeyInformation
		Rich text area	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.ToxicityToReproductionOnOtherStudies.DescriptionOfKeyInformation.KeyInfo
Link to relevant study records	If other studies relevant to toxicity to reproduction are available should be reported here. The specifics should be	Header 3	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.ToxicityToReproduction

	reported in the section "Description of key information".		onOtherStudies.LinkToRelevantStudyRecords
Additional information	<p>Provide additional information related to the endpoint, for example:</p> <ul style="list-style-type: none"> - information on the potential data gaps - relevance of the results for the risk assessment - the rationale for the choice of the key study(ies) and the choice for the key value that characterises the endpoint - the rationale for any user-derived values for the sake of transparency -the possible reasons for differentiating results when several studies were identified to be relevant for the assessment. <p>If there is no additional information to be reported this field may be left empty.</p>	Header 3	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.ToxicityToReproductionOnOtherStudies.AdditionalInformation
		Rich text area	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.ToxicityToReproductionOnOtherStudies.AdditionalInformation.AdditionalInfo
Mode of Action Analysis / Human Relevance Framework		Header 2	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.MoAAAnalysisHumanRelevanceFramework
	This section is for incorporation of the WHO/IPCS Template Mode of Action Analysis / Human relevance framework at	Rich text area	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.MoAAAnalysisHumanRelevanceFramework.Mo

	http://echa.europa.eu/web/guest/support/guidance-on-reach-and-clp-implementation/formats . The template is also available in HTML format that can be easily uploaded in this text area where relevant		AAAnalysisHumanRelevanceFramework
Additional information	Discussion(Header 1) – common block If available, for other routes than oral provide additional information related to the endpoint, for example: Reproduction target / critical effect, Relevant parental reference point (e.g. NOAELs), Relevant reproductive reference point (e.g. NOAELs), Relevant offspring reference point (e.g. NOAELs), If there is no additional information to be reported this field may be left empty.	Header 1	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.Discussion
Justification for classification or non-classification		Header 1	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.JustificationForClassificationOrNonClassification
	The available information should be compared against the classification criteria and the reasons for fulfilling or not fulfilling the classification criteria should be presented.	Rich text area	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.JustificationForClassificationOrNonClassification.JustificationForClassificationOrNonClassification

5.6 Reproductive toxicity (includes reproduction toxicity to mammals) – Endpoint study record

Purpose:

Possible effects on reproductive physiology and the development of progeny shall be investigated and reported concerning the following aspects:

- Impairment of male and female reproductive functions or capacity, for example from effects on oestrus cycle, sexual behaviour, any aspect of spermatogenesis or oogenesis, or hormonal activity or physiological response which would interfere with the capacity to fertilise, fertilisation itself or development of the fertilised ovum up to and including implantation.
- Harmful effects on the progeny, for example any effect interfering with normal development, both before and after birth. This includes morphological malformations such as anogenital distance, nipple retention, and functional disturbances (such as reproductive and neurological effects).

Multigeneration studies (e.g. two-generation toxicity study and/or 1-extended one generation study) should be reported using this endpoint study record.

ENDPOINT_STUDY_RECORD.ToxicityReproduction – v.8.5 (Final)			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityReproduction.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityReproduction.DataSource
Materials and methods	Material and methods – common block Applicable test guideline, e.g: Reproductive toxicity (one-/two generation studies): <ul style="list-style-type: none"> - Method B.35 Two-generation reproduction toxicity study (Annex to Regulation (EC) No 440/2008). - OECD Test Guideline 416: Two- Generation Reproduction Toxicity. - OECD Test Guideline 443: Extended One-generation 	Header 1	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods

	Reproduction Toxicity. - pre-natal developmental toxicity studies - Method B.31 Prenatal developmental toxicity study (Annex to Regulation (EC) No 440/2008). - OECD Test Guideline 414: Prenatal developmental toxicity study. - OECD Test Guideline 426: Developmental neurotoxicity study.		
Limit test	Indicate if the experiment was a limit test.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.LimitTest
Justification for study design	A justification of the study design should be provided if the relevant test guideline used allows some flexibility, particularly regarding - the selection of doses, - length of pre-mating exposure period, producing an F2 generation, - termination day for F2 generation, - including additional cohorts to assess developmental neurotoxicity and/or developmental immunotoxicity.	Text template	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.JustificationForStudyDesign
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.TestMaterials
Test animals	Test animals (OHT: Repeated dose toxicity) – common block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.TestAnimals

Administration / exposure		Header 2	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.AdministrationExposure
Route of administration	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.AdministrationExposure.RouteOfAdministration
Type of inhalation exposure (if applicable)	If route of administration is 'inhalation', indicate type of inhalation exposure, e.g. 'nose only'. Any remarks can be entered in the supplementary remarks subfield.	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.AdministrationExposure.TypeOfInhalationExposureIfApplicable
Mass median aerodynamic diameter (MMAD)	Specify the particle size distribution in terms of mass median aerodynamic diameter (MMAD). Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.AdministrationExposure.MassMedianAerodynamicDiameter
Geometric standard deviation (GSD)	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Decimal	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.AdministrationExposure.GeometricStandardDeviation
Remarks on MMAD	Enter any remarks related to the mass	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMetho

	median aerodynamic diameter.		ds.AdministrationExposure.RemarksOnMMAD
Vehicle	Select the vehicle used. If not available from picklist, select 'other'. Note that some of the vehicles provided in this list are used for specific routes of administration only.	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.AdministrationExposure.Vehicle
Details on exposure	Select freetext template for the respective route of administration and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.AdministrationExposure.DetailsOnExposure
Details on mating procedure	Briefly describe the mating procedure. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.AdministrationExposure.DetailsOnMatingProcedure
Analytical verification of doses or concentrations	Indicate whether the doses or concentrations were analytically verified.	Closed list with remarks	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.AdministrationExposure.AnalyticalVerificationOfDosesOrConcentrations
Details on analytical verification of doses or concentrations	For robust study summaries or as requested by the regulatory programme, include a short description on the method of analysis in the supplementary remarks field. If any problems occurred in any of these procedures, then they	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.AdministrationExposure.DetailsOnAnalyticalVerificationOfDosesOrConcentrations

	<p>should be reported in more detail. If this could have affected the veracity or conclusions of the study, discuss this in field 'Rationale for reliability incl. deficiencies'.</p> <p>Further route-dependent information to be included:</p> <ul style="list-style-type: none"> - For oral studies: State whether the analytical data indicated that the difference between nominal and actual dosage (if diet is route of administration) or concentrations (for drinking water study) was acceptable. If diet is the route of administration, briefly record when and at what dose levels the dosage analyses were made and include the results (range of values) of (i) Homogeneity analysis, (ii) Stability analysis and (iii) Concentration analysis. It may be appropriate to include a cross-reference to another study in which stability analysis was performed and reported. If so, a justification should also be included briefly explaining the rationale of referring to another study. - For inhalation studies: State whether the analytical data indicated that the difference between nominal and actual concentrations was acceptable. 		
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	- For dermal studies: State whether the analytical data indicated that the difference between nominal and actual concentrations of the test substance in the vehicle was acceptable.		
Duration of treatment / exposure	Indicate duration of treatment or exposure (with unit) for each reproductive phase and generation, e.g. (P) Males: [...] days/weeks before mating. (P) Females: [...] days/weeks before mating, [...] days/weeks during mating, [...] days/weeks during resulting pregnancies, [...] days/weeks through weaning of their F1 offspring. (F1) Males: [...] days/weeks at weaning, during growth into adulthood, mating and production of an F2 generation, until weaning of the F2 generation. (F1) Females: [...] days/weeks at weaning, during growth into adulthood, mating and production of an F2 generation, until weaning of the F2 generation.	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.AdministrationExposure.DurationOfTreatmentExposure
Frequency of treatment	Indicate the frequency of the administration of doses to the test animals (e.g., 'daily, 7 days each week'). Use of non-standard dosing regime (e.g. a five-day	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.AdministrationExposure.FrequencyOfTreatment

	per week regime) should be justified.		
Doses / concentrations	Indicate the dose or concentration levels applied and the basis of quantity used. Copy this block of fields for each numeric value and to record values on a different basis, i.e. mg/kg bw/day (nominal), mg/kg bw/day (actual dose received), mg/kg diet, mg/L drinking water, mg/kg bw (total dose), ppm if applicable. Conversion of the dose / conc. values to the relevant unit used for the effect levels may be required.		ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.AdministrationExposure.DosesConcentrations
Dose / conc.	Enter numeric value.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.DoseConc
Remarks	Enter any remarks related to dose / concentration values.	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.Remarks
Doses / concentrations			
No. of animals per sex per dose	Indicate number of animals used per dose group, e.g. [#] (P) males caged with [#] (P) females; [#] (F1) males, [#] (F1) females. For robust study summaries or as requested by the regulatory programme, also include a detailed table on the animal assignment in the rich text field 'Any other information on results	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.AdministrationExposure.NoOfAnimalsPerSexPerDose

	incl. tables'. Upload predefined or other appropriate table(s) if available and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1').		
Control animals	Indicate whether and what type of concurrent control groups were used. Multiple selection is possible. If not listed, select 'other' and specify.	Multi select open list with remarks	ENDPOINT_STUDY_RE CORD.ToxicityReproduc tion.MaterialsAndMetho ds.AdministrationExpos ure.ControlAnimals
Details on study design	Include any details on the study design including a brief description on dose selection and animal assignment rationale if appropriate. As appropriate state study type(s) and briefly describe the results from range-finding or other studies used as basis for dose selection. More comprehensive details may be attached. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RE CORD.ToxicityReproduc tion.MaterialsAndMetho ds.AdministrationExpos ure.DetailsOnStudyDesi gn
Positive control	Indicate if a positive control was used and if necessary indicate purity, Lot/batch No.	Multi-line text	ENDPOINT_STUDY_RE CORD.ToxicityReproduc tion.MaterialsAndMetho ds.AdministrationExpos ure.PositiveControl
Examinations		Header 2	ENDPOINT_STUDY_RE CORD.ToxicityReproduc tion.MaterialsAndMetho ds.Examinations

Parental animals: Observations and examinations	<p>Indicate which clinical examinations were performed in the parental animals and the time schedule for those examinations. State if any examination was not performed and with what parental generation as applicable. Also indicate the dose groups that were examined if not all. As appropriate include detailed table(s) in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate tables(s) if available and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1').</p> <p>If the study is a combined repeated dose toxicity / reproduction toxicity study or includes a developmental neurotoxicity part, include a note in the block 'Cross-reference' and describe these study parts separately in the respective data point entry form(s), i.e. 'Repeated dose toxicity (route x)' or 'Neurotoxicity'.</p> <p>Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or</p>	Text template	ENDPOINT_STUDY_RE CORD.ToxicityReproduc tion.MaterialsAndMetho ds.Examinations.Parent alAnimalsObservationsA ndExaminations
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	that are requested by the respective regulatory programme.		
Oestrous cyclicity (parental animals)	Indicate whether and how [e.g., vaginal smear] and for how long [x cycles or x weeks] the oestrous cyclicity was determined. Indicate whether a screening for normal cycles (in a pre-treatment period) has been performed.	Multi-line text	ENDPOINT_STUDY_RE CORD.ToxicityReproduc tion.MaterialsAndMetho ds.Examinations.Estrou sCyclicityParentalAnimal s
Sperm parameters (parental animals)	Indicate which sperm parameters were examined. State if any examination was not performed and with what parental generation as applicable. Also indicate the dose groups that were examined if not all.	Text template	ENDPOINT_STUDY_RE CORD.ToxicityReproduc tion.MaterialsAndMetho ds.Examinations.Sperm ParametersParentalAni mals
Litter observations	Indicate which litter observations were made. State if any examination was not performed and with what generation as applicable. Also indicate the dose groups that were examined if not all. In parentheses, include the time of observation (lactation day), e.g. (Day 0). As an alternative option, include detailed table(s) in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) if available and tailor it/them to your needs. Use table numbers in the sequence in which you	Text template	ENDPOINT_STUDY_RE CORD.ToxicityReproduc tion.MaterialsAndMetho ds.Examinations.LitterO bservations

	<p>refer to them in the Remarks text (e.g. '... see Table 1').</p> <p>Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.</p>		
Postmortem examinations (parental animals)	<p>Indicate when the surviving parental males/females were sacrificed and the postmortem examinations performed. Use freetext template and delete/add elements as appropriate. As an alternative option, include detailed table(s) in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) if any and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1').</p> <p>Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.</p>	Text template	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.Examinations.PostmortemExaminationsParentalAnimals
Postmortem examinations (offspring)	<p>Indicate details on gross pathological and histopathological examinations. Also indicate those dose groups which were examined if not all. Use</p>	Text template	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.Examinations.PostmortemExaminationsOffspring

	<p>freetext template and delete/add elements as appropriate. As an alternative option or in addition, include a table and refer to respective table no. (use predefined or other appropriate table(s) if any and tailor it/them to your needs). Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.</p>		
Statistics	<p>List parameters that were analysed by which test methods. Indicate whether these are appropriate. Statistical analysis of e.g. anogenital distance (AGD) and nipple retention should be based on individual pup data, taking litter effects into account. Where appropriate, the litter is the unit of analysis. Statistical analysis of pup body weight should be based on individual pup data, taking litter size into account. Due to the limited dimensions of some study (e.g. screening tests), statistical analyses in the form of tests for "significance" may be of limited value for many endpoints, especially reproductive endpoints. In these cases, some of the most widely used methods, especially parametric tests for</p>	Multi-line text	<p>ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.Examinations.Statistics</p>

	<p>measures of central tendency, are inappropriate. If statistical analyses are used then the method chosen should be appropriate for the distribution of the variable examined and be selected prior to the start of the study.</p> <p>Note: General statistical assumptions need not be stated unless there are deviations from generally applied techniques. Animals excluded from analyses should be in table footnotes.</p>		
Reproductive indices	Describe which reproductive indices were calculated from breeding and parturition records of animals in the study. Include formulas or descriptions as provided in the study report.	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.Examinations.ReproductiveIndices
Offspring viability indices	Describe which viability indices were calculated from lactation records of litters in the study. Include formulas or descriptions as provided in the study report.	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.Examinations.OffspringViabilityIndices
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion
Results: P0 (first parental generation)		Header 2	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussi

			on.ResultsOfExaminationParentalGeneration
General toxicity (P0)		Header 3	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationParentalGeneration.GeneralToxicityP0
Clinical signs	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationParentalGeneration.GeneralToxicityP0.ObservClinSigns
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationParentalGeneration.GeneralToxicityP0.DescriptionIncidenceAndSeverityObservClinSigns
Dermal irritation (if dermal study)	Indicate whether any effects were observed and whether they were	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussi

	treatment-related or not. Select 'not examined' or 'not specified' as applicable.		on.ResultsOfExaminationParentalGeneration.GeneralToxicityP0.ObservDermalIrritationIfDermalStudy
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationParentalGeneration.GeneralToxicityP0.DescriptionIncidenceAndSeverityObservDermalIrritationIfDermalStudy
Mortality	Indicate whether mortality was observed and whether it was treatment-related or not.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationParentalGeneration.GeneralToxicityP0.ObservMortality
Description (incidence)	Describe the incidence of mortality by sex and dose group. An explanation should be provided when there was a need to humanely sacrifice	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationParentalGeneration.GeneralToxicityP0.DescriptionIncidenceMortality

	animals in pain or showing signs of severe and enduring distress.		
Body weight and weight changes	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable. The effects should be also considered in relation to organ weight.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.ObservBodyweight
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.DescriptionIncidenceAndSeverityObservBodyweight
Food consumption and compound intake (if feeding study)	Indicate whether any effects were observed and whether they were treatment-related or	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminatio

	not. Select 'not examined' or 'not specified' as applicable.		nsParentalGeneration.GeneralToxicityP0.ObservFoodConsum
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationnsParentalGeneration.GeneralToxicityP0.DescriptionIncidenceAndSeverityObservFoodConsum
Food efficiency	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationnsParentalGeneration.GeneralToxicityP0.ObservFoodEfficiency
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationnsParentalGeneration.GeneralToxicityP0.DescriptionIncidenceAndSeve

	<p>effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.</p> <p>Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p> <p>NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		rityObservFoodEfficiency
Water consumption and compound intake (if drinking water study)	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.ObservWaterConsum
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.DescriptionIncidenceAndSeverityObservWaterConsum

	incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Ophthalmological findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.ObservationOphthalm
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.DescriptionIncidenceAndSeverityObservationOphthalm

	programme some form of a table(s) (predefined table) may be mandatory.		
Haematological findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RE CORD.ToxicityReproduc tion.ResultsAndDiscussi on.ResultsOfExaminatio nsParentalGeneration.G eneralToxicityP0.Observ Haematol
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RE CORD.ToxicityReproduc tion.ResultsAndDiscussi on.ResultsOfExaminatio nsParentalGeneration.G eneralToxicityP0.Descri ptionIncidenceAndSeve rityObservHaematol
Clinical biochemistry findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RE CORD.ToxicityReproduc tion.ResultsAndDiscussi on.ResultsOfExaminatio nsParentalGeneration.G eneralToxicityP0.Observ ClinChem

Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Effects seen on hormone levels should be described. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.DescriptionIncidenceAndSeverityObservClinChem
Endocrine findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.EndocrineFindings
Description (incidence and severity)	Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.DescriptionIncidenceAndSeverityEndocrine

	<p>Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p> <p>NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Urinalysis findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.ObservUrin
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.</p> <p>Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the</p>	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.DescriptionIncidenceAndSeverityObservUrin

	<p>toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Behaviour (functional findings)	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.ObservNeurobehaviour
Description (incidence and severity)	<p>Where relevant describe functional investigations in relation to motor activity, sensory function, grip strength or bizarre behaviour (e.g. walking backwards). Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the</p>	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.DescriptionIncidenceAndSeverityObservNeurobehaviour

	<p>results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Immunological findings	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.ImmunologicalFindings
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.DescriptionIncidenceAndSeverityImmunologicalFindings
Organ weight findings including	<p>Indicate whether any effects were observed</p>	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduc

organ / body weight ratios	and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.		tion.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.ObservOrganWeights
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Include (both) body weight, organ weights and relative weights (related to bw). Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.DescriptionIncidenceAndSeverityObservOrganWeights
Gross pathological findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.ObservGrpathol

Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.DescriptionIncidenceAndSeverityObservGrpathol
Neuropathological findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.ObservNeuropathol
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows,	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.DescriptionIncidenceAndSeverityObservNeuropathol

	<p>whether the effects are reversible or irreversible.</p> <p>Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p> <p>NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Histopathological findings: non-neoplastic	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.ObservHistopathol
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description (using scores) where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.</p> <p>Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such</p>	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.DescriptionIncidenceAndSeverityObservHistopathol

	<p>tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p> <p>NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Histopathological findings: neoplastic	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.ObservHistopatholNeoplastic
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.</p> <p>Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p> <p>NOTE: Depending on the regulatory programme some form of a table(s)</p>	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.DescriptionIncidenceAndSeverityObservHistopatholNeoplastic

	(predefined table) may be mandatory.		
Other effects	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.OtherEffects
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.DescriptionIncidenceAndSeverityOtherEffects
Reproductive function / performance (P0)		Header 3	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.ReproductiveFunctionPerformanceP0

Reproductive function: oestrous cycle	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable. Indicate if it is oestrous cycles pre-treatment effects or treatment related.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.ReproductiveFunctionPerformanceP0.ObservEstrousParent
Description (incidence and severity)	Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.ReproductiveFunctionPerformanceP0.DescriptionIncidenceAndSeverityObservEstrousParent
Reproductive function: sperm measures	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.ReproductiveFunctionPer

			formanceP0.ObservSpermParent
Description (incidence and severity)	Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.ReproductiveFunctionPerformanceP0.DescriptionIncidenceAndSeverityObservSpermParent
Reproductive performance	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.ReproductiveFunctionPerformanceP0.ObservReproPerformParent
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.ReproductiveFunctionPerformanceP0.DescriptionIncidenceAndSeverityO

	<p>effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.</p> <p>Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p> <p>NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		bservReproPerformParent
Details on results (P0)		Header 3	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.DetailsOnResultsP0
	Provide any other relevant details if not entered in the specific "Description" fields for the examined parameters.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.DetailsOnResultsP0.DetailsOnResults
Effect levels (P0)		Header 3	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.EffectLevelsP0
			ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.EffectLevelsP0.Efflevel

Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.EffectLevelsP0.Efflevel.KeyResult
Dose descriptor	Select the relevant dose descriptor, i.e. the exposure level that corresponds to a quantified level of effects, e.g. NOAEL or LOAEL. If a benchmark dose / concentration was calculated, select appropriate BMD indicator (e.g. 'BMD05' or 'BMD:') and specify in the related text field). If the critical effects at a specific dose or concentration level are reported only, select 'dose. level:' or 'conc. level:' and specify. Where no value could be achieved based on the method and boundaries used, the upper or lower dose level for the relevant dose descriptor can be reported as appropriate with relevant qualifier, e.g. NOAEL >200 mg/kg bw/day or NOAEL <200 mg/kg bw/day. An additional explanation may be given in field 'Remarks on result', e.g. 'not determinable due to absence of adverse toxic effects'.	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.EffectLevelsP0.Efflevel.Endpoint
Effect level	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.EffectLevelsP0.Efflevel.EffectLevel

	'<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.		
Based on	Indicate whether the concentration is based on the test material (test mat.), active ingredient (act. ingr.) or element. As appropriate the measured / addressed fraction can be specified for either of these entities by selecting the relevant item, e.g. 'element (dissolved fraction)' or 'test mat. (total fraction)'. Further information can be given in the supplementary remarks field, e.g. for specifying the type of fraction if it is not clear per se from the test material specification. Select 'not specified' if the effect concentration type is not known.	Open list with remarks	ENDPOINT_STUDY_RE CORD.ToxicityReproduc tion.ResultsAndDiscussi on.ResultsOfExaminatio nsParentalGeneration.E ffectLevelsP0.Efflevel.B asedOn
Sex	Select from drop-down list.	Closed list	ENDPOINT_STUDY_RE CORD.ToxicityReproduc tion.ResultsAndDiscussi on.ResultsOfExaminatio nsParentalGeneration.E ffectLevelsP0.Efflevel.S ex
Basis for effect level	Indicate the parameter(s) used to establish the given effect level. Multi-selection of different pre-defined values is possible. If none is available, you can select 'other:'. Any explanations can always be entered in the related	Multi select open list with remarks (32000)	ENDPOINT_STUDY_RE CORD.ToxicityReproduc tion.ResultsAndDiscussi on.ResultsOfExaminatio nsParentalGeneration.E ffectLevelsP0.Efflevel.B asis

	supplementary text field.		
Remarks on result	<p>This field can be used for:</p> <ul style="list-style-type: none"> - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:' 	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.EffectLevelsP0.Efflevel.RemarksOnResults
Target system / organ toxicity (P0)		Header 3	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.TargetSystemOrganToxicityP0
	<p>Record the target system(s) where toxicity was observed that is considered of biological relevance and the specific target organ(s).</p> <p>Copy this block of fields for referring to different target systems, lowest effective dose(s) / concentration(s) and/or treatment relationship, dose response relationship and relevance for humans.</p>		ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.TargetSystemOrganToxicityP0.TargetSystemOrganToxicity
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment	Check box	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.TargetSystemOrganToxicity

	or classification purpose.		ityP0.TargetSystemOrganToxicity.KeyResult
Critical effects observed	Flag to indicate if critical effects were observed in the study within specific organs or systems.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.TargetSystemOrganToxicityP0.TargetSystemOrganToxicity.CriticalEffectsObserved
Lowest effective dose / conc.	Enter a numeric value and select the unit in the next field for indicating the lowest dose / concentration with significant and/or severe toxic effects on the target organ(s) affected.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.TargetSystemOrganToxicityP0.TargetSystemOrganToxicity.LowestEffectiveDoseConc
System	Select any specific system where toxicity was observed that is considered of biological relevance.	Open list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.TargetSystemOrganToxicityP0.TargetSystemOrganToxicity.System
Organ	Select from the multiple drop-down list the target organ(s) where toxicity was observed. This field provides context-related picklist values depending on the selection made in the preceding field 'System'.	Multi select open list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.TargetSystemOrganToxicityP0.TargetSystemOrganToxicity.Organ
Treatment related	Flag to indicate if the effects in systems and/or organs are treatment related.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.TargetSystemOrganToxicityP0.TargetSystemOrganToxicity.TreatmentRelated
Dose response relationship	Flag to indicate if the effects observed and reported in systems and/or organs are in a dose-response manner	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.T

	(monotonic or non-monotonic).		argetSystemOrganToxicityP0.TargetSystemOrganToxicity.DoseResponseRelationship
Relevant for humans	Flag to indicate if the effects observed and reported in systems and/or organs on the basis of animal experiments are also relevant for humans. Choose "no" from the picklist if the effects in target system/organ are species specific and not relevant for humans.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.TargetSystemOrganToxicityP0.TargetSystemOrganToxicity.RelevantForHumans
Results: P1 (second parental generation)		Header 2	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration
General toxicity (P1)		Header 3	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1
Clinical signs	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.ObservClinSigns
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data,	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.DescriptionIncidenceAndSeverityObservClinSigns

	<p>include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Dermal irritation (if dermal study)	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	<p>ENDPOINT_STUDY_RE CORD.ToxicityReproduc tion.ResultsAndDiscussi on.ResultsP1SecondPar entalGeneration.Genera lToxicityP1.ObservDerm alIrritationIfDermalStud y</p>
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat</p>	Text area	<p>ENDPOINT_STUDY_RE CORD.ToxicityReproduc tion.ResultsAndDiscussi on.ResultsP1SecondPar entalGeneration.Genera lToxicityP1.DescriptionI ncidenceAndSeverityOb servDermalIrritationIfD ermalStudy</p>

	the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Mortality	Indicate whether mortality was observed and whether it was treatment-related or not.	Closed list	ENDPOINT_STUDY_RE CORD.ToxicityReproduc tion.ResultsAndDiscussi on.ResultsP1SecondPar entalGeneration.Genera lToxicityP1.ObservMort ality
Description (incidence)	Describe the incidence of mortality by sex and dose group. An explanation should be provided when there was a need to humanely sacrifice animals in pain or showing signs of severe and enduring distress.	Text area	ENDPOINT_STUDY_RE CORD.ToxicityReproduc tion.ResultsAndDiscussi on.ResultsP1SecondPar entalGeneration.Genera lToxicityP1.DescriptionI ncidenceMortality
Body weight and weight changes	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RE CORD.ToxicityReproduc tion.ResultsAndDiscussi on.ResultsP1SecondPar entalGeneration.Genera lToxicityP1.ObservBody weight
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such	Text area	ENDPOINT_STUDY_RE CORD.ToxicityReproduc tion.ResultsAndDiscussi on.ResultsP1SecondPar entalGeneration.Genera lToxicityP1.DescriptionI ncidenceAndSeverityOb servBodyweight

	<p>tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p> <p>NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Food consumption and compound intake (if feeding study)	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.ObservFoodConsum
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.</p> <p>Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p> <p>NOTE: Depending on the regulatory programme some form of a table(s)</p>	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.DescriptionIncidenceAndSeverityObservFoodConsum

	(predefined table) may be mandatory.		
Food efficiency	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.ObservFoodEfficiency
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.DescriptionIncidenceAndSeverityObservFoodEfficiency
Water consumption and compound intake (if drinking water study)	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.ObservWaterConsum

Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.DescriptionIncidenceAndSeverityObservWaterConsum
Ophthalmological findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.ObservOpthalm
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows,	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.DescriptionIncidenceAndSeverityObservOpthalm

	<p>whether the effects are reversible or irreversible.</p> <p>Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p> <p>NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Haematological findings	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.ObservHaematol
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.</p> <p>Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should</p>	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.DescriptionIncidenceAndSeverityObservHaematol

	<p>mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p> <p>NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Clinical biochemistry findings	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.ObservClinChem
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p> <p>NOTE: Depending on the regulatory programme some form of a table(s)</p>	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.DescriptionIncidenceAndSeverityObservClinChem

	(predefined table) may be mandatory.		
Endocrine findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.EndocrineFindings
Description (incidence and severity)	Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.DescriptionIncidenceAndSeverityEndocrine
Urinalysis findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.ObservUrinary
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.DescriptionI

	<p>related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.</p> <p>Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p> <p>NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		ncidenceAndSeverityObservUrin
Behaviour (functional findings)	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.ObservNeurobehaviour
Description (incidence and severity)	<p>Where relevant describe functional investigations in relation to motor activity, sensory function, grip strength or bizarre behaviour (e.g. walking backwards).</p> <p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the</p>	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.DescriptionIncidenceAndSeverityObservNeurobehaviour

	<p>effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.</p> <p>Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p> <p>NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Immunological findings	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.ImmunologicalFindings
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.</p> <p>Particularly with comprehensive data, include a table in the rich text field 'Any other information on results</p>	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.DescriptionIncidenceAndSeverityImmunologicalFindings

	incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Organ weight findings including organ / body weight ratios	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.ObservOrganWeights
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.DescriptionIncidenceAndSeverityObservOrganWeights

	programme some form of a table(s) (predefined table) may be mandatory.		
Gross pathological findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.ObservGrpat hol
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.DescriptionIncidenceAndSeverityObservGrpat hol
Neuropathological findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.ObservNeuropathol

Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.DescriptionIncidenceAndSeverityObservNeuropathol
Histopathological findings: non-neoplastic	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.ObservHistopathol
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows,	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.DescriptionIncidenceAndSeverityObservHistopathol

	<p>whether the effects are reversible or irreversible.</p> <p>Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p> <p>NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Histopathological findings: neoplastic	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	ENDPOINT_STUDY_RE CORD.ToxicityReproduc tion.ResultsAndDiscussi on.ResultsP1SecondPar entalGeneration.Genera lToxicityP1.ObservHisto patholNeoplastic
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.</p> <p>Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should</p>	Text area	ENDPOINT_STUDY_RE CORD.ToxicityReproduc tion.ResultsAndDiscussi on.ResultsP1SecondPar entalGeneration.Genera lToxicityP1.DescriptionI ncidenceAndSeverityOb servHistopatholNeoplas tic

	<p>mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p> <p>NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Other effects	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.OtherEffects
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p> <p>NOTE: Depending on the regulatory programme some form of a table(s)</p>	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.DescriptionIncidenceAndSeverityOtherEffects

	(predefined table) may be mandatory.		
Details on results	Provide any other relevant details if not entered in the specific "Description" fields for the examined parameters.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.DetailsOnResults
Reproductive function / performance (P1)		Header 3	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.ReproductiveFunctionPerformanceP1
Reproductive function: oestrous cycle	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.ReproductiveFunctionPerformanceP1.ReproductiveFunctionEstrousCycle
Description (incidence and severity)	Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE:	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.ReproductiveFunctionPerformanceP1.DescriptionIncidenceAndSeverityReproductiveFunctionEstrousCycle

	Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Reproductive function: sperm measures	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.ReproductiveFunctionPerformanceP1.ReproductiveFunctionSpermMeasures
Description (incidence and severity)	Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.ReproductiveFunctionPerformanceP1.DescriptionIncidenceAndSeverityReproductiveFunctionSpermMeasures
Reproductive performance	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.ReproductiveFunctionPerformance

	examined' or 'not specified' as applicable.		nceP1.ReproductivePerformance
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.ReproductiveFunctionPerformanceP1.DescriptionIncidenceAndSeverityReproductivePerformance
Details on results (P1)		Header 3	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.DetailsOnResultsP1
	Provide any other relevant details if not entered in the specific "Description" fields for the examined parameters.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.DetailsOnResultsP1.DetailsOnResults
Effect levels (P1)		Header 3	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondPar

			entalGeneration.EffectLevelsP1
			ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.EffectLevelsP1.Efflevel
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.EffectLevelsP1.Efflevel.KeyResult
Dose descriptor	As appropriate, include remarks, e.g. a short description of the content of the attached document if the file name is not self-explanatory.	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.EffectLevelsP1.Efflevel.Endpoint
Effect level	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.EffectLevelsP1.Efflevel.EffectLevel
Based on	Indicate whether the concentration is based on the test material (test mat.), active ingredient (act. ingr.) or element. As appropriate the measured / addressed fraction can be specified for either of these entities by selecting the relevant item, e.g. 'element (dissolved fraction)' or 'test mat. (total fraction)'. Further information can be given in the	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.EffectLevelsP1.Efflevel.BasedOn

	supplementary remarks field, e.g. for specifying the type of fraction if it is not clear per se from the test material specification. Select 'not specified' if the effect concentration type is not known.		
Sex	Select from drop-down list.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.EffectLevelsP1.Efflevel.Sex
Basis for effect level	Indicate the parameter(s) used to establish the given effect level. Multi-selection of different pre-defined values is possible. If none is available, you can select 'other:'. Any explanations can always be entered in the related supplementary text field.	Multi select open list with remarks (32000)	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.EffectLevelsP1.Efflevel.Basis
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.EffectLevelsP1.Efflevel.RemarksOnResults
Target system / organ toxicity (P1)		Header 3	ENDPOINT_STUDY_RECORD.ToxicityReproduc

			tion.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.TargetSystemOrganToxicityP1
	Record the target system(s) where toxicity was observed that is considered of biological relevance and the specific target organ(s). Copy this block of fields for referring to different target systems, lowest effective dose(s) / concentration(s) and/or treatment relationship, dose response relationship and relevance for humans.		ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.TargetSystemOrganToxicityP1.TargetSystemOrganToxicity
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.TargetSystemOrganToxicityP1.TargetSystemOrganToxicity.KeyResult
Critical effects observed	Flag to indicate if critical effects were observed in the study within specific organs or systems.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.TargetSystemOrganToxicityP1.TargetSystemOrganToxicity.CriticalEffectsObserved
Lowest effective dose / conc.	Enter a numeric value and select the unit in the next field for indicating the lowest dose / concentration with significant and/or severe toxic effects on the target organ(s) affected.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.TargetSystemOrganToxicityP1.TargetSystemOrganToxicity.LowestEffectiveDoseConc
System	Select any specific system where toxicity was observed that is considered of biological relevance.	Open list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.TargetSystemOrganToxicityP1

			.TargetSystemOrganTo xicity.System
Organ	Select from the multiple drop-down list the target organ(s) where toxicity was observed. This field provides context-related picklist values depending on the selection made in the preceding field 'System'.	Multi select open list	ENDPOINT_STUDY_RE CORD.ToxicityReproduc tion.ResultsAndDiscussi on.ResultsP1SecondPar entalGeneration.Target SystemOrganToxicityP1 .TargetSystemOrganTo xicity.Organ
Treatment related	Flag to indicate if the effects in systems and/or organs are treatment related. Please indicate if maternal toxicity is seen.	Closed list	ENDPOINT_STUDY_RE CORD.ToxicityReproduc tion.ResultsAndDiscussi on.ResultsP1SecondPar entalGeneration.Target SystemOrganToxicityP1 .TargetSystemOrganTo xicity.TreatmentRelated
Dose response relationship	Flag to indicate if the effects observed and reported in systems and/or organs are in a dose-response manner (monotonic or non-monotonic).	Closed list	ENDPOINT_STUDY_RE CORD.ToxicityReproduc tion.ResultsAndDiscussi on.ResultsP1SecondPar entalGeneration.Target SystemOrganToxicityP1 .TargetSystemOrganTo xicity.DoseResponseRel ationship
Relevant for humans	Flag to indicate if the effects observed and reported in systems and/or organs on the basis of animal experiments are also relevant for humans. Choose "no" from the picklist if the effects in target system/organ are species specific and not relevant for humans.	Closed list	ENDPOINT_STUDY_RE CORD.ToxicityReproduc tion.ResultsAndDiscussi on.ResultsP1SecondPar entalGeneration.Target SystemOrganToxicityP1 .TargetSystemOrganTo xicity.RelevantForHuma ns
Results: F1 generation		Header 2	ENDPOINT_STUDY_RE CORD.ToxicityReproduc tion.ResultsAndDiscussi on.ResultsOfExaminatio nsOffspring
General toxicity (F1)		Header 3	ENDPOINT_STUDY_RE CORD.ToxicityReproduc tion.ResultsAndDiscussi on.ResultsOfExaminatio

			nsOffspring.GeneralToxicityF1
Clinical signs	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.ObservClinOffspring
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.DescriptionIncidenceAndSeverityObservClinOffspring
Dermal irritation (if dermal study)	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.DermalIrritationOffspringIfDermalStudy

Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.DescriptionIncidenceAndSeverityDermalIrritationOffspringIfDermalStudy
Mortality / viability	Indicate whether any effects were observed and whether they were treatment-related or not, adverse or not and irreversible or reversible. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.ObservViabilityOf fspring
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.DescriptionIncidenceAndSeverityObservViabilityOffspring

	<p>adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p> <p>NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Body weight and weight changes	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable. Please indicate if maternal toxicity is seen.</p>	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.ObservBodyweightOffspring
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the</p>	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.DescriptionIncidenceAndSeverityObservBodyweightOffspring

	rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Food consumption and compound intake (if feeding study)	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.ObservFoodConsumOffspring
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.DescriptionIncidenceAndSeverityObservFoodConsumOffspring

	NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Food efficiency	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RE CORD.ToxicityReproduc tion.ResultsAndDiscussi on.ResultsOfExaminatio nsOffspring.GeneralToxi cityF1.ObservFoodEffici encyOffspring
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RE CORD.ToxicityReproduc tion.ResultsAndDiscussi on.ResultsOfExaminatio nsOffspring.GeneralToxi cityF1.DescriptionIncide nceAndSeverityObservF oodEfficiencyOffspring
Water consumption and compound intake (if drinking water study)	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not	Closed list	ENDPOINT_STUDY_RE CORD.ToxicityReproduc tion.ResultsAndDiscussi on.ResultsOfExaminatio nsOffspring.GeneralToxi

	examined' or 'not specified' as applicable.		cityF1.ObservWaterConsumOffspring
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.DescriptionIncidenceAndSeverityObservWaterConsumOffspring
Ophthalmological findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.ObservOphthalmOffspring
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.DescriptionIncidenceAndSeverityObservOphthalmOffspring

	<p>adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Haematological findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.ObservHaematolOffspring
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.DescriptionIncidenceAndSeverityObservHaematolOffspring

	<p>accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p> <p>NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Clinical biochemistry findings	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.ObservClinChemOffspring
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.</p> <p>Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p> <p>NOTE: Depending on the regulatory programme some form</p>	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.DescriptionIncidenceAndSeverityObservClinChemOffspring

	of a table(s) (predefined table) may be mandatory.		
Urinalysis findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.ObservUrinOffspring
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.DescriptionIncidenceAndSeverityObservUrinOffspring
Sexual maturation	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.ObservMaturationOffspring

Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.DescriptionIncidenceAndSeverityObservationMaturationOffspring
Anogenital distance (AGD)	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.AnogenitalDistance
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows,	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.DescriptionIncidenceAndSeverityAnogenitalDistance

	<p>whether the effects are reversible or irreversible.</p> <p>Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p> <p>NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Nipple retention in male pups	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.NippleRetentionInMalePups
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.DescriptionIncidenceAndSeverityNippleRetentionInMalePups

	<p>accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p> <p>NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Organ weight findings including organ / body weight ratios	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable. Please indicate if maternal toxicity is seen.</p>	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.ObservOrganWeightsOffspring
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p>	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.DescriptionIncidenceAndSeverityObservOrganWeightsOffspring

	NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Gross pathological findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RE CORD.ToxicityReproduc tion.ResultsAndDiscussi on.ResultsOfExaminatio nsOffspring.GeneralToxi cityF1.ObservGrpatholo ffspring
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Please indicate the scores of these malformations or number of pups where this is seen. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RE CORD.ToxicityReproduc tion.ResultsAndDiscussi on.ResultsOfExaminatio nsOffspring.GeneralToxi cityF1.DescriptionIncide nceAndSeverityObservG rpatholOffspring

Histopathological findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.ObservHistopathologyOffspring
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.DescriptionIncidenceAndSeverityObservHistopathologyOffspring
Other effects	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.OtherEffectsOffspring
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminatio

	<p>qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.</p> <p>Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p> <p>NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		nsOffspring.GeneralToxicityF1.DescriptionIncidenceAndSeverityOtherEffectsOffspring
Developmental neurotoxicity (F1)		Header 3	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.DevelopmentalNeurotoxicityF1
Behaviour (functional findings)	<p>Where relevant describe functional investigations in relation to motor activity, sensory function, grip strength or bizarre behaviour (e.g. walking backwards).</p> <p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations</p>	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.DevelopmentalNeurotoxicityF1.BehaviourFunctionalFindings

	<p>were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.</p> <p>Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p> <p>NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the</p>	Text area	<p>ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.DevelopmentalNeurotoxicityF1.DescriptionIncidenceAndSeverityBehaviourFunctionalFindings</p>

	results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Developmental immunotoxicity (F1)		Header 3	ENDPOINT_STUDY_RE CORD.ToxicityReproduc tion.ResultsAndDiscussi on.ResultsOfExaminatio nsOffspring.Developme ntalImmunotoxicityF1
Developmental immunotoxicity	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RE CORD.ToxicityReproduc tion.ResultsAndDiscussi on.ResultsOfExaminatio nsOffspring.Developme ntalImmunotoxicityF1.D evelopmentalImmunoto xicity
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory	Text area	ENDPOINT_STUDY_RE CORD.ToxicityReproduc tion.ResultsAndDiscussi on.ResultsOfExaminatio nsOffspring.Developme ntalImmunotoxicityF1.D escriptionIncidenceAnd SeverityDevelopmentalI mmunotoxicity

	programme some form of a table(s) (predefined table) may be mandatory.		
Details on results (F1)		Header 3	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.DetailsOnResultsF1
	Provide any other relevant details if not entered in the specific "Description" fields for the examined parameters.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.DetailsOnResultsF1.DetailsOnResults
Effect levels (F1)		Header 3	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.EffectLevelsF1
			ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.EffectLevelsF1.Efflevel
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.EffectLevelsF1.Efflevel.KeyResult
Dose descriptor	As appropriate, include remarks, e.g. a short description of the content of the attached document if the file name is not self-explanatory.	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.EffectLevelsF1.Efflevel.Endpoint
Generation	Select the generation (e.g. 'P') the effect level refers to.	Open list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.EffectLevelsF1.Efflevel.Generation
Effect level	Enter a single numeric value in the first numeric field if you	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussi

	select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.		on.ResultsOfExamination nsOffspring.EffectLevels F1.Efflevel.EffectLevel
Based on	Indicate whether the concentration is based on the test material (test mat.), active ingredient (act. ingr.) or element. As appropriate the measured / addressed fraction can be specified for either of these entities by selecting the relevant item, e.g. 'element (dissolved fraction)' or 'test mat. (total fraction)'. Further information can be given in the supplementary remarks field, e.g. for specifying the type of fraction if it is not clear per se from the test material specification. Select 'not specified' if the effect concentration type is not known.	Open list with remarks	ENDPOINT_STUDY_RE CORD.ToxicityReproduc tion.ResultsAndDiscussi on.ResultsOfExamination nsOffspring.EffectLevels F1.Efflevel.BasedOn
Sex	Select from drop-down list.	Closed list	ENDPOINT_STUDY_RE CORD.ToxicityReproduc tion.ResultsAndDiscussi on.ResultsOfExamination nsOffspring.EffectLevels F1.Efflevel.Sex
Basis for effect level	Indicate the parameter(s) used to establish the given effect level. Multi-selection of different pre-defined values is possible. If none is available, you can select 'other:'. Any explanations can	Multi select open list with remarks (32000)	ENDPOINT_STUDY_RE CORD.ToxicityReproduc tion.ResultsAndDiscussi on.ResultsOfExamination nsOffspring.EffectLevels F1.Efflevel.Basis

	always be entered in the related supplementary text field.		
Remarks on result	<p>This field can be used for:</p> <ul style="list-style-type: none"> - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:' 	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.EffectLevelsF1.Efflevel.RemarksOnResults
Target system / organ toxicity (F1)		Header 3	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.TargetSystemOrganToxicityF1
	<p>Record the target system(s) where toxicity was observed that is considered of biological relevance and the specific target organ(s). Copy this block of fields for referring to different target systems, lowest effective dose(s) / concentration(s) and/or treatment relationship, dose response relationship and relevance for humans.</p>		ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.TargetSystemOrganToxicityF1.TargetSystemOrganToxicity
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment	Check box	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.TargetSystem

	or classification purpose.		mOrganToxicityF1.TargetSystemOrganToxicity.KeyResult
Critical effects observed	Flag to indicate if critical effects were observed in the study within specific organs or systems.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.TargetSystemOrganToxicityF1.TargetSystemOrganToxicity.CriticalEffectsObserved
Lowest effective dose / conc.	Enter a numeric value and select the unit in the next field for indicating the lowest dose / concentration with significant and/or severe toxic effects on the target organ(s) affected.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.TargetSystemOrganToxicityF1.TargetSystemOrganToxicity.LowestEffectiveDoseConc
System	Select any specific system where toxicity was observed that is considered of biological relevance.	Open list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.TargetSystemOrganToxicityF1.TargetSystemOrganToxicity.System
Organ	Select from the multiple drop-down list the target organ(s) where toxicity was observed. This field provides context-related picklist values depending on the selection made in the preceding field 'System'.	Multi select open list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.TargetSystemOrganToxicityF1.TargetSystemOrganToxicity.Organ
Treatment related	Flag to indicate if the effects in systems and/or organs are treatment related.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.TargetSystemOrganToxicityF1.TargetSystemOrganToxicity.TreatmentRelated
Dose response relationship	Flag to indicate if the effects observed and reported in systems and/or organs are in a dose-response manner.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.TargetSystemOrganToxicityF1.Target

			etSystemOrganToxicity.DoseResponseRelationship
Relevant for humans	Flag to indicate if the effects observed and reported in systems and/or organs on the basis of animal experiments are also relevant for humans. Choose "no" from the picklist if the effects in target system/organ are species specific and not relevant for humans.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.TargetSystemOrganToxicityF1.TargetSystemOrganToxicity.RelevantForHumans
Results: F2 generation		Header 2	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation
General toxicity (F2)		Header 3	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2
Clinical signs	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.ObservClinOffspring
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.DescriptionIncidenceAndSeverityObservClinOffspring

	incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Dermal irritation (if dermal study)	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.DermalIrritationOffspringIfDermalStudy
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.DescriptionIncidenceAndSeverityDermalIrritationOffspringIfDermalStudy

	programme some form of a table(s) (predefined table) may be mandatory.		
Mortality / viability	Indicate whether any effects were observed and whether they were treatment-related or not, adverse or not and irreversible or reversible. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.ObservViabilityOffspring
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.DescriptionIncidenceAndSeverityObservViabilityOffspring
Body weight and weight changes	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation

	examined' or 'not specified' as applicable.		.GeneralToxicityF2.ObservBodyweightOffspring
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.DescriptionIncidenceAndSeverityObservBodyweightOffspring
Food consumption and compound intake (if feeding study)	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.ObservFoodConsumOffspring
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.DescriptionIncidenceAndSeverityObservFoodConsumOffspring

	<p>adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p> <p>NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Food efficiency	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.ObservFoodEfficiencyOffspring
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative</p>	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.DescriptionIncidenceAndSeverityObservFoodEfficiencyOffspring

	<p>accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p> <p>NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Water consumption and compound intake (if drinking water study)	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.ObservWaterConsumOffspring
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.</p> <p>Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p> <p>NOTE: Depending on the regulatory programme some form</p>	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.DescriptionIncidenceAndSeverityObservWaterConsumOffspring

	of a table(s) (predefined table) may be mandatory.		
Ophthalmological findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.ObservOphthalmOffspring
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.DescriptionIncidenceAndSeverityObservOphthalmOfspring
Haematological findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.ObservHaematolOffspring

Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.DescriptionIncidenceAndSeverityObservHaematolOffspring
Clinical biochemistry findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.ObservClinChemOffspring
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows,	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.DescriptionIncidenceAndSeverityObservClinChemOffspring

	<p>whether the effects are reversible or irreversible.</p> <p>Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p> <p>NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Urinalysis findings	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.ObservUrinOffspring
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.</p> <p>Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should</p>	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.DescriptionIncidenceAndSeverityObservUrinOffspring

	<p>mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p> <p>NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Sexual maturation	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	<p>ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.ObservMaturationOffspring</p>
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.</p> <p>Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p> <p>NOTE: Depending on the regulatory programme some form of a table(s)</p>	Text area	<p>ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.DescriptionIncidenceAndSeverityObservMaturationOffspring</p>

	(predefined table) may be mandatory.		
Anogenital distance (AGD)	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.AnogenitalDistance
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.</p> <p>Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p> <p>NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.DescriptionIncidenceAndSeverityAnogenitalDistance
Nipple retention in male pups	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.NippleRetentionInMalePups

Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.DescriptionIncidenceAndSeverityNippleRetentionInMalePups
Organ weight findings including organ / body weight ratios	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.ObservOrganWeightsOffspring
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows,	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.DescriptionIncidenceAndSeverityObservOrganWeightsOffspring

	<p>whether the effects are reversible or irreversible.</p> <p>Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p> <p>NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Gross pathological findings	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.ObservGrpatholOffspring
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.</p> <p>Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should</p>	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.DescriptionIncidenceAndSeverityObservGrpatholOffspring

	<p>mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p> <p>NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Histopathological findings	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	<p>ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.ObservHistopatholOffspring</p>
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p> <p>NOTE: Depending on the regulatory programme some form of a table(s)</p>	Text area	<p>ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.DescriptionIncidenceAndSeverityObservHistopatholOffspring</p>

	(predefined table) may be mandatory.		
Other effects	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.OtherEffectsOffspring
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.DescriptionIncidenceAndSeverityOtherEffectsOffspring
Developmental neurotoxicity (F2)		Header 3	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.DevelopmentalNeurotoxicityOff1Generation
Behaviour (functional findings)	Indicate whether any effects were observed and whether they were	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussi

	treatment-related or not. Select 'not examined' or 'not specified' as applicable.		on.ResultsF2Generation .DevelopmentalNeurotoxicityOfF1Generation.Be haviourFunctionalFindin gs
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RE CORD.ToxicityReproduc tion.ResultsAndDiscussi on.ResultsF2Generation .DevelopmentalNeuroto xicityOfF1Generation.D escriptionIncidenceAnd SeverityBehaviourFunc tionalFindings
Developmental immunotoxicity (F2)		Header 3	ENDPOINT_STUDY_RE CORD.ToxicityReproduc tion.ResultsAndDiscussi on.ResultsF2Generation .DevelopmentalImmuno toxicityOfF1Generation
Developmental immunotoxicity	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RE CORD.ToxicityReproduc tion.ResultsAndDiscussi on.ResultsF2Generation .DevelopmentalImmuno toxicityOfF1Generation. DevelopmentalImmuno toxicity

Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.DevelopmentalImmunotoxicityOfF1Generation.DescriptionIncidenceAndSeverityDevelopmentalImmunotoxicity
Details on results (F2)		Header 3	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.DetailsOnResultsF2
	Provide any other relevant details if not entered in the specific "Description" fields for the examined parameters.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.DetailsOnResultsF2.DetailsOnResults
Effect levels (F2)		Header 3	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.EffectLevelsF2
			ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion

			on.ResultsF2Generation.EffectLevelsF2.Efflevel
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.EffectLevelsF2.Efflevel.KeyResult
Dose descriptor	Select the relevant dose descriptor, i.e. the exposure level that corresponds to a quantified level of effects, e.g. NOAEL or LOAEL. If a benchmark dose / concentration was calculated, select appropriate BMD indicator (e.g. 'BMD05' or 'BMD:') and specify in the related text field). If the critical effects at a specific dose or concentration level are reported only, select 'dose. level:' or 'conc. level:' and specify. Where no value could be achieved based on the method and boundaries used, the upper or lower dose level for the relevant dose descriptor can be reported as appropriate with relevant qualifier, e.g. NOAEL >200 mg/kg bw/day or NOAEL <200 mg/kg bw/day. An additional explanation may be given in field 'Remarks on result', e.g. 'not determinable due to absence of adverse toxic effects'.	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.EffectLevelsF2.Efflevel.Endpoint
Generation	Select the generation (e.g. 'P') the effect level refers to.	Open list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation

			.EffectLevelsF2.Efflevel. Generation
Effect level	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RE CORD.ToxicityReproduc tion.ResultsAndDiscussi on.ResultsF2Generation .EffectLevelsF2.Efflevel. EffectLevel
Based on	Indicate whether the concentration is based on the test material (test mat.), active ingredient (act. ingr.) or element. As appropriate the measured / addressed fraction can be specified for either of these entities by selecting the relevant item, e.g. 'element (dissolved fraction)' or 'test mat. (total fraction)'. Further information can be given in the supplementary remarks field, e.g. for specifying the type of fraction if it is not clear per se from the test material specification. Select 'not specified' if the effect concentration type is not known.	Open list with remarks	ENDPOINT_STUDY_RE CORD.ToxicityReproduc tion.ResultsAndDiscussi on.ResultsF2Generation .EffectLevelsF2.Efflevel. BasedOn
Sex	Select from drop-down list.	Closed list	ENDPOINT_STUDY_RE CORD.ToxicityReproduc tion.ResultsAndDiscussi on.ResultsF2Generation .EffectLevelsF2.Efflevel. Sex
Basis for effect level	Indicate the parameter(s) used to establish the given effect level. Multi-selection of different	Multi select open list with remarks (32000)	ENDPOINT_STUDY_RE CORD.ToxicityReproduc tion.ResultsAndDiscussi on.ResultsF2Generation

	pre-defined values is possible. If none is available, you can select 'other:'. Any explanations can always be entered in the related supplementary text field.		.EffectLevelsF2.Efflevel. Basis
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.EffectLevelsF2.Efflevel. RemarksOnResults
Target system / organ toxicity (F2)		Header 3	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.TargetSystemOrganToxicityF2
	Record the target system(s) where toxicity was observed that is considered of biological relevance and the specific target organ(s). Copy this block of fields for referring to different target systems, lowest effective dose(s) / concentration(s) and/or treatment relationship, dose response relationship and relevance for humans.		ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.TargetSystemOrganToxicityF2.TargetSystemOrganToxicity

Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.TargetSystemOrganToxicityF2.TargetSystemOrganToxicity.KeyResult
Critical effects observed	Flag to indicate if critical effects were observed in the study within specific organs or systems.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.TargetSystemOrganToxicityF2.TargetSystemOrganToxicity.CriticalEffectsObserved
Lowest effective dose / conc.	Enter a numeric value and select the unit in the next field for indicating the lowest dose / concentration with significant and/or severe toxic effects on the target organ(s) affected.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.TargetSystemOrganToxicityF2.TargetSystemOrganToxicity.LowestEffectiveDoseConc
System	Select any specific system where toxicity was observed that is considered of biological relevance.	Open list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.TargetSystemOrganToxicityF2.TargetSystemOrganToxicity.System
Organ	Select from the multiple drop-down list the target organ(s) where toxicity was observed. This field provides context-related picklist values depending on the selection made in the preceding field 'System'.	Multi select open list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.TargetSystemOrganToxicityF2.TargetSystemOrganToxicity.Organ
Treatment related	Flag to indicate if the effects in systems and/or organs are treatment related.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.TargetSystemOrganToxicityF2.TargetSystemOrganToxicity.TreatmentRelated
Dose response relationship	Flag to indicate if the effects observed and reported in systems	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion

	and/or organs are in a dose-response manner.		on.ResultsF2Generation.TargetSystemOrganToxicityF2.TargetSystemOrganToxicity.DoseResponseRelationship
Relevant for humans	Flag to indicate if the effects observed and reported in systems and/or organs on the basis of animal experiments are also relevant for humans. Choose "no" from the picklist if the effects in target system/organ are species specific and not relevant for humans.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.TargetSystemOrganToxicityF2.TargetSystemOrganToxicity.RelevantForHumans
Overall reproductive toxicity		Header 2	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ReproductiveToxicity
	Record if reproductive toxicity was observed in the study. If yes, indicate the lowest effective dose / concentration, whether the reproductive effects occurred in the absence or presence of other toxic effects, are treatment and dose-response related and of human relevance.		ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ReproductiveToxicity.ReproductiveToxicity
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ReproductiveToxicity.ReproductiveToxicity.KeyResult
Reproductive effects observed	Flag to indicate if reproductive toxicity was observed in the study.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ReproductiveToxicity.ReproductiveToxicity.ReproductiveEffectsObserved
Lowest effective dose / conc.	Enter a numeric value and select the unit in	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.ToxicityReproduc

	the next field for indicating the lowest dose / concentration with significant and/or severe toxic effects on the target organ(s) affected.		tion.ResultsAndDiscussion.ReproductiveToxicity.LowestEffectiveDoseConc
Treatment related	Flag to indicate if the reproductive effects are treatment related.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ReproductiveToxicity.TreatmentRelated
Relation to other toxic effects	Flag to indicate if the reproductive effects occur in the absence of other toxic effects or are or are not a secondary non-specific consequence of other toxic effects.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ReproductiveToxicity.RelationToOtherToxicEffects
Dose response relationship	Flag to indicate if the reproductive effects are in a dose-response manner.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ReproductiveToxicity.DoseResponseRelationship
Relevant for humans	Flag to indicate if the reproductive effects are in a dose-response manner.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ReproductiveToxicity.RelevantForHumans
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityReproduction.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ApplicantSummaryAndConclusion

5.6.1 Generational studies (includes reproduction toxicity to mammals) – Endpoint study record

Purpose:

Multigeneration studies (e.g. two-generation toxicity study and/or 1-extended one generation study) should be reported using the endpoint study record under 5.6-toxicity to reproduction.

Other reproductive toxicity studies not covered by the endpoint study record under 5.6-toxicity to reproduction should be reported by using this template.

ENDPOINT_STUDY_RECORD.ToxicityReproductionOther - v.7.4 (Final)			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.DataSource
Materials and methods	Material and methods – common block Type of method: Indicate if study was in vivo or in vitro test. If in vitro test, describe study design in field 'Any other information on materials and methods incl. tables'. If a specific template for in vitro assays is provided include the data in that template instead.	Header 1	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.MaterialsAndMethods
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.MaterialsAndMethods.TestMaterials
Test animals	Test animals (OHT: Repeated dose toxicity) – common block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.MaterialsAndMethods.TestAnimals
Administration / exposure		Header 2	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.MaterialsAndMethods.AdministrationExposure
Route of administration	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.MaterialsAndMethods.AdministrationExposure.RouteOfAdministration

Type of inhalation exposure (if applicable)	If route of administration is 'inhalation', indicate type of inhalation exposure, e.g. 'nose only'. Any remarks can be entered in the supplementary remarks subfield.	Open list with remarks	ENDPOINT_STUDY_REC ORD.ToxicityReproducti onOther.MaterialsAndM ethods.AdministrationEx posure.TypeOfInhalatio nExposureIfApplicable
Vehicle	Select 'unchanged (no vehicle)' if none was used or select vehicle used if any. If not available from picklist, select 'other' and specify. Further information can be given in the supplementary remarks field. Note that some of the vehicles provided in this list are used for specific routes of administration only.	Open list with remarks	ENDPOINT_STUDY_REC ORD.ToxicityReproducti onOther.MaterialsAndM ethods.AdministrationEx posure.Vehicle
Details on exposure	Select freetext template for the respective type of study and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_REC ORD.ToxicityReproducti onOther.MaterialsAndM ethods.AdministrationEx posure.DetailsOnExposu re
Analytical verification of doses or concentrations	Indicate whether the doses or concentrations were analytically verified.	Closed list with remarks	ENDPOINT_STUDY_REC ORD.ToxicityReproducti onOther.MaterialsAndM ethods.AdministrationEx posure.AnalyticalVerifica tionOfDosesOrConcentr ations
Details on analytical verification of doses or concentrations	For robust study summaries or as requested by the regulatory programme, include a short description on the method of analysis in the supplementary remarks field. If any problems occurred in any of these procedures, then they should be reported in more detail. If this could have affected the veracity or conclusions of the study, discuss this in field 'Rationale for reliability incl. deficiencies'. Further route-dependent information to be included: - For oral studies: State whether the analytical data indicated that the variance between nominal and actual dosage (if diet is route of administration) or concentrations (for drinking water study) was acceptable. If diet is the route of administration, briefly record when and at what dose levels the dosage analyses were made and include the results (range of values) of (i) Homogeneity analysis, (ii) Stability analysis and (iii) Concentration analysis. It may be appropriate to include a cross-reference to	Text area	ENDPOINT_STUDY_REC ORD.ToxicityReproducti onOther.MaterialsAndM ethods.AdministrationEx posure.DetailsOnAnalyti calVerificationOfDosesO rConcentrations

	<p>another study in which stability analysis was performed and reported. If so, a justification should also be included briefly explaining the rationale of referring to another study.</p> <p>- For inhalation studies: State whether the analytical data indicated that the variance between nominal and actual concentrations was acceptable.</p> <p>- For dermal studies: State whether the analytical data indicated that the variance between nominal and actual concentrations of the test substance in the vehicle was acceptable.</p>		
Duration of treatment / exposure	Indicate duration of administration / exposure in days of pregnancy counting from day 0 of pregnancy, i.e. 6-14 days pc, 6-17 days pc, 6-18 days pc or other.	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.MaterialsAndMethods.AdministrationExposure.DurationOfTreatmentExposure
Frequency of treatment	Indicate duration of administration / exposure in days of pregnancy counting from day 0 of pregnancy, i.e. 6-14 days pc, 6-17 days pc, 6-18 days pc or other.	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.MaterialsAndMethods.AdministrationExposure.FrequencyOfTreatment
Duration of test	Indicate the complete duration of the test.	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.MaterialsAndMethods.AdministrationExposure.DurationOfTest
Doses / concentrations	Indicate the dose or concentration levels applied and the basis of quantity used. Copy this block of fields for each numeric value and to record values on a different basis, i.e. mg/kg bw/day (nominal), mg/kg bw/day (actual dose received), mg/kg diet, mg/L drinking water, mg/kg bw (total dose), ppm if applicable. Conversion of the dose / conc. values to the relevant unit used for the effect levels may be required.		ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.MaterialsAndMethods.AdministrationExposure.DosesConcentrations
Dose / conc.	Enter numeric value.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.DoseConc
Remarks	Enter any remarks related to dose / concentration values.	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.MaterialsAndMethods.AdministrationEx

			posure.DosesConcentrations.Remarks
Doses / concentrations			
No. of animals per sex per dose	Depending on type of study specify either number of dams or number of males and females.	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.MaterialsAndMethods.AdministrationExposure.NoOfAnimalsPerSexPerDose
Control animals	Indicate whether and what type of concurrent control groups were used. Multiple selection is possible. If not listed, select 'other' and specify.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.MaterialsAndMethods.AdministrationExposure.ControlAnimals
Details on study design	Give details on the study design. As an option you may include an excerpt from the study report.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.MaterialsAndMethods.AdministrationExposure.DetailsOnStudyDesign
Statistics	List parameters that were analyzed by which test methods.	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.MaterialsAndMethods.AdministrationExposure.Statistics
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.ResultsAndDiscussion
Effect levels	Effect levels (OHT 67-69, 72-74) – common block Select the relevant dose descriptor, i.e. the exposure level that corresponds to a quantified level of effects, e.g. NOAEL or LOAEL. If a benchmark dose / concentration was calculated, select appropriate BMD indicator (e.g. 'BMD05' or 'BMD:' and specify in the related text field). If the critical effects at a specific dose or concentration level are reported only, select 'dose. level:' or 'conc. level:' and specify. Where no value could be achieved based on the method and boundaries used, the upper or lower dose level for the relevant	Header 2	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.ResultsAndDiscussion.EffectLevels

	dose descriptor can be reported as appropriate with relevant qualifier, e.g. NOAEL >200 mg/kg bw/day or NOAEL <200 mg/kg bw/day. An additional explanation may be given in field 'Remarks on result', e.g. 'not determinable due to absence of adverse toxic effects'.		
Observed effects		Header 2	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.ResultsAndDiscussion.ObservedEffects
Any other information on results incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.ApplicantSummaryAndConclusion

5.6.2 Developmental toxicity studies (includes reproduction toxicity to mammals) – Endpoint study record

Purpose:

The developmental toxicity studies reported, taken together with other relevant data and information on the active substance, shall be sufficient to permit the assessment of effects on embryonic and foetal development, following repeated exposure to the active substance, and in particular shall be sufficient: (a) to identify direct and indirect effects on embryonic and foetal development resulting from exposure to the active substance; (b) to identify any maternal toxicity; (c) to establish the relationship between observed responses and dose in both dam and offspring; (d) to establish reference point (e.g. NOAELs) for maternal toxicity and pup development; (e) to provide additional information on adverse effects in pregnant as compared with non-pregnant females; (f) to provide additional information on any enhancement of general toxic effects of pregnant animals.

ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity - v.8.5 (Final)			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.DataSource
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.MaterialsAndMethods

Limit test	Indicate if the experiment was a limit test.	Closed list	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.MaterialsAndMethods.LimitTest
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.MaterialsAndMethods.TestMaterials
Test animals	Test animals (OHT: Repeated dose toxicity) – common block Select species as appropriate. If not available from picklist, select 'other' and specify "i.e. rat or rabbit".	Header 2	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.MaterialsAndMethods.TestAnimals
Administration / exposure		Header 2	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.MaterialsAndMethods.AdministrationExposure
Route of administration	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.MaterialsAndMethods.AdministrationExposure.RouteOfAdministration
Type of inhalation exposure (if applicable)	If route of administration is 'inhalation', indicate type of inhalation exposure, e.g. 'nose only'. Any remarks can be entered in the supplementary remarks subfield.	Open list with remarks	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.MaterialsAndMethods.AdministrationExposure.TypeOfInhalationExposureIfApplicable
Vehicle	Select 'unchanged (no vehicle)' if none was used or select vehicle used if any. If not available from picklist, select 'other' and specify. Further information can be given in the supplementary remarks field. Note that some of the vehicles provided in this list are used for specific routes of administration only.	Open list with remarks	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.MaterialsAndMethods.AdministrationExposure.Vehicle
Mass median aerodynamic diameter (MMAD)	For inhalation studies, specify the mass median aerodynamic diameter (MMAD) of the distribution of particle sizes. Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.MaterialsAndMethods.AdministrationExposure.MassMedianAerodynamicDiameter
Geometric standard deviation (GSD)	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the	Decimal	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.MaterialsAndMethods

	second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.		.AdministrationExposure.Geo metricStandardDeviation
Remarks on MMAD	Enter any remarks related to the mass median aerodynamic diameter.	Multi-line text	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTerato genicity.MaterialsAndMethods .AdministrationExposure.Rem arksOnMMAD
Details on exposure	Select freetext template for the respective type of study and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTerato genicity.MaterialsAndMethods .AdministrationExposure.Deta ilsOnExposure
Analytical verification of doses or concentrations	Indicate whether the doses or concentrations were analytically verified.	Closed list with remarks	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTerato genicity.MaterialsAndMethods .AdministrationExposure.Anal yticalVerificationOfDosesOrCo ncentrations
Details on analytical verification of doses or concentrations	For robust study summaries or as requested by the regulatory programme, include a short description on the method of analysis in the supplementary remarks field. If any problems occurred in any of these procedures, then they should be reported in more detail. If this could have affected the veracity or conclusions of the study, discuss this in field 'Rationale for reliability incl. deficiencies'. Further route-dependent information to be included: - For oral studies: State whether the analytical data indicated that the variance between nominal and actual dosage (if diet is route of administration) or concentrations (for drinking water study) was acceptable. If diet is the route of administration, briefly record when and at what dose levels the dosage analyses were made and include the results (range of values) of (i) Homogeneity analysis, (ii) Stability analysis and (iii) Concentration analysis. It may	Text area	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTerato genicity.MaterialsAndMethods .AdministrationExposure.Deta ilsOnAnalyticalVerificationOfD osesOrConcentrations

	<p>be appropriate to include a cross-reference to another study in which stability analysis was performed and reported. If so, a justification should also be included briefly explaining the rationale of referring to another study.</p> <p>- For inhalation studies: State whether the analytical data indicated that the variance between nominal and actual concentrations was acceptable.</p> <p>- For dermal studies: State whether the analytical data indicated that the variance between nominal and actual concentrations of the test substance in the vehicle was acceptable.</p>		
Details on mating procedure	<p>Briefly describe the mating procedure.</p> <p>Use freetext template and delete/add elements as appropriate.</p> <p>Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.</p>	Text template	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.MaterialsAndMethods .AdministrationExposure.DetailsOnMatingProcedure
Duration of treatment / exposure	<p>Indicate duration of administration / exposure in days of pregnancy counting from day 0 of pregnancy, i.e. 6-14 days pc, 6-17 days pc, 6-18 days pc or other.</p>	Multi-line text	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.MaterialsAndMethods .AdministrationExposure.DurationOfTreatmentExposure
Frequency of treatment	<p>In the case of an inhalation or dermal study include the daily exposure duration, e.g. '4 hours per day'. Use of non-standard dosing regime should be justified.</p>	Multi-line text	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.MaterialsAndMethods .AdministrationExposure.FrequencyOfTreatment
Duration of test	<p>Indicate the complete duration of the test.</p>	Multi-line text	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.MaterialsAndMethods .AdministrationExposure.DurationOfTest
Doses / concentrations	<p>Enter any remarks related to dose / concentration values.</p>		ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.MaterialsAndMethods .AdministrationExposure.DosesConcentrations
Dose / conc.	<p>Indicate the dose or concentration levels applied and the basis of quantity used. Copy this block of fields for each numeric value and to record values on a different basis, i.e. mg/kg bw/day (nominal), mg/kg</p>	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.MaterialsAndMethods .AdministrationExposure.DosesConcentrations.DoseConc

	bw/day (actual dose received), mg/kg diet ,mg/L drinking water, mg/kg bw (total dose), ppm if applicable. Conversion of the dose / conc. values to the relevant unit used for the effect levels may be required.		
Remarks	Enter numeric value.	Multi-line text	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.MaterialsAndMethods .AdministrationExposure.DosesConcentrations.Remarks
Doses / concentrations			
No. of animals per sex per dose	Enter number of females per dose, e.g. '20' or specify according to dose if different numbers were used and explain why. For robust study summaries or as requested by the regulatory programme, also include a detailed table on the animal assignment in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Note: Specific tables may be required.	Multi-line text	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.MaterialsAndMethods .AdministrationExposure.NoOfAnimalsPerSexPerDose
Control animals	Indicate whether and what type of concurrent control groups were used. Multiple selection is possible. If not listed, select 'other' and specify.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.MaterialsAndMethods .AdministrationExposure.ControlAnimals
Details on study design	Include any further details on the study design including a brief description on dose selection and animal assignment rationale if appropriate. Use data from range-finding study if available. More comprehensive details may be attached. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.MaterialsAndMethods .AdministrationExposure.DetailsOnStudyDesign

Examinations		Header 2	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTerato genicity.MaterialsAndMethods .Examinations
Maternal examinations	Indicate if and which examinations were performed in the dams and the time schedule for those examinations. Also indicate the dose groups that were examined if not all. When tabulating parameters examined, refer to respective table no. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTerato genicity.MaterialsAndMethods .Examinations.MaternalExami nations
Ovaries and uterine content	Indicate if ovaries and uterine contents were examined and the type of examinations. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTerato genicity.MaterialsAndMethods .Examinations.OvariesAndUte rineContent
Blood sampling	Indicate if plasma or serum were examined and the type of examinations. Use freetext template to indicate the volume of whole blood examined.	Text template	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTerato genicity.MaterialsAndMethods .Examinations.BloodSampling
Fetal examinations	Indicate if and which examinations were performed in the fetuses. Describe in detail, i.e. external, soft tissue and skeletal examinations, including assignment of fetuses and standard/non-standard methodologies used. Indicate how many per litter were used, i.e. all, half, a distinct number, or any other. When tabulating parameters examined, refer to respective table no. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by	Text template	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTerato genicity.MaterialsAndMethods .Examinations.FetalExaminati ons

	the respective regulatory programme.		
Statistics	List parameters that were analyzed by which test methods. Indicate whether these are appropriate. Differentiate between parametric and non-parametric analysis. Note: General statistical assumptions need not be stated unless there are deviations from generally applied techniques. Animals excluded from analyses should be in table footnotes.	Multi-line text	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.MaterialsAndMethods.Examinations.Statistics
Indices	Describe which indices were calculated from cesarean section records of animals in the study. Include formulas or descriptions as provided in the study report.	Multi-line text	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.MaterialsAndMethods.Examinations.Indices
Historical control data	Describe whether historical control data were provided to allow comparison with concurrent controls. State source of data and what data were included.	Multi-line text	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.MaterialsAndMethods.Examinations.HistoricalControlData
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsIncTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion
Results: maternal animals		Header 2	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals
General toxicity (maternal animals)	Results of examinations (OHT: Repeated dose toxicity: oral) – common block	Header 3	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.GeneralToxicityMaternalAnimals
Maternal developmental toxicity		Header 3	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalDevelopmentalToxicity
Number of abortions	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalDevelopmentalToxicity.NumberOfAbortions

Description (incidence and severity)	<p>Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.</p> <p>Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p> <p>NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>	Text area	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalDevelopmentalToxicity. DescriptionIncidenceAndSeverityNumberOfAbortions
Pre- and post-implantation loss	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalDevelopmentalToxicity. PreAndPostImplantationLoss
Description (incidence and severity)	<p>Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.</p> <p>Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p> <p>NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>	Text area	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalDevelopmentalToxicity. DescriptionIncidenceAndSeverityPreAndPostImplantationLoss

Total litter losses by resorption	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalDevelopmentalToxicity.TotalLitterLossesByResorption
Description (incidence and severity)	Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalDevelopmentalToxicity.DescriptionIncidenceAndSeverityTotalLitterLossesByResorption
Early or late resorptions	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalDevelopmentalToxicity.EarlyOrLateResorptions
Description (incidence and severity)	Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details	Text area	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalDevelopmentalToxicity.DescriptionIncidenceAndSeverityEarlyOrLateResorptions

	presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Dead fetuses	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalDevelopmentalToxicity. DeadFetuses
Description (incidence and severity)	Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalDevelopmentalToxicity. DescriptionIncidenceAndSeverityDeadFetuses
Changes in pregnancy duration	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalDevelopmentalToxicity. ChangesInPregnancyDuration
Description (incidence and severity)	Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative	Text area	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalDevelopmentalToxicity. DescriptionIncidenceAndSeverityChangesInPregnancyDuration

	<p>accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p> <p>NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Changes in number of pregnant	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalDevelopmentalToxicity.ChangesInNumberOfPregnant
Description (incidence and severity)	<p>Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.</p> <p>Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p> <p>NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>	Text area	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalDevelopmentalToxicity.DescriptionIncidenceAndSeverityChangesInNumberOfPregnant
Other effects	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalDevelopmentalToxicity.OtherEffects
Description (incidence and severity)	<p>Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or</p>	Text area	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalDevelopmentalToxicity.DescriptionIncidenceAndSeverityOtherEffects

	<p>irreversible.</p> <p>Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p> <p>NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Details on maternal toxic effects	Provide any other relevant details if not entered in the specific "Description" fields for the examined parameters.	Text area	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalDevelopmentalToxicity.ResultsDetailsMaternal
Effect levels (maternal animals)	<p>Effect levels (OHT 67-69, 72-74) – common block</p> <p>Select the relevant dose descriptor, i.e. the exposure level that corresponds to a quantified level of effects, e.g. NOAEL or LOAEL. If a benchmark dose / concentration was calculated, select appropriate BMD indicator (e.g. 'BMD05' or 'BMD:' and specify in the related text field). If the critical effects at a specific dose or concentration level are reported only, select 'dose. level:' or 'conc. level:' and specify.</p> <p>Where no value could be achieved based on the method and boundaries used, the upper or lower dose level for the relevant dose descriptor can be reported as appropriate with relevant qualifier, e.g. NOAEL >200 mg/kg bw/day or NOAEL <200 mg/kg bw/day. An additional explanation may be given in field 'Remarks on result', e.g. 'not determinable due to absence of adverse toxic effects'.</p>	Header 3	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.EffectLevelsMaternalAnimals
Maternal abnormalities		Header 3	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalAbnormalities

	Record if any abnormalities were observed in the study and where they are located. Describe the incidence and severity of effects by dose group. Copy this block of fields for referring to different developmental endpoints where the indicated effect is located if the type of effects is different.		ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalAbnormalities.Maternal Abnormalities
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalAbnormalities.Maternal Abnormalities.KeyResult
Abnormalities	Indicate whether any abnormalities were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable. Developmental abnormalities in dams include number of pregnant / non-pregnant dams, number of dams with abortions, early deliveries, stillbirths, resorptions and/or dead fetuses, mean number of implantations, live fetuses (pups), resorptions (early and late), dead fetuses, abortions and stillbirths per litter (with implants), pre and post implantation loss: number and percent, number of corpora lutea, duration of pregnancy, gravid uterine weight.	Closed list	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalAbnormalities.Maternal Abnormalities.Abnormalities
Localisation	Select from the multiple drop-down list the developmental endpoint(s) where the indicated effect is located. Multiple items can be selected if they are all covered by the effects description given in the preceding field. Otherwise copy this block of fields and create additional lines as needed.	Multi select open list	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalAbnormalities.Maternal Abnormalities.Localisation
Description (incidence and severity)	Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.	Text area	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalAbnormalities.Maternal Abnormalities.DescriptionIncidenceAndSeverity

	<p>Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p> <p>NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Results (fetuses)		Header 2	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses
Fetal body weight changes	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.FetalBodyWeightChanges
Description (incidence and severity)	<p>Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.</p> <p>Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p> <p>NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>	Text area	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.DescriptionIncidenceAndSeverity
Reduction in number of live offspring	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.ReductionInNumberOfLiveOffspring

Description (incidence and severity)	Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.DescriptionIncidenceAndSeverityReductionInNumberOfLiveOffspring
Changes in sex ratio	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.ChangesInSexRatio
Description (incidence and severity)	Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.DescriptionIncidenceAndSeverityChangesInSexRatio
Changes in litter size and weights	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not	Closed list	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussio

	examined' or 'not specified' as applicable.		n.ResultsFetuses.ChangesInLitterSizeAndWeights
Description (incidence and severity)	<p>Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.</p> <p>Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p> <p>NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>	Text area	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.DescriptionIncidenceAndSeverityChangesInLitterSizeAndWeights
Anogenital distance of all rodent fetuses	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.AnogenitalDistanceOfAllRodentFetuses
Description (incidence and severity)	<p>Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.</p> <p>Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p> <p>NOTE: Depending on the regulatory programme some form of a table(s)</p>	Text area	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.DescriptionIncidenceAndSeverityChangesInAnogenitalDistance

	(predefined table) may be mandatory.		
Changes in postnatal survival	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.ChangesInPostnatalSurvival
Description (incidence and severity)	Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.DescriptionIncidenceAndSeverityChangesInPostnatalSurvival
External malformations	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.ExternalMalformations
Description (incidence and severity)	Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).	Text area	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.DescriptionIncidenceAndSeverityExternalMalformations

	NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Skeletal malformations	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.SkeletalMalformations
Description (incidence and severity)	Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.DescriptionIncidenceAndSeveritySkeletalMalformations
Visceral malformations	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.VisceralMalformations
Description (incidence and severity)	Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the	Text area	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.DescriptionIncidenceAndSeverityVisceralMalformations

	<p>results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Other effects	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.OtherEffects
Description (incidence and severity)	<p>Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>	Text area	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.DescriptionIncidenceAndSeverityOtherEffects
Details on embryotoxic / teratogenic effects	<p>Provide any other relevant details if not entered in the specific "Description" fields for the examined parameters.</p>	Text area	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.ResultsDetailsDevelop
Effect levels (fetuses)	<p>Effect levels (OHT 67-69, 72-74) – common block Select the relevant dose descriptor, i.e. the exposure level that corresponds to a quantified level of effects, e.g. NOAEL or LOAEL. If a benchmark dose / concentration was calculated, select appropriate BMD indicator (e.g. 'BMD05' or 'BMD:' and specify in the related text field). If the critical effects at a specific dose or concentration level are reported only, select 'dose. level:' or 'conc. level:' and specify.</p>	Header 3	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.EffectLevelsFetuses

	Where no value could be achieved based on the method and boundaries used, the upper or lower dose level for the relevant dose descriptor can be reported as appropriate with relevant qualifier, e.g. NOAEL >200 mg/kg bw/day or NOAEL <200 mg/kg bw/day. An additional explanation may be given in field 'Remarks on result', e.g. 'not determinable due to absence of adverse toxic effects'.		
Fetal abnormalities		Header 3	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.FetalAbnormalities
	Record if any abnormalities were observed in the study and where they are located. Describe the incidence and severity of effects by dose group. Copy this block of fields for referring to different developmental endpoints where the indicated effect is located if the type of effects is different.		ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.FetalAbnormalities.FetalAbnormalities
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.FetalAbnormalities.FetalAbnormalities.KeyResult
Abnormalities	Indicate whether any abnormalities were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable. Fetal abnormalities include mean number and percent of live offspring; sex ratio; mean fetal/pup body weight by sex and with sexes combined; external, soft tissue and skeletal malformations and other relevant alterations; number and percent of fetuses and litters with malformations (including runts) and/or variations as well as description and incidences of malformations and main variations (and/or retardations).	Closed list	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.FetalAbnormalities.FetalAbnormalities.Abnormalities

Localisation	Select from the multiple drop-down list the fetal endpoint(s) where the indicated effect is located. Multiple items can be selected if they are all covered by the effects description given in the preceding field. Otherwise copy this block of fields and create additional lines as needed.	Multi select open list	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.FetalAbnormalities.FetalAbnormalities.Localisation
Description (incidence and severity)	Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.FetalAbnormalities.FetalAbnormalities.DescriptionIncidenceAndSeverity
Overall developmental toxicity		Header 2	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.DevelopmentalToxicity
	Record whether developmental toxicity was observed in the study. If yes, indicate the lowest effective dose / concentration, whether the developmental effects occurred in the absence or presence of maternal toxicity, are treatment and dose-response related and of human relevance.		ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.DevelopmentalToxicity.DevelopmentalToxicity
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.DevelopmentalToxicity.KeyResult
Developmental effects observed	Flag to indicate if developmental toxicity was observed in the study.	Closed list	ENDPOINT_STUDY_RECORD. DevelopmentalToxicityTerato

			genicity.ResultsAndDiscussion.DevelopmentalToxicity.DevelopmentalToxicity.DevelopmentalEffectsObserved
Lowest effective dose / conc.	Enter a numeric value and select the unit in the next field for indicating the lowest dose / concentration with significant and/or severe toxic effects on the target organ(s) affected.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.DevelopmentalToxicity.DevelopmentalToxicity.LowestEffectiveDoseConc
Treatment related	Flag to indicate if the reproductive effects are treatment related.	Closed list	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.DevelopmentalToxicity.DevelopmentalToxicity.TreatmentRelated
Relation to maternal toxicity	Flag to indicate if the reproductive effects occur in the absence of other toxic effects or are or are not a secondary non-specific consequence of other toxic effects.	Closed list	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.DevelopmentalToxicity.DevelopmentalToxicity.RelationToMaternalToxicity
Dose response relationship	Flag to indicate if the reproductive effects are in a dose-response manner.	Closed list	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.DevelopmentalToxicity.DevelopmentalToxicity.DoseResponseRelationship
Relevant for humans	Flag to indicate if the reproductive effects on the basis of animal experiments are also relevant for humans. Choose "no" from the picklist if the effects in target system/organ are species specific and not relevant for humans.	Closed list	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.DevelopmentalToxicity.DevelopmentalToxicity.RelevantForHumans
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ApplicantSummaryAndConclusion

5.7 Neurotoxicity studies, including delayed polyneuropathy studies – Endpoint Summary

Purpose:

The document should contain the information needed to be reported according to the list of end points for neurotoxicity

(SANCO/12592/2012-rev. 2, 22 March 2019). Neurotoxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.7)

In case that there are not specific neurotoxicity studies available, a statement on whether neurotoxicity have been properly addressed in general toxicity studies and whether there is a neurotoxic potential should be included.

Please noted the developmental neurotoxicity studies should be reported under 5.6 by using the template reproductive toxicity.

ENDPOINT_SUMMARY.Neurotoxicity - v.6.2 (Final)			
Name	Instructions	Type	Field Path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.Neurotoxicity.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.Neurotoxicity.KeyValueForChemicalSafetyAssessment
Effect on neurotoxicity: via oral route		Header 2	ENDPOINT_SUMMARY.Neurotoxicity.KeyValueForChemicalSafetyAssessment.EffectOnNeurotoxicityViaOralRoute
Link to relevant study records		Header 3	ENDPOINT_SUMMARY.Neurotoxicity.KeyValueForChemicalSafetyAssessment.EffectOnNeurotoxicityViaOralRoute.LinkToRelevantStudyRecords
Endpoint conclusion	Endpoint conclusion (Species version) – common block “Adverse effect observed” should be chosen if adverse effects were observed at or below the limit dose level. “No adverse effect observed” should be chosen if no adverse effects were observed at or below the limit dose level.	Header 3	ENDPOINT_SUMMARY.Neurotoxicity.KeyValueForChemicalSafetyAssessment.EffectOnNeurotoxicityViaOralRoute.EndpointConclusion

	<p>If “No study available” is chosen, a justification needs to be provided.</p> <p>The primary dose descriptor in this endpoint is the NOAEL. In some studies also the BMDL (benchmark dose level). The LOAEL should be used only if NOAEL is not available. The selection of the dose descriptor should only refer to neurotoxic effects. Other effects and dose descriptors should be reported in the section “Description of key information”.</p> <p>Define the duration of the selected robust study summary in the relative field</p> <p>The species reported in the selected robust study summary should be reported in the relative field.</p>		
Effect on neurotoxicity: via inhalation route		Header 2	ENDPOINT_SUMMARY.Neurotoxicity.KeyValueForChemicalSafetyAssessment.EffectOnNeurotoxicityViaInhalationRoute
Link to relevant study records		Header 3	ENDPOINT_SUMMARY.Neurotoxicity.KeyValueForChemicalSafetyAssessment.EffectOnNeurotoxicityViaInhalationRoute.LinkToRelevantStudyRecords
Results		Read-only	ENDPOINT_SUMMARY.Neurotoxicity.KeyValueForChemicalSafetyAssessment.EffectOnNeurotoxicityViaInhalationRoute.LinkToRelevantStudyRecords.Results

<p>Endpoint conclusion</p>	<p>Endpoint conclusion (Species version) – common block</p> <p>“Adverse effect observed” should be chosen if adverse effects were observed at or below the limit dose level.</p> <p>“No adverse effect observed” should be chosen if no adverse effects were observed at or below the limit dose level.</p> <p>If “No study available” is chosen, a justification needs to be provided.</p> <p>The primary dose descriptor in this endpoint is the NOAEL. In some studies also the BMDL (benchmark dose level). The LOAEL should be used only if NOAEL is not available. The selection of the dose descriptor should only refer to neurotoxic effects. Other effects and dose descriptors should be reported in the section “Description of key information”.</p> <p>Define the duration of the selected robust study summary in the relative field</p> <p>The species reported in the selected robust study summary should be reported in the relative field.</p>	<p>Header 3</p>	<p>ENDPOINT_SUMMARY. Neurotoxicity.KeyValue ForChemicalSafetyAssessment.EffectOnNeurotoxicityViaInhalationRoute.EndpointConclusion</p>
<p>Effect on neurotoxicity: via dermal route</p>		<p>Header 2</p>	<p>ENDPOINT_SUMMARY. Neurotoxicity.KeyValue ForChemicalSafetyAssessment.EffectOnNeurotoxicityViaDermalRoute</p>

Link to relevant study records		Header 3	ENDPOINT_SUMMARY.Neurotoxicity.KeyValueForChemicalSafetyAssessment.EffectOnNeurotoxicityViaDermalRoute.LinkToRelevantStudyRecords
Endpoint conclusion	<p>Endpoint conclusion (Species version) – common block</p> <p>Adverse effect observed” should be chosen if adverse effects were observed at or below the limit dose level.</p> <p>“No adverse effect observed” should be chosen if no adverse effects were observed at or below the limit dose level.</p> <p>If “No study available” is chosen, a justification needs to be provided.</p> <p>The primary dose descriptor in this endpoint is the NOAEL. In some studies also the BMDL (benchmark dose level). The LOAEL should be used only if NOAEL is not available. The selection of the dose descriptor should only refer to neurotoxic effects. Other effects and dose descriptors should be reported in the section “Description of key information”.</p> <p>Define the duration of the selected robust study summary in the relative field</p>	Header 3	ENDPOINT_SUMMARY.Neurotoxicity.KeyValueForChemicalSafetyAssessment.EffectOnNeurotoxicityViaDermalRoute.EndpointConclusion
Mode of Action Analysis / Human Relevance Framework		Header 2	ENDPOINT_SUMMARY.Neurotoxicity.KeyValueForChemicalSafetyAssessment.MoAAAnalysisHu

			manRelevanceFramework
	<p>This section is for incorporation of the WHO/IPCS Template Mode of Action Analysis / Human relevance framework at http://echa.europa.eu/web/guest/support/guidance-on-reach-and-clp-implementation/formats. The template is also available in HTML format that can be easily uploaded in this textarea where relevant</p>	Rich text area	ENDPOINT_SUMMARY.Neurotoxicity.KeyValueForChemicalSafetyAssessment.MoAAAnalysisHumanRelevanceFramework.MoAAAnalysisHumanRelevanceFramework
Additional information	<p>Discussion(Header 1) – common block</p> <p>Provide additional information related to the endpoint, for example:</p> <ul style="list-style-type: none"> - Acute neurotoxicity (mention data if available, or 'study not required' if data are not required), and dose descriptor (e.g. NOAEL) - Repeated neurotoxicity (mention data if available, or 'study not required' if data are not required), and dose descriptor (e.g. NOAEL) - Additional studies (e.g. delayed neurotoxicity, developmental neurotoxicity) (mention study results.), and dose descriptor (e.g. NOAEL) <p>If there is no additional information to be reported this field may be left empty.</p>	Header 1	ENDPOINT_SUMMARY.Neurotoxicity.Discussion

Justification for classification or non-classification		Header 1	ENDPOINT_SUMMARY.Neurotoxicity.JustificationForClassificationOrNonClassification
	The available information should be compared against the classification criteria and the reasons for fulfilling or not fulfilling the classification criteria should be presented.	Rich text area	ENDPOINT_SUMMARY.Neurotoxicity.JustificationForClassificationOrNonClassification.JustificationForClassificationOrNonClassification

5.7 Neurotoxicity studies, including delayed polyneuropathy studies – Endpoint study record

Purpose:

Such studies shall be performed for active substances with structures that are similar or related to those capable of inducing neurotoxicity, and for active substances which induce specific indications of potential neurotoxicity, neurological signs or neuropathological lesions in toxicity studies at dose levels not associated with marked general toxicity. Performance of such studies shall also be considered for substances with a neurotoxic mode of pesticidal action. Neurotoxicity studies in rodents shall provide sufficient data to evaluate the potential neurotoxicity of the active substance (neurobehavioural and neuropathological effects) after single and repeated exposure.

ENDPOINT_STUDY_RECORD.Neurotoxicity - v.9.5 (Final)			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.Neurotoxicity.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.Neurotoxicity.DataSource
Materials and methods	Material and methods – common block Applicable test guideline, e.g. "OECD 424 Method B.43".	Header 1	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods
Test guideline			
Limit test	Indicate if the experiment was a limit test.	Closed list	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.LimitTest
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.Neurotoxicity.

			MaterialsAndMethods. TestMaterials
Test animals	Test animals (OHT: Repeated dose toxicity) – common block	Header 2	ENDPOINT_STUDY_R ECORD.Neurotoxicity. MaterialsAndMethods. TestAnimals
Administration / exposure		Header 2	ENDPOINT_STUDY_R ECORD.Neurotoxicity. MaterialsAndMethods. AdministrationExposur e
Route of administration	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list	ENDPOINT_STUDY_R ECORD.Neurotoxicity. MaterialsAndMethods. AdministrationExposur e.RouteOfAdministrati on
Vehicle	Select 'unchanged (no vehicle)' if none was used or select vehicle used if any. If not available from picklist, select 'other' and specify. Further information can be given in the supplementary remarks field. Note that some of the vehicles provided in this list are used for specific routes of administration only.	Open list with remarks	ENDPOINT_STUDY_R ECORD.Neurotoxicity. MaterialsAndMethods. AdministrationExposur e.Vehicle
Mass median aerodynamic diameter (MMAD)	For inhalation studies, specify the mass median aerodynamic diameter (MMAD) of the distribution of particle sizes. Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_R ECORD.Neurotoxicity. MaterialsAndMethods. AdministrationExposur e.MassMedianAerodyn amicDiameter
Geometric standard deviation (GSD)	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Decimal	ENDPOINT_STUDY_R ECORD.Neurotoxicity. MaterialsAndMethods. AdministrationExposur e.GeometricStandardD eviation
Remarks on MMAD	Enter any remarks related to the mass median aerodynamic diameter.	Multi-line text	ENDPOINT_STUDY_R ECORD.Neurotoxicity. MaterialsAndMethods. AdministrationExposur e.RemarksOnMMAD
Details on exposure	Select freetext template for the respective type of study and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_R ECORD.Neurotoxicity. MaterialsAndMethods. AdministrationExposur e.DetailsOnExposure

Analytical verification of doses or concentrations	Indicate whether the doses or concentrations were analytically verified.	Closed list with remarks	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.AdministrationExposure.AnalyticalVerificationOfDosesOrConcentrations
Details on analytical verification of doses or concentrations	<p>For robust study summaries or as requested by the regulatory programme, include a short description on the method of analysis in the supplementary remarks field. If any problems occurred in any of these procedures, then they should be reported in more detail. If this could have affected the veracity or conclusions of the study, discuss this in field 'Rationale for reliability incl. deficiencies'.</p> <p>Further route-dependent information to be included:</p> <ul style="list-style-type: none"> - For oral studies: State whether the analytical data indicated that the difference between nominal and actual dosage (if diet is route of administration) or concentrations (for drinking water study) was acceptable. <p>If diet is the route of administration, briefly record when and at what dose levels the dosage analyses were made and include the results (range of values) of (i) Homogeneity analysis, (ii) Stability analysis and (iii) Concentration analysis. It may be appropriate to include a cross-reference to another study in which stability analysis was performed and reported. If so, a justification should also be included briefly explaining the rationale of referring to another study.</p> <ul style="list-style-type: none"> - For inhalation studies: State whether the analytical data indicated that the difference between nominal and actual concentrations was acceptable. - For dermal studies: State whether the analytical data indicated that the difference between nominal and actual concentrations of the test substance in the vehicle was acceptable. 	Text area	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.AdministrationExposure.DetailsOnAnalyticalVerificationOfDosesOrConcentrations
Duration of treatment / exposure	Indicate duration in days, weeks or months, e.g. '28 days' or '18 months'.	Multi-line text	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.AdministrationExposure.DurationOfTreatmentExposure

Frequency of treatment	Indicate the frequency of the administration of doses to the test animals (e.g., 'daily, 7 days each week'). Use of non-standard dosing regime (e.g. a five-day per week regime) should be justified.	Multi-line text	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.AdministrationExposure.FrequencyOfTreatment
Doses / concentrations	Indicate the dose or concentration levels applied and the basis of quantity used. Copy this block of fields for each numeric value and to record values on a different basis, i.e. mg/kg bw/day (nominal), mg/kg bw/day (actual dose received), mg/kg diet ,mg/L drinking water, mg/kg bw (total dose), ppm if applicable. Conversion of the dose / conc. values to the relevant unit used for the effect levels may be required.		ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.AdministrationExposure.DosesConcentrations
Dose / conc.	Enter numeric value.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.DoseConc
Remarks	Enter any remarks related to dose / concentration values.	Multi-line text	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.Remarks
Doses / concentrations			
No. of animals per sex per dose	Enter value or specify according to dose if different number of animals per dose or test, e.g. '10 in each dose group of FOB'. For robust study summaries or as requested by the regulatory programme, also include a detailed table on the animal assignment in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) if any and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). For a developmental neurotoxicity study it should be noted: The method of animal assignment should have minimized potential problems related to litter effects, i.e., by using one pup/sex/litter (or one measure/litter, e.g., mean body weight for each litter). When allocating animals to FOB and	Multi-line text	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.AdministrationExposure.NoOfAnimalsPerSexPerDose

	<p>motor activity testing, the same individual animals should have been evaluated at all scheduled time points.</p> <p>For the selection of animals and testing paradigms for cognitive (learning and memory) assessment, it is important to ensure that tasks were selected and/or animals allocated so that comparable assessments of learning were made at both times, i.e., shortly after PND 21 and around PND 60. Indicate whether the same or different animals were used for assessments at the weanling and adult ages. In general, the use of separate animals at the two time points is preferred, because for many tasks, initial learning (PND 21) may confound later (PND 60) assessment of learning. If the same animals were used at both times, different tasks would likely have been necessary. The selection of the test for assessing learning should have been adequately justified regardless of whether the same or a different task was used.</p>		
Control animals	<p>Indicate whether and what type of concurrent control groups were used. Multiple selection is possible. If not listed, select 'other' and specify.</p>	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.AdministrationExposure.ControlAnimals
Details on study design	<p>Include any details on the study design including a brief description of the rationale for dose selection, animal assignment and selection of satellite groups including the duration of the post-exposure recovery period. As appropriate state study type(s) and briefly describe the results from range-finding or other studies used as basis for dose selection. More comprehensive details may be attached.</p> <p>Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.</p> <p>For a developmental neurotoxicity study it should be noted: Dose selection rationale should be discussed, including information from the prenatal developmental or two-generation reproduction studies, if applicable. Any pilot study data (including biomarker data, such as cholinesterase</p>	Text template	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.AdministrationExposure.DetailsOnStudyDesign

	activity) or pharmacokinetic data (e.g., milk or blood levels of test substance, or data that established time of peak effect) should be described in detail. If these data were submitted in a separate study report, the methods and results (including detailed tables of analytical results) should be presented in a separate record (include a reference in the block 'Cross-reference'); alternatively, they could be appended to this record.		
Examinations		Header 2	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.Examinations
Observations and clinical examinations performed and frequency	Indicate if and which examinations were performed and the time schedule for those examinations. Also indicate the dose groups that were examined if not all. When tabulating parameters examined, refer to respective table no. If other observations (e.g. haematology) are reported in another study summary (e.g. repeated dose toxicity), include a note in the block 'Cross-reference' and refer to that summary. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.Examinations.ObservationsAndClinicalExaminationsPerformedAndFrequency
Specific biochemical examinations	If specific biochemical determinations were made, provide details on the sampling, the tissues tested (e.g. plasma, whole blood, RBCs, brain (whole brain or regions)) and methodology. When tabulating parameters examined, refer to respective table no. Use freetext template and delete/add elements as appropriate (e.g. delete items on NTE activity if not applicable). Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.Examinations.SpecificBiochemicalExaminations
Neurobehavioural examinations performed and frequency	Provide details on the neurobehavioural examinations performed and frequency. Use freetext template and delete/add elements as appropriate (e.g. delete items on NTE activity if not applicable). Enter any details that could be relevant for evaluating this study summary or that are	Text template	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.Examinations.NeurobehaviouralExaminationsPerformedAndFrequency

	<p>requested by the respective regulatory programme.</p> <p>Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables' and refer to respective table no., e.g. 'see Table 1' (use predefined table if any).</p> <p>Narrative accompanying such tabular data should address the toxicological significance of the results and not repeat what is presented in the table(s).</p>		
Sacrifice and (histo)pathology	<p>Indicate details on gross pathological and histopathological examinations. Also indicate those dose groups which were examined.</p> <p>Use freetext template and delete/add elements as appropriate (e.g. delete items on NTE activity if not applicable). Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.</p> <p>Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables' and refer to respective table no., e.g. 'see Table 1' (use predefined table if any).</p> <p>Narrative accompanying such tabular data should address the toxicological significance of the results and not repeat what is presented in the table(s).</p> <p>Specific guidance for acute or subchronic neurotoxicity:</p> <p>Indicate when and how were animals sacrificed, how many were perfused, what parameters were measured (e.g. brain weight, length and width), what were the procedures for perfusion, what tissues were evaluated, what type of staining was used, how were sections prepared (thickness, embedding media, number of sections). How many animals from each sex and treatment group were evaluated?</p> <p>Specific guidance for developmental neurotoxicity studies: see freetext template.</p> <p>Tables are optional, particularly for postmortem examinations of the offspring and the specific morphometric measures taken.</p>	Text template	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.Examinations.SacrificeAndHistoPathology
Other examinations	Describe any other examinations.	Text area	ENDPOINT_STUDY_RECORD.Neurotoxicity.

			MaterialsAndMethods.Examinations.OtherExaminations
Positive control	<p>Briefly describe the positive control data cited, and its acceptability for use with the current study.</p> <p>For positive control data to be acceptable, it must demonstrate the sensitivity of the test method to detect changes in the measured parameters. These data do not have to be from studies using prenatal exposures. However, the laboratory must demonstrate competence in evaluation of effects in neonatal animals perinatally exposed to chemicals and establish test norms for the appropriate age group. For observational measures, the data should demonstrate the ability to detect major neurotoxic endpoints, including limb weakness, paralysis, tremor, and autonomic signs; motor activity positive control data should demonstrate the ability to detect both increases and decreases in motor activity; pathology positive control data should demonstrate the ability to detect central and peripheral nervous system pathology (separate groups may be used to demonstrate each type of pathology, for example, acrylamide for peripheral nervous system pathology and trimethyl tin for central nervous system pathology).</p> <p>The methods should be completely described, and must be the same as those used in the study being evaluated (for example, the same equipment should be used, motor activity sessions should be of the same duration, the observation arena should be the same, the same sections should be evaluated for neuropathology, using the same types of stains, etc.), and preferably the same personnel should have conducted the testing. The data presentation should be complete enough to evaluate the sensitivity of the method, including individual data and measures of variability. Statistical evaluations used to demonstrate sensitivity should also be the same as those used in the study being evaluated. The number of animals per test group should not be greater than that</p>	Multi-line text	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.Examinations.Positive Control

	used in the study under evaluation. Positive control data should also demonstrate inter-observer reliability for the FOB (i.e., the same results should be seen regardless of who is doing the observations). The positive control data should have been collected within a reasonable time frame before the current study, e.g., the last few years. New data should also be collected when observational personnel or other critical laboratory elements change.		
Statistics	List parameters that were analysed and the statistical methods used; include a statement that the Reviewer considers the analyses used to be appropriate. If inappropriate, provide alternative/rationale.	Multi-line text	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.Examinations.Statistics
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.Neurotoxicity.ResultsAndDiscussion
Results of examinations	Results of examinations (OHT: Repeated dose toxicity: oral) – common block	Header 2	ENDPOINT_STUDY_RECORD.Neurotoxicity.ResultsAndDiscussion.ResultsOfExaminations
Effect levels	Effect levels (OHT 67-69, 72-74) – common block	Header 2	ENDPOINT_STUDY_RECORD.Neurotoxicity.ResultsAndDiscussion.EffectLevels
			ENDPOINT_STUDY_RECORD.Neurotoxicity.ResultsAndDiscussion.EffectLevels.Efflevel
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.Neurotoxicity.ResultsAndDiscussion.EffectLevels.Efflevel.KeyResult
Dose descriptor	Select the relevant dose descriptor, i.e. the exposure level that corresponds to a quantified level of effects, e.g. NOAEL or LOAEL. If a benchmark dose / concentration was calculated, select appropriate BMD indicator (e.g. 'BMD05' or 'BMD:' and specify in the related text	Open list with remarks	ENDPOINT_STUDY_RECORD.Neurotoxicity.ResultsAndDiscussion.EffectLevels.Efflevel.Endpoint

	<p>field). If the critical effects at a specific dose or concentration level are reported only, select 'dose. level:' or 'conc. level:' and specify.</p> <p>Where no value could be achieved based on the method and boundaries used, the upper or lower dose level for the relevant dose descriptor can be reported as appropriate with relevant qualifier, e.g. NOAEL >200 mg/kg bw/day or NOAEL <200 mg/kg bw/day. An additional explanation may be given in field 'Remarks on result', e.g. 'not determinable due to absence of adverse toxic effects'.</p>		
Effect level	<p>Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.</p>	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.Neurotoxicity.ResultsAndDiscussion.EffectLevels.Efflevel.EffectLevel
Based on	<p>Indicate whether the concentration is based on the test material (test mat.), active ingredient (act. ingr.) or element. As appropriate the measured / addressed fraction can be specified for either of these entities by selecting the relevant item, e.g. 'element (dissolved fraction)' or 'test mat. (total fraction)'. Further information can be given in the supplementary remarks field, e.g. for specifying the type of fraction if it is not clear per se from the test material specification.</p> <p>Select 'not specified' if the effect concentration type is not known.</p>	Open list with remarks	ENDPOINT_STUDY_RECORD.Neurotoxicity.ResultsAndDiscussion.EffectLevels.Efflevel.BasedOn
Sex	Select from drop-down list.	Closed list	ENDPOINT_STUDY_RECORD.Neurotoxicity.ResultsAndDiscussion.EffectLevels.Efflevel.Sex
Basis for effect level	<p>Indicate the parameter(s) used to establish the given effect level. Multi-selection of different pre-defined values is possible. If none is available, you can select 'other:'. Any explanations can always be entered in the related supplementary text field.</p>	Multi select open list with remarks (32000)	ENDPOINT_STUDY_RECORD.Neurotoxicity.ResultsAndDiscussion.EffectLevels.Efflevel.Basis
Remarks on result	<p>This field can be used for:</p> <ul style="list-style-type: none"> - giving a qualitative description of results in addition to or if no numeric value(s) 	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.Neurotoxicity.ResultsAndDiscussion.

	were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:'		EffectLevels.Efflevel.RemarksOnResults
Target system / organ toxicity	Target system (OHT RepDoseTox etc.) - Target system BLOCK -OHT 67-69- 72- 73- 76- 77- common block	Header 2	ENDPOINT_STUDY_RECORD.Neurotoxicity.ResultsAndDiscussion.TargetSystemOrganToxicity
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.Neurotoxicity.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.Neurotoxicity.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.Neurotoxicity.ApplicantSummaryAndConclusion

5.8 Other toxicological studies – Endpoint Summary

Purpose:

Chemical (Active and Product): Provide summary information of the most relevant study(-ies) from which the key value for chemical assessment is extrapolated. Provide only the most relevant details (according to Other toxicological studies). This endpoint study record should be used for those studies where no specific IUCLID document is available. In certain cases, it can be necessary to carry out supplementary studies to further clarify the adverse human effects

Microorganisms (Active): Provide a summary of additional studies investigating chronic mammalian toxicity, pathogenicity and infectiveness, carcinogenicity and reproductive toxicity (if available). Provide only the most relevant details.

Microorganism (Product): Provide a summary of the additional information on mode of toxic action, toxicological profile and all other known toxicological aspects of the microorganism shall be submitted. Special attention shall be given to co-formulants. Provide a summary on additional acute toxicity studies for a combination of plant protection products where the product label includes requirements for the use of the plant protection product with other plant protection products and/or with adjuvants as a tank mix.

ENDPOINT_SUMMARY.AdditionalToxicologicalInformation - v.3.0 (Final)			
Name	Instructions	Type	Field Path
Administrative data	Administrative data summary – common block Provide a brief description of additional toxicological studies and effects.	Header 1	ENDPOINT_SUMMARY.AdditionalToxicologicalInformation.AdministrativeDataSummary
Additional information	Discussion (Header 1) – common block Provide additional information related to the endpoint, for example: <ul style="list-style-type: none"> - An overview summary table with conclusion on the toxicological profile of metabolites (i.e. genotoxicity and general toxicity) found as residues in crops and/or livestock and/or in groundwater. - Supplementary studies on the active substance (State which study was performed and in what species and the outcome, if applicable also the NOAEL and LOAEL.) - Endocrine disrupting properties (State which study was performed and in what species and the outcome, if applicable also the NOAEL and LOAEL.) - Studies performed on metabolites or impurities. Especially the acute toxicity and genotoxicity should be highlighted. Present other parameters if more examined. <p>If there is no additional information to be reported this field may be left empty. <i>See IUCLID templates for PPP Risk Assessment - Template 5.4 - Template summary table on the assessment of the toxicological profile of metabolites</i> [http://doi.org/10.5281/zenodo.4557353]"</p>	Header 1	ENDPOINT_SUMMARY.AdditionalToxicologicalInformation.Discussion

5.8 Other toxicological studies – Endpoint study record

Purpose:

Under IUCLID if a metabolite is entered in the Metabolites Information document a dataset is created and the study should be reported in this dataset if the test material is the metabolite.

This endpoint study record should be used for those studies where not specific IUCLID document can be used.

As example, comparative in vitro metabolism studies should be currently reported by using this template. In certain cases, it can be necessary to carry out supplementary studies to further clarify the adverse human effects.

In particular, if results from earlier studies indicate that the micro-organism may cause long-term health effects, studies on chronic toxicity, pathogenicity and infectiveness, carcinogenicity and reproductive toxicity must be carried out. Furthermore, where a toxin is produced, kinetic studies must be performed. Studies required must be designed on an individual basis, in the light of the particular parameters to be investigated and the objectives to be achieved. Before performing such studies, the applicant shall seek agreement of the competent authorities on the type of study to be performed.

ENDPOINT_STUDY_RECORD.AdditionalToxicologicalInformation - v.6.3 (Final)			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.AdditionalToxicologicalInformation.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.AdditionalToxicologicalInformation.Data Source
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.AdditionalToxicologicalInformation.MaterialsAndMethods
Type of study / information	Indicate the type of information provided in this record and include any relevant information in fields 'Any other information on materials and methods incl. tables', 'Any other information on results incl. tables' and/or 'Overall remarks' as appropriate. Note: Include only information that does not fit into any of the specific chapters. Use chapter 'Specific investigations: other studies' for studies on behavioural effects, biochemical or cellular interactions, chemobiokinetics general studies, cytotoxicity, endocrine system modulation, hematotoxicity, hepatotoxicity, mechanistic studies,	Multi-line text	ENDPOINT_STUDY_RECORD.AdditionalToxicologicalInformation.MaterialsAndMethods.TypeOfStudyInformation

	methaemoglobinaemia, nephrotoxicity, phototoxicity, respiratory irritation, splenic toxicity, or toxicogenomics.		
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.AdditionalToxicologicalInformation.MaterialsAndMethods.TestMaterials
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.AdditionalToxicologicalInformation.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.AdditionalToxicologicalInformation.ResultsAndDiscussion
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.AdditionalToxicologicalInformation.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.AdditionalToxicologicalInformation.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.AdditionalToxicologicalInformation.ApplicantSummaryAndConclusion

5.8.2 Supplementary studies on the active substance

5.8.2.1 Immunotoxicity – Endpoint Summary

Purpose:

Summary information of to the most relevant study(ies) from which the key value for chemical safety assessment is extrapolated. Provide only the most relevant details, which could be: species, outcome also reference points (e.g. NOAEL)., if applicable.

In case that there are not specific immunotoxicity studies available, a statement on whether immunotoxicity has been properly addressed in general toxicity studies and whether there is a immunotoxicity potential should be included.

Please note the developmental immunotoxicity studies should be reported under 5.6 by using the template reproductive toxicity.

(Regulation (EU) N° 283/2013, Annex Part A, point 5.8)

ENDPOINT_SUMMARY.Immunotoxicity - v.6.2 (Final)			
Name	Instructions	Type	Field Path
Administrative data	Administrative data summary – common block Provide a brief description of the immunotoxicity studies and effects.	Header 1	ENDPOINT_SUMMARY.Immunotoxicity.AdministrativeDataSummary
		Rich text area	ENDPOINT_SUMMARY.Immunotoxicity.KeyInformation.KeyInformation
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.Immunotoxicity.KeyValueForChemicalSafetyAssessment
Effect on immunotoxicity: via oral route		Header 2	ENDPOINT_SUMMARY.Immunotoxicity.KeyValueForChemicalSafetyAssessment.EffectOnImmunotoxicityViaOralRoute
Link to relevant study records		Header 3	ENDPOINT_SUMMARY.Immunotoxicity.KeyValueForChemicalSafetyAssessment.EffectOnImmunotoxicityViaOralRoute.LinkToRelevantStudyRecords
Endpoint conclusion	Endpoint conclusion (Species version) – common block “Adverse effect observed” should be chosen if adverse effects were observed at or below the limit dose level. “No adverse effect observed” should be chosen if no adverse effects were observed at or below the limit dose level. If “No study available” is chosen, a justification needs to be provided.	Header 3	ENDPOINT_SUMMARY.Immunotoxicity.KeyValueForChemicalSafetyAssessment.EffectOnImmunotoxicityViaOralRoute.EndpointConclusion

	<p>The primary dose descriptor in this endpoint is the NOAEL. In some studies also the BMDL (benchmark dose level). The LOAEL should be used only if NOAEL is not available. The selection of the dose descriptor should only refer to immunotoxic effects. Other effects and dose descriptors should be reported in the section "Description of key information".</p> <p>Define the duration of the selected robust study summary.</p> <p>The species reported in the selected robust study summary should be reported in the relative field .</p>		
Effect on immunotoxicity: via inhalation route		Header 2	ENDPOINT_SUMMARY.I mmunotoxicity.KeyValu eForChemicalSafetyAss essment.EffectOnImmu notoxicityViaInhalation Route
Link to relevant study records		Header 3	ENDPOINT_SUMMARY.I mmunotoxicity.KeyValu eForChemicalSafetyAss essment.EffectOnImmu notoxicityViaInhalation Route.LinkToRelevantSt udyRecords
Results		Read-only	ENDPOINT_SUMMARY.I mmunotoxicity.KeyValu eForChemicalSafetyAss essment.EffectOnImmu notoxicityViaInhalation Route.LinkToRelevantSt udyRecords.Results
Endpoint conclusion	Endpoint conclusion (Species version) – common block	Header 3	ENDPOINT_SUMMARY.I mmunotoxicity.KeyValu eForChemicalSafetyAss essment.EffectOnImmu

	<p>"Adverse effect observed" should be chosen if adverse effects were observed at or below the limit dose level.</p> <p>"No adverse effect observed" should be chosen if no adverse effects were observed at or below the limit dose level.</p> <p>If "No study available" is chosen, a justification needs to be provided.</p> <p>The primary dose descriptor in this endpoint is the NOAEL. In some studies also the BMDL (benchmark dose level). The LOAEL should be used only if NOAEL is not available. The selection of the dose descriptor should only refer to immunotoxic effects. Other effects and dose descriptors should be reported in the section "Description of key information".</p> <p>Define the duration of the selected robust study summary.</p> <p>The species reported in the selected robust study summary should be reported in the relative field .</p>		nototoxicityViaInhalation Route.EndpointConclusi on
Effect on immunotoxicity: via dermal route		Header 2	ENDPOINT_SUMMARY.I mmunotoxicity.KeyValu eForChemicalSafetyAss essment.EffectOnImmu notoxicityViaDermalRou te
Link to relevant study records		Header 3	ENDPOINT_SUMMARY.I mmunotoxicity.KeyValu eForChemicalSafetyAss

			essment.EffectOnImmunotoxicityViaDermalRoute.LinkToRelevantStudyRecords
Endpoint conclusion	<p>Endpoint conclusion (Species version) – common block</p> <p>“Adverse effect observed” should be chosen if adverse effects were observed at or below the limit dose level.</p> <p>“No adverse effect observed” should be chosen if no adverse effects were observed at or below the limit dose level.</p> <p>If “No study available” is chosen, a justification needs to be provided.</p> <p>The primary dose descriptor in this endpoint is the NOAEL. In some studies also the BMDL (benchmark dose level). The LOAEL should be used only if NOAEL is not available. The selection of the dose descriptor should only refer to immunotoxic effects. Other effects and dose descriptors should be reported in the section “Description of key information”.</p> <p>Define the duration of the selected robust study summary.</p> <p>The species reported in the selected robust study summary should be reported in the relative field .</p>	Header 3	ENDPOINT_SUMMARY.Immunotoxicity.KeyValueForChemicalSafetyAssessment.EffectOnImmunotoxicityViaDermalRoute.EndpointConclusion
Mode of Action Analysis / Human		Header 2	ENDPOINT_SUMMARY.Immunotoxicity.KeyValue

Relevance Framework			eForChemicalSafetyAssessment.MoAAAnalysisHumanRelevanceFramework
	This section is for incorporation of the WHO/IPCS Template Mode of Action Analysis / Human relevance framework at http://echa.europa.eu/web/guest/support/guidance-on-reach-and-clp-implementation/formats . The template is also available in HTML format that can be easily uploaded in this text area where relevant	Rich text area	ENDPOINT_SUMMARY.Immunotoxicity.KeyValueForChemicalSafetyAssessment.MoAAAnalysisHumanRelevanceFramework
Additional information	Discussion(Header 1) – common block	Header 1	ENDPOINT_SUMMARY.Immunotoxicity.Discussion
Justification for classification or non-classification		Header 1	ENDPOINT_SUMMARY.Immunotoxicity.JustificationForClassificationOrNonClassification
	The available information should be compared against the classification criteria and the reasons for fulfilling or not fulfilling the classification criteria should be presented.	Rich text area	ENDPOINT_SUMMARY.Immunotoxicity.JustificationForClassificationOrNonClassification.JustificationForClassificationOrNonClassification

5.8.2.1 Immunotoxicity – Endpoint study record

Purpose:

Supplementary studies shall be carried out on the immunotoxicological potential where they are necessary to further clarify observed effects taking into account the results of the available toxicological and metabolism studies and the most important exposure routes.

ENDPOINT_STUDY_RECORD.Immunotoxicity - v.7.5 (Final)			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.Immunotoxicity.AdministrativeData

Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.Immunotoxicity.DataSource
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods
Limit test	Indicate if the experiment was a limit test.	Closed list	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.LimitTest
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.TestMaterials
Test animals	Test animals (OHT: Repeated dose toxicity) – common block	Header 2	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.TestAnimals
Administration / exposure		Header 2	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.AdministrationExposure
Route of administration	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.AdministrationExposure.RouteOfAdministration
Vehicle	Select 'unchanged (no vehicle)' if none was used or select vehicle used if any. If not available from picklist, select 'other' and specify. Further information can be given in the supplementary remarks field. Note that some of the vehicles provided in this list are used for specific routes of administration only.	Open list with remarks	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.AdministrationExposure.Vehicle
Mass median aerodynamic diameter (MMAD)	For inhalation studies, specify the mass median aerodynamic diameter (MMAD) of the distribution of particle sizes. Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.AdministrationExposure.MassMedianAerodynamicDiameter
Geometric standard deviation (GSD)	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Decimal	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.AdministrationExposure.GeometricStandardDeviation
Remarks on MMAD	Enter any remarks related to the mass median aerodynamic diameter.	Multi-line text	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.AdministrationExposure.RemarksOnMMAD

Details on exposure	Select freetext template for the respective type of study and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.Immunotoxicity.Materials AndMethods.Administration Exposure.DetailsOnExposure
Analytical verification of doses or concentrations	Indicate whether the doses or concentrations were analytically verified.	Closed list with remarks	ENDPOINT_STUDY_RECORD.Immunotoxicity.Materials AndMethods.Administration Exposure.AnalyticalVerificationOfDosesOrConcentrations
Details on analytical verification of doses or concentrations	<p>For robust study summaries or as requested by the regulatory programme, include a short description on the method of analysis in the supplementary remarks field. If any problems occurred in any of these procedures, then they should be reported in more detail. If this could have affected the veracity or conclusions of the study, discuss this in field 'Rationale for reliability incl. deficiencies'.</p> <p>Further route-dependent information to be included:</p> <ul style="list-style-type: none"> - For oral studies: State whether the analytical data indicated that the variance between nominal and actual dosage (if diet is route of administration) or concentrations (for drinking water study) was acceptable. If diet is the route of administration, briefly record when and at what dose levels the dosage analyses were made and include the results (range of values) of (i) Homogeneity analysis, (ii) Stability analysis and (iii) Concentration analysis. It may be appropriate to include a cross-reference to another study in which stability analysis was performed and reported. If so, a justification should also be included briefly explaining the rationale of referring to another study. - For inhalation studies: State whether the analytical data indicated that the variance between nominal and actual concentrations was acceptable. - For dermal studies: State whether the analytical data indicated that the variance between nominal and actual concentrations of the test substance in the vehicle was acceptable. 	Text area	ENDPOINT_STUDY_RECORD.Immunotoxicity.Materials AndMethods.Administration Exposure.DetailsOnAnalyticalVerificationOfDosesOrConcentrations
Duration of treatment / exposure	Indicate duration in days, weeks or months, e.g. '28 days' or '18 months'.	Multi-line text	ENDPOINT_STUDY_RECORD.Immunotoxicity.Materials AndMethods.Administration

			Exposure.DurationOfTreatmentExposure
Frequency of treatment	Indicate the frequency of the administration of doses to the test animals (e.g., 'daily, 7 days each week'). Use of non-standard dosing regime (e.g. a five-day per week regime) should be justified.	Multi-line text	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.AdministrationExposure.FrequencyOfTreatment
Doses / concentrations	Indicate the dose or concentration levels applied and the basis of quantity used. Copy this block of fields for each numeric value and to record values on a different basis, i.e. mg/kg bw/day (nominal), mg/kg bw/day (actual dose received), mg/kg diet ,mg/L drinking water, mg/kg bw (total dose), ppm if applicable. Conversion of the dose / conc. values to the relevant unit used for the effect levels may be required.		ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.AdministrationExposure.DosesConcentrations
Dose / conc.	Enter numeric value.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.DoseConc
Remarks	Enter any remarks related to dose / concentration values.	Multi-line text	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.Remarks
Doses / concentrations			
No. of animals per sex per dose	Enter value or specify according to dose if different number of animals per dose, e.g. '10 in each dose group of main study; 10 f and 5 m in interim sacrifice group'. Also specify number of animals in recovery group if applicable. For robust study summaries or as requested by the regulatory programme, also include a detailed table on the animal assignment in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Note: Specific tables may be required.	Multi-line text	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.AdministrationExposure.NoOfAnimalsPerSexPerDose
Control animals	Indicate whether and what type of concurrent control groups were used. Multiple selection is possible. If not listed, select 'other' and specify.	Multi select open	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.AdministrationExposure.ControlAnimals

		list with remarks	
Details on study design	<p>Include any details on the study design including a brief description of the rationale for dose selection, animal assignment and selection of satellite groups including the duration of the post-exposure recovery period. As appropriate state study type(s) and briefly describe the results from range-finding or other studies used as basis for dose selection. More comprehensive details may be attached.</p> <p>Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.</p>	Text template	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.AdministrationExposure.DetailsOnStudyDesign
Examinations		Header 2	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.Examinations
Observations and clinical examinations performed and frequency	<p>Indicate if and which examinations were performed and the time schedule for those examinations. Also indicate the dose groups that were examined if not all. As appropriate include detailed table(s) in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1').</p> <p>If other observations (e.g. haematology) are reported in another study summary (e.g. repeated dose toxicity), include a note in the block 'Cross-reference' and refer to that summary.</p> <p>Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.</p>	Text template	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.Examinations.ObservationsAndClinicalExaminationsPerformedAndFrequency
Sacrifice and pathology	<p>Indicate if and which examinations were performed. Also indicate the dose groups that were examined if not all. Note if not all collected tissues were examined. As appropriate include detailed table(s) in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence</p>	Text template	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.Examinations.SacrificeAndPathology

	<p>in which you refer to them in the Remarks text (e.g. '... see Table 1').</p> <p>Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.</p>		
Cell viabilities	<p>Indicate if and which examinations were performed and give details on the method and test protocol, the dose groups and number of animals examined.</p> <p>Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.</p>	Text template	ENDPOINT_STUDY_RECORD.Immunotoxicity.Materials AndMethods.Examinations.CellViabilities
Humoral immunity examinations	<p>Indicate if and which examinations were performed and give details on the method and test protocol, the dose groups and number of animals examined. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.</p> <p>Example of brief description of protocol: 'Spleen IgM antibody response to a T-dependent antigen, sheep erythrocytes (sRBC) - Day 4 response: Animals were exposed to the test substance or positive control for 28 days, then injected intravenously to sheep erythrocytes on day 25. On day 29 (peak day of IgM response), the animals were sacrificed, spleens were removed and weighed, then spleen cells were prepared on day 30. The primary response to sheep erythrocytes was measured using a modified hemolytic plaque assay (Jerne, N.K., et al., Plaque forming cells: Methodology and Theory. Transpl. Rev. 18:130-191, 1974). Cell counts were performed and the number of cells/spleen, AFC/spleen and AFC/106 spleen cells were determined.'</p> <p>Example of brief description of protocol for Enzyme-Linked Immunosorbent Assay (ELISA): 'The effects of test substance on antibody response to antigen were determined by an ELISA using methods described by Temple et al. (1995). Test animals were dosed with test material for ... days. Animals were exposed to sheep</p>	Text template	ENDPOINT_STUDY_RECORD.Immunotoxicity.Materials AndMethods.Examinations.HumoralImmunityExaminations

	erythrocytes on day...IgM titers in serum were determined ... days after immunization.'		
Specific cell-mediated immunity	Indicate if and which examinations were performed and give details on the method and test protocol, the dose groups and number of animals examined. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Describe cell harvest and culture and proliferation measurement ((3H) thymidine) incorporation, etc.	Text template	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.Examinations.SpecificCellMediatedImmunity
Non-specific cell-mediated immunity	Indicate if and which examinations were performed and give details on the method and test protocol, the dose groups and number of animals examined. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Example of brief description of protocol: 'Following ... days of exposure to test material or positive control, the effects of test substance on spontaneous cytotoxic activity were determined by incubating splenocytes from treated and control animals with 51Cr-labeled YAC-1 lymphoma cells (target cell). Following a 4-hour incubation period, the amount of radiolabel released from target cells was determined (measure of NK cytotoxicity).'	Text template	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.Examinations.NonSpecificCellMediatedImmunity
Other functional activity assays	Indicate if and which examinations were performed and give details on the method and test protocol, the dose groups and number of animals examined. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Example of brief description of protocol: 'On day 30, a single cell suspension was prepared from each spleen and incubated in flat bottom microtiter plates (RPMI media supplemented with 10% fetal bovine serum and 5x10 ⁻⁵ 2-mercaptoethanol). The spleen cells were cultured in either non-treated or anti-CD3-treated wells (100 µL of 1 µg/mL anti-CD3) and incubated at 4°C overnight. Prior to	Text template	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.Examinations.OtherFunctionalActivityAssays

	<p>harvest on day 3, the cells were pulsed with 3H-thymidine for 18-24 hours.'</p> <p>Example of brief description of protocol for enumeration total B cells, total T cells and T cell subpopulations: 'Following ... days of dosing, single cell preparations from each spleen were seeded at 1x10⁶ cells/well into a 96-well microtiter plate. Phenotypic analysis of total B cell, T cell, and T cell subpopulations were conducted using monoclonal antibody conjugates to fluorescein isothiocyanate (FITC) or phycoerythrin (PE). The specific monoclonal antibodies used were: OX19 conjugated to PE to enumerate total T-cells (CD5+), OX38 conjugated to FITC to enumerate CD4+ cells (T helper cells) and OX8 conjugated to FITC to enumerate CD8+ cells (T suppressor/cytotoxic cells). For both the CD4+ and CD8+ cells, a double label with OX19 was used. OX33 conjugated to FITC was used to enumerate CD45+ (B lymphocytes). Following the initial staining with antibody and washing with staining buffer, the DNA specific fluorescent stain propidium iodide (PI) was added to each well as a viability stain. Following a 5 minute incubation with PI, the cells were washed once with staining buffer and then enumerated on a Coulter Epics XL-MCL Flow Cytometer. At least 5,000 cells were counted for each sample.'</p>		
Other examinations	Describe any other examinations.	Text area	ENDPOINT_STUDY_RECORD.Immunotoxicity.Materials AndMethods.Examinations. OtherExaminations
Positive control	Briefly describe the positive control data cited, and its acceptability for use with the current study. Criteria for acceptability include the positive demonstration of sensitivity of the test methods to detect changes in the measured parameters.	Multi-line text	ENDPOINT_STUDY_RECORD.Immunotoxicity.Materials AndMethods.Examinations. PositiveControl
Statistics	List parameters that were analysed and the statistical methods used; include a statement that the Reviewer considers the analyses used to be appropriate. If inappropriate, provide alternative/rationale.	Multi-line text	ENDPOINT_STUDY_RECORD.Immunotoxicity.Materials AndMethods.Examinations. Statistics
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.Immunotoxicity.Materials AndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables

Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.Immunotoxicity.ResultsAndDiscussion
Results of examinations	Results of examinations (OHT: Repeated dose toxicity: oral) – common block	Header 2	ENDPOINT_STUDY_RECORD.Immunotoxicity.ResultsAndDiscussion.ResultsOfExaminations
Specific immunotoxic examinations		Header 3	ENDPOINT_STUDY_RECORD.Immunotoxicity.ResultsAndDiscussion.ResultsOfExaminations.SpecificImmunotoxicExaminations
Cell viabilities	Indicate whether any effects were observed and whether they were treatment-related or not, adverse or not and irreversible or reversible. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.Immunotoxicity.ResultsAndDiscussion.ResultsOfExaminations.SpecificImmunotoxicExaminations.CellViabilities
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.Immunotoxicity.ResultsAndDiscussion.ResultsOfExaminations.SpecificImmunotoxicExaminations.DescriptionIncidenceAndSeverityCellViabilities
Humoral immunity examinations	Indicate whether any effects were observed and whether they were treatment-related or not, adverse or not and irreversible or reversible. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.Immunotoxicity.ResultsAndDiscussion.ResultsOfExaminations.SpecificImmunotoxicExaminations.HumoralImmunityExaminations
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any	Text area	ENDPOINT_STUDY_RECORD.Immunotoxicity.ResultsAndDiscussion.ResultsOfExaminations.SpecificImmunotoxicExaminations.DescriptionIncidenceAndSeverityHumoralImmunityExaminations

	<p>other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Specific cell-mediated immunity	<p>Indicate whether any effects were observed and whether they were treatment-related or not, adverse or not and irreversible or reversible. Select 'not examined' or 'not specified' as applicable.</p>	Close d list	ENDPOINT_STUDY_RECORD.Immunotoxicity.ResultsAndDiscussion.ResultsOfExaminations.SpecificImmunotoxicExaminations.SpecificCellMediatedImmunity
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.</p> <p>Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>	Text area	ENDPOINT_STUDY_RECORD.Immunotoxicity.ResultsAndDiscussion.ResultsOfExaminations.SpecificImmunotoxicExaminations.DescriptionIncidenceAndSeveritySpecificCellMediatedImmunity
Non-specific cell-mediated immunity	<p>Indicate whether any effects were observed and whether they were treatment-related or not, adverse or not and irreversible or reversible. Select 'not examined' or 'not specified' as applicable.</p>	Close d list	ENDPOINT_STUDY_RECORD.Immunotoxicity.ResultsAndDiscussion.ResultsOfExaminations.SpecificImmunotoxicExaminations.NonSpecificCellMediatedImmunity
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.</p> <p>Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat</p>	Text area	ENDPOINT_STUDY_RECORD.Immunotoxicity.ResultsAndDiscussion.ResultsOfExaminations.SpecificImmunotoxicExaminations.DescriptionIncidenceAndSeverityNonSpecificCellMediatedImmunity

	the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Other functional activity assays	Indicate whether any effects were observed and whether they were treatment-related or not, adverse or not and irreversible or reversible. Select 'not examined' or 'not specified' as applicable.	Close d list	ENDPOINT_STUDY_RECORD.Immunotoxicity.ResultsAndDiscussion.ResultsOfExaminations.SpecificImmunotoxicExaminations.OtherFunctionalActivityAssays
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.Immunotoxicity.ResultsAndDiscussion.ResultsOfExaminations.SpecificImmunotoxicExaminations.DescriptionIncidenceAndSeverityOtherFunctionalActivityAssays
Other findings	Report results related to pathogenicity, infectiveness or clearance in studies with micro-organisms	Close d list	ENDPOINT_STUDY_RECORD.Immunotoxicity.ResultsAndDiscussion.ResultsOfExaminations.SpecificImmunotoxicExaminations.OtherFindings
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.Immunotoxicity.ResultsAndDiscussion.ResultsOfExaminations.SpecificImmunotoxicExaminations.DescriptionIncidenceAndSeverityOtherFindings

Effect levels	Effect levels (OHT 67-69, 72-74) – common block	Header 2	ENDPOINT_STUDY_RECORD.Immunotoxicity.ResultsAndDiscussion.EffectLevels
Target system / organ toxicity	Target system (OHT RepDoseTox etc.) - Target system BLOCK -OHT 67-69-72- 73- 76- 77- common block	Header 2	ENDPOINT_STUDY_RECORD.Immunotoxicity.ResultsAndDiscussion.TargetSystemOrganToxicity
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.Immunotoxicity.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.Immunotoxicity.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.Immunotoxicity.ApplicantSummaryAndConclusion

5.8.2.2 Toxic effects on livestock – Endpoint summary

Purpose:

Summary information of to the most relevant study(ies) providing data to establish maximum residue levels for food of animal origin. In case studies on toxic effects on livestock are available (currently not a data requirement under EU pesticide legislation) should be summarised by using this template. It is not mandatory to fill this template in case there are not data available.

ENDPOINT_SUMMARY.ToxicEffectsLivestockPets - v.5.0 (Final)			
Name	Instructions	Type	Field Path
Administrative data	Administrative data summary – common block Provide a brief description of the relevant study and effects	Header 1	ENDPOINT_SUMMARY.ToxicEffectsLivestockPets.AdministrativeDataSummary
Additional information	Discussion(Header 1) – common block	Header 1	ENDPOINT_SUMMARY.ToxicEffectsLivestockPets.Discussion

5.8.2.2 Toxic effects on livestock – Endpoint study record

Purpose:

Provide data in order to determine the residue in products of animal origin which will result from residues in feedingstuffs or fodder crops.

ENDPOINT_STUDY_RECORD.ToxicEffectsLivestock - v.6.4 (Final)			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicEffectsLivestock.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicEffectsLivestock.DataSource
Materials and methods	Material and methods – common block Applicable test guideline: OECD 503 study on metabolism.	Header 1	ENDPOINT_STUDY_RECORD.ToxicEffectsLivestock.MaterialsAndMethods
Limit test	Indicate if the experiment was a limit test.	Closed list	ENDPOINT_STUDY_RECORD.ToxicEffectsLivestock.MaterialsAndMethods.LimitTest
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.ToxicEffectsLivestock.MaterialsAndMethods.TestMaterials
Test animals	Test animals (OHT: Repeated dose toxicity) – common block	Header 2	ENDPOINT_STUDY_RECORD.ToxicEffectsLivestock.MaterialsAndMethods.TestAnimals
Route of exposure	Indicate to which route of exposure the information or description of experimental study refers to.	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicEffectsLivestock.MaterialsAndMethods.AdministrationExposure.RouteOfExposure
Vehicle	Select the vehicle used. If not available from picklist, select 'other' and specify. If no vehicle was used, select 'unchanged (no vehicle)'. Further information can be given in the supplementary remarks field. Note that some of the vehicles provided in this list are used for specific routes of administration only.	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicEffectsLivestock.MaterialsAndMethods.AdministrationExposure.Vehicle
Details on exposure	Select freetext template for the respective route of administration and delete/add elements as appropriate.	Text template	ENDPOINT_STUDY_RECORD.ToxicEffectsLivestock.MaterialsAndMethods

	Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.		ods.AdministrationExposure.DetailsOnExposure
Analytical verification of doses or concentrations	Indicate whether the doses or concentrations were analytically verified.	Closed list with remarks	ENDPOINT_STUDY_RECORD.ToxicEffectsLives tock.MaterialsAndMethods.AdministrationExposure.AnalyticalVerificationOfDosesOrConcentrations
Details on analytical verification of doses or concentrations	<p>For robust study summaries or as requested by the regulatory programme, include a short description on the method of analysis in the supplementary remarks field. If any problems occurred in any of these procedures, then they should be reported in more detail. If this could have affected the veracity or conclusions of the study, discuss this in field 'Rationale for reliability incl. deficiencies'.</p> <p>Further route-dependent information to be included:</p> <ul style="list-style-type: none"> - For oral studies: State whether the analytical data indicated that the variance between nominal and actual dosage (if diet is route of administration) or concentrations (for drinking water study) was acceptable. If diet is the route of administration, briefly record when and at what dose levels the dosage analyses were made and include the results (range of values) of (i) Homogeneity analysis, (ii) Stability analysis and (iii) Concentration analysis. It may be appropriate to include a cross-reference to another study in which stability analysis was performed and reported. If so, a justification should also be included briefly explaining the rationale of referring to another study. - For inhalation studies: State whether the analytical data indicated that the variance between nominal and actual concentrations was acceptable. - For dermal studies: State whether the analytical data indicated that the variance between nominal and actual 	Text area	ENDPOINT_STUDY_RECORD.ToxicEffectsLives tock.MaterialsAndMethods.AdministrationExposure.DetailsOnAnalyticalVerificationOfDosesOrConcentrations

	concentrations of the test substance in the vehicle was acceptable.		
Duration of treatment / exposure	Indicate duration in days, weeks or months, e.g. '5 days' or '10 weeks'.	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicEffectsLives tock.MaterialsAndMethods.AdministrationExposure.DurationOfTreatmentExposure
Frequency of treatment	Indicate the frequency of the administration of doses to the test animals (e.g., 'once' or 'daily injections' or '2 doses per day, 7 days per week'). Use of non-standard dosing regime (e.g. a five-day per week regime) should be justified.	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicEffectsLives tock.MaterialsAndMethods.AdministrationExposure.FrequencyOfTreatment
Post exposure period	Indicate observation period (in days, weeks, months) after last exposure to the test material.	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicEffectsLives tock.MaterialsAndMethods.AdministrationExposure.PostExposurePeriod
Doses / concentrations	Indicate the dose or concentration levels applied and the basis of quantity used. Copy this block of fields for each numeric value and to record values on a different basis, i.e. mg/kg bw/day (nominal), mg/kg bw/day (actual dose received), mg/kg diet ,mg/L drinking water, mg/kg bw (total dose), ppm if applicable. Conversion of the dose / conc. values to the relevant unit used for the effect levels may be required.		ENDPOINT_STUDY_RECORD.ToxicEffectsLives tock.MaterialsAndMethods.AdministrationExposure.DosesConcentrations
Dose / conc.	Enter numeric value.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.ToxicEffectsLives tock.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.DoseConc
Remarks	Enter any remarks related to dose / concentration values.	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicEffectsLives tock.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.Remarks
Doses / concentrations			
No. of animals per sex per dose	Enter value or specify if different number of animals were used per sex and/or dose level.	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicEffectsLives tock.MaterialsAndMethods.AdministrationExposure.NoOfAnimalsPerSexPerDose

Control animals	Indicate whether and what type of concurrent control groups were used. Multiple selection is possible. If not listed, select 'other' and specify.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.ToxicEffectsLives tock.MaterialsAndMethods.AdministrationExposure.ControlAnimals
Further details on study design	Include any details on the study design including a brief description of the rationale for dose selection (e.g. consideration of known or suspected nonlinearities or inflection points in the dose response, toxicokinetics, precursor lesions, markers of effect, or indicators of the operation of key underlying biological process, key (or suspected) aspects of mode of action, consideration of anticipated human exposure level), animal assignment and selection of satellite groups including the duration of the post-exposure recovery period. As appropriate state study type(s) and briefly describe the results from range-finding or other studies used as basis for dose selection. More comprehensive details may be attached. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.ToxicEffectsLives tock.MaterialsAndMethods.AdministrationExposure.FurtherDetailsOnStudyDesign
Examinations		Header 2	ENDPOINT_STUDY_RECORD.ToxicEffectsLives tock.MaterialsAndMethods.Examinations
Observations and examinations performed and frequency	Indicate if and which examinations were performed and the time schedule for those examinations. Also indicate the dose groups that were examined if not all. As appropriate include detailed table(s) in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that	Text template	ENDPOINT_STUDY_RECORD.ToxicEffectsLives tock.MaterialsAndMethods.Examinations.ObservationsAndExaminationsPerformedAndFrequency

	are requested by the respective regulatory programme.		
Sacrifice and pathology	<p>Indicate if and which examinations were performed. Also indicate the dose groups that were examined if not all. Note if not all collected tissues were examined. As appropriate include detailed table(s) in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1').</p> <p>Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.</p>	Text template	ENDPOINT_STUDY_RECORD.ToxicEffectsLives tock.MaterialsAndMethods.Examinations.SacrificeAndPathology
Other examinations	Describe any other examinations.	Text area	ENDPOINT_STUDY_RECORD.ToxicEffectsLives tock.MaterialsAndMethods.Examinations.OtherExaminations
Statistics	List parameters that were analysed and the statistical methods used; include a statement that the Reviewer considers the analyses used to be appropriate. If inappropriate, provide alternative/rationale.	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicEffectsLives tock.MaterialsAndMethods.Examinations.Statistics
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.ToxicEffectsLives tock.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.ToxicEffectsLives tock.ResultsAndDiscussion
Clinical signs and mortality	<p>Indicate whether any treatment-related effects were observed. In the supplementary remarks field related to this list field, describe the effects by dose (if 'yes') or provide any further explanation (if 'no effects'), e.g. stating that effects were observed, but considered negligible.</p> <p>Select 'not examined' or 'no data' as applicable.</p>	Closed list with remarks (2000)	ENDPOINT_STUDY_RECORD.ToxicEffectsLives tock.ResultsAndDiscussion.ObservClinSigns

Body weight and weight gain	Indicate whether any treatment-related effects were observed. In the supplementary remarks field related to this list field, describe the effects by dose (if 'yes') or provide any further explanation (if 'no effects'), e.g. stating that effects were observed, but considered negligible. Select 'not examined' or 'no data' as applicable.	Closed list with remarks (2000)	ENDPOINT_STUDY_RECORD.ToxicEffectsLives tock.ResultsAndDiscussion.ObservBodyweight
Food consumption and compound intake (if feeding study)	Indicate whether any treatment-related effects were observed. In the supplementary remarks field related to this list field, describe the effects by dose (if 'yes') or provide any further explanation (if 'no effects'), e.g. stating that effects were observed, but considered negligible. Select 'not examined' or 'no data' as applicable.	Closed list with remarks (2000)	ENDPOINT_STUDY_RECORD.ToxicEffectsLives tock.ResultsAndDiscussion.ObservFoodConsum
Water consumption and compound intake (if drinking water study)	Indicate whether any treatment-related effects were observed. In the supplementary remarks field related to this list field, describe the effects by dose (if 'yes') or provide any further explanation (if 'no effects'), e.g. stating that effects were observed, but considered negligible. Select 'not examined' or 'no data' as applicable. Water consumption may not be specifically requested under the respective test guideline, unless the substance was administered in the drinking water.	Closed list with remarks (2000)	ENDPOINT_STUDY_RECORD.ToxicEffectsLives tock.ResultsAndDiscussion.ObservWaterConsum
Haematology	Indicate whether any treatment-related effects were observed. In the supplementary remarks field related to this list field, describe the effects by dose (if 'yes') or provide any further explanation (if 'no effects'), e.g. stating that effects were observed, but considered negligible. Select 'not examined' or 'no data' as applicable.	Closed list with remarks (2000)	ENDPOINT_STUDY_RECORD.ToxicEffectsLives tock.ResultsAndDiscussion.ObservHaematol
Clinical chemistry	Indicate whether any treatment-related effects were observed. In the supplementary remarks field related to this list field, describe the effects by dose (if 'yes') or provide any further explanation (if 'no effects'), e.g. stating that effects were observed, but	Closed list with remarks (2000)	ENDPOINT_STUDY_RECORD.ToxicEffectsLives tock.ResultsAndDiscussion.ObservClinChem

	considered negligible. Select 'not examined' or 'no data' as applicable.		
Urinalysis	Indicate whether any treatment-related effects were observed. In the supplementary remarks field related to this list field, describe the effects by dose (if 'yes') or provide any further explanation (if 'no effects'), e.g. stating that effects were observed, but considered negligible. Select 'not examined' or 'no data' as applicable.	Closed list with remarks (2000)	ENDPOINT_STUDY_RECORD.ToxicEffectsLives tock.ResultsAndDiscussion.ObservUrin
Gross pathology and organ weights	Indicate whether any treatment-related effects were observed. In the supplementary remarks field related to this list field, describe the effects by dose (if 'yes') or provide any further explanation (if 'no effects'), e.g. stating that effects were observed, but considered negligible. Select 'not examined' or 'no data' as applicable.	Closed list with remarks (2000)	ENDPOINT_STUDY_RECORD.ToxicEffectsLives tock.ResultsAndDiscussion.ObservGrpathol
Histopathology	Indicate whether any treatment-related effects were observed. In the supplementary remarks field related to this list field, describe the effects by dose (if 'yes') or provide any further explanation (if 'no effects'), e.g. stating that effects were observed, but considered negligible. Select 'not examined' or 'no data' as applicable.	Closed list with remarks (2000)	ENDPOINT_STUDY_RECORD.ToxicEffectsLives tock.ResultsAndDiscussion.ObservHistopathol
Details on results	Describe the effects by dose level for each of the previous fields answered 'yes'. If answered 'no effects', you may provide any further explanations, e.g. stating that effects were observed, but considered negligible and not of biological or statistical significance (to be explained why). Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables' and refer to respective table no., e.g. 'see Table 1' (use predefined	Text template	ENDPOINT_STUDY_RECORD.ToxicEffectsLives tock.ResultsAndDiscussion.ResultsDetails

	table if any). Narrative accompanying such tabular data should address the toxicological significance of the results and not repeat what is presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) may be mandatory.		
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.ToxicEffectsLives tock.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicEffectsLives tock.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicEffectsLives tock.ApplicantSummaryAndConclusion

Links to support material:

Guidelines for residue data under Directive 91/414/EEC and Regulation EC 396/2005 (Appendix G-livestock feeding studies):

https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_mrl_guidelines_app-g.pdf

5.8.3 Endocrine disrupting properties (includes ecotoxicity studies on terrestrial vertebrates) – Endpoint study record

Purpose:

If there is evidence that the active substance may have endocrine disrupting properties, additional information or specific studies shall be required: — to elucidate the mode/mechanism of action, — to provide sufficient evidence for relevant adverse effects. Studies required shall be designed on an individual basis and taking into account Union or internationally agreed guidelines, in the light of the particular parameters to be investigated and the objectives to be achieved.

ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening - v.4.3 (Final)			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.DataSource

Materials and methods	Material and methods – common block Applicable test guideline: OECD 229, OECD 230, OECD 231, OECD 234.	Header 1	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods
Test type		Text	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.TestType
Limit test	Indicate if the experiment was a limit test.	Closed list	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.LimitTest
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.TestMaterials
Test animals	Test animals (OHT: Repeated dose toxicity) – common block	Header 2	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.TestAnimals
State	Select as appropriate.	Closed list	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.TestAnimals.State
Administration / exposure		Header 2	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.AdministrationExposure
Route of administration	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.AdministrationExposure.RouteOfAdministration
Details on route of administration	For robust study summaries or as requested by the regulatory programme, provide details explaining the choice of the oral route and method of administration.	Multi-line text	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.AdministrationExposure.DetailsOnRouteOfAdministration
Vehicle	Select the vehicle used. If not available from picklist, select 'other' and specify. Further information can be given in the supplementary remarks field. Note that some of the vehicles	Open list with remarks	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.AdministrationExposure.Vehicle

	provided in this list are used for specific routes of administration only.		
Details on oral exposure	Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. The use of an aqueous solution/suspension should be considered first and the most common approach is to use a solution/suspension in oil (e.g. corn, peanut, sesame or olive oil). However, as these oils have different caloric and fat content, thus the vehicle might affect total metabolizable energy (ME) intake.	Text template	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.AdministrationExposure.DetailsOnOralExposure
Analytical verification of doses or concentrations	Indicate whether the doses or concentrations were analytically verified.	Closed list with remarks	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.AdministrationExposure.AnalyticalVerificationOfDosesOrConcentrations
Details on analytical verification of doses or concentrations	For robust study summaries or as requested by the regulatory programme, include a short description on the method of analysis. State whether the analytical data indicated that the difference between nominal and actual dosage (if diet is route of administration) or concentrations (for drinking water study) was acceptable. If diet is the route of administration, briefly record when and at what dose levels the dosage analyses were made and include the results (range of values) of (i) Homogeneity analysis, (ii) Stability analysis and (iii) Concentration analysis. If any problems occurred in any of these procedures, then they should be reported in more detail. If this could have affected the veracity or conclusions of the study, discuss this in field 'Rationale for reliability incl. deficiencies'. It may be appropriate to include a cross-reference to another study in which stability analysis was performed and reported. If so, a justification	Text area	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.AdministrationExposure.DetailsOnAnalyticalVerificationOfDosesOrConcentrations

	should also be included briefly explaining the rationale of referring to another study.		
Duration of treatment / exposure	Indicate duration in days, e.g. '7 days'.	Multi-line text	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.AdministrationExposure.DurationOfTreatmentExposure
Frequency of treatment	Indicate the frequency of the administration of doses to the test animals (e.g., 'daily, 7 days each week'). Use of non-standard dosing regime (e.g. a five-day per week regime) should be justified.	Multi-line text	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.AdministrationExposure.FrequencyOfTreatment
Doses / concentrations	Indicate the dose or concentration levels applied and the basis of quantity used. Copy this block of fields for each numeric value and to record values on a different basis, i.e. mg/kg bw/day (nominal), mg/kg bw/day (actual dose received), mg/kg diet ,mg/L drinking water, mg/kg bw (total dose), ppm if applicable. Conversion of the dose / conc. values to the relevant unit used for the effect levels may be required.		ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.AdministrationExposure.DosesConcentrations
Dose / conc.	Enter numeric value.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.DoseConc
Remarks	Enter any remarks related to dose / concentration values.	Multi-line text	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.Remarks
Doses / concentrations			
No. of animals per sex per dose	Enter value or specify according to dose if different number of animals per dose, e.g. '10 in each dose group of main study; 10 f and 5 m in interim sacrifice group'. Also specify number of animals in recovery group if applicable. For robust study summaries or as requested by the regulatory programme, also include a detailed table on the animal assignment in the rich text field 'Any other information on results incl. tables'. Upload predefined	Multi-line text	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.AdministrationExposure.NoOfAnimalsPerSexPerDose

	<p>or other appropriate table(s) if any and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1').</p> <p>Note: Specific tables may be required.</p>		
Control animals	<p>Indicate whether and what type of concurrent control groups were used. If not available from picklist, select 'other' and specify. Copy field if more than one type of control was used.</p>	Multi select open list with remarks	ENDPOINT_STUDY_RECO RD.EndocrineDisrupterMa mmalianScreening.Materi alsAndMethods.Administr ationExposure.ControlAni mals
Details on study design	<p>Include any details on the study design including a brief description of the rationale for dose selection (e.g. consideration of known or suspected nonlinearities or inflection points in the dose response, toxicokinetics, precursor lesions, markers of effect, or indicators of the operation of key underlying biological process, key (or suspected) aspects of mode of action, consideration of anticipated human exposure level), animal assignment and selection of satellite groups including the duration of the post-exposure recovery period. As appropriate state study type(s) and briefly describe the results from range-finding or other studies used as basis for dose selection. More comprehensive details may be attached.</p> <p>Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.</p>	Text template	ENDPOINT_STUDY_RECO RD.EndocrineDisrupterMa mmalianScreening.Materi alsAndMethods.Administr ationExposure.DetailsOnS tudyDesign
Positive control	<p>Uterotrophic Bioassay: Indicate data from the Baseline Positive Control Test and periodic positive control data (reference oestrogen: 17α-ethinyl estradiol).</p> <p>Hershberger Bioassay: Indicate that a reference androgen agonist (Testosterone Propionate) or a reference androgen antagonist (Flutamide) have been used.</p>	Multi-line text	ENDPOINT_STUDY_RECO RD.EndocrineDisrupterMa mmalianScreening.Materi alsAndMethods.Administr ationExposure.PositiveCo ntrol
Examinations		Header 2	ENDPOINT_STUDY_RECO RD.EndocrineDisrupterMa mmalianScreening.Materi

			alsAndMethods.Examinations
Observations and examinations performed and frequency	<p>Indicate if and which examinations were performed and the time schedule for those examinations. Also indicate the dose groups that were examined if not all. As appropriate include detailed table(s) in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) if any and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1').</p> <p>If other observations (e.g. neurotoxicity, immunotoxicity) are reported in another study summary, include a note in the block 'Cross-reference' and refer to that summary. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.</p>	Text template	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.Examinations.ObservationsAndExaminationsPerformedAndFrequency
Sacrifice and pathology	<p>Indicate if and which examinations were performed. Also indicate the dose groups that were examined if not all. Note if not all collected tissues were examined. As appropriate include detailed table(s) in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) if any and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1').</p> <p>Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.</p>	Text template	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.Examinations.SacrificeAndPathology
Other examinations	Describe any other examinations.	Text area	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.Examinations.OtherExaminations
Statistics	List parameters that were analysed and the statistical methods used;	Multi-line text	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMa

	include a statement that the Reviewer considers the analyses used to be appropriate. If inappropriate, provide alternative/rationale.		malianScreening.MaterialsAndMethods.Examinations.Statistics
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.ResultsAndDiscussion
Endocrine disrupting potential	Indicate the endocrine disrupting potential derived from the test results. If positive or ambiguous, include dose(s) / concentration(s) in the supplementary remarks field or representative table. Upload predefined or other appropriate table(s) if any in the rich text field 'Any other information on results incl. tables' and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '...see Table 1')	Closed list with remarks	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.ResultsAndDiscussion.EndocrineDisruptingPotential
Maximum tolerated dose level exceeded	Indicate whether the maximum tolerated dose has been exceeded or not with respect to the endocrine disrupting potential specified in the previous field. This is in particular relevant if the no positive potential has been found.	Closed list with remarks	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.ResultsAndDiscussion.MaximumToleratedDoseLevelExceeded
Results of examinations	Results of examinations (OHT: Repeated dose toxicity: oral) – common block	Header 2	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.ResultsAndDiscussion.ResultsOfExaminations
Effect levels	Effect levels (OHT 67-69, 72-74) – common block Select the relevant dose descriptor, i.e. the exposure level that corresponds to a quantified level of effects, e.g. NOAEL or LOAEL. If a benchmark dose / concentration was calculated, select appropriate BMD indicator (e.g. 'BMD05' or 'BMD:' and specify in the related text field). If the critical effects at a specific dose or concentration level are reported only, select 'dose. level:' or 'conc. level:' and specify.	Header 2	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.ResultsAndDiscussion.EffectLevels

	Where no value could be achieved based on the method and boundaries used, the upper or lower dose level for the relevant dose descriptor can be reported as appropriate with relevant qualifier, e.g. NOAEL >200 mg/kg bw/day or NOAEL <200 mg/kg bw/day. An additional explanation may be given in field 'Remarks on result', e.g. 'not determinable due to absence of adverse toxic effects'.		
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.ApplicantSummaryAndConclusion

5.8.4 Intermediate effects - mechanistic information

Purpose

This OECD Harmonised Template (OHT) aims to collect non-apical observations obtained from methods such as *in vitro* testing or from other classes of methods (e.g. *ex vivo* or *in silico* methods) providing mechanistic information, i.e. effects on molecular, subcellular, cell, tissue or organ level that can be relevant to the hazard assessment (e.g. through Defined Approaches, Integrated Approaches on Testing and Assessment, as part of weight of evidence and are underpinned by Adverse Outcome Pathways).

In the area of pesticides this OHT can be used for example to:

- 1) Report level 1 and level 2 data and studies of the conceptual framework for testing and assessment of endocrine disrupters submitted for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009.
- 2) Mechanistic information relevant for understanding the mode of action of tumour formation if applicable.

Reporting apical vs mechanistic knowledge using OECD Harmonised Templates

In the context of chemical hazard and risk assessment, two classes of knowledge are relevant:

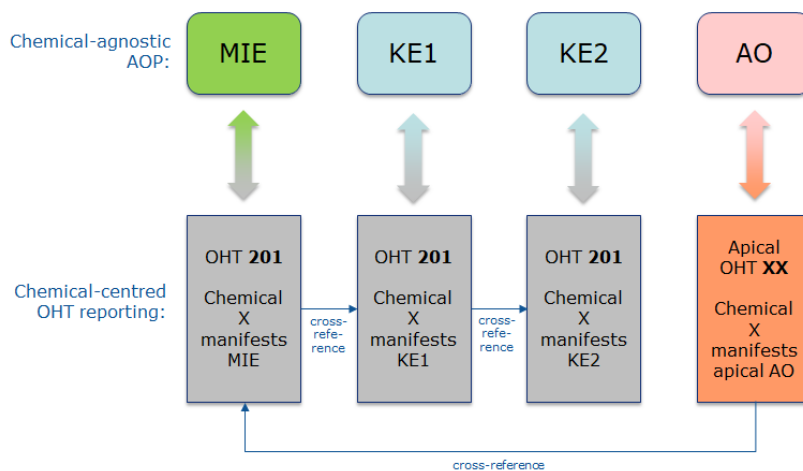
Apical Knowledge	Mechanistic Knowledge
Knowledge about traditional, directly measured whole-organism outcomes of exposure in in vivo tests, generally death, reproductive failure, tumour formation, skin/eye irritation, skin/respiratory sensitisation or developmental dysfunction.	Knowledge about the sequence of events leading from the exposure to an effective dose of a chemical to the production of a specific biological response in the target organ, in most cases measured in non-in-vivo tests.
"One in-vivo test tells us whether an adverse outcome has been observed or not."	"A series of tests, mainly non-animal , tells us why an adverse outcome is likely to manifest itself or not."

OECD Harmonised Templates allow reporting both kinds of knowledge, if available, and they can complement each other.

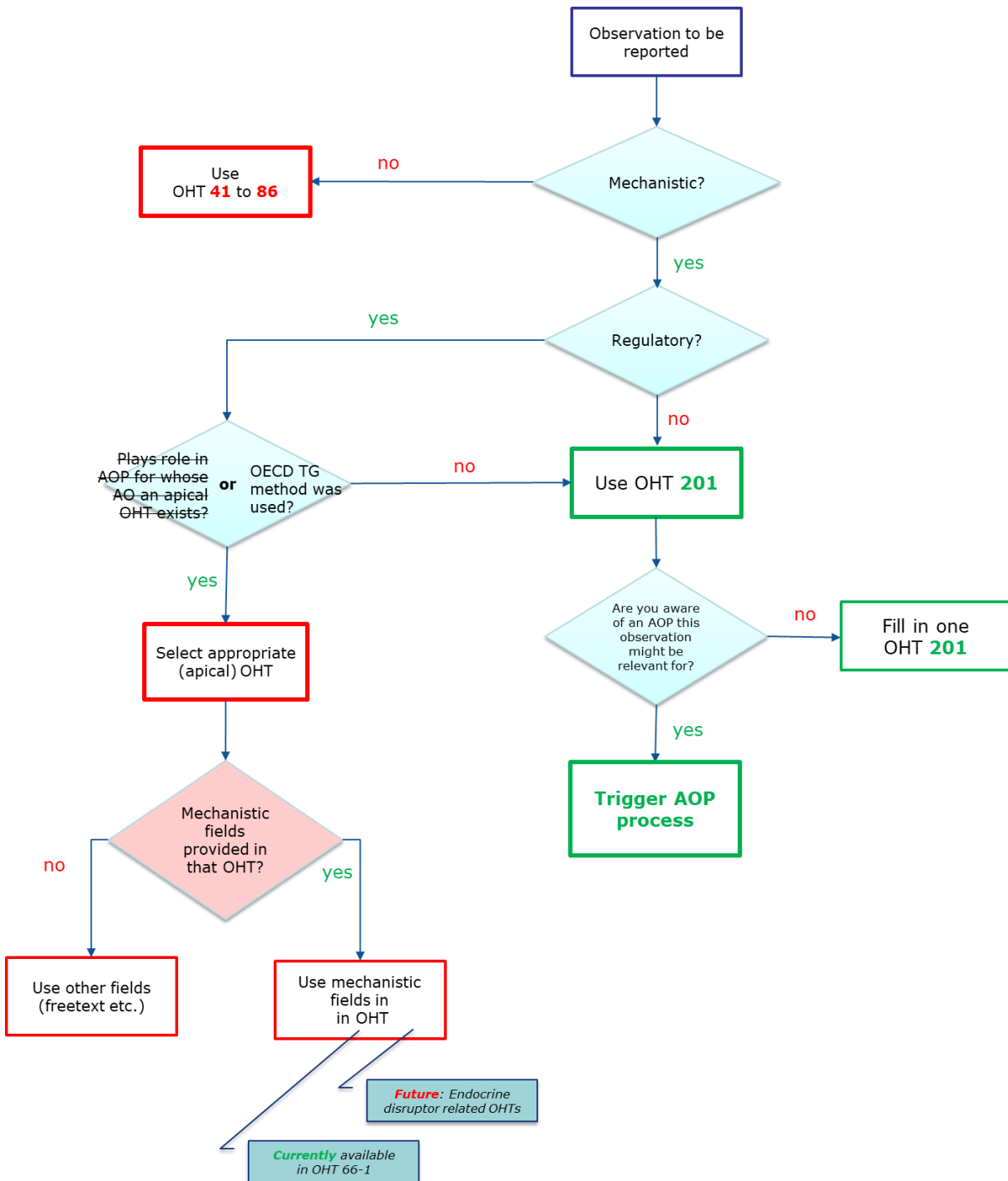
Report apical knowledge ... ↓↓↓	Report mechanistic knowledge ...	
<p>For effects on biotic systems, use: OHTs 41 to 57</p> <p>For health effects, use: OHTs 58 to 84 & 86</p>	<p><i>In a regulatory context: If Mechanistic Knowledge was generated according to an OECD Test Guideline for which an (apical) endpoint OHT²⁰ was created</i></p> <p>↓↓↓</p>	<p><i>In all other cases</i></p> <p>↓↓↓</p>
	<p>Use the suitable endpoint OHT, and there, use the mechanism-oriented fields, if available, else use appropriate other fields.</p>	<p>Use OHT 201</p>

If **OHT 201** is used, it is possible to depict (part of) an AOP by reporting individual observed Intermediate Effects as manifestations of an AOP Key Event:

²⁰ Example: future endocrine disruptor related TG methods

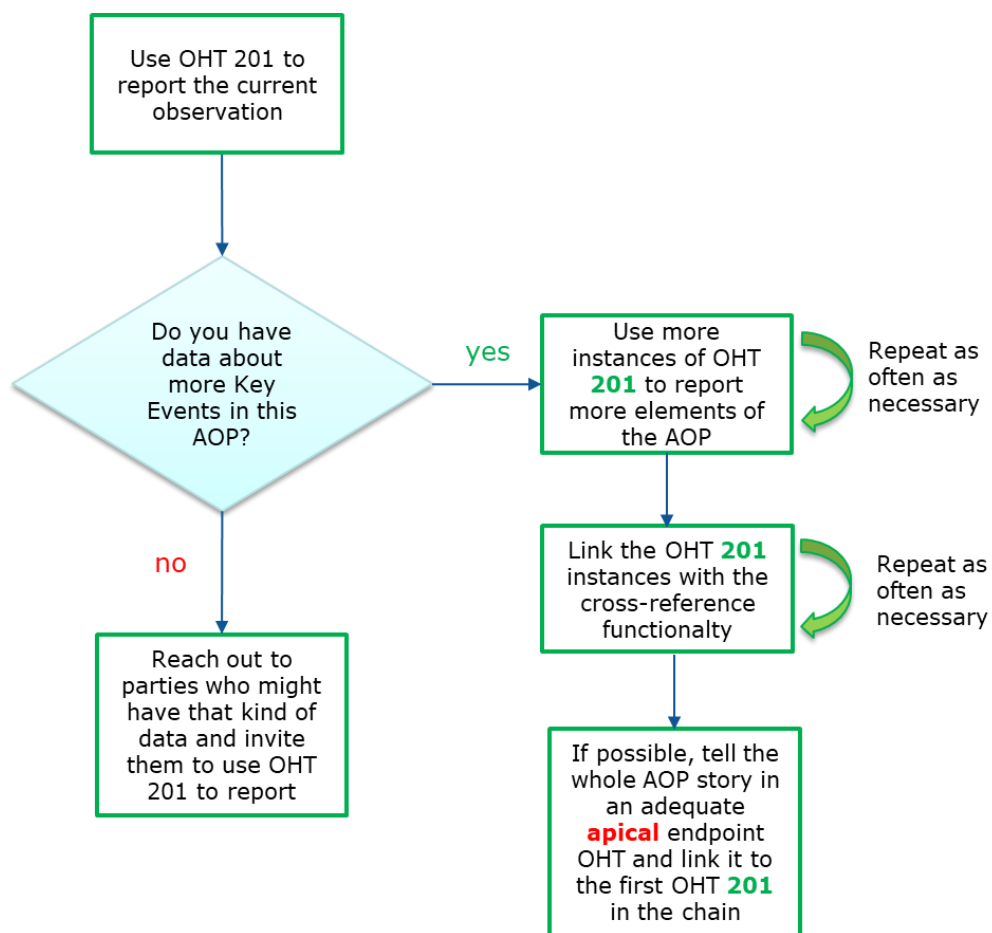


Overview Flowcharts



See next page for "AOP Process"

AOP Process



Fields to be completed

FLEXIBLE_RECORD.IntermediateEffects v.5.0 (Final)		
Field name	Instructions	Field Path
Administrative data		FLEXIBLE_RECORD.Intermediate Effects.AdministrativeData
	Confidentiality	FLEXIBLE_RECORD.Intermediate Effects.AdministrativeData.Data Protection
Reason / purpose for cross-reference	Picklist: Select the appropriate reason of the cross-reference, i.e.: - adverse outcome pathway (AOP) (in case the mechanistic	FLEXIBLE_RECORD.Intermediate Effects.AdministrativeData.Cross Reference.ReasonPurpose

	<p>information is related to a key event that is part of an AOP). Consult the AOP wiki at: https://aopwiki.org) and provide the reference in the remarks field</p> <ul style="list-style-type: none"> - assessment report (for referring to a record that contains an assessment report as attachment) - defined approach for combining with results from another in vitro method - reference to other assay used for mechanistic information derivation (for optional indication in a study summarising if reference is made to the outcome of another assay) - reference to same study (e.g. if different test systems/in vitro models were used and the results recorded in different records, or different test materials were assessed in the same study, using common reference and control items) - reference to other study (e.g. if another study provides mechanistic information or key event relevant for the same Adverse Outcome Pathway or if another study is considered relevant in the interpretation of the test results) - other: (to be specified) 	
Cross-reference		
Study objective(s) / purpose / aim	Specify the objective, purpose and/or aim of the study explaining clearly why the study	FLEXIBLE_RECORD.Intermediate Effects.AdministrativeData.Study Objectives

	<p>was performed and what (regulatory) question is answered. For example:</p> <ul style="list-style-type: none"> - determination of skin sensitising properties of the test chemical by measurement of CD54 and CD86 expression in THP-1 cells after exposure to the CV75 concentration. - gather information on mode of action. - derive a point of departure. 	
Effect identification	<p>The effect has to be identified by providing a 'Process', 'Object' and 'Action'. As a minimum, the 'Process' and 'Action' or the 'Object' and 'Action' must be identified. More than one combination can be provided (e.g. Cell Activation, CD54 molecule, increased & Cell Activation, CD86 molecule, increased). If both Process and Object are provided they have to be concordant with the chosen Action (e.g. both process and object are increased or decreased).</p> <p>See Yves et. al (2017) https://www.liebertpub.com/doi/10.1089/aivt.2017.0017 and the website https://aopwiki.org/ for the concept and its implementation in practice, respectively.</p> <p>If no suitable terms are available in picklist for Process and Object, please select 'Other' and introduce a new ontology-based term. Please consult the Ontology Lookup Service (OLS) to retrieve the terms that best describe the mechanisms you</p>	FLEXIBLE_RECORD.Intermediate Effects.EffectIdentification

	<p>are reporting. OLS is a repository of the latest versions of biomedical ontologies and it is available at https://www.ebi.ac.uk/ols/index (Jupp S. et al. (2015) A new Ontology Lookup Service at EMBL-EBI. In: Malone, J. et al. (eds.) Proceedings of SWAT4LS International Conference 2015).</p> <p>For each effect identified with a process, object and action (P/O/A), the results can be reported in the reporting section.</p> <p>Please use the following P/O/A for existing OECD test guidelines and methods.</p> <p>TG442C, DPRA and ADRA:</p> <p>protein binding / - / increase</p> <p>TG442D, Keratinosens:</p> <p>keratinocyte activation / aldo-keto reductase family 1 member C2 (AKR1C2) / increase</p> <p>TG442D, Lusens:</p> <p>keratinocyte activation / NAD(P)H dehydrogenase [quinone] 1 (NQ01) / increase</p> <p>TG442E, h-CLAT:</p> <p>cell activation / CD54 molecule (intercellular adhesion molecule 1) / increase</p> <p>and</p> <p>cell activation / CD86 molecule / increase</p>	
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	<p>TG442E, U-SENS:</p> <p>cell activation / CD54 molecule (intercellular adhesion molecule 1) / increase</p> <p>TG442E, IL8 LUC:</p> <p>cell activation / interleukin 8 (IL8) / increase</p> <p>TG455, ERTA STTA, VM7Luc and ERα CALUX:</p> <p>nuclear receptor activity / estrogen receptor alpha / increase, agonism</p> <p>and</p> <p>nuclear receptor activity / estrogen receptor alpha / decrease, antagonism</p> <p>TG456, H295R Steroidogenesis Assay:</p> <p>steroid hormone biosynthetic process / estradiol / alteration</p> <p>and</p> <p>steroid hormone biosynthetic process / testosterone / alteration</p> <p>TG458, ARTA STTA, AR-CALUX and 22Rv1/MMTV GR-KO:</p> <p>nuclear receptor activity / androgen receptor / increase, agonism</p> <p>and</p> <p>nuclear receptor activity / androgen receptor / decrease, antagonism</p>	
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	<p>TG493, hrER binding FW assay and CERi assay:</p> <p>Nuclear receptor binding / estrogen receptor alpha / binder–non binder</p>	
P/O/A details		FLEXIBLE_RECORD.Intermediate Effects.EffectIdentification.Details
Process	<p>Picklist: Process represents the dynamics of the underlying biological system (e.g., receptor binding) (Ives et al, 2017). The Process is also used to annotate Key events in the Adverse Outcome Pathway Wiki (https://aopwiki.org/) as described in Ives et al, 2017, doi:10.1089/aivt.2017.0017).</p> <p>Select the process that best describes the mechanistic information observed or select 'other' to specify the Process and provide a term. Please consult the Ontology Lookup Service (OLS) which is available at https://www.ebi.ac.uk/ols/index to choose a Process term. If possible please select as Process one term belonging to the following ontology Gene Ontology (GO).</p> <p>For most terms there will be several options. It is therefore important to also copy the preferred ontology identifier into the remarks field.</p> <p>Cytotoxicity data should only be reported as a process (e.g. cell death) when it is the scope of the study to determine cytotoxicity. In cases where</p>	FLEXIBLE_RECORD.Intermediate Effects.EffectIdentification.Details.Process

	cytotoxicity is measured for supporting information e.g. for dose selection/elimination, it should not be considered as a process. Such data are reported as 'Other observations'.	
Object	<p>Picklist: Object represents the subject of the (biological) effect observed, for example, a specific biological receptor that is activated or inhibited The Object is also used to annotate Key events in the Adverse Outcome Pathway Wiki (https://aopwiki.org/) as described in Ives et al, 2017, doi:10.1089/aivt.2017.0017).</p> <p>It is optional to record both Process and Object. If both Process and Object are recorded they have to be concordant with the chosen Action.</p> <p>Select the object that best describes the subject of the effect observed or select 'other' to specify the Object and provide a term. Please consult the Ontology Lookup Service (OLS) which is available at https://www.ebi.ac.uk/ols/index to choose a Process term. If possible please select as Object one term belonging to the following ontologies protein Ontology (PR) or Chemical Entities of Biological Interest (ChEBI).</p> <p>For most terms there will be several options. It is therefore important to also copy the preferred ontology identifier into the remarks field.</p> <p>More than one object can be provided e.g. when changes of</p>	FLEXIBLE_RECORD.Intermediate Effects.EffectIdentification.Details.Object

	more than one biomarker is measured.	
Action	<p>Picklist: Action represents the type of effect observed e.g. "decrease" in the case where a receptor is inhibited to indicate a decrease in the signalling by that receptor. Action is also used to annotate Key events in the Adverse Outcome Pathway Wiki (https://aopwiki.org/) as described in Ives et al, 2017, doi:10.1089/aivt.2017.0017). Action is used together with the field Process and/or Object.</p> <p>The Action field is always required to describe the effect observed and it can form the following syntaxes "Process, Action" e.g. "gene expression, increase" or "Process, Object, Action" e.g. receptor activity, estrogen receptor, increase.</p> <p>Select the Action that best describes the effect observed or select 'other' to specify the action and provide a term</p>	FLEXIBLE_RECORD.Intermediate Effects.EffectIdentification.Details.EffectAction
P/O/A details		
Details on effect identification	Enter any relevant details concerning the Effect Identification. E.g. in case of selection of more than one triplet for "Process, Object, Action" or when a meaningful term was not found.	FLEXIBLE_RECORD.Intermediate Effects.EffectIdentification.Effect Details
Context	<p>This repeatable block of fields allows for indicating in which target system (on organ level) the observed effect(s) play a role. This may be used in the AOP / MOA building as appropriate.</p> <p>Copy this block of fields for</p>	FLEXIBLE_RECORD.Intermediate Effects.EffectIdentification.Context

	referring to different target systems if applicable. For a given system, multiple organs can be selected.	
System	Picklist: Select the specific system where the observed effect(s) play a role. More than one 'Context' item can be created.	FLEXIBLE_RECORD.Intermediate Effects.EffectIdentification.Context.System
Organ	<p>Picklist: Select from the multiple drop-down list the target organ(s) addressed. This field provides context-related picklist values depending on the selection made in the preceding field 'System'.</p> <p>Guidance for field condition: Conditional picklist</p>	FLEXIBLE_RECORD.Intermediate Effects.EffectIdentification.Context.Organ
Remarks	Include any remarks as appropriate.	FLEXIBLE_RECORD.Intermediate Effects.EffectIdentification.Context.Remarks
Context		
Materials and methods		FLEXIBLE_RECORD.Intermediate Effects.MaterialsAndMethods
Test system		FLEXIBLE_RECORD.Intermediate Effects.MaterialsAndMethods.TestSystem
Type of test system	<p>Picklist: A test system is any biological, chemical or physical system or a combination thereof used in a study (OECD (2018), Guidance Document on Good In Vitro Method Practices (GIVIMP), OECD Series on Testing and Assessment, No. 286, OECD Publishing, Paris).</p> <p>Examples of physical chemical based test systems: serum protein, peptide, enzyme.</p>	FLEXIBLE_RECORD.Intermediate Effects.MaterialsAndMethods.TestSystem.TestSystemType

	<p>Select complex biological test system for example in case of: 3D model, induced pluripotent stem cells, organ on a chip, co-cultures, etc.</p> <p>Select 'other:' in case you don't find a suitable option, for example when your test system is a test kit or a lower in vivo organism.</p>	
Test system identity	<p>Picklist: The test systems listed are those from existing test guidelines. Select the test system used or select other and provide the test system identity. Furthermore, provide information on:</p> <ul style="list-style-type: none"> - Source / supplier - Catalogue / batch number - Species and strain (as relevant) of the origin of the test system. <p>In case a co-culture of cell lines is used, or S9 mix or microsomes are used in combination with a cell line, the user is asked select 'other' and to provide the identity of all components under 'remarks'. In the later fields for 'details on the test system' and 'metabolic competence' the test system can be further described.</p>	FLEXIBLE_RECORD.Intermediate Effects.MaterialsAndMethods.TestSystem.TestSystemIdentity
Genetic modification of the test system	<p>Picklist : When applicable, provide the following information on the genetic modification:</p> <ul style="list-style-type: none"> - Gene inserted - Gene species (e.g. human, rat, 	FLEXIBLE_RECORD.Intermediate Effects.MaterialsAndMethods.TestSystem.GeneticModOfSystem

	<p>mouse)</p> <p>- Additional information on modification</p>	
Details of the test system	<p>Freetext template: TEST SYSTEM DESCRIPTION</p> <p>Provide a short description of the test system, including (species, organ, tissue or cell type (e.g. human monocytoc leukemia cell line or human cryopreserved pooled liver tissue homogenate 9000 g fraction (S9):</p> <p>For cell lines:</p> <ul style="list-style-type: none"> - Number of passages used, if applicable: - Cell cycle length, doubling time or proliferation index: - Measures taken for avoiding or screening for contamination by mycoplasma, bacteria, fungi and virus - Periodically checked for karyotype stability: [yes/no] - Differentiation performed [yes/no], describe: <p>MEDIA USED and incubation conditions</p> <ul style="list-style-type: none"> - Type and composition of media, including use of serum and antibiotics: - Incubation conditions such as CO2 concentration, humidity level, temperature, if applicable: 	FLEXIBLE_RECORD.Intermediate Effects.MaterialsAndMethods.TestSystem.TestSystemDetails
Metabolic competence of the test system	<p>Picklist: Select the option that fits best and describe the knowledge about the metabolic competence (i.e. Phase I and/or II biotransformation capacity) of the test system under remarks.</p>	FLEXIBLE_RECORD.Intermediate Effects.MaterialsAndMethods.TestSystem.MetabolicCompetence

	<p>For example, when the test system used is cryopreserved human pooled liver tissue homogenate 9000 g fraction (S9) procured from a commercial supplier, select "metabolic activity, specify" and specify:</p> <p>contains phase I and II metabolic enzymes present in the microsomal (e.g. cytochrome P450s, Flavin-containing monooxygenase, uridine 5'-diphospho-glucuronosyltransferases, carboxylesterases) and cytosolic (e.g. sulfotransferases, glutathione S-transferases, methyltransferases, N-acetyl transferases, xanthine oxidase, aldehyde oxidase) fractions.</p>	
Detection method		FLEXIBLE_RECORD.Intermediate Effects.MaterialsAndMethods.DetectionMethod
Detection method used	<p>Picklist: Indicate the readout used. Select a detection method type from the picklist and provide the type of instrument (e.g. HPLC, Spectrophotometer, Flow cytometer) or chose 'other: and specify the type or equipment used / analysis performed.</p>	FLEXIBLE_RECORD.Intermediate Effects.MaterialsAndMethods.DetectionMethod.DetectionMethodUsed
Details on detection method	<p>Quantitative analytical methods:</p> <p>'Briefly describe further details on the principles of the method used to detect the analytes (to be specified, e.g. "parent compound", "parent and transformation products" or "transformation product:") in matrices. Use free text template and delete/add elements as appropriate. For</p>	FLEXIBLE_RECORD.Intermediate Effects.MaterialsAndMethods.DetectionMethod.DetailsOnDetectionMethod

	<p>example, add specific parameters in the case of inorganic chemicals. As an option you may include an excerpt from the study report.</p> <p>Note: If a residue analytical method is recorded, the details for the so-called data collection or data-gathering method should be specified here. As to the terms "data collection method" and "enforcement method" see help text for field "Instrument / detector".</p> <p>Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.</p> <p>Freetext template:</p> <p>Option 1: Semi or non-quantitative detection methods</p> <p>SEMI OR NON-QUANTITATIVE DETECTION METHODS</p> <p>Instrument type and model:</p> <p>Option 2 Option 2: Quantitative analytical methods</p> <p>QUANTITATIVE ANALYTICAL METHODS</p> <p>Instrument type and model:</p> <p>COMPOUND (ANALYTE): ...</p>	
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	<ul style="list-style-type: none"> - Method ID: - Extraction solvent/technique: - Cleanup strategies: - Derivatisation (if any): - Instrument/detector (if further details): - Standardisation method: - Stability of standard solution: - Retention times: - Detection limit (Limit of Quantification) - Other: <p>INTERFERING SUBSTANCE(S):</p> <p>STABILITY OF PARENT AND TRANSFORMATION PRODUCTS AT VARIOUS STAGES OF ANALYSIS:</p> <p>PROBLEMS / PRECAUTIONS:</p> <ul style="list-style-type: none"> - Special problems encountered: - Precautions to be taken during: - analysis of samples: - handling of samples: - storage of samples: <p>TOTAL TIME FOR COMPLETION:</p>	
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Test design		FLEXIBLE_RECORD.Intermediate Effects.MaterialsAndMethods.TestDesign
Test material preparation		FLEXIBLE_RECORD.Intermediate Effects.MaterialsAndMethods.TestDesign.TestMaterialPreparation
Concentration selection of the test material	<p>Picklist: For data interpretation it is important to know on what basis the highest concentration tested was selected.</p> <p>Prior information of response and interference with the test system can e.g. be obtained through literature or with experimental data in a dose-range finding experiment.</p> <p>Example for TG442E (h-CLAT)</p> <p>Highest concentration to be used is either of the following concentrations:</p> <ul style="list-style-type: none"> - 1.2-fold the CV75 concentration of the test chemical, i.e. the concentration where 25% of the cells is dead. - Maximum 5000 µg/mL for non-cytotoxic test chemicals that dissolve or stably disperse in the solvent saline and subsequently in medium. - Maximum 1000 µg/mL for non-cytotoxic test chemicals that dissolve in DMSO and subsequently in medium. <p>Any free text explanation can be given in the adjacent text field to justify the dose level selected.</p>	FLEXIBLE_RECORD.Intermediate Effects.MaterialsAndMethods.TestDesign.TestMaterialPreparation.ConcentrationSelection

Vehicle / solvent	<p>Picklist: If a vehicle or solvent was used, select the relevant item or use 'other:' and specify. You can give further relevant information in the supplementary remarks field, e.g. lot/batch no., purity, concentration, etc.</p> <p>In case a solvent is used that is different from those recommended in the in vitro method Standard Operating Procedure or test guideline, a justification for the choice must be provided.</p>	FLEXIBLE_RECORD.Intermediate Effects.MaterialsAndMethods.TestDesign.TestMaterialPreparation.Vehicle
Dilution steps / dose intervals	<p>Indicate if the test material was further diluted before exposure of the test system. In case of dose range, provide the amount of concentrations and dilution factor.</p> <p>Example description: The test material was first diluted in 70% ethanol and subsequently diluted 500-fold in cell culture medium. Another 2-fold dilution was executed in the well to obtain a total of 1000-fold dilution and a final solvent concentration of 0.07%.</p> <p>Freetext template:</p> <p>DILUTION STEPS PERFORMED</p> <p>Provide the following information (where available):</p> <p>- Dilution steps from 'stock solution' in the vehicle/solvent including the final % of vehicle/solvent in the exposure medium</p>	FLEXIBLE_RECORD.Intermediate Effects.MaterialsAndMethods.TestDesign.TestMaterialPreparation.DilutionStepsDoseIntervals

	<ul style="list-style-type: none"> - Dose intervals in case of dose range - Number of concentrations prepared 	
Control and reference items		FLEXIBLE_RECORD.IntermediateEffects.MaterialsAndMethods.TestDesign.ControlAndReferenceItems
Controls / reference items used	Indicate whether controls / reference substances were used. If 'yes' is selected, the details can be entered in the repeatable block 'Controls / reference substances'.	FLEXIBLE_RECORD.IntermediateEffects.MaterialsAndMethods.TestDesign.ControlAndReferenceItems.ControlsReferenceItemsUsed
Controls / reference items	<p>Indicate whether solvent/vehicle controls, negative controls, true negative controls (i.e. negative reference substances) and/or positive controls (i.e. positive reference substances) were tested concurrently. Repeat this block of fields as necessary.</p> <p>In case of a robust study summary or as requested by the regulatory programme, also provide information in the supplementary remarks field, e.g. to the identity, supplier, lot and purity of the control substance(s) and the concentration / amount applied.</p> <p>Guidance for field condition: Condition: Block of fields active only if 'Controls / reference substances used' is 'yes'</p>	FLEXIBLE_RECORD.IntermediateEffects.MaterialsAndMethods.TestDesign.ControlAndReferenceItems.ControlsReferenceSubstances
Type of controls used	Picklist: Select the type of control used to demonstrate the proper performance of the test system and therefore the validity of the experiments. More than one control/reference item can be provided.	FLEXIBLE_RECORD.IntermediateEffects.MaterialsAndMethods.TestDesign.ControlAndReferenceItems.ControlsReferenceSubstances.TypeOfControls

	<p>See (GIVIMP, OECD guidance document 286 in the series on testing and assessment).</p> <p>Solvent / vehicle controls consist of solvent or vehicle alone, without test item (test material), and otherwise treated in the same way as the treatment groups.</p> <p>Negative / untreated controls consist of culture medium without solvent / vehicle or test item, and otherwise treated in the same way as the treatment groups.</p> <p>True negative controls include items (e.g. chemicals) with known lack of activity.</p> <p>Positive controls include items with known activity.</p> <p>Reference items are substances with known activity, used as basis for comparison with the test item (test material).</p>	
Description of reference and control items used	<p>Picklist: Select the reference or control item used or provide the name and identifier (e.g. CAS number), and in the remarks field the purity and concentration (range) used.</p> <p>If 'other:' is selected, provide the name and identity (CAS number) in the additional text field.</p> <p>For each selection (including the 'other:'), provide purity (%) and concentration (range or single concentration) in the field 'Remarks'.</p>	<p>FLEXIBLE_RECORD.Intermediate Effects.MaterialsAndMethods.TestDesign.ControlAndReferenceItems.ControlsReferenceSubstances.ControlOrReferenceItemsUsed</p>

Remarks	Additional information, such as solvents used.	FLEXIBLE_RECORD.Intermediate Effects.MaterialsAndMethods.TestDesign.ControlAndReferenceItems.ControlsReferenceSubstances.Remarks
Controls / reference items		
Experimental conditions		FLEXIBLE_RECORD.Intermediate Effects.MaterialsAndMethods.TestDesign.ExperimentalConditions
Number of replicates	<p>Provide the number of replicates per concentration and the number of independent experiments performed. For each experiment, valid or invalid, results should be reported.</p> <p>NUMBER OF REPLICATIONS:</p> <ul style="list-style-type: none"> - Number of replicates per concentration (single, duplicate, triplicate) - Number of independent experiments 	FLEXIBLE_RECORD.Intermediate Effects.MaterialsAndMethods.TestDesign.ExperimentalConditions.NumberOfReplicates
Experimental conditions	<p>Use free text template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. EFSA/ECHA Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009; OECD Programme, Pesticides NAFTA or EU REACH) thereof.</p> <p>Concentration of biological test systems is usually expressed as cell density (amount of cells/cm² or cells/ml seeded) or</p>	FLEXIBLE_RECORD.Intermediate Effects.MaterialsAndMethods.TestDesign.ExperimentalConditions.ExperimentalConditions

	<p>confluence (%).</p> <p>Concentration of physical chemical test systems is usually expressed in mg/ml or molarity.</p> <p>Incubation conditions are e.g. temperature, CO₂, concentration, humidity level, etc.</p> <p>A vessel can e.g. be a test tube or cell culture plates with 24, 96 or 384 wells.</p> <p>Freetext template:</p> <p>METHOD OF TREATMENT/ EXPOSURE:</p> <ul style="list-style-type: none"> - Concentration of the test system (e.g. cell density or number of cells used) - Description how the test material was added to the test system (e.g. in medium, in suspension) <p>TREATMENT AND HARVEST SCHEDULE:</p> <ul style="list-style-type: none"> - Pre-incubation period, if applicable - Exposure duration / duration of treatment - Frequency of administration, e.g. single, repeated or continuous - Harvest time after the end of treatment (sampling/recovery times) 	
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	<ul style="list-style-type: none"> - Incubation conditions - Vessel type used for exposure - OTHER: 	
Additional analysis: e.g. cytotoxicity assay or other	<p>Picklist: This picklist was established on basis of GIVIMP annex I (OECD, 2018).</p> <p>Select the viability assay used to measure cytotoxicity:</p> <p>Select 'other cytotoxicity assay' in case another type of cytotoxicity assay was used. Select 'other type of analysis' in case another or another type of analysis was performed that is important for the interpretation of results (e.g. pH, autofluorescence, etc.).</p> <p>In the remarks field any additional information can be provided.</p>	FLEXIBLE_RECORD.Intermediate Effects.MaterialsAndMethods.TestDesign.ExperimentalConditions.AdditionalAnalysis
Data analysis		FLEXIBLE_RECORD.Intermediate Effects.MaterialsAndMethods.TestDesign.DataAnalysis
Acceptance criteria for the test material results	<p>Acceptance criteria: Criteria for when results can be accepted, i.e. a set of well-defined parameters describing aspects of the method such as range for positive and negative controls (GIVIMP, OECD, 2018).</p> <p>For cell-based methods, the acceptance criteria should include the level of cytotoxicity or other type of interference that is accepted / not accepted.</p> <p>Any free text explanation can be given to specify which criteria exist for acceptance of results, e.g. related to reference and</p>	FLEXIBLE_RECORD.Intermediate Effects.MaterialsAndMethods.TestDesign.DataAnalysis.AcceptanceCriteria

	<p>control substances or vehicle/solvent control, cytotoxicity or other interference, capturing of full dose-response, minimum/maximum response to be observed or outliers.</p> <p>Freetext template:</p> <p>Provide a description or list of the study acceptance criteria:</p>	
Data calculation and statistics	<p>Provide the method used to calculate the results from raw data to the parameters calculated, such as normalisation, use of calibration curve, subtraction of control values, calculation of averages, Standard deviations etc.</p> <p>List the statistical methods used to derive the parameters to be reported. Include a statement on the appropriateness of the statistical analysis used. Parameters, their explanation and values should be provided in the "Test results" section.</p> <p>Example of data calculation and statistical analysis performed:</p> <p>Relative Light Units raw data were copied to commercially available software Graphpad Prism for hill curve fitting (variable slope, four parameters). Subsequently, the EC50 value and its CV were calculated.</p> <p>Specify if outlier analysis is performed and what (statistical) method was used to exclude values.</p> <p>Calculations performed - Statistical methods used</p>	FLEXIBLE_RECORD.Intermediate Effects.MaterialsAndMethods.TestDesign.DataAnalysis.DataCalculationAndStatistics

	- Where relevant, provide the method used to exclude outliers.	
Evaluation / data interpretation criteria	<p>Describe the evaluation criteria used in the study to judge if the test material is positive, negative or equivocal. For example:</p> <p>When there is more than 10% binding to the androgen receptor (as expressed in relative light units) for more than two concentrations, the result is 'positive'.</p> <p>h-CLAT: When the RFI of CD86 is equal to or greater than 150% in at least one tested concentration (with cell viability $\geq 50\%$), the result for the test material is positive. The EC150 value is calculated where possible.</p> <p>DPRA: The mean of cysteine and lysine depletion is: Less than 6.38%: minimal reactivity.</p> <p>Between 6.38% and 22.62%: low reactivity</p> <p>Between 22.62% and 42.47%: moderate reactivity.</p> <p>More than 42.47%: high reactivity.</p> <p>Consider also precipitation and co-elution.</p> <p>Evaluation / data interpretation criteria: - Results will be expressed as:</p>	FLEXIBLE_RECORD.Intermediate Effects.MaterialsAndMethods.TestDesign.DataAnalysis.EvaluationDataInterpretationCriteria

Any other information on materials and methods incl. tables		FLEXIBLE_RECORD.Intermediate Effects.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
	<p>In this field, you can enter any information on materials and methods, for which no distinct field is available, or transfer free text from other databases. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. You can also upload any htm or html document.</p> <p>Here you may for example provide details on specific material or reagents used. In case of TG442E, h-CLAT you could provide the information on the type of antibodies used, as these are essential components of the method.</p> <p>Note: One rich text editor field each is provided for the MATERIALS AND METHODS and RESULTS section. In addition the fields 'Overall remarks' and 'Executive summary' allow rich text entry.</p>	FLEXIBLE_RECORD.Intermediate Effects.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables.OtherInformation
Results and discussion		FLEXIBLE_RECORD.Intermediate Effects.ResultsAndDiscussion
Test results		
Test results	Report the parameters obtained and effective concentration(s) for the type of effect specified in the 'Test results' fields. Copy this field block for entering more than one experiment if necessary, e.g. for a test guideline or if different	FLEXIBLE_RECORD.Intermediate Effects.ResultsAndDiscussion.TestResults.TestResults

	<p>concentration ranges were tested.</p> <p>One experiment may include more than one replicate for each tested concentration. An independent experiment is usually carried out with independently prepared controls, test system, reagents used for analysis and on a different time.</p> <p>Set this flag if a key observation should be identified for the conclusion section.</p>	
Details of the effect identification	<p>Select the relevant item of effect identification details indicated under 'Details'.</p> <p>Remarks: Dynamic picklist values: - Process / Object / Action (combination 1) - Process / Object / Action (combination 2) - ...</p>	FLEXIBLE_RECORD.IntermediateEffects.ResultsAndDiscussion.TestResults.TestResults.DetailsOfTheEffectIdentification
Key result	<p>Set this flag if a key observation should be identified for the conclusion section.</p>	FLEXIBLE_RECORD.IntermediateEffects.ResultsAndDiscussion.TestResults.TestResults.KeyObservation
Concentration selection of the test material	<p>Picklist: For data interpretation it is important to know on what basis the highest concentration tested was selected.</p> <p>Prior information of response and interference with the test system can e.g. be obtained through literature or with experimental data in a dose-range finding experiment.</p> <p>Example for TG442E (h-CLAT)</p>	FLEXIBLE_RECORD.IntermediateEffects.ResultsAndDiscussion.TestResults.TestResults.ConcentrationSelection

	<p>Highest concentration to be used is either of the following concentrations:</p> <ul style="list-style-type: none"> - 1.2-fold the CV75 concentration of the test chemical, i.e. the concentration where 25% of the cells is dead. - Maximum 5000 µg/mL for non-cytotoxic test chemicals that dissolve or stably disperse in the solvent saline and subsequently in medium. - Maximum 1000 µg/mL for non-cytotoxic test chemicals that dissolve in DMSO and subsequently in medium. <p>Any free text explanation can be given in the adjacent text field to justify the dose level selected.</p>	
Concentration range tested	<p>Indicate the lowest and highest concentration tested.</p> <p>Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.</p>	FLEXIBLE_RECORD.Intermediate Effects.ResultsAndDiscussion.TestResults.TestResults.ConcentrationRangeTested
Number of replicates and outliers	<p>Specify the number of replicates per concentration and if any values were excluded after outlier analysis.</p> <ul style="list-style-type: none"> - Number of replicates: - Information on outlier removal: - Impact of outlier removal on the results: 	FLEXIBLE_RECORD.Intermediate Effects.ResultsAndDiscussion.TestResults.TestResults.NumberOfReplicatesAndOutliers

Parameter and result		FLEXIBLE_RECORD.Intermediate Effects.ResultsAndDiscussion.Te stResults.TestResults.Parameter AndResult
Parameter	<p>Picklist : This picklist displays either the parameters specific to the selected method, or general parameters in case another method is used.</p> <p>Provide the relevant parameters, representative of the effect measured, that are calculated for your method. Existing test guidelines and OHTs for in vitro methods (e.g. OHT 66-1) may provide additional suggestions for other type of parameters.</p> <p>For guideline methods, all relevant parameters are listed.</p> <p>In case of a non-guideline method, the listed parameters are from existing OECD test guidelines, where the use of the parameters is explained. E.g. CV75 is the test chemical concentration that results in 75% cell viability. The PC value is obtained by interpolation in case a full dose response is not obtained for the test material.</p> <p>Provide in the remarks field, other information that provides explanation of the parameter. E.g. when % depletion is selected, provide information on what is depleted (e.g. cysteine, lysine, etc.).</p> <p>Explanation of some parameters:</p> <p>EC 1.5, 150 and 200 represents the concentration where the test material triggers the effect at</p>	FLEXIBLE_RECORD.Intermediate Effects.ResultsAndDiscussion.Te stResults.TestResults.Parameter AndResult.Parameter

	<p>the limit (e.g. 1.5, 150 or 200) prescribed by the method used.</p> <p>No-observed effect concentration (NOEC) is defined as the test concentration below the lowest concentration that did result in a significant effect in the specific experiment.</p> <p>Lowest-observed effect concentration (LOEC) is the lowest concentration out of the tested concentrations at which a statistically significant difference from the control group is observed.</p> <p>PC10, 50, 80 represents the concentration of a test material where the response is 10, 50 or 80% of the response induced by the reference chemical. PC values can be used when incomplete or ambiguous dose response curves are obtained and EC values cannot be calculated..</p> <p>CL, in vitro, INT is in vitro intrinsic (metabolic) clearance.</p>	
Result for the parameter	Provide the result for the selected parameter and select the appropriate unit.	FLEXIBLE_RECORD.Intermediate Effects.ResultsAndDiscussion.TestResults.TestResults.ParameterAndResult.ParameterResult
Parameter and result		
Other observations		FLEXIBLE_RECORD.Intermediate Effects.ResultsAndDiscussion.TestResults.TestResults.OtherObservation
Observation	Picklist: Indicate other observations that are important for results interpretation such as information on cytotoxic concentrations, precipitation observed at specific	FLEXIBLE_RECORD.Intermediate Effects.ResultsAndDiscussion.TestResults.TestResults.OtherObservation.Observation

	<p>concentrations, other parameters measured. Specify the observation and respective test concentration(s). Alternatively or in addition, use the field 'Any other information on results incl. tables'. If you refer to table(s), use appropriate table numbers (e.g. '... see Table 1').</p> <p>Note: Specific tables may be required. Consult the programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) thereof.</p>	
Concentration	Provide the result for other observations and select the appropriate unit.	FLEXIBLE_RECORD.IntermediateEffects.ResultsAndDiscussion.TestResults.TestResults.OtherObservation.Concentration
Other observations		FLEXIBLE_RECORD.IntermediateEffects.ResultsAndDiscussion.TestResults.TestResults.OtherObservation
Results for the test material	<p>Picklist: The options in the picklist are derived from existing in vitro OECD test guidelines.</p> <p>Indicate the result of the test conducted.</p> <p>In the remarks field additional information can be added. For example when selecting binder additional information could be 'competitive', 'non competitive', 'specific' or 'non-specific'.</p> <p>Example of results from TG442C, DPRA:</p> <ul style="list-style-type: none"> - Minimal reactivity - Low reactivity 	FLEXIBLE_RECORD.IntermediateEffects.ResultsAndDiscussion.TestResults.TestResults.ResultsForTheTestMaterial

	<ul style="list-style-type: none"> - Moderate reactivity - High reactivity 	
Acceptance of results	<p>Picklist: Select the element for which acceptance criteria exist and indicate in the remarks field if the results are valid or invalid.</p> <p>In case results are invalid, please describe in the next field 'Remarks on results' why the result is invalid (e.g. precipitation observed, toxicity of the test material, co-elution with the peptide, etc.), and what is the impact of invalid data on the results.</p>	FLEXIBLE_RECORD.IntermediateEffects.ResultsAndDiscussion.TestResults.TestResults.AcceptanceOfResults
Remarks on results	<p>This field can be used for:</p> <ul style="list-style-type: none"> - explaining expert judgement, in case it was applied; - providing a justification; - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - providing information in case a result may be over-estimated or under-estimated; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; - explaining the impact on the results in case one or more acceptance criteria were not met; - any additional information. 	FLEXIBLE_RECORD.IntermediateEffects.ResultsAndDiscussion.TestResults.TestResults.RemarksOnResults

Attached material		FLEXIBLE_RECORD.IntermediateEffects.ResultsAndDiscussion.TestResults.TestResults.AttachedMaterial
Type of attachment	<p>Picklist: Choose the type of document from the picklist or select 'other:'.</p> <p>For test guidelines that provide a reporting template (data analysis file), that file must be completed and can be uploaded here or in the overall results section.</p> <p>Upload file(s) containing data or results by clicking the 'Select files' button. As appropriate, enter any additional information, e.g. language. The file name and the filename extension is displayed after uploading the document.</p>	FLEXIBLE_RECORD.IntermediateEffects.ResultsAndDiscussion.TestResults.TestResults.AttachedMaterial.AttachmentType
Attachment	Attach the document indicated in the field "Type of attachment".	FLEXIBLE_RECORD.IntermediateEffects.ResultsAndDiscussion.TestResults.TestResults.AttachedMaterial.Attachment
Attached material		FLEXIBLE_RECORD.IntermediateEffects.OverallRemarksAttachments.AttachedBackgroundMaterial.AttachedDocument
Test results		
Overall remarks, attachments		FLEXIBLE_RECORD.IntermediateEffects.OverallRemarksAttachments
Overall remarks	In this field, you can enter any overall remarks or transfer free text from other databases. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. You can also	FLEXIBLE_RECORD.IntermediateEffects.OverallRemarksAttachments.RemarksOnResults

	<p>upload any htm or html document.</p> <p>Note: One rich text editor field each is provided for the MATERIALS AND METHODS and RESULTS section. In addition the fields 'Overall remarks' and 'Executive summary' allow rich text entry.</p>	
Attached background material	<p>Attach any background document that cannot be inserted in any rich text editor field, particularly image files (e.g. an image of a structural formula).</p> <p>Copy this block of fields for attaching more than one file.</p>	FLEXIBLE_RECORD.IntermediateEffects.OverallRemarksAttachments.AttachedBackgroundMaterial
Attached document	<p>Provide any additional documents relevant for the submission, not already provided under the methods or results section or in the full study report. Choose the type of document from the picklist or select other.</p> <p>Examples are:</p> <ul style="list-style-type: none"> - Scientific publication - GLP documentation - (Q)SAR: supporting information - Data analysis file (calculation of parameters) - Data supporting the reliability and sensitivity of the method - Specific information on the test material or test system - Justification 	FLEXIBLE_RECORD.IntermediateEffects.OverallRemarksAttachments.AttachedBackgroundMaterial.AttachedDocument

	<p>- Expert judgement</p> <p>- Other</p> <p>For test guidelines that provide a reporting template (data analysis file), that file must be completed and can be uploaded here if not yet done in the results section.</p> <p>Upload file by clicking the upload icon. As appropriate, enter any additional information, e.g. language. The file name is displayed after uploading the document.</p>	
Remarks	<p>As appropriate, include remarks, e.g. a short description of the content of the attached document if the file name is not self-explanatory.</p> <p>If required, an electronic copy of the full study report or QSAR QPRF reporting forms can be attached as WORD, pdf or other document type.</p>	FLEXIBLE_RECORD.IntermediateEffects.OverallRemarksAttachments.AttachedBackgroundMaterial.Remarks
Attached background material		
Attached full study report	If required, an electronic copy of the full study report or QSAR QPRF reporting forms can be attached as WORD, pdf or other document type.	FLEXIBLE_RECORD.IntermediateEffects.OverallRemarksAttachments.AttachedStudyReport
Attached (sanitised) documents for publication	If required, an electronic copy of a public (non-confidential) version of the full study report or other relevant documents can be attached. These attachments should be sanitised if needed.	FLEXIBLE_RECORD.IntermediateEffects.OverallRemarksAttachments.AttachedSanitisedDocsForPublication
Applicant's summary and conclusion		FLEXIBLE_RECORD.IntermediateEffects.ApplicantSSummaryAndConclusion

Interpretation of results / observations		FLEXIBLE_RECORD.IntermediateEffects.ApplicantSSummaryAndConclusion.InterpretationOfResultsObservations
Overall results and conclusion	<p>Provide the overall result for the test material, on basis of one or more experiments and all observations reported in this template.</p> <p>Convey a clear statement on the mechanistic information obtained.</p> <p>Add the effect concentration in the next fields.</p> <p>Example from h-CLAT: The RFI of CD86 is greater than 150% at 2 tested concentrations (with cell viability \geq 50%) in 2 of 2 experiments. Therefore the test material is activating dendritic cells and is a possible skin sensitizer.</p>	FLEXIBLE_RECORD.IntermediateEffects.ApplicantSSummaryAndConclusion.InterpretationOfResultsObservations.OverallResults
Type of result	Picklist: Indicate if the results are qualitative when the result is yes/no or positive/negative or quantitative when dose-response information is obtained and an effect level (concentration) can be determined.	FLEXIBLE_RECORD.IntermediateEffects.ApplicantSSummaryAndConclusion.InterpretationOfResultsObservations.TypeOfResult
Effect concentration	<p>Picklist: Where available, provide the effect concentration taking into account results from more than one experiment.</p> <p>Explanation of some parameters:</p> <p>EC 1.5, 150 and 200 represents the concentration where the test material triggers the effect at the limit (e.g. 1.5, 150 or 200) prescribed by the method used.</p>	FLEXIBLE_RECORD.IntermediateEffects.ApplicantSSummaryAndConclusion.InterpretationOfResultsObservations.EffectConcentrationChoice

	<p>No-observed effect concentration (NOEC) is defined as the test concentration below the lowest concentration that did result in a significant effect in the specific experiment.</p> <p>Lowest-observed effect concentration (LOEC) is the lowest concentration out of the tested concentrations at which a statistically significant difference from the control group is observed.</p> <p>PC10, 50, 80 represents the concentration of a test material where the response is 10, 50 or 80% of the response induced by the reference chemical. PC values can be used when incomplete or ambiguous dose response curves are obtained and EC values cannot be calculated.</p>	
Concentration	Provide the effect concentration and select the appropriate unit.	FLEXIBLE_RECORD.IntermediateEffects.ApplicantSSummaryAndConclusion.InterpretationOfResultsObservations.Concentration
Remarks	Include any remarks as appropriate.	FLEXIBLE_RECORD.IntermediateEffects.ApplicantSSummaryAndConclusion.InterpretationOfResultsObservations.Remarks
Executive summary		FLEXIBLE_RECORD.IntermediateEffects.ApplicantSSummaryAndConclusion.ExecutiveSummary
	If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective free text template if available from the drop-down list or copy it from	FLEXIBLE_RECORD.IntermediateEffects.ApplicantSSummaryAndConclusion.ExecutiveSummary.ExecutiveSummary

	<p>the corresponding document.</p> <p>You may also provide information on other existing data or studies that confirm the results obtained.</p> <p>Consult the programme-specific guidance (e.g. EFSA/ECHA Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009; OECD HPVC, Pesticides NAFTA or EU REACH) thereof.</p>	
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5.9 Medical data – Endpoint summary

Purpose:

Where available and without prejudice to Article 10 of Council Directive 98/24/EC (1), practical data and information relevant to the recognition of the symptoms of poisoning and on the effectiveness of first aid and therapeutic measures shall be submitted. Such data and information shall include reports of any studies investigating antidote pharmacology or safety pharmacology. Where relevant, the effectiveness of potential antagonists to poisoning shall be investigated and reported.

Data and information relevant to the effects of human exposure, where available, shall be used to confirm the validity of extrapolations made and conclusions reached with respect to target organs, dose-response relationships, and the reversibility of adverse effects. Such data may be generated following accidental, occupational exposure or incidents of intentional self-poisoning, and shall be reported if available.

The document should contain the information needed to be reported according to the list of end points for medical data SANCO/12483/2014– rev. 3

(https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_doss_temp-list-endpoints_rev-3.pdf?)

For microorganisms this document should be used to summarise the available data for 5.1 Basic information including Medical surveillance on manufacturing plant personnel, Sensitisation/allergenicity observations and Direct observation e.g. clinical cases

ENDPOINT_SUMMARY.ExposureRelatedObservationsHumans - v.5.0 (Final)			
Name	Instructions	Type	Field Path
Administrative data	Administrative data summary – common block Provide brief description of relevant studies and effects e.g. Limited; new active substance,-no detrimental effects on health in manufacturing personnel. For example: - Limited; new active substance, - no detrimental effects on health in manufacturing personnel	Header 1	ENDPOINT_SUMMARY.ExposureRelatedObservationsHumans.AdministrativeDataSummary
Additional information	Discussion (Header 1) – common block Provide additional information related to the potential effects on human health of the micro-organism, including consideration of its pathogenic potential, its ability to infect and its toxicological effects.	Header 1	ENDPOINT_SUMMARY.ExposureRelatedObservationsHumans.Discussion

5.9.1 Medical surveillance on manufacturing plant personnel and monitoring studies– Endpoint study record

Purpose:

Chemical and Microorganism (Active): Available reports of occupational health surveillance programmes, supported with detailed information on the design of the programme and on exposure to the active must be submitted. Such reports should, where feasible, include data relevant to the mechanism of action of the active and report of adverse health effects, including allergenic responses to chemicals in humans. These reports shall, where available, include data from persons exposed in manufacturing plants or after application of the active (e.g. in efficacy trials).

ENDPOINT_STUDY_RECORD.HealthSurveillanceData - v.7.3 (Final)			
Name	Instructions	Type	Filed Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.HealthSurveillanceData.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.HealthSurveillanceData.Data Source
Reference	Literature reference	Literature reference list	ENDPOINT_STUDY_RECORD.HealthSurveillanceData.Data Source.Reference
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.HealthSurveillanceData.MaterialsAndMethods
Study type	Select the appropriate study type. Optionally, include details in the supplementary remarks field. Definitions: - Biological effect monitoring: involves the measurement of a biological change that is non-adverse and reversible (in contrast to medical monitoring), e.g. liver toxicity biomarkers (i.e. activity of aminotransferase and other enzymes). - Biological exposure monitoring: measurement of biomarkers to assess the exposure from dietary, environmental or occupational sources. Biomarkers of exposure include either the measurement of levels of chemical agents and their metabolites in body fluids, tissue, cells or excreta, or the measurement of biological responses such as cytogenetic and reversible physiological changes in the exposed individuals. - Health record from industry: a review of medical records and occupational exposure. - Health record, other: any other review of medical history and records (e.g. exposed non-occupational).	Open list with remarks	ENDPOINT_STUDY_RECORD.HealthSurveillanceData.MaterialsAndMethods.StudyType

	<ul style="list-style-type: none"> - Medical monitoring: aims to measure early signs and symptoms of adverse effects for preventive reasons. - Medical screening: method for detecting disease or body dysfunction before an individual would normally seek medical care. Aim: early diagnosis and treatment. - Other: any other type of study or information, e.g. self-reported symptoms. 		
Endpoint addressed	<p>If the study recorded gives useful information on one or several of the classic endpoints, select the endpoint(s) addressed from the picklist. Multiple selection is possible. If not listed, select 'other' and specify.</p> <p>NOTE: The list of endpoints provided is a generic list. Some endpoints may not be applicable for the type of study summarised in this record.</p>	Multi select open list	ENDPOINT_STUDY_RECORD.HealthSurveillanceData.MaterialsAndMethods.EndpointAddressed
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.HealthSurveillanceData.MaterialsAndMethods.TestMaterials
Test material information	Test material	Entity reference field	ENDPOINT_STUDY_RECORD.HealthSurveillanceData.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Method		Header 2	ENDPOINT_STUDY_RECORD.HealthSurveillanceData.MaterialsAndMethods.Method
Type of population	<p>Indicate whether subjects of the general population and/or from an occupational environment were investigated. If 'Other' is selected, please include additional details in the free text box.</p> <p>If two independent studies are reported by the same report, use two separate records.</p>	Multi select open list	ENDPOINT_STUDY_RECORD.HealthSurveillanceData.MaterialsAndMethods.Method.TypeOfPopulation
Ethical approval	Where ethical approval is required, indicate whether and what kind of consent was received from the persons studied. Include details in the supplementary remarks field. If 'not applicable' or 'no' is selected, give reasoning as appropriate in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.HealthSurveillanceData.MaterialsAndMethods.Method.EthicalApproval
Details on study design	Include detailed information on the design of the health surveillance programme and exposure to the substance in question and to other chemicals. Include or attach tables as appropriate.	Text area	ENDPOINT_STUDY_RECORD.HealthSurveillanceData.MaterialsAndMethods.Method.DetailsOnStudyDesign

Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.HealthSurveillanceData.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.HealthSurveillanceData.ResultsAndDiscussion
Results	Describe the results of the health surveillance study. In addition, include or attach tables and/or an excerpt from the study report.	Text area	ENDPOINT_STUDY_RECORD.HealthSurveillanceData.ResultsAndDiscussion.Results
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.HealthSurveillanceData.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.HealthSurveillanceData.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.HealthSurveillanceData.ApplicantSummaryAndConclusion

5.9.2 Data collected on humans – Endpoint study record

Purpose:

Where available, reports from studies with humans, such as tests on toxicokinetics and metabolism, or tests on skin irritation or skin sensitisation, shall be submitted. In general, the reference values shall be based on animal studies, but if appropriate scientifically valid and ethically generated human data are available and show that humans are more sensitive and lead to lower regulatory limit values, these data shall take precedence over animal data.

This document can also be used to report Dislodgeable Foliar Residues studies cited in operator exposure assessments.

Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.DataSource
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.MaterialsAndMethods
Type of study / information	Briefly indicate the type of information (which does not fit into any of the specific chapter.)	Multi-line text	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.MaterialsAndMethods.TypeOfStudyInformation
Endpoint addressed	If the study recorded gives useful information on one or several of the classic endpoints, select the endpoint(s) addressed from the picklist. Multiple selection is possible. If not listed, select 'other' and specify. NOTE: The list of endpoints provided is a generic list. Some endpoints may not be applicable for the type of study summarised in this record.	Multi-select open list	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.MaterialsAndMethods.EndpointAddressed
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.MaterialsAndMethods.TestMaterials
Method		Header 2	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.MaterialsAndMethods.Method
Ethical approval	Where ethical approval is required, indicate whether and what kind of consent was received from the persons studied. Include details in the supplementary remarks field. If 'not applicable' or 'no' is selected, give reasoning as appropriate.	Open list with remarks	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.MaterialsAndMethods.Method.EthicalApproval
Details on study design	Describe the study design including any relevant information from a study report, publication or other source. Include or attach tables or excerpts from study report as appropriate.	Text area	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.MaterialsAndMethods.Method.DetailsOnStudyDesign
Exposure assessment	Indicate whether the exposure was measured or estimated. For robust study summaries or as requested by the regulatory programme, provide further details in the following freetext field.	Closed list with remarks	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.MaterialsAndMethods.Method.ExposureAssessment

Details on exposure	<p>Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from the study report.</p> <p>Explanations:</p> <ul style="list-style-type: none"> - TYPE OF EXPOSURE: Characterise type of exposure including information on manufacturing / processing / use as applicable. If available, describe special exposure situations / workplaces. - TYPE OF EXPOSURE MEASUREMENT: Indicate relevant predefined type(s); delete those being not applicable. - EXPOSURE LEVELS: Give exposure level(s) reported (with units) or insert/attach table, for several exposure conditions and levels. - EXPOSURE PERIOD: Describe when subjects were exposed and duration of exposure, i.e., hours, hours per day, days, days per week, weeks, months, years, person years, other. - POSTEXPOSURE PERIOD: State period of time elapsed between last exposure/first examination or time study was conducted. - DESCRIPTION / DELINEATION OF EXPOSURE GROUPS / CATEGORIES: If several exposure groups (e.g. different concentrations or durations) are analysed, identify the exposure groups or categories, number of subjects within each group, sex, other categorical descriptions, etc. 	Text template	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.MaterialsAndMethods.Method.DetailsOnExposure
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.ResultsAndDiscussion
Results	Provide exposure data as available and describe any relevant outcome of the study. If appropriate present the data in tabular form and/or attach excerpt(s) from the study report.	Text area	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.ResultsAndDiscussion.Results
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.OverallRemarksAttachments

Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.ApplicantSummaryAndConclusion
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5.9.3 Direct observations – Endpoint study record

Purpose:

Chemical: Available reports from the open literature, relating to clinical cases and poisoning incidents, shall be submitted.

Microorganism (Active): Available reports from the open literature on the microorganism or closely related members of the taxonomic group (relating to clinical cases) shall be submitted.

Such reports shall, where available, contain complete descriptions of the nature, level and duration of exposure, as well as the clinical symptoms observed, first aid and therapeutic measures applied and measurements and observations made, as well as follow up studies undertaken.

ENDPOINT_STUDY_RECORD.DirectObservationsClinicalCases - v.7.3 (Final)			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block For micro-organisms, direct observations and clinical cases should be considered as supporting information.	Header 1	ENDPOINT_STUDY_RECORD.DirectObservationsClinicalCases.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.DirectObservationsClinicalCases.DataSource
Reference	Literature reference	Literature reference list	ENDPOINT_STUDY_RECORD.DirectObservationsClinicalCases.DataSource.Reference
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.DirectObservationsClinicalCases.MaterialsAndMethods
Study type	Select type of medical data.	Open list with remarks	ENDPOINT_STUDY_RECORD.DirectObservationsClinicalCases.MaterialsAnd

			Methods.Study Type
Endpoint addressed	If the study recorded gives useful information on one or several of the classic endpoints, select the endpoint(s) addressed from the picklist. Multiple selection is possible. If not listed, select 'other' and specify. NOTE: The list of endpoints provided is a generic list. Some endpoints may not be applicable for the type of study summarised in this record.	Multi select open list	ENDPOINT_STUDY_RECORD. DirectObservationsClinicalCases.MaterialsAndMethods.EndpointAddressed
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD. DirectObservationsClinicalCases.MaterialsAndMethods.TestMaterials
Test material information	Test material	Entity reference field	ENDPOINT_STUDY_RECORD. DirectObservationsClinicalCases.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Method		Header 2	ENDPOINT_STUDY_RECORD. DirectObservationsClinicalCases.MaterialsAndMethods.Method
Type of population	Indicate whether subjects of the general population and/or from an occupational environment were investigated. If 'Other' is selected, please include additional details in the free text box. If two independent studies are reported by the same report, use two separate records.	Multi select open list	ENDPOINT_STUDY_RECORD. DirectObservationsClinicalCases.MaterialsAndMethods.Method.TypeOfPopulation
Subjects	Describe the subject(s) examined based on the freetext template (delete/add elements as appropriate). As an option you may include an excerpt from the study report.	Text template	ENDPOINT_STUDY_RECORD. DirectObservationsClinicalCases.MaterialsAndMethods.Method.Subjects
Ethical approval	Where ethical approval is required, indicate whether and what kind of consent was received from the persons studied. Include details in the supplementary remarks	Open list with remarks	ENDPOINT_STUDY_RECORD. DirectObservationsClinicalCase

	field. If 'not applicable' or 'no' is selected, give reasoning as appropriate in the supplementary remarks field.		s.MaterialsAnd Methods.Method d.EthicalAppro val
Route of exposure	Indicate the route of exposure. Multiple selection is possible. If not listed, select 'other' and specify.	Multi select open list with remarks	ENDPOINT_ST UDY_RECORD. DirectObservati onsClinicalCase s.MaterialsAnd Methods.Method d.RouteOfExpo sure
Reason of exposure	Indicate the reason of exposure e.g. intentional or occupational unintentional.	Open list	ENDPOINT_ST UDY_RECORD. DirectObservati onsClinicalCase s.MaterialsAnd Methods.Method d.ReasonOfExp osure
Exposure assessment	Indicate whether the exposure was measured or estimated.	Closed list with remarks	ENDPOINT_ST UDY_RECORD. DirectObservati onsClinicalCase s.MaterialsAnd Methods.Method d.ExposureAss essment
Details on exposure	Describe type and incidence of exposure including quantitative data if available, i.e. state if single or multiple exposure, duration, exposure concentrations (if inhalation), amount of chemical or micro-organisms ingested, dermal contact etc. Include methods of analysis if data available. If exposure was estimated, describe how this was done, if available.	Text area	ENDPOINT_ST UDY_RECORD. DirectObservati onsClinicalCase s.MaterialsAnd Methods.Method d.DetailsOnExp osure
Examinations	Indicate type of examinations performed and at what time after start of exposure. Use freetext template (delete/add elements as appropriate). As an option you may include an excerpt from the study report.	Text template	ENDPOINT_ST UDY_RECORD. DirectObservati onsClinicalCase s.MaterialsAnd Methods.Method d.Examinations
Medical treatment	Indicate if and what medical treatment exposed / intoxicated persons received.	Text area	ENDPOINT_ST UDY_RECORD. DirectObservati onsClinicalCase s.MaterialsAnd Methods.Method d.MedicalTreat ment

Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD. DirectObservationsClinicalCases.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD. DirectObservationsClinicalCases.ResultsAndDiscussion
Clinical signs	Describe any relevant signs and symptoms observed.	Text area	ENDPOINT_STUDY_RECORD. DirectObservationsClinicalCases.ResultsAndDiscussion.ClinicalSigns
Results of examinations	Describe the results of examinations based on freetext template (delete/add elements as appropriate). As an option you may include an excerpt from the study report.	Text template	ENDPOINT_STUDY_RECORD. DirectObservationsClinicalCases.ResultsAndDiscussion.RsExaminations
Effectivity of medical treatment	Indicate whether and during what time intoxicated persons responded to medical treatment.	Text area	ENDPOINT_STUDY_RECORD. DirectObservationsClinicalCases.ResultsAndDiscussion.EffectivityMedicalTreatment
Outcome of incidence	Describe the clinical manifestation of signs and symptoms, partial or total recovery after what time etc. If reported, give data on any follow-up examinations.	Text area	ENDPOINT_STUDY_RECORD. DirectObservationsClinicalCases.ResultsAndDiscussion.Outcome
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD. DirectObservationsClinicalCases.ResultsAndDiscussion.AnyOtherInformation

			OnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.DirectObservationsClinicalCases.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.DirectObservationsClinicalCases.ApplicantSummaryAndConclusion

5.9.4 Epidemiological studies – Endpoint study record

Purpose:

Provide data of relevant epidemiological studies, if available.

ENDPOINT_STUDY_RECORD.EpidemiologicalData - v.7.3 (Final)			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.EpidemiologicalData.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.EpidemiologicalData.DataSource
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.EpidemiologicalData.MaterialsAndMethods
Study type	Select appropriate study type.	Open list with remarks	ENDPOINT_STUDY_RECORD.EpidemiologicalData.MaterialsAndMethods.StudyType
Endpoint addressed	If the study recorded gives useful information on one or several of the classic endpoints, select the endpoint(s) addressed from the picklist. Multiple selection is possible. If not listed, select 'other' and specify. NOTE: The list of endpoints provided is a generic list.	Multi select open	ENDPOINT_STUDY_RECORD.EpidemiologicalData.MaterialsAndMethods.EndpointAddressed

	Some endpoints may not be applicable for the type of study summarised in this record.	n list	
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.EpidemiologicalData.MaterialsAndMethods.TestMaterials
Method		Header 2	ENDPOINT_STUDY_RECORD.EpidemiologicalData.MaterialsAndMethods.Method
Type of population	Indicate whether subjects of the general population and/or from an occupational environment were investigated. If two independent studies are reported by the same report, use two separate records.	Multi select open list	ENDPOINT_STUDY_RECORD.EpidemiologicalData.MaterialsAndMethods.Method.TypeOfPopulation
Ethical approval	Where ethical approval is required, indicate whether and what kind of consent was received from the persons studied. Include details in the supplementary remarks field. If 'not applicable' or 'no' is selected, give reasoning as appropriate.	Open list with remarks	ENDPOINT_STUDY_RECORD.EpidemiologicalData.MaterialsAndMethods.Method.EthicalApproval
Details on study design	Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from the study report. Explanations: - HYPOTHESIS TESTED: If study type is cohort or case control study, state the hypothesis(es) tested in this study. - STUDY PERIOD: Give dates during which the data were collected (from ... to ...) - SETTING: Indicate the setting where this study took place, e.g., occupational, residential, hospital-based, clinical practice, environmental (e.g., fenceline of waste sites, air monitoring); its geographic location(s); and any other pertinent information. - STUDY POPULATION: Include details on the study population using the predefined items and inserting additional ones if required. Alternatively include or attach a table and refer to respective Table no. - COMPARISON POPULATION: Indicate one of the predefined types; delete those being not applicable. Provide details, e.g., note the parameters that were 'matched' (i.e., smoking, age, sex, etc.). - HEALTH EFFECTS STUDIED: Describe as appropriate. Note whether the diagnosis of the effects was made blind to exposure status. Alternatively include or attach a table and refer to respective Table no.	Text template	ENDPOINT_STUDY_RECORD.EpidemiologicalData.MaterialsAndMethods.Method.DetailsOnStudyDesign

Exposure assessment	Indicate whether the exposure was measured or estimated. For robust study summaries or as requested by the regulatory programme, provide further details in the following freetext field.	Closed list with remarks	ENDPOINT_STUDY_RECORD.EpidemiologicalData.MaterialsAndMethods.Method.ExposureAssessment
Details on exposure	Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from the study report. Explanations: - TYPE OF EXPOSURE: Characterise type of exposure including information on manufacturing / processing / use as applicable. If available, describe special exposure situations / workplaces. - TYPE OF EXPOSURE MEASUREMENT: Indicate relevant predefined type(s); delete those being not applicable. - EXPOSURE LEVELS: Give exposure level(s) reported (with units) or insert/attach table, for several exposure conditions and levels. - EXPOSURE PERIOD: Describe when subjects were exposed and duration of exposure, i.e., hours, hours per day, days, days per week, weeks, months, years, person years, other. - POSTEXPOSURE PERIOD: State period of time elapsed between last exposure/first examination or time study was conducted. - DESCRIPTION / DELINEATION OF EXPOSURE GROUPS / CATEGORIES: If several exposure groups (e.g. different concentrations or durations) are analysed, identify the exposure groups or categories, number of subjects within each group, sex, other categorical descriptions, etc.	Text template	ENDPOINT_STUDY_RECORD.EpidemiologicalData.MaterialsAndMethods.Method.DetailsOnExposure
Statistical methods	Describe all statistical methods used and the data to which they were applied (include sample size and power calculations, if available).	Multi-line text	ENDPOINT_STUDY_RECORD.EpidemiologicalData.MaterialsAndMethods.Method.StatisticalMethods
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.EpidemiologicalData.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.EpidemiologicalData.ResultsAndDiscussion
Results	Provide exposure data as available. Give numbers of cases for each effect/disease/parameter under consideration,	Text	ENDPOINT_STUDY_RECORD.Epidemiolo

	include measures of disease frequency (SMRs, ORs, PMRs, RR, prevalence, incidence, adjusted and/or crude rates), correlations, distributions etc., statistical data (significance, confidence intervals). If appropriate present the data in tabular form. Upload predefined table in the rich text field 'Any other information on results incl. tables' or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1').	template	gicalData.ResultsAndDiscussion.Results
Confounding factors	Indicate any (possible) confounding factor(s), e.g. multi chemical exposure or smoking, and discuss their influence on the observed causal association.	Text area	ENDPOINT_STUDY_RECORD.EpidemiologicalData.ResultsAndDiscussion.ConfoundingFactors
Strengths and weaknesses	Explain findings and discuss any other factors, i.e. bias, validity issues, reliability issues (including the adequacy of the exposure estimation or measurements), representativeness concerns, unique nature of study, influence of past exposures, latency, turnover rates in occupation studies.	Text area	ENDPOINT_STUDY_RECORD.EpidemiologicalData.ResultsAndDiscussion.StrengthsWeaknesses
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.EpidemiologicalData.ResultsAndDiscussion.AnyOtherInformationOnResultsIncTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.EpidemiologicalData.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.EpidemiologicalData.ApplicantSummaryAndConclusion

6. Residues in or on treated products, food and feed - Endpoint summary

General note on instructions for section 6: please follow the instructions of the common blocks by clicking on the reference link, **unless specific instructions are provided**.

Purpose:

Provide an overall conclusion on the residues information submitted in Section 6 and to address any points where a suitable sub-section could not be identified. This summary can also be useful for specific MRL purposes of application, such as "include an active substance in Annex IV".

ENDPOINT_SUMMARY.ResiduesInFoodAndFeedingstuffs v.5.0 (Final)			
Name	Instructions	Type	Field path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.ResiduesInFoodAndFeedingstuffs.AdministrativeDataSummary
	See Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	Confidentiality	ENDPOINT_SUMMARY.ResiduesInFoodAndFeedingstuffs.AdministrativeDataSummary.DataProtection
Description of key information	<p>Please report here an overall narrative summary of the residue section. Indicate whether all data requirements were fulfilled in all sub-sections of Section 6. Should it not be the case, please indicate the main deviations/missing data/substantive arguments that support the overall conclusions of the residue section.</p> <p>For MRL applications, this rich text field should be used by the applicant to report, in accordance with article 7 1b of Regulation 396/2005, a presentation of the application dossier including: (i) a summary</p>	Header 1	ENDPOINT_SUMMARY.ResiduesInFoodAndFeedingstuffs.KeyInformation

	<p>of the application; (ii) the main substantive arguments.</p> <p>In this rich text field, you may also address any points where a suitable sub-section could not be identified. For example, this can be useful for specific purposes for MRL application (e.g. include an active substance in IV”) or for any other specific cases for which the standard endpoint summaries may not be fully suitable. However, there is no need to repeat tables and summaries that are duly reported in the respective endpoint summaries of the detailed sections. For example, residue trials data selected to derive and propose a MRL shall be reported in Section 6.3.</p>		
Additional information	Discussion(Header 1) – common block	Header 1	ENDPOINT_SUMMARY. ResiduesInFoodAndFee dingstuffs.Discussion
Attached background material			ENDPOINT_SUMMARY. ResiduesInFoodAndFee dingstuffs.Discussion.At tachedBackgroundMate rial
Attached document	The original file only needs to be attached here if it differs from the file in Attached (sanitised) documents for publication.	Single file attachment	ENDPOINT_SUMMARY. ResiduesInFoodAndFee dingstuffs.Discussion.At tachedBackgroundMate rial.AttachedDocument
Remarks		Text	ENDPOINT_SUMMARY. ResiduesInFoodAndFee dingstuffs.Discussion.At tachedBackgroundMate rial.Remarks
Attached background material	You can attach here any useful document		

	that support the above statement. However, do not repeat the attachments that are already reported in the respective endpoint summaries of the detailed sections. For example, the MRL OECD calculator.xls shall be reported in Sections 6.3 and 6.7.2, but <u>not</u> here.		
Attached (sanitised) documents for publication	Same as above with sanitized version for the document(s).	Attachments list	ENDPOINT_SUMMARY. ResiduesInFoodAndFeedingstuffs.Discussion. AttachedSanitisedDocsFor Publication

6.1 Storage stability of residues – Endpoint summary

Purpose:

Provide a summary overview of the demonstrated freezer storage stability period per compound per matrix and to conclude whether the storage stability of residues in matrices of plant and animal origin was sufficiently elucidated in the context of the present application.

ENDPOINT_SUMMARY.StabilityResiduesCommodities v.2.4 (Final)			
Name	Instructions	Type	Field path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY. StabilityResiduesCommodities.AdministrativeDataSummary
	Set the confidentiality flag and regulatory purpose. Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	Confidentiality	ENDPOINT_SUMMARY. StabilityResiduesCommodities.AdministrativeDataSummary.DataProtection
Link to relevant study record(s)		Header 1	ENDPOINT_SUMMARY. StabilityResiduesCommodities.LinkToRelevantStudyRecord
Study name / type	Provide here the link to the most relevant study (or studies) from which	Endpoint reference list	ENDPOINT_SUMMARY. StabilityResiduesComm

	the key value(s) for the storage stability of residues is/are derived.		odities.LinkToRelevantStudyRecord.Link
Results		Read-only	ENDPOINT_SUMMARY.StabilityResiduesComm odities.LinkToRelevantStudyRecord.Results
Description of key information	Please make a statement as to whether the storage stability of residues in matrices of plant and animal origin was sufficiently elucidated in the context of the present application (according to the relevant data requirements and OECD test guidelines 506) and highlight data gap(s) and the non-standard uncertainty(ies), if any. Respective detailed parameters on the available key studies used for risk assessment should be reported in the detailed blocks below (one repeatable block for "storage stability - plant" and one repeatable block for "storage stability - animal").	Header 1	ENDPOINT_SUMMARY.StabilityResiduesComm odities.KeyInformation
		Rich text area	ENDPOINT_SUMMARY.StabilityResiduesComm odities.KeyInformation.KeyInformation
Storage stability - plant	Repeat this block to create one row per key result (e.g. one row for each combination stability matrix/compound(s) covered with the most critical storage stability conditions).		ENDPOINT_SUMMARY.StabilityResiduesComm odities.KeyInformation.StorageStabilityPlant
Category	Select the matrix to which the key results	Open list with remarks	ENDPOINT_SUMMARY.StabilityResiduesComm

	apply (e.g. commodities with "high water content"). Category defined according to OECD TG 506.		odities.KeyInformation.StorageStabilityPlant.Category
Commodity	Indicate the commodity(ies) tested in the study (multi-selection is possible). Select from the list of commodities of plant and animal origin to which MRLs apply according to Annex I of Reg. (EC) No 396/2005. Tested commodities can also be feed items (e.g. forage) or processed food product (e.g. grapefruit juice).	Multi select open list with remarks	ENDPOINT_SUMMARY.StabilityResiduesCommodities.KeyInformation.StorageStabilityPlant.Commodity
Compound(s) covered	Indicate which compound(s) were tested for storage stability. If parent and metabolites were tested independently, please report it in different rows. If the sum of parent and metabolites was tested for stability, please specify it in this field.	Text	ENDPOINT_SUMMARY.StabilityResiduesCommodities.KeyInformation.StorageStabilityPlant.CompoundSCovered
Substance(s)	Link (cross reference) to the substance(s) indicated in the above field.	Entity reference list	ENDPOINT_SUMMARY.StabilityResiduesCommodities.KeyInformation.StorageStabilityPlant.SubstanceS
Temperature (°C)	EU PPP: Residue stability summary block-common block Indicate the temperature tested in the study in degrees Celcius (e.g. -18°C).	Decimal	ENDPOINT_SUMMARY.StabilityResiduesCommodities.KeyInformation.StorageStabilityPlant.Temperature
Tested period (length of the study)	Enter the entire period (as number) for which stability of the compounds was tested. The preferred reporting unit is months (m). Enter data using one	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.StabilityResiduesCommodities.KeyInformation.StorageStabilityPlant.TestedPeriod

	decimal point, e.g. 244 days would be 3.8 months using an average of 30.4 days per month. If the period is lower than one month, report in full days. Example: If the study investigated storage stability for 24 months but residues are only stable for 12 months, please report 24 months in the present field.		
Demonstrated stability period	Enter the period (as number) for which stability of the compounds was demonstrated. The preferred reporting format for storage stability is months (m). Enter data using one decimal point, e.g. 244days would be 3.8 months using an average of 30.4 days per month. If stability is lower than one month, report in full days.	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.StabilityResiduesCommodities.KeyInformation.StorageStabilityPlant.DemonstratedStability
Remarks	Add here any relevant information on the preparation of the samples and/or on any specific storage conditions for which stability has been shown. Examples for additional comments: - Mode of fortification, e.g. whole commodity or homogenised; - Analysis of fortified samples or samples from metabolism studies with incurred residues; For specific cases, e.g. stability of sum of compounds sharing	Multi-line text	ENDPOINT_SUMMARY.StabilityResiduesCommodities.KeyInformation.StorageStabilityPlant.Remarks

	common moiety, use the same field to explain.		
Storage stability - plant			
Storage stability - animal	Repeat this block to create one row per key result (e.g. one row for each combination animal commodity(ies)/compound(s) covered with the most critical storage stability conditions). Fields and instruction are the same as for storage stability in plant matrices.		ENDPOINT_SUMMARY. StabilityResiduesCommodities.KeyInformation. StorageStabilityAnimal
Category		Open list with remarks	ENDPOINT_SUMMARY. StabilityResiduesCommodities.KeyInformation. StorageStabilityAnimal. Category
Commodity	Commodity(ies) covered by the stability study(ies). Indicate the commodity(ies) tested in the study (multi-selection is possible). Select from the list of commodities of animal origin.	Multi select open list with remarks	ENDPOINT_SUMMARY. StabilityResiduesCommodities.KeyInformation. StorageStabilityAnimal. Commodity
Compound(s) covered	Indicate which compound(s) were tested for storage stability. If parent and metabolites were tested independently, please report it in different rows. If the sum of parent and metabolites was tested for stability, please specify it in this field.	Text	ENDPOINT_SUMMARY. StabilityResiduesCommodities.KeyInformation. StorageStabilityAnimal. CompoundSCovered
Substance(s)	Link (cross reference) to the substance(s) indicated in the above field.	Entity reference list	ENDPOINT_SUMMARY. StabilityResiduesCommodities.KeyInformation. StorageStabilityAnimal. SubstanceS

Temperature (°C)	EU PPP: Residue stability summary block-common block Indicate the temperature tested in the study in degrees Celcius (e.g. -18°C).	Decimal	ENDPOINT_SUMMARY.StabilityResiduesComm odities.KeyInformation.StorageStabilityAnimal.Temperature
Tested period (length of the study)	Enter the entire period (as number) for which stability of the compounds was tested. The preferred reporting unit is months (m). Enter data using one decimal point, e.g. 244 days would be 3.8 months using an average of 30.4 days per month. If the period is lower than one month, report in full days. Example: If the study investigated storage stability for 24 months but residues are only stable for 12 months, please report 24 months in the present field.	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.StabilityResiduesComm odities.KeyInformation.StorageStabilityAnimal.TestedPeriod
Demonstrated stability period	Enter the period (as number) for which stability of the compounds was demonstrated. The preferred reporting format for storage stability is months (m). Enter data using one decimal point, e.g. 244 days would be 3.8 months using an average of 30.4 days per month. If stability is lower than one month, report in full days.	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.StabilityResiduesComm odities.KeyInformation.StorageStabilityAnimal.DemonstratedStability
Remarks	Please report the same text as for stability in plant for the similar field.	Multi-line text	ENDPOINT_SUMMARY.StabilityResiduesComm odities.KeyInformation.StorageStabilityAnimal.Remarks

Storage stability - animal			
Additional information	Discussion(Header 1) – common block	Header 1	ENDPOINT_SUMMARY.StabilityResiduesCommodities.Discussion

6.1 Storage stability of residues – Endpoint study record

Purpose:

The aim of these studies is to demonstrate the time period for which stability has been shown in representative commodities from crops, by extrapolation to processed fractions derived from crops, and products of animal origin.

ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod v.5.3 (Final)			
Name	Instructions	Type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.AdministrativeData
	See Confidentiality of dossiers Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	Confidentiality	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.AdministrativeData.DataProtection
Endpoint	Select from picklist the relevant endpoint (here 'stability of residues in stored commodities'). In some cases there is only one endpoint title, which may be entered automatically depending on the software application. If multiple study types are covered by the same data entry form, the specific study type should be selected. If none matches, select the more generic endpoint description '<Generic endpoint>', other' (e.g. Skin	Closed list with remarks	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.AdministrativeData.Endpoint

	<p>irritation / corrosion, other) and give an explanation in the adjacent text field. The generic endpoint title reflects the title of the corresponding OECD Harmonised Template (OHT).</p> <p>Please note: For (Q)SAR studies the generic endpoint title should be selected, normally with no need to fill in the adjacent text field, as '(Q)SAR' needs to be indicated in field 'Type of information' and the model should be described in field 'Justification of non-standard information' or 'Attached justification'. A specific endpoint title may be used, if addressed by the (Q)SAR information, i.e. the model behind has been validated by experimental data addressing this endpoint.</p> <p>Note: For the purpose of OHTs, an 'endpoint' is defined in the rather broad sense as an observable or measurable inherent property of a chemical substance which may be specified by the relevant regulatory framework as 'information requirement' (e.g. Boiling point, Sub-chronic toxicity: oral, Fish early-life stage toxicity). In a narrower sense, the term</p>		
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	'(eco)toxicity endpoint' refers to an outcome or effect observed in a study.		
Type of information	<p>Select the appropriate type of information, e.g. 'experimental study', 'experimental study planned' or, if alternatives to testing apply, '(Q)SAR', 'read-across ...'. In the case of calculated data, the value 'calculation (if not (Q)SAR)' should only be chosen if the study report does not clearly indicate whether it is based on '(Q)SAR'. If the information is taken from a handbook or review article, select the relevant item, e.g. 'experimental study', if this is provided in the information source. Otherwise select 'not specified'. Please note: In field 'Reference type' the option 'review article or handbook' should be selected. In general, the option 'not specified' should be selected if the submitter lacks the knowledge of the type of information. The option 'other:' can be used if another than a pre-defined item applies.</p> <p>In the case of read-across, follow the instructions related to the relevant legislation, for instance as to whether the (robust) study summary should be entered in a separate data set defined for the read-</p>	Open list with remarks	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.AdministrativeData.StudyResultType

	<p>across (source) substance and referenced in the target substance dataset.</p> <p>If 'experimental study planned' or 'experimental study planned (based on read-across)' is indicated (in some legislations also defined as 'testing proposal' or 'undertaking of intended submission'), the submitter should include as much information as possible on the planned study in order to support the evaluation of the proposal. Typically, this would include at least the test guideline, information on the test material, the species and the route of administration in the corresponding distinct fields, as appropriate. Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on whether specific fields should be completed and/or further details should be attached in field 'Attached background material'.</p>		
Adequacy of study	<p>Indicate the adequacy of a (robust) study summary in terms of usefulness for hazard/risk assessment purposes depending on the relevant legislation. Note: This field is only applicable (or active) if neither 'waiving of standard information'</p>	Closed list	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.AdministrativeData.PurposeFlag

	<p>nor 'experimental study planned' has been selected in field 'Type of information'.</p> <p>Explanation:</p> <ul style="list-style-type: none"> - key study: In general, a key study is the study that has been identified as most suitable to describe an endpoint from the perspective of quality, completeness and representativity of data. - supporting study: Any other adequate study that is considered supportive for the key study or key studies. - weight of evidence: A record that contributes to a weight of evidence justification for the non-submission of a particular (adequate) study. The weight of evidence justification is normally endpoint-related, i.e. based on all available records included in the weight of evidence evaluation a short reasoning for why a given record is used in this respect can be provided in field 'Detailed justification / remarks'. - disregarded due to major methodological deficiencies: study that demonstrates a higher concern than the key study/ies, but is not used as key study because of flaws in the methodology or documentation. This phrase should be selected for justifying why a potentially critical result has not 		
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	<p>been used for the hazard assessment. The lines of argumentation should be provided in field 'Rationale for reliability incl. deficiencies', accompanied by the appropriate reliability score.</p> <p>- other information: any other non-relevant information which does not need to be flagged specifically as 'disregarded due to major methodological deficiencies'.</p> <p>Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field.</p>		
Robust study summary	<p>Set this flag if relevant for the respective regulatory programme or if otherwise useful as filter for printing or exporting records flagged as 'Robust Study Summary' or in combination with 'Adequacy of study'.</p> <p>Explanation: The term 'Robust Study Summary' is actually used only to describe the technical content of a very detailed summary of an experimental study or of any other relevant information. It is a priori no synonym with the term 'Key study', although a key study should usually be submitted in the form</p>	Check box	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.AdministrativeData.Robust Study

	<p>of Robust Study Summary. However, a Robust Summary may also be useful for other adequate studies that are considered supportive of the key study or even for inadequate studies if they can be used for a weight-of-evidence analysis. Also for studies that are flawed, but indicate critical results, Robust Study Summaries highlighting the weaknesses of the studies need to be elaborated. Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field.</p>		
Used for classification	<p>Set this flag if relevant for the respective regulatory programme or if otherwise useful as filter for printing or exporting records flagged as 'Used for classification'. Explanation: In some use cases it may be necessary to indicate those records that are used for the classification of that substance, e.g. according to UN GHS. If not relevant, disregard this field. Consult any programme-specific guidance (e.g. OECD</p>	Check box	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.AdministrativeData.UsedForClassification

	Programme, Pesticides NAFTA or EU REACH) on how to use this field.		
Used for SDS	Set this flag if relevant for the respective regulatory programme or if otherwise useful as filter for printing or exporting records flagged as 'SDS information'. Explanation: 'SDS' stands for Safety Data Sheet. In some use cases it may be necessary to indicate those records that are used for the compilation of SDS information. If not relevant, disregard this field. Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field.	Check box	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.AdministrativeData.UsedForMSDS
Study period	If applicable indicate the period during which the study was conducted, i.e. start and end date, using an unambiguous date format, e.g. 'From 12 MAY 1999 to 15 AUG 2000' or 'From May 12, 1999 to Aug. 15, 2000'. Note: Independent of the study period the in-life period (i.e. the phase of a study following treatment in	Text	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.AdministrativeData.StudyPeriod

	which the test system is alive/growing) may have to be specified for some toxicology endpoints.		
Reliability	<p>Enter an appropriate reliability score, according to Klimisch et al. (1997):</p> <p>1 = reliable without restrictions: "studies or data [...] generated according to generally valid and/or internationally accepted testing guidelines (preferably performed according to GLP) or in which the test parameters documented are based on a specific (national) testing guideline [...] or in which all parameters described are closely related/comparable to a guideline method."</p> <p>2 = reliable with restrictions: "studies or data [...] (mostly not performed according to GLP), in which the test parameters documented do not totally comply with the specific testing guideline, but are sufficient to accept the data or in which investigations are described which cannot be subsumed under a testing guideline, but which are nevertheless well documented and</p>	Open list	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.AdministrativeData.Reliability

	<p>scientifically acceptable."</p> <p>3 = not reliable: "studies or data [...] in which there were interferences between the measuring system and the test substance or in which organisms/test systems were used which are not relevant in relation to the exposure (e.g. non-physiological pathways of application) or which were carried out or generated according to a method which is not acceptable, the documentation of which is not sufficient for assessment and which is not convincing for an expert judgment."</p> <p>4 = not assignable: "studies or data [...] which do not give sufficient experimental details and which are only listed in short abstracts or secondary literature (books, reviews, etc.)."</p> <p>The 'other:' option may be selected if a different scoring system is used. Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field.</p>		
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	<p>Note: This field is only applicable (or active) if neither 'waiving of standard information' nor 'experimental study planned' has been selected in field 'Type of information'.</p> <p>Note: The term reliability defines the inherent quality of a test report or publication relating to preferably standardised methodology and the way the method and results are described. More detailed criteria can be selected in field 'Justification'.</p>		
Rationale for reliability incl. deficiencies	<p>Select an appropriate standard justification from the picklist, e.g. 'Comparable to guideline study with acceptable restrictions'. Additional explanations (e.g. deficiencies observed) can be entered in the related supplementary text field. Particularly if reliability scores 2 or 3 are assigned, indicate the concrete arguments for defending a study or relevant deficiencies.</p> <p>For QSAR results (i.e. 'Type of information' is '(Q)SAR') some pre-defined phrases are provided for indicating if the prediction results are considered reliable based on the</p>	Open list with remarks (32000)	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.AdministrativeData.RationalReliability

	<p>scientifically validity of the (Q)SAR model used, its applicability to the query substance, and the adequacy of reporting. Please note: If (Q)SAR results are flagged as key study in field 'Adequacy of study', the relevance of the model used for the regulatory endpoint should be documented in the field where the (Q)SAR model is described, i.e. 'Justification for type of information', 'Attached justification' or 'Cross-reference'.</p>		
Data waiving	<p>If appropriate, indicate here that the study has been waived, i.e. not performed. Select the basis from the picklist (e.g. 'study technically not feasible' or 'other justification'). Include a more detailed justification in the field 'Justification for data waiving' and, as needed, in field 'Justification for type of information', 'Attached justification' and/or 'Cross-reference'. Please note: the option 'study scientifically not necessary / other information available' covers cases where it can be justified that performance of a specific study prescribed by the relevant legislation is</p>	Closed list	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.AdministrativeData.DataWaiving

	<p>scientifically not necessary because reliable information is provided in other part(s) of the submission document. The option 'study waived due to provisions of other regulation' can be used for indicating that another, overlapping regulation allows or requires the waiving of a specific information requirement. This should then be detailed in the justification fields.</p> <p>If waiving is based on several lines of argumentation (e.g. 'exposure considerations' and 'study scientifically not necessary / other information available'), create separate records for each.</p> <p>Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use data waivers.</p>		
Justification for data waiving	<p>In addition to the more generic justification selected in the preceding field 'Data waiving', it is possible to provide a detailed justification. To this end you can either select one or multiple specific standard phrase(s) if it/they give</p>	Multi select open list with remarks (32000)	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.AdministrativeData.DataWaivingJustification

	<p>an appropriate rationale of the description given in the preceding field 'Data waiving' or 'other:' and enter free text. Additional specific explanations should be provided if the pre-defined phrase(s) do not sufficiently describe the justification.</p> <p>More details can be provided using the following fields:</p> <ul style="list-style-type: none"> - Text field adjacent to this field 'Justification for data waiving' (available after selecting any picklist item in this field); - Field 'Justification for type of information'; - Field 'Attached justification'; - Cross-reference (for referencing / linking to a justification or information referred to in the justification which is stored in another record, e.g. a record describing physico-chemical properties information used to support a data waiver) <p>Please note: The pre-defined phrases are not necessarily exhaustive and may not always apply. Consult the guidance documents and waiving options in the relevant regulatory frameworks. If no suitable phrase is</p>		
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	available from the picklist, enter a free text justification using the 'other:' option.		
Justification for type of information	<p>This field can be used for entering free text. As appropriate, one of the freetext templates can be selected (e.g. Justification for read-across (analogue)) to use pre-defined headers and bulleted elements. Delete/add elements as appropriate.</p> <p>Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on what should be taken into account when providing justifications or whether specific reporting formats should be used.</p> <p>Explanations:</p> <p>Option 1: Type 'Waiving of standard information':</p> <p>This field should be used for entering any further lines of argumentation, if necessary, in addition to those provided in the field 'Justification for data waiving'.</p> <p>Option 2: Type 'Experimental study</p>	Text template	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.AdministrativeData.JustificationForTypeOfInformation

	<p>planned / Testing proposal':</p> <p>Further details can be entered here on the study design / methodology proposed in addition to details given in the distinct fields on test guideline, test material, species, route of administration and other relevant fields.</p> <p>Option 3: Type 'QSAR prediction':</p> <p>Based on this freetext template details on the QSAR model used can be given, in addition to the information provided in field 'Principles of method if other than guideline'.</p> <p>Please note: Any information that can be re-used for several study summaries can be entered once and then assigned to the relevant studies using either the 'Attached justification' or 'Cross-reference' feature.</p> <p>Option 4: Type 'Read-across (analogue)' and Option 5: Type 'Read-across (category)'</p> <p>This freetext template can be used and modified as appropriate for providing a justification for read-</p>		
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	<p>across, particularly if it is endpoint-specific.</p> <p>Please note: Any information that can be re-used for several study summaries can be entered once and then assigned to the relevant studies using either the 'Attached justification' or 'Cross-reference' feature.</p>		
Attached justification	<p>The Attached justification feature can be used in case the justification is best provided in form of attached document(s). Copy this block of fields for attaching more than one file.</p> <p>Refer to the relevant legislation-specific guidance document as to the recommended use of the Attached justification feature.</p>		ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.AdministrativeData.AttachedJustification
Attached justification	Upload file by clicking the upload icon.	Single file attachment	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.AdministrativeData.AttachedJustification.AttachedJustification
Reason / purpose	<p>Indicate the reason for / purpose of the attached document.</p> <p>Select the relevant item from the picklist or, if none applies, select 'justification, other:' and specify.</p>	Closed list with remarks	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.AdministrativeData.AttachedJustification.ReasonPurpose
Attached justification			

Cross-reference	<p>The cross-reference feature can be used to refer to related information that is provided in another record of the dataset. This can be done either by entering just free text in the 'Remarks' field or by creating a link to the relevant record. The field 'Reason / purpose' allows for selecting a standard reason from the picklist and optionally to add free text explanation in the related supplementary text field.</p> <p>Refer to the relevant legislation-specific guidance document as to the recommended use of cross-references.</p>		ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.AdministrativeData.CrossReference
Reason / purpose for cross-reference	<p>Select the appropriate reason of the cross-reference, i.e.</p> <ul style="list-style-type: none"> - assessment report (for referring to a record that contains an assessment report as attachment) - data waiving: supporting information (for referring to a record containing relevant endpoint information that is used to justify a data waiver) - exposure-related information (for referring to a record containing exposure-related information that is used for instance to justify a data waiver) 	Open list with remarks	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.AdministrativeData.CrossReference.ReasonPurpose

	<ul style="list-style-type: none"> - read-across source (for linking to another study summary used for read-across. This can be useful in cases where results are derived from one or several read-across sources and recorded in a separate (target) study summary.) - read-across supporting information (for linking to another record which contains read-across justification that applies also for the current study summary) - (Q)SAR model reporting (OMRF) (for referring to a record containing the relevant model description. Note: The (Q)SAR prediction should be reported specifically for each endpoint in the field 'Justification for type of information'.) - reference to other assay used for intermediate effect derivation (for optional indication in a study summarising 'intermediate effects' if reference is made to the outcome of another assay) - reference to same study (e.g. if different species were tested and the results recorded in different records), - reference to other study (e.g. if another 		
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	study is considered relevant in the interpretation of the test results), - other: (to be specified).		
Related information	As appropriate, select the record containing the related information, thus creating a link.	Endpoint reference field	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.AdministrativeData.CrossReference.RelatedInformation
Remarks	This field can be used for including any remarks.	Text area	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.AdministrativeData.CrossReference.Remarks
Cross-reference			
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.DataSource
Reference	Literature reference v.5.1 (Final) Indicate the bibliographic reference of the study report or publication the study summary is based on. Provide general information such as Title, Author, Year, Bibliographic source, Testing Facility, Report Number, Study number, Report date etc., as requested in the core template for literature search (http://www.oecd.org/ehs/templates/Generic%20elements%20for%20all%20OHTs%20(added%20online%20Feb%202017).zip). Always enter the primary reference in the first block of fields or sort it to the first	Literature reference list	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.DataSource.Reference

	<p>position, if there are more than one reference to be cited. Copy this block of fields for specifying any other references related to this record (e.g. report of a preliminary study or other documentation). If results of a study report have been published, indicate the full citation of that publication(s) in addition to the reference of the original study.</p>		
Data access	<p>Select appropriate indication for data access. Enter 'Not applicable' if the summary consists of information that is commonly accessible such as guidance on safe use. Select 'data submitter has permission to refer' if the information requirement can be covered based on a permission to refer to old data as issued by the relevant regulatory agency. In addition, provide, in the adjacent free-text field, the statement according to instructions you received from the relevant regulatory authority together with the permission to refer.</p>	Open list with remarks	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.DataSource.DataAccess
Data protection claimed	<p>Indicate as appropriate. Note: 'yes' should be selected only if 'Data submitter is data owner' or 'Data submitter has Letter of Access'. Options 'yes, but willing to share' or 'yes, but not willing to</p>	Closed list with remarks	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.DataSource.DataProtection Claimed

	<p>share' may be relevant for specific regulatory programmes where the submitter is requested to indicate whether he is willing to share studies conducted (e.g. with vertebrates). In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. 'for justification see attached document X')</p>		
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.MaterialsAndMethods
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.MaterialsAndMethods.Test Materials
Radiolabelling	<p>Indicate if labelled or non-labelled test material was used. Generally, stability studies are carried out with non-labelled test material. In this case, please indicate "No" in this field.</p> <p>In the rare cases where the commodities used for stability study were obtained from metabolism studies using radiolabelled material, please indicate "Yes" in this field.</p>	Open list with remarks	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.MaterialsAndMethods.Test Materials.Radiolabelling
Study design		Header 2	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.MaterialsAndMethods.StudyDesign

Test commodity(ies)	To select the commodity(ies) tested in the study. In the context PPP applications, preferably use the picklists of commodities of plant and animal origin to which MRLs apply according to Annex I of Reg. (EC) No 396/2005.	Multi select open list	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.MaterialsAndMethods.StudyDesign.Commodity
Details on stored commodities	Provide detailed description of commodities / matrices stored (whether raw or processed).	Text area	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.MaterialsAndMethods.StudyDesign.DetailsOnStoredCommodities
Storage temperature	Specify the storage temperature.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.MaterialsAndMethods.StudyDesign.StorageTemperature
Duration of storage	Specify the total duration of the storage.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.MaterialsAndMethods.StudyDesign.DurationOfStorage
Other storage conditions	Specify the freezer type and additional storage conditions, e.g. dark or potential control condition including any special storage conditions, e.g. stabilizer added, humidity control, acid or base, temperature, lighting, container types/size, commodity form (extract/macerate/etc.), sample sizes/weight(s), duration, etc. You can choose the corresponding picklist item and give an explanation in the	Multi select closed list with remarks (2000)	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.MaterialsAndMethods.StudyDesign.OtherStorageConditions

	<p>supplementary remarks field. .</p> <p>You can choose the corresponding picklist item and give an explanation in the supplementary remarks field.</p>		
Sampling and analytical methodology		Header 2	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.MaterialsAndMethods.SamplingAndAnalyticalMethodology
Details on sample collection	<p>Include details on sampling time (age of raw commodity in days at each sampling time), number of samples/replicates. Use freetext template and delete/add elements as appropriate.</p>	Text template	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.MaterialsAndMethods.SamplingAndAnalyticalMethodology.DetailsOnSampleCollection
Details on sample handling and preparation	<p>Studies may be either performed on samples from treated crops or animals with incurred residues or by fortification experiments. In the latter case, aliquots of prepared control samples shall be spiked with a known amount of chemical before storage under normal storage conditions.</p> <p>Include details on the sample handling and preparation. Use freetext template and delete/add elements as appropriate. The following information should be addressed: Handling and shipping of commodities, any preparation done prior to extraction (e.g. homogenised samples). It should be clear</p>	Text template	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.MaterialsAndMethods.SamplingAndAnalyticalMethodology.DetailsOnSampleHandlingAndPreparation

	<p>whether samples contain incurred residues or if samples were spiked/fortified with the active substance/metabolites; whether samples were homogenised or not.</p> <p>Use "insert existing templates" and delete/add elements as appropriate.</p> <p>E.g. <i>RAC</i> samples were homogenized and fortified with <i>test material</i> at about <i>X</i> mg/kg.</p>		
Details on analytical methodology	<p>Provide details on the analytical method, i.e. describe methods fully or reference them if previously submitted. The method and its validation should be reported in Section 4 of the dossier 'Analytical methods', using a specific study record. Please cross-refer to the analytical methods and its validation using the "cross reference" block (see instructions in common block)</p> <p>Use freetext template and delete/add elements as appropriate, or upload predefined table(s), if any, in rich text field 'Any other information on materials and methods incl. tables' or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').</p>	Text template	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.MaterialsAndMethods.SamplingAndAnalyticalMethodology.DetailsOnAnalyticalMethodology

Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
	In this field, you can enter any information on materials and methods, for which no distinct field is available, or transfer free text from other databases. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. You can also upload any htm or html document.	Rich text area	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables.OtherInformation
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion
Residue data	<u>Specify the residue level of each analyte determined for a given commodity. Copy this block of fields for recording the results of multiple samplings, i.e. for each tested commodity at each storage period.</u>		ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion.ResidueLevels
Test commodity	Select the tested commodity for which results are reported in this block. In the context PPP applications, preferably use the picklists of commodities of plant and animal origin to	Open list	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion.ResidueLevels.TestCommodity

	which MRLs apply according to Annex I of Reg. (EC) No 396/2005.		
Other details on test commodity	As appropriate, provide details on the test commodity analysed.	Multi-line text	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion.ResidueLevels.OtherDetailsOnTestCommodity
Fortification date (day 0)	Enter the date when the sample was fortified and put into storage (day 0)	Date	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion.ResidueLevels.FortificationDateDay0
Storage removal date (day X)	Enter the date when the stored sample was removed from storage for analysis (day X)	Date	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion.ResidueLevels.StorageRemovalDateDayX
Sample ID	Provide the code of the sample if any.	Text	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion.ResidueLevels.AnalysisSampleID
Sample description	Include a description of the sample.	Text	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion.ResidueLevels.AnalysisSampleDescription
Storage period	Enter the storage period. This value should correspond to the difference between fortification and storage removal dates.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion.ResidueLevels.StoragePeriod
Fortification rate / spike level of stored sample	Enter the fortification level for the sample.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion.ResidueLevels.FortifRateStoredSample

Analyte measured	<p>Specify residue level of each analyte determined for a given commodity sample at a given storage period. Copy this block of fields for recording the results for multiple analytes (if any).</p> <p>If only one analyte (e.g. parent compound) is analysed in the study, there is no need to repeat this block.</p>		ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion.ResidueLevels.AnalyteMeasured
Analyte identity	<p>Click the Link button to navigate to the Substances Inventory and select the relevant substance name for indicating the identity (i.e. CAS number, CAS name, IUPAC name, SMILES code, molecular formula, structural formula etc.). If not available in the inventory, create a new one.</p> <p>Once stored in the Substances Inventory a reference substance can be re-used in the data set.</p> <p>Depending on the user interface of the software used the identity of the reference substance may only be displayed in a shortened form (e.g. comprising the CAS and IUPAC name), with a link for navigating to the actual</p>	Entity reference field	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion.ResidueLevels.AnalyteMeasured.AnalyteIdentity

	<p>record containing the reference substance information.</p> <p>If several compounds are directly analysed together by the analytical method (e.g. a common moiety method), a specific reference substance (being directly a sum of analytes) should be created and referred to. In this case, the results can be directly reported for the sum of compounds. In case of isomers please specify if the analyte measured is the sum of isomers (without distinction of isomers) or if specific isomer(s) were analysed separately. A corresponding reference substance may need to be created.</p>		
Extraction date	Enter the date of extraction.	Date	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion.ResidueLevels.AnalyteMeasured.ExtractionDate
Analysis date	Enter the date of extraction.	Date	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion.ResidueLevels.AnalyteMeasured.AnalysisDate
Method ID	Identify the analytical method that was used to obtain this result. This should cross-reference with the	Text	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion.ResidueLevels.AnalyteMeasured.MethodID

	method(s) described in the method portion of this template).		
Residue level	<p>Enter the result as measured (i.e. based on the measured analyte) as concentration and % spiking level, without re-calculation and correction for storage stability.</p> <p><u>Copy this block of fields for recording the results of multiple analytical repetitions, and report the mean of analytical repetitions after the repeated blocks.</u></p>		ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion.ResidueLevels.AnalyteMeasured.ResidueLevel
Analysed sample ID	Report the sample number/ID that was measured.	Text	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion.ResidueLevels.AnalyteMeasured.ResidueLevel.AnalysedSampleID
Residue level	Report the measured level of the residue mentioned afore.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion.ResidueLevels.AnalyteMeasured.ResidueLevel.ResidueLevel
Residue level (% of nominal spiking level)	Enter the percentage of the nominal spiking level for the residue level determined in freezer storage stability sample as compared with the fortification level provided above.	Decimal	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion.ResidueLevels.AnalyteMeasured.ResidueLevelOfNominalSpikingLevel
Residue level			

Mean residue level	Enter the mean residue level from the repeated analytical repetitions, determined in freezer storage stability sample including unit.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion.ResidueLevels.AnalyteMeasured.MeanResidueLevel
Mean residue level (% of nominal spiking level)	Enter the mean percentage of the nominal spiking level from the repeated analytical repetitions, for the residue level determined in freezer storage stability sample.	Decimal	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion.ResidueLevels.AnalyteMeasured.MeanResidueLevelOfNominalSpikingLevel
Procedural recovery	Enter the result of the procedural recoveries for the given commodity at a given storage period. <u>Copy this block of fields for recording the results of mutiple analytical repetitions, and report the mean of analytical repetitions after the repeated blocks.</u>		ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion.ResidueLevels.AnalyteMeasured.ProceduralRecovery
Control Sample ID	Report the control sample number/ID that was used to measure the procedural recovery.	Text	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion.ResidueLevels.AnalyteMeasured.ProceduralRecovery.ControlSampleID
Procedural recovery control (%)	Enter the percentage of the procedural recovery determined in freezer storage stability control sample.	Decimal	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion.ResidueLevels.AnalyteMeasured.ProceduralRecovery.ProceduralRecoveryControl

Procedural recovery			
Mean procedural recovery control (%)	Enter the mean percentage, from the repeated analytical repetitions, of the procedural recovery for freshly spiked control sample.	Decimal	ENDPOINT_STUDY_RE CORD.StabilityOfResidu esInStoredCommod.Res ultsAndDiscussion.Resid ueLevels.AnalyteMeasur ed.MeanProceduralReco veryControl
Analyte measured			
Residue data			
Storage stability of residues (Sample Integrity)	<p>Briefly describe the conditions, which residues of [parent and/or metabolites] appeared to be [stable or [decreased or increased] by [percentage]].</p> <p><u>Example:</u> The residue of [parent and/or metabolites] decreased slowly with time. After [x months] of storage it amounted to [XX]% of the initial value and after [y months] of storage it amounted to [YY]% of the initial value</p> <p>Please make one statement per commodity.</p> <p>(Optional) Provide graph of residue stability in matrix as applicable as percent recovery over time, in an attachment (in the block below).</p>	Text area	ENDPOINT_STUDY_RE CORD.StabilityOfResidu esInStoredCommod.Res ultsAndDiscussion.Stora geStability
Any other information on results incl. tables		Header 2	ENDPOINT_STUDY_RE CORD.StabilityOfResidu esInStoredCommod.Res ultsAndDiscussion.AnyO therInformationOnResul tsInclTables
	In this field, you can enter any other remarks on the results. You can	Rich text area	ENDPOINT_STUDY_RE CORD.StabilityOfResidu esInStoredCommod.Res

	<p>also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format.</p> <p>NB: According to OECD 506 guidance correction for day zero recovery and/or procedural recovery is not recommended.</p> <p>Other formats can be used provided that all information requested in OECD TG 506 is reported and that they are readable by the system.</p>		<p>ultsAndDiscussion.AnyOtherInformationOnResultsInclTables.OtherInformation</p>
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ApplicantSummaryAndConclusion
Conclusions	The assessment and conclusion of the applicant should be reported here.	Text area	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ApplicantSummaryAndConclusion.Conclusions
Executive summary	<p>Briefly summarise the relevant aspects of the study(ies) including the conclusions reached. If a specific format is prescribed, copy it from the corresponding document.</p> <p><u>Example:</u></p> <p>Samples of [ground or whole crop/matrix]</p>	Rich text area	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ApplicantSummaryAndConclusion.ExecutiveSummary

	<p>were fortified with [analytes] at a level of [fortification level] and put into storage at [temperature]. At intervals of [xx, yy, and zz] months, stored samples and freshly fortified samples were analyzed for residues of [list analytes].</p> <p>At each storage interval, [analytes] were determined using Method [Method ID], a [describe method]. Acceptable [method validation and] concurrent recoveries were reported for [matrices] samples at fortification levels of [xx] mg/kg (ppm), thus validating the method. The limit of quantitation (LOQ) was [xx] ppm per analyte for [matrices].</p> <p>Under these conditions, residues of [active ingredient and metabolites (if applicable)] were stable {or [decreased or increased] by [percentage]} in [crop/matrix] for [duration of time].</p>		
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6.2 Metabolism, distribution and expression of residues

6.2.1 Metabolism of residues in plants and in rotational crops – Endpoint summary

Purpose:

Provide a summary of the key metabolism studies on residues in primary and rotational crops and used to conclude whether the nature of residues in plant (primary and rotational crops) was sufficiently elucidated. Please briefly summarize the parameters of the key metabolism studies.

When an endpoint is characterized in more than one metabolite study, it is suggested to create several endpoint study records in IUCLID, one for each of the respective studies. The full reports, containing the results from the separate studies, should be attached to the literature reference entity of each endpoint study record. However, just a single endpoint summary should be created for those studies and cross reference to each endpoint study record should be added.

ENDPOINT_SUMMARY.MetabolismPlants v.1.1 (Final)			
Name	Instructions	Type	Field path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.MetabolismPlants.AdministrativeDataSummary
		Confidentiality	ENDPOINT_SUMMARY.MetabolismPlants.AdministrativeDataSummary.DataProtection
Description of key information		Header 1	ENDPOINT_SUMMARY.MetabolismPlants.KeyInformation
	Please make a statement whether the nature of residues in plant (primary and rotational crops) was sufficiently elucidated in the context of the present application and highlight data gap(s) and the non-standard uncertainty(ies) (according to the relevant data requirements OECD TG 501 and OECD TG 502), if any. For rotational crop studies, please make a statement here whether the study parameters cover the maximum soil concentration expected for the active substance (and its soil	Rich text area	ENDPOINT_SUMMARY.MetabolismPlants.KeyInformation.KeyInformation

	metabolites), considering the use and use pattern under assessment. Respective detailed parameters on the available key studies used for risk assessment should be reported in the repeatable block below.		
Primary crops	Repeat this block to create one row per key metabolism study. This table should mimic the current list of end points summary table. There is no need to report the detailed results of the studies but please be accurate on the study key parameters.		ENDPOINT_SUMMARY. MetabolismPlants.KeyInformation.PrimaryCrops
Link to relevant studies	Provide here the link to the relevant study(ies) corresponding to the created row.	Endpoint reference list	ENDPOINT_SUMMARY. MetabolismPlants.KeyInformation.PrimaryCrops.RelevantStudies
Crop groups	Picklist (based representative crop groups defined in Annex 1 of OECD TG 501): Indicate the metabolism crop group covered by the study(ies) reported in this row (e.g. root crops). If the group is not in the picklist, please use "other" specify the group in the opening cells.	Closed list	ENDPOINT_SUMMARY. MetabolismPlants.KeyInformation.PrimaryCrops.CropGroups
Commodity	Indicate the commodity(ies) for which nature of residues was investigated in the study. Multi-selection is possible (E.g. wheat grain + wheat straw).	Multi select open list with remarks	ENDPOINT_SUMMARY. MetabolismPlants.KeyInformation.PrimaryCrops.Commodity
Treatment type	Indicate the type of treatment (e.g. foliar) tested in the study. If	Multi select open list with remarks	ENDPOINT_SUMMARY. MetabolismPlants.KeyIn

	different types of treatments were tested in the same study, please create a separate row for each of the treatment type.		formation.PrimaryCrops.TreatmentType
Application rate	Indicate the application rate (with the unit) tested in the study (e.g. 1 kg a.s./ha). If different application rates were tested in the same study, there is the possibility to report both in the same cells (e.g. 1 kg a.s./ha; 2 kg a.s./ha) or to create separate rows as more appropriate.	Multi-line text	ENDPOINT_SUMMARY. MetabolismPlants.KeyInformation.PrimaryCrops .ApplicationRate
DAT	DAT (days after treatment): Indicate the time (in days) between treatment and sampling. Possibility to report a series of figures (e.g. 1; 3; 7; 14) and to specify the sampled commodities (e.g. 1 (fruit); 3 (leaves)...).	Multi-line text	ENDPOINT_SUMMARY. MetabolismPlants.KeyInformation.PrimaryCrops .Dat
Primary crops			
Rotational crops	Repeat this block to create one row per key metabolism study. This table should mimic the current list of end points summary table. There is no need to report the detailed results of the studies but please be accurate on the study key parameters.		ENDPOINT_SUMMARY. MetabolismPlants.KeyInformation.RotationalCrops
Link to relevant studies	Provide here the link to the relevant study(ies) corresponding to the created row.	Endpoint reference list	ENDPOINT_SUMMARY. MetabolismPlants.KeyInformation.RotationalCrops.RelevantStudies
Crop groups	Picklist (based on representative crop groups defined in OECD TG 502): Indicate the metabolism crop group	Open list	ENDPOINT_SUMMARY. MetabolismPlants.KeyInformation.RotationalCrops.CropGroups

	covered by the study(ies) reported in this row (e.g. root/tuber crops). If the group is not in the picklist, please use "other" specify the group in the opening cells.		
Commodity	Indicate the commodity(ies) for which nature of residues was investigated in the study. Multi-selection is possible (E.g. wheat grain + wheat straw).	Multi select open list with remarks	ENDPOINT_SUMMARY. MetabolismPlants.KeyInformation.RotationalCrops.Commodity
PBI	PBI (Plant back interval): Indicate the time (in days) between treatment (application of active substance on previous crops or on bare soil) and planting. There is the possibility to report a series of figures (e.g. 30, 120 or 365 days).	Multi-line text	ENDPOINT_SUMMARY. MetabolismPlants.KeyInformation.RotationalCrops.Pbi
Application rate	Indicate the application rate (with the unit) tested in the study (e.g. 1 kg a.s./ha). If different application rates were tested in the same study, there is the possibility to report both in the same cells (e.g. 1 kg a.s./ha; 2 kg a.s./ha) or to create separate rows as more appropriate.	Multi-line text	ENDPOINT_SUMMARY. MetabolismPlants.KeyInformation.RotationalCrops.ApplicationRate
Remarks	Indicate if the application was made on "bare soil" or on "growing crops". If application is done on growing crops, please specify the growth stage at application (BBCH scale) to be able to calculate the foliar	Multi-line text	ENDPOINT_SUMMARY. MetabolismPlants.KeyInformation.RotationalCrops.Remarks

	interception accordingly.		
Rotational crops			
Additional information	Discussion(Header 1) – common block	Header 1	ENDPOINT_SUMMARY. MetabolismPlants.Discussion
	This section can be used to add any additional useful text. If there is no additional information to be reported this field may be left empty.	Rich text area	ENDPOINT_SUMMARY. MetabolismPlants.Discussion.Discussion
Attached background material			ENDPOINT_SUMMARY. MetabolismPlants.Discussion.AttachedBackgroundMaterial
Attached document	The original file only needs to be attached here if it differs from the file in Attached (sanitised) documents for publication.	Single file attachment	ENDPOINT_SUMMARY. MetabolismPlants.Discussion.AttachedBackgroundMaterial.AttachedDocument
Remarks		Text	ENDPOINT_SUMMARY. MetabolismPlants.Discussion.AttachedBackgroundMaterial.Remarks
Attached background material	Add any additional document that supports the above key information (e.g. calculation tables, graphs). The depicted metabolic pathways can be uploaded here.		
Attached (sanitised) documents for publication	Add any additional document that support the above key results (e.g. calculation tables, graphs) after sanitisation. The overview of metabolism studies [cf. residue Template 6.2 (http://doi.org/10.5281/zenodo.4621089)] can be uploaded here by the applicant, although not mandatory. The uploaded file should not contain confidential	Attachments list	ENDPOINT_SUMMARY. MetabolismPlants.Discussion.AttachedSanitisedDocsForPublication

	material. Please note that the overview of the metabolism studies (excel file) will be generated later by the EMS/RMS during the risk assessment phase, provided that all MSS-composer xml-files of the metabolism studies are available to the RMS/EMS.		
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6.2.1 Metabolism of residues in plants and in rotational crops – Endpoint study record

Purpose:

The results of the studies of metabolism in crops are used to elucidate the degradation pathway of the active substance and require the identification of the metabolism and/or degradation products when a pesticide is applied to a crop directly or indirectly.

Studies of metabolism in crops fulfil several major purposes:

- 1) Provide an estimate of the total residues in the various commodities after crop treatment, which allows determination of the distribution of residues within the crop, e.g., whether the pesticide is absorbed through roots or foliage or whether translocation occurs;
- 2) Identify the components of the terminal residue in the various commodities, thus indicating the components to be analysed for in residue quantification studies (i.e., the residue definition(s) for both risk assessment and enforcement).
- 3) Elucidate the metabolic pathway of the active ingredient in treated crops.

Currently, the general recommendation is to use a separate tool ("MSS composer") to report metabolism studies. Therefore, detailed parameters concerning the materials and methods and the results of the metabolism studies shall be contained in the XML-file created with the "MSS-composer" and there is no need to fill out all the fields in the present document. Those fields marked as "Field not mandatory in the study record" do not need to be filled out here, provided that the MSS composer file is duly compiled.

However, an endpoint study record shall be created for each metabolism study submitted in the IUCLID dossier. In addition, all the fields marked as "mandatory" in this document shall be fulfilled in IUCLID to ensure a minimum structured data and to make best use of the report generator.

The XML-files created with the MSS-composer should be uploaded in IUCLID as defined in this chapter and as defined in the general workflow for metabolism studies (see support material). Specific instructions for the mandatory fields in the MSS composer are also given in chapter 4 of the general workflow for metabolism studies (see support material).

Important note: the applicant should import MSS/DER-file into the latest available version of MetaPath to validate the data BEFORE attaching the composers to the IUCLID dossier.

ENDPOINT_STUDY_RECORD.MetabolismInCrops v. 6.6 (Final)			
Name	Instructions	Type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.MetabolismInCrops.AdministrativeData
		Confidentiality	ENDPOINT_STUDY_RECORD.MetabolismInCrops.AdministrativeData.DataProtection
Endpoint	Select relevant endpoint from picklist (for metabolism studies in primary crops, please use the option "metabolism of residues in crops")	Closed list with remarks	ENDPOINT_STUDY_RECORD.MetabolismInCrops.AdministrativeData.Endpoint
Type of information		Open list with remarks	ENDPOINT_STUDY_RECORD.MetabolismInCrops.AdministrativeData.StudyResultType
Adequacy of study		Closed list	ENDPOINT_STUDY_RECORD.MetabolismInCrops.AdministrativeData.PurposeFlag
Robust study summary		Checkbox	ENDPOINT_STUDY_RECORD.MetabolismInCrops.AdministrativeData.RobustStudy
Used for classification		Checkbox	ENDPOINT_STUDY_RECORD.MetabolismInCrops.AdministrativeData.UsedForClassification
Used for SDS		Checkbox	ENDPOINT_STUDY_RECORD.MetabolismInCrops.AdministrativeData.UsedForMSDS
Study period		Text	ENDPOINT_STUDY_RECORD.MetabolismInCrops.AdministrativeData.StudyPeriod
Reliability		Open list	ENDPOINT_STUDY_RECORD.MetabolismInCrops.AdministrativeData.Reliability
Rationale for reliability incl. deficiencies		Open list with remarks (32000)	ENDPOINT_STUDY_RECORD.MetabolismInCrops.AdministrativeData.RationalReliability

Data waiving		Closed list	ENDPOINT_STUDY_RECORD.MetabolismInCrops.AdministrativeData.DataWaiving
Justification for data waiving		Multi select open list with remarks (32000)	ENDPOINT_STUDY_RECORD.MetabolismInCrops.AdministrativeData.DataWaivingJustification
Justification for type of information		Text template	ENDPOINT_STUDY_RECORD.MetabolismInCrops.AdministrativeData.JustificationForTypeOfInformation
Attached justification			ENDPOINT_STUDY_RECORD.MetabolismInCrops.AdministrativeData.AttachedJustification
Attached justification		Single file attachment	ENDPOINT_STUDY_RECORD.MetabolismInCrops.AdministrativeData.AttachedJustification.AttachedJustification
Reason / purpose		Closed list with remarks	ENDPOINT_STUDY_RECORD.MetabolismInCrops.AdministrativeData.AttachedJustification.ReasonPurpose
Attached justification			
Cross-reference			ENDPOINT_STUDY_RECORD.MetabolismInCrops.AdministrativeData.CrossReference
Reason / purpose for cross-reference		Open list with remarks	ENDPOINT_STUDY_RECORD.MetabolismInCrops.AdministrativeData.CrossReference.ReasonPurpose
Related information		Endpoint reference field	ENDPOINT_STUDY_RECORD.MetabolismInCrops.AdministrativeData.CrossReference.RelatedInformation
Remarks		Text area	ENDPOINT_STUDY_RECORD.MetabolismInCrops.

			AdministrativeData.Cross Reference.Remarks
Cross- reference			
Data source	Data source (Literature Reference) – common block The XML-file created with the MSS-composer should be attached in the literature reference.	Header 1	ENDPOINT_STUDY_RECORD.MetabolismInCrops.DataSource
Reference	<p>Indicate the bibliographic reference of the study report or publication the study summary is based on. Select item from 'Literature Reference' database or create 'New Reference'.</p> <p>If you entered the study in the MSS composer, the XML-files created with the MSS-composer should be attached in the LITERATURE entity, to which reference is made here. These XML-files shall contain all the data fields on material and methods and on results and discussions that were not directly reported in the present study record.</p> <p>In the field "attached documents", please use the function "select files" and attach here each XML-file associated to study referred to in this LITERATURE ENTITY.</p> <p>If you did not enter yourself the study in the MSS composer because the XML-files linked to this study record already exist (and are available to the Regulatory Authorities), the attachment of the XML-files is not required. In such a case, please report the corresponding individual file number in the field "other study identifier(s)" to help the Regulatory Authority identifying the corresponding file(s) in the database.</p>	Literature reference list	ENDPOINT_STUDY_RECORD.MetabolismInCrops.DataSource.Reference
Data access		Open list with remarks	ENDPOINT_STUDY_RECORD.MetabolismInCrops.DataSource.DataAccess
Data protection claimed		Close d list with remarks	ENDPOINT_STUDY_RECORD.MetabolismInCrops.DataSource.DataProtectionClaimed
Materials and methods	Material and methods – common block MATERIALS AND METHODS	Header 1	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods

	<p>This part of the metabolism study should mainly be reported in a separate tool which is the "MSS composer". Therefore, all detailed parameters concerning the materials and methods of the metabolism studies should be contained in the XML-file created with the "MSS-composer" and there is no need to fill out all the fields in the present section. However, the fields marked as "mandatory" shall be fulfilled to ensure a minimum structured data and to make best use of the report generator.</p>		
Background information	Mandatory field in the study record.	Rich text area	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.BackgroundInformation
Product type	The product type is already reported in Section 3.2 (Effect on harmful organism, function, mode of action and possible resistance). This field is optional.	Open list with remarks	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.ProductType
Test guideline	<p>Mandatory field in the study record.</p> <p>Indicate according to which test guideline the study was conducted. If no test guideline was explicitly followed, but the methodology used is equivalent or similar to a specific guideline, you can indicate so in the 'Qualifier' subfield preceding the field 'Guideline'.</p> <p>Add one block of fields for each guideline when more than one guideline is followed (e.g. US EPA in addition to OECD guideline).</p>		ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.Guideline
Qualifier	<p>Mandatory field in the study record.</p> <p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - 'according to guideline' (if a given test guideline was followed); - 'equivalent or similar to guideline' (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - 'no guideline followed' (if none of above qualifiers apply. If so, fill in field 'Principles of method if other than guideline'); - 'no guideline available' (if so, fill in field 'Principles of method if other than guideline'); - 'no guideline required' (if so, fill in field 'Principles of method if other than guideline'); 	Closed list	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.Guideline.Qualifier
Guideline	<p>Mandatory field in the study record.</p> <p>Select the applicable test guideline, e.g. 'OECD TG 501' (for primary crops) or 'OECD TG 502' (for</p>	Open list	ENDPOINT_STUDY_RECORD.MetabolismInCrops.

	<p>rotational crops). If the test guideline used is not listed, choose 'other:' and specify the test guideline in the related text field. Information on the version and date of the guideline used and/or any other specifics can be entered in the next field 'Version / remarks'.</p> <p>If no test guideline can be specified, this should be indicated in the preceding field 'Qualifier'.</p> <p>The method used should then be shortly described in the field 'Principles of method if other than guideline', while details can be given in other distinct fields.</p> <p>Please note: Test guidelines used for the validation of (Q)SAR models should be reported in the description of the relevant model in field 'Justification for type of information' or 'Attached justification'.</p>		MaterialsAndMethods.Guideline.Guideline
Version / remarks	<p>Mandatory field in the study record.</p> <p>In this text field, you can enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline); - To indicate if the study was performed prior to the adoption of the test guideline specified; - To indicate if the methodology used was based on an extension of the test guideline specified; - To indicate what protocol was followed for methods that allow the optional determination of more than one parameter if this cannot be indicated in a distinct field of the Materials and methods section. 	Multi-line text	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.Guideline.VersionRemarks
Deviations	<p>Mandatory field in the study record.</p> <p>In case a test guideline or other standardised method was used, indicate if there are any deviations. Briefly state relevant deviations in the supplementary remarks field (e.g. 'other test system used', 'different exposure duration'); details should be described in the respective fields of the section MATERIALS AND METHODS.</p>	Closed list with remarks	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.Guideline.Deviation
Test guideline			
Principles of method if other than guideline	<p>Mandatory field in the study record.</p> <p>If no guideline was followed, include a description of the principles of the test protocol or estimated method used in the study. As appropriate use either</p>	Text template	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.MethodNoGuideline

	<p>of the pre-defined free text template options for 'Method of non-guideline study' or '(Q)SAR'. Delete / add elements and edit text set in square brackets [...] as appropriate.</p> <p>For a non-guideline experimental study, a high-level free text template can be used for summarising the principle of test, test conditions and parameters analysed / observed.</p> <p>If the free text template for (Q)SAR is selected, indicate the QSAR model(s) or platform including version and the software tool(s) used. Detailed justification of the model and prediction should be provided in field(') 'Justification for type of informat'on', 'Attached justificat'on' and/r 'Cross-refere'ce' as appropriate.</p> <p>Details should be entered in appropriate distinct fields of section MATERIALS AND METHODS if available. Also provide a justification for using this method if appropriate.</p>		
GLP compliance	<p>Mandatory field in the study record.</p> <p>Indicate whether the study was conducted following Good Laboratory Practice or not. In ca'e 'yes' is selected, a Quality Assurance (QA) statement must be provided with the report. You can give an explanation in the supplementary remarks field, e.g. for explaining why GLP was not complied with or for specifying which (national) GLP was followed.</p>	Closed list with remarks	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.GLPComplianceStatement
Test material	<p>Test Material – common block</p> <p>This part of the metabolism study should be reported via the "MSS composer". However, test material information and specific details on test material used for the study shall also be entered here to link the present study record to the test materials created in this dataset.</p>	Header 2	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestMaterials
Test material information	Mandatory field in the study record.	Entity reference field	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Additional test material information	If relevant.	Entity reference field	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestMaterials.AdditionalTestMaterialInformation
Specific details on test material	Mandatory field in the study record.	Text template	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestMaterials.SpecificDetail

used for the study			sOnTestMaterialUsedForTheStudy
Specific details on test material used for the study (confidential)	Mandatory field in the study record.	Text template	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestMaterials.SpecificDetailsOnTestMaterialUsedForTheStudyConfidential
Radiolabelling	Mandatory field in the study record. Indicate if labelled or non-labelled test material was used. Details on labelled material should be described in field 'Details on test material'.	Open list with remarks	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestMaterials.Radiolabelling
Radiolabelled test material	Mandatory field in the study record. This information shall also be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestMaterials.RadiolabelledTestMaterial
Radiolabel no.	Mandatory field in the study record. This information shall also be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Closed list	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestMaterials.RadiolabelledTestMaterial.RadiolabelNo
SMILES notation	Mandatory field in the study record. This information shall also reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Multi-line text	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestMaterials.RadiolabelledTestMaterial.SMILESNotation
Radiochemical purity (%)	Mandatory field in the study record. This information shall also reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Range (Decimal)	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestMaterials.RadiolabelledTestMaterial.RadiochemicalPurity
Specific activity as received	Mandatory field in the study record. This information shall also reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestMaterials.RadiolabelledTestMaterial.SpecificActivityAsReceived
Specific activity of dose	Mandatory field in the study record. This information shall also reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestMaterials.RadiolabelledTestMaterial.SpecificActivityOfDose

Remarks	Field not mandatory. Use this field to enter any remarks.	Text	ENDPOINT_STUDY_REC ORD.MetabolismInCrops. MaterialsAndMethods.Te stMaterials.Radiolabelled TestMaterial.Remarks
Radiolabe lled test material			
Crop informatio n		Head er 2	ENDPOINT_STUDY_REC ORD.MetabolismInCrops. MaterialsAndMethods.Te stSiteAndCropInformatio n
Test crops	Field not mandatory in the study record. (there is no need to open the subfields 'test crops no, type of rotational crops, crops, crop code, crop variety, scientific name, crop group, growth stage at app, growth stage at harvest, harvested commodities, harvested procedure). This information shall be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		ENDPOINT_STUDY_REC ORD.MetabolismInCrops. MaterialsAndMethods.Te stSiteAndCropInformatio n.TestCrops
Other details on test crops	Field not mandatory in the study record. This information shall be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Text templ ate	ENDPOINT_STUDY_REC ORD.MetabolismInCrops. MaterialsAndMethods.Te stSiteAndCropInformatio n.DetailsOnTestCrops
Test site and soil properties		Head er 2	ENDPOINT_STUDY_REC ORD.MetabolismInCrops. MaterialsAndMethods.Te stSiteAndSoilProperties
Test site type	Field not mandatory in the study record. This information shall be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Open list	ENDPOINT_STUDY_REC ORD.MetabolismInCrops. MaterialsAndMethods.Te stSiteAndSoilProperties.T estSiteType
Soil properties	This field is not mandatory in the study record. Therefore, there is no need to open all the subfields below (soil type no, soil type, ph, etc...) which are also not mandatory.		ENDPOINT_STUDY_REC ORD.MetabolismInCrops. MaterialsAndMethods.Te stSiteAndSoilProperties.S oilProperties
Other details on test site	Field not mandatory in the study record. This information shall be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Text area	ENDPOINT_STUDY_REC ORD.MetabolismInCrops. MaterialsAndMethods.Te stSiteAndSoilProperties.D etailsOnTestSite
Environm ental conditions		Head er 2	ENDPOINT_STUDY_REC ORD.MetabolismInCrops.

			MaterialsAndMethods.EnvironmentalConditions
Temperature	Field not mandatory in the study record. This information shall be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Text area	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.EnvironmentalConditions.Temperature
Rainfall	Field not mandatory in the study record. This information shall be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Text area	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.EnvironmentalConditions.Rainfall
Lighting	Field not mandatory in the study record. This information shall be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Text area	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.EnvironmentalConditions.Lighting
Potential for photodegradation of substance	Field not mandatory in the study record. This information shall be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Text area	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.EnvironmentalConditions.PotentialForPhotodegradationOfSubstance
Application		Header 2	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.Application
Use pattern information	Field not mandatory in the study record. This information shall be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record). To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.Application. Use pattern information
Other details on application	Field not mandatory in the study record. This information shall be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Text area	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.Application.OtherDetailsOnApplication
Further details on study design	Field not mandatory in the study record. This information shall be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Text area	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.Application.FurtherDetailsOnStudyDesign
Sampling and analysis		Header 2	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.SamplingAndAnalysis

of crop plants			
Details on sampling	Field not mandatory in the study record. This information shall be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Text area	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.SamplingAndAnalysis.DetailsOnSampling
Details on extraction and analysis	Field not mandatory in the study record. This information shall be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Text area	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.SamplingAndAnalysis.DetailsOnExtractionAndAnalysis
Details on identification and characterisation	Field not mandatory in the study record. This information shall be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Text area	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.SamplingAndAnalysis.DetailsOnIdentificationAndCharacterisation
Flowchart of extraction and fractionation schemes	Field not mandatory in the study record. This information shall be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.SamplingAndAnalysis.FlowchartOfExtractionAndFractionationSchemes
Sampling and analysis of soil		Header 2	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.SamplingAndAnalysisOfSoil
Details on sampling of soil	Field not mandatory in the study record. This information shall be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Text area	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.SamplingAndAnalysisOfSoil.DetailsOnSamplingOfSoil
Details on analytical methodology for soil residues	Field not mandatory in the study record. This information shall be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Text area	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.SamplingAndAnalysisOfSoil.DetailsOnAnalyticalMethodologyForSoilResidues
Appendix: Treatment groups	Field not mandatory in the study record. This information shall be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Header 2	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.AppendixTreatmentGroups
Any other information on materials	Any other information on materials and methods incl. tables - (H2) – common block Field not mandatory.	Header 2	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.AnyOtherInformationOnMaterials

and methods incl. tables	<p>In this field, you can enter any information on materials and methods, for which no distinct field is available, or transfer free text from other databases. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. You can also upload any htm or html document.</p> <p>Note: One rich text editor field each is provided for the MATERIALS AND METHODS and RESULTS section. In addition, the fields 'Overall remarks' and 'Executive summary' allow rich text entry.</p>		erialsAndMethodsInclTables
Results and discussion	<p>This part of the metabolism study should mainly be reported in a separate tool which is the "MSS composer". Therefore, all detailed results of the metabolism studies should be contained in the XML-file created with the "MSS-composer" and there is no need to fill out the fields of the present section. However, the fields marked as "mandatory" shall be fulfilled to ensure a minimum structured data and to make best use of the report generator.</p>	Header 1	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion
Total radioactive residues		Header 2	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.TotalRadioactiveResidues
Extraction efficiency of radioactive residues using enforcement method	<p>Field not mandatory in the study record.</p> <p>This information shall be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).</p>		ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.TotalRadioactiveResidues.ExtractionEfficiencyOfRadioactiveResiduesUsingEnforcementMethod
Quantitation	<p>Field not mandatory in the study record.</p> <p>This information can be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).</p>	Multi-line text	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.TotalRadioactiveResidues.Quantitation
TRR results	<p>Field not mandatory in the study record.</p> <p>This information shall be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).</p>		ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.TotalRadioactiveResidues.TRRResults
Other details on total radioactive residues (TRRs)	<p>Field not mandatory in the study record.</p> <p>This information shall be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).</p>	Text area	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.TotalRadioactiveResidues

Extraction / characterisation, and distribution of residues		Header 2	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.ExtractionCharacterisationAndDistributionOfResidues
Distribution of parent and metabolites	Field not mandatory in the study record. This information shall be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.ExtractionCharacterisationAndDistributionOfResidues.DistributionOfParentAndMetabolites
Other details on distribution of residues	Field not mandatory in the study record. This information shall be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Text area	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.ExtractionCharacterisationAndDistributionOfResidues.OtherDetailsOnDistributionOfResidues
Storage stability of residues		Header 2	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.StorageStabilityOfResidues
Summary of storage conditions	Field not mandatory in the study record. This information shall be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.StorageStabilityOfResidues.SummaryOfStorageConditions
Storage stability of residues (Sample Integrity)	Field not mandatory in the study record. This information shall be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Text area	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.StorageStabilityOfResidues.StorageStability
Summary of radioactive residues in crops		Header 2	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops
Characterisation and identification of radioactive residues	Field not mandatory in the study record. This information shall be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.CharacterisationAndIdentificationOfResidues
Other details on	Field not mandatory in the study record. This information shall be reported via the MSS composer	Text area	ENDPOINT_STUDY_RECORD.MetabolismInCrops.

characterisation and identification of residues	(please make sure that this information is available in the XML-file attached to this record).		ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.OtherDetailsOnCharacterisationAndIdentificationOfResidues
Summary of radioactive residues in soil		Header 2	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInSoil
Radioactive residues in soil	Field not mandatory in the study record. This information can be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		
Proposed metabolic pathway		Header 2	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.ProposedMetabolicPathway
Identification of compounds from metabolism study	Field not mandatory in the study record. This information shall be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.ProposedMetabolicPathway.IdentificationOfCompoundsFromMetabolismStudy
Metabolic pathway	Field not mandatory in the study record. This information shall be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Rich text area	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.ProposedMetabolicPathway.MetabolicPathway
Metabolic map (picture/graph)	Field not mandatory in the study record. This information shall be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Image	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.ProposedMetabolicPathway.MetabolicMapPictureGraph
Appendix: Metabolites and their parents in treatment groups	Field not mandatory in the study record. This information shall be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Header 2	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.AppendixMetabolitesAndTheirParentsInTreatmentGroups
Any other information on results incl. tables	Field not mandatory in the study record. In this field, you can enter any other remarks on results. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. Note: One rich text editor field each is provided for the MATERIALS AND METHODS and RESULTS	Header 2	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables

	section. In addition, the fields 'Overall remarks' and 'Executive summary' allow rich text entry.		
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_REC ORD.MetabolismInCrops. OverallRemarksAttachments
Overall remarks	In this field, you can enter any overall remarks or transfer free text from other databases. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. You can also upload any htm or html document. If you entered the study in the MSS composer and/or if the XML-file created with the MSS-composer is available to you, please generate a word report from the MSS-composer (using the adequate feature in the MSS-composer software) and copy/paste the content of this report in this field. Additional text can be added to complement the basic report generated by the MSS-composer.	Rich text area	ENDPOINT_STUDY_REC ORD.MetabolismInCrops. OverallRemarksAttachments.RemarksOnResults
Attachments	Attach any background document that cannot be inserted in any rich text editor field, particularly image files (e.g. an image of a structural formula).		ENDPOINT_STUDY_REC ORD.MetabolismInCrops. OverallRemarksAttachments.Attachments
Illustration (picture/graph)		Image	ENDPOINT_STUDY_REC ORD.MetabolismInCrops. OverallRemarksAttachments.IllustrationPicGraph
Applicants summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_REC ORD.MetabolismInCrops. ApplicantSummaryAndConclusion
Conclusions	Mandatory field in the study record. Write here the Applicant's conclusion of the metabolism study in context of the application.	Text area	ENDPOINT_STUDY_REC ORD.MetabolismInCrops. ApplicantSummaryAndConclusion.Conclusions
Executive summary	Mandatory field in the study record. Briefly summarise the relevant aspects of the study including the conclusions reached in the context of the application.	Rich text area	ENDPOINT_STUDY_REC ORD.MetabolismInCrops. ApplicantSummaryAndConclusion.ExecutiveSummary

Links to support material:

Please find specific instructions on how to structure the results of metabolism studies plants and livestock under the following link:

<https://www.efsa.europa.eu/en/applications/pesticides/tools>

From the page, users will find all instructions to download the MSS composer (part of the Metapath software package), link to the technical manual for the MSS-composer, detailed information on the data flow for metabolism studies and access to the databases of metapath files.

Specific instructions on the process workflow for metabolism data (including the list of mandatory fields in the MSS composer) are available in the following document: <https://zenodo.org/record/4785179>

6.2.2 Metabolism of residues in livestock (incl. fish) – Endpoint summary

Purpose:

Provide a summary of the key parameters of metabolism studies on livestock for individual groups of animals used to conclude whether the nature of residues in livestock/fish was sufficiently elucidated. Please briefly summarize the parameters of the key metabolism studies.

When an endpoint is characterized in more than one metabolite study, it is suggested to create several endpoint study records in IUCLID, one for each of the respective studies. The full reports, containing the results from the separate studies, should be attached to the literature reference entity of each endpoint study record. However, just a single endpoint summary should be created for those studies and cross reference to each endpoint study record should be added.

ENDPOINT_SUMMARY.MetabolismInLivestock v.3.0 (Final)			
Name	Instructions	IUCLID6 DataType	IUCLID6 Path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.MetabolismInLivestock.AdministrativeDataSummary
		Confidentiality	ENDPOINT_SUMMARY.MetabolismInLivestock.AdministrativeDataSummary.DataProtection
Link to relevant study record(s)		Header 1	ENDPOINT_SUMMARY.MetabolismInLivestock.LinkToRelevantStudyRecord
Study name / type	Provide here the link to the most relevant study(ies) from which the key values for magnitude of residues in commodities of animal origin are derived.	Endpoint reference list	ENDPOINT_SUMMARY.MetabolismInLivestock.LinkToRelevantStudyRecord.Link
Results		Read-only	ENDPOINT_SUMMARY.MetabolismInLivestock.LinkToRelevantStudyRecord.Results
Description of key information	Please make a statement whether the nature of residues in commodities of animal	Header 1	ENDPOINT_SUMMARY.MetabolismInLivestock.KeyInformation

	<p>origin was sufficiently investigated in the context of the present dossier (according to the relevant data requirements and OECD TG 503) and highlight data gap(s) and the non-standard uncertainty(ies), if any. If studies reported in this summary are not guideline or GLP compliant, if deviation from guidance are observed (e.g. not validated analytical method), please report it here.</p> <p>Respective detailed parameters on the available key studies used for risk assessment should be reported in a table format. Please use the recommended format, available on knowledge junction [cf. residue Template 6.1 (http://doi.org/10.5281/zenodo.4621833)], Table 6.2.2].</p>		
		Rich text area	ENDPOINT_SUMMARY. MetabolismInLivestock. KeyInformation.KeyInformation
Additional information	Discussion(Header 1) – common block	Header 1	ENDPOINT_SUMMARY. MetabolismInLivestock. Discussion
	<p>Provide additional information related to the endpoint, for example:</p> <ul style="list-style-type: none"> - information on the potential data gaps - relevance of the results for the risk assessment - the rationale for the choice of the key study(ies) and the 	Rich text area	ENDPOINT_SUMMARY. MetabolismInLivestock. Discussion.Discussion

	<p>choice for the key value that characterises the endpoint</p> <ul style="list-style-type: none"> - the rationale for any user-derived values for the sake of transparency -the possible reasons for differentiating results when several studies were identified to be relevant for the assessment. <p>If there is no additional information to be reported this field may be left empty.</p>		
Attached background material			ENDPOINT_SUMMARY. MetabolismInLivestock. Discussion.AttachedBackgroundMaterial
Attached document	The original file only needs to be attached here if it differs from the file in Attached (sanitised) documents for publication.	Single file attachment	ENDPOINT_SUMMARY. MetabolismInLivestock. Discussion.AttachedBackgroundMaterial.AttachedDocument
Remarks	Possibility to add any additional useful text on this section. If there is no additional information to be reported this field may be left empty	Text	ENDPOINT_SUMMARY. MetabolismInLivestock. Discussion.AttachedBackgroundMaterial.Remarks
Attached background material	Add any additional document that supports the above key information (e.g. calculation tables, graphs). The depicted metabolic pathways can be uploaded here.		
Attached (sanitised) documents for publication	Add any additional document that support the above key results (e.g. calculation tables, graphs). The overview of metabolism studies [cf. residue Template 6.2 (http://doi.org/10.5281/zenodo.4621089)] can	Attachments list	ENDPOINT_SUMMARY. MetabolismInLivestock. Discussion.AttachedSanitisedDocsForPublication

	be uploaded here by the applicant, although not mandatory. The uploaded file should not contain confidential material. Please note that the overview of the metabolism studies (excel file) will be generated later by the EMS/RMS during the risk assessment phase, provided that all MSS-composer xml-files of the metabolism studies are available to the RMS/EMS.		
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6.2.2 Metabolism of residues in livestock (incl. fish) – Endpoint study record

Purpose:

The results of the studies of metabolism in livestock are used to elucidate the degradation pathway of the active ingredient and require the identification of the metabolism and/or degradation products when a pesticide is applied to a crop directly or indirectly.

Studies of metabolism in livestock fulfil several major purposes:

- 1) provide an estimate of total terminal residues in edible animal products;
- 2) identify the major components of the total terminal residue in edible animal products;
- 3) indicate the distribution of residues between relevant edible animal products;
- 4) provide evidence whether or not a residue should be classified as fat soluble;
- 5) quantify the total residue in certain animal products (milk or eggs) and excreta;
- 6) quantify the major components of the residue and to show the efficiency of extraction procedures for these components’
- 7) characterise and quantify conjugated and bound residues;
- 8) indicate the components to be analysed for in residue quantification studies (livestock feeding studies);
- 9) generate data from which a decision on the need for feeding studies on food producing animals can be made

Currently, the general recommendation is to use a separate tool (“MSS composer”) to report metabolism studies. Therefore, detailed parameters concerning the materials and methods and the results of the metabolism studies shall be contained in the XML-file created with the “MSS-composer” and there is no need to fill out all the fields in the present document. Those fields marked as “Field not mandatory in the study record” do not need to be filled out here, provided that the MSS composer file is duly compiled.

However, the fields marked as “mandatory” in this document shall be fulfilled in IUCLID to ensure a minimum structured data and to make best use of the report generator.

The XML-files created with the MSS-composer should be uploaded in IUCLID as defined in this chapter and as defined in the general workflow for metabolism studies (see support material). Specific instructions for

the mandatory fields in the MSS composer are also given in chapter 4 of the general workflow for metabolism studies (see support material).

Important note: the applicant should import MSS/DER-file into the latest available version of MetaPath to validate the data BEFORE attaching the composers to the IUCLID dossier.

ENDPOINT_STUDY_RECORD.MetabolismInLivestock v.6.7			
Name	Instructions	Type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.AdministrativeData
Data source	Data source (Literature Reference) – common block The XML-file created with the MSS-composer should be attached in the literature reference.	Header 1	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.DataSource
Reference	Indicate the bibliographic reference of the study report or publication the study summary is based on. Select item from 'Literature Reference' database or create 'New Reference'. If you entered in the study in the MSS composer, the XML-files created with the MSS-composer should be attached in the LITERATURE entity, to which reference is made here. These XML-files shall contain all the data fields on material and methods and on results and discussions that were not directly reported in the present study record.	Literature reference list	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.DataSource.Reference

	<p>In the field "attached documents", please use the function "select files" and attach here each XML-file associated to study referred to in this LITERATURE ENTITY.</p> <p>If you did not enter yourself the study in the MSS composer because the XML-files linked to this study record already exist (and are available to the Regulatory Authorities), the attachment of the XML-files is not required. In such a case, please report the corresponding individual file number in the field "other study identifier(s)" to help the Regulatory Authority identifying the corresponding file(s) in the database.</p>		
Data access		Open list with remarks	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.DataSource.DataAccess
Data protection claimed		Closed list with remarks	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.DataSource.DataProtectionClaimed
Materials and methods	<p>Material and methods – common block</p> <p>This part of the metabolism study should mainly be reported in a separate tool which is the "MSS composer". Therefore,</p>	Header 1	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods

	all detailed parameters concerning the materials and methods of the metabolism studies should be contained in the XML-file created with the "MSS-composer" and there is no need to fill out all the fields in the present section. However, the fields marked as "mandatory" shall be fulfilled to ensure a minimum structured data and to make best use of the report generator		
Background information	Mandatory field in the study record.	Rich text area	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.BackgroundInformation
Product type	Field not mandatory. The product type is already reported in Section 3.2 (Effect on harmful organism, function, mode of action and possible resistance). This field is optional.	Open list with remarks	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.ProductType
Type of study	Mandatory field in the study record.	Open list	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.TypeOfStudy
Test guideline	Mandatory field in the study record.		ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.Guideline
Qualifier		Closed list	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.Guideline.Qualifier

Guideline		Open list	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.Guideline.Guideline
Version / remarks		Multi-line text	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.Guideline.VersionRemarks
Deviations		Closed list with remarks	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.Guideline.Deviation
Test guideline			
Principles of method if other than guideline	Mandatory field in the study record.	Text template	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.MethodNoGuideline
GLP compliance	Mandatory field in the study record.	Closed list with remarks	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.GLPComplianceStatement
Test material	<p>Test Material – common block</p> <p>This part of the metabolism study should be reported via the “MSS composer”. However, test material information and specific details on test material used for the study shall also be entered here to link the present study record to the test materials created in this dataset.</p>	Header 2	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.TestMaterials

Test material information	Mandatory field in the study record	Entity reference field	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Additional test material information	If relevant.	Entity reference field	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.TestMaterials.AdditionalTestMaterialInformation
Specific details on test material used for the study	Mandatory field in the study record	Text template	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.TestMaterials.SpecificDetailsOnTestMaterialUsedForTheStudy
Specific details on test material used for the study (confidential)	Mandatory field in the study record.	Text template	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.TestMaterials.SpecificDetailsOnTestMaterialUsedForTheStudyConfidential
Radiolabelling	Mandatory field in the study record. Indicate if labelled or non-labelled test material was used. Details on labelled material should be described in field 'Details on test material'.	Open list with remarks	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.TestMaterials.Radiolabelling
Radiolabelled test material	Mandatory field in the study record. This information shall also be reported via the MSS composer (please make sure that this information is available in the XML-file		ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.TestMaterials.RadiolabelledTestMaterial

	attached to this record).		
Radiolabel no	Mandatory field in the study record. This information shall also be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Closed list	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.TestMaterials.RadiolabelledTestMaterial
SMILES notation	Mandatory field in the study record. This information shall also be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Multi-line text	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.TestMaterials.RadiolabelledTestMaterial.SMILESNotation
Radiochemical purity(%)	Mandatory field in the study record. This information shall also be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Range (Decimal)	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.TestMaterials.RadiolabelledTestMaterial.RadiochemicalPurity
Specific activity as received	Mandatory field in the study record. This information shall also be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.TestMaterials.RadiolabelledTestMaterial.SpecificActivityAsReceived
Specific activity of dose	Mandatory field in the study record. This information shall also be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.TestMaterials.RadiolabelledTestMaterial.SpecificActivityOfDose

Remarks	Field not mandatory. Use this field to enter any remarks	Text	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.TestMaterials.RadiolabelledTestMaterial.Remark
Radiolabelled test material			
Test animals		Header 2	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.TestAnimals
General test animal information	Field not mandatory in the study record. This information shall be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.TestAnimals.GeneralTestAnimalInformation
Other details on housing conditions and test animals	Field not mandatory in the study record. This information shall be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Text area	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.TestAnimals.DetailsOnHousingConditionsAndTestAnimals
Test animal dietary regime	Field not mandatory in the study record. This information shall be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.TestAnimals.TestAnimalDietaryRegime
Other details on dietary regime	Field not mandatory in the study record. This information shall be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Text area	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.TestAnimals.DetailsOnDietaryRegime

Administration / exposure		Header 2	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.AdministrationExposure
Test animal dosing regime	Field not mandatory in the study record. This information shall be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.AdministrationExposure.TestAnimalDosingRegime
Other details on dosing	Field not mandatory in the study record. This information shall be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Text template	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.AdministrationExposure.DetailsOnDosing
No. of animals per dose group	Field not mandatory in the study record. This information shall be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Multi-line text	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.AdministrationExposure.NoOfAnimalsPerDoseGroup
Rationale for selection of dose group	Field not mandatory in the study record. This information can be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Multi-line text	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.AdministrationExposure.RationaleForSelectionOfDoseGroup
Analysis of feed and water	Field not mandatory in the study record. This information can be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Multi-line text	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.AdministrationExposure.AnalysisOfFeedAndWater

Further details on study design	Field not mandatory in the study record. This information shall be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Text area	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.AdministrationExposure.FurtherDetailsOnStudyDesign
Sampling and analysis		Header 2	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.SamplingAndAnalysis
Sample collection	Field not mandatory in the study record. This information shall be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.SamplingAndAnalysis.SampleCollection
Details on sampling	Field not mandatory in the study record. This information shall be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Rich text area	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.SamplingAndAnalysis.DetailsOnSamplingAndAnalyticalMethods
Details on extraction and analysis	Field not mandatory in the study record. This information shall be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Rich text area	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.SamplingAndAnalysis.DetailsOnExtractionAndAnalysis
Details on identification and characterisation	Field not mandatory in the study record. This information shall be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Rich text area	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.SamplingAndAnalysis.DetailsOnIdentificationAndCharacterisation

Flowchart of extraction and fractionation schemes	Field not mandatory in the study record. This information shall be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.SamplingAndAnalysis.FlowchartOfExtractionAndFractionationSchemes
Appendix: Treatment groups	Field not mandatory in the study record. This information shall be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Header 2	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.AppendixTreatmentGroups
Any other information on materials and methods incl. tables	<p>Any other information on materials and methods incl. tables - (H2) – common block</p> <p>Field not mandatory. In this field, you can enter any information on materials and methods, for which no distinct field is available, or transfer free text from other databases. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. You can also upload any htm or html document.</p> <p>Note: One rich text editor field each is provided for the MATERIALS AND METHODS and RESULTS section. In addition, the fields 'Overall remarks' and</p>	Header 2	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables

	'Executive summary' allow rich text entry.		
Results and discussion	This part of the metabolism study should mainly be reported in a separate tool which is the "MSS composer". Therefore, all detailed results of the metabolism studies should be contained in the XML-file created with the "MSS-composer" and there is no need to fill out the fields of the present section. However, the fields marked as "mandatory" shall be fulfilled to ensure a minimum structured data and to make best use of the report generator.	Header 1	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion
Total radioactive residues		Header 2	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.TotalRadioactiveResidues
Extraction efficiency of radioactive residues using enforcement method	Field not mandatory in the study record. This information shall be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.TotalRadioActiveResidues.ExtractionEfficiencyOfRadioactiveResiduesUsingEnforcementMethod
Quantitation	Field not mandatory in the study record. This information shall be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Multi-line text	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.TotalRadioActiveResidues.Quantitation
TRR results	Field not mandatory in the study record. This		ENDPOINT_STUDY_RECORD.MetabolismIn

	information shall be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		Livestock.ResultsAnd Discussion.TotalRadio activeResidues.TRRR esults
TRRs reached plateau at end of dosing	Field not mandatory in the study record. This information shall be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Open list	ENDPOINT_STUDY_RECORD.MetabolismIn Livestock.ResultsAnd Discussion.TotalRadio activeResidues.TRRs ReachedPlateauAtEnd OfDosing
TRRs as a function of time	Field not mandatory in the study record. This information shall be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		ENDPOINT_STUDY_RECORD.MetabolismIn Livestock.ResultsAnd Discussion.TotalRadio activeResidues.TRRs AsAFunctionOfTime
Graphical plot of TRRs as a function of time	Field not mandatory in the study record. This information shall be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		ENDPOINT_STUDY_RECORD.MetabolismIn Livestock.ResultsAnd Discussion.TotalRadio activeResidues.Graph icalPlotOfTRRsAsAFu nctionOfTime
Other details on total radioactive residues (TRRs)	Field not mandatory in the study record. This information shall be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Text area	ENDPOINT_STUDY_RECORD.MetabolismIn Livestock.ResultsAnd Discussion.TotalRadio activeResidues.TotalR adioactiveResidues
Extraction, characterisation, and distribution of residues		Header 2	ENDPOINT_STUDY_RECORD.MetabolismIn Livestock.ResultsAnd Discussion.Extraction CharacterisationAndD istributionOfResidues

Distribution of parent and metabolites	Field not mandatory in the study record. This information shall be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.ExtractionCharacterisationAndDistributionOfResidues.DistributionOfParentAndMetabolites
Other details on distribution of residues	Field not mandatory in the study record. This information shall be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Text area	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.ExtractionCharacterisationAndDistributionOfResidues.DistributionOfResidues
Storage stability of residues		Header 2	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.StorageStabilityOfResidues
Summary of storage conditions	Field not mandatory in the study record. This information shall be reported via the MSS composer (please make sure that this information is available in the XML-file attached		ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.StorageStabilityOfResidues.SummaryOfStorageConditions
Storage stability of residues (Sample integrity)	Field not mandatory in the study record. This information shall be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Text area	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.StorageStabilityOfResidues.StorageStability
Summary of characterisation and identification of radioactive residues		Header 2	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.SummaryOfCharacterisationAn

			dIdentificationOfRadioactiveResidues
Characterisation and identification of radioactive residues	Field not mandatory in the study record. This information shall be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.SummaryOfCharacterisationAndIdentificationOfRadioactiveResidues. Characterisation and identification of radioactive residues
Other details on characterisation and identification of residues	Field not mandatory in the study record. This information shall be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Text area	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.SummaryOfCharacterisationAndIdentificationOfRadioactiveResidues. Other details on characterisation and identification of residues
General health of animal	Field not mandatory in the study record. This information can be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Text area	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.SummaryOfCharacterisationAndIdentificationOfRadioactiveResidues. General health of animal
Proposed metabolic pathway		Header 2	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.ProposedMetabolicPathway
Identification of compounds from metabolism study	Field not mandatory in the study record. This information shall be reported via the MSS composer (please make		ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.Proposed

	sure that this information is available in the XML-file attached to this record).		MetabolicPathway.Id entificationOfCompoundsFromMetabolismStudy
Metabolic pathway	Field not mandatory in the study record. This information shall be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Rich text area	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.ProposedMetabolicPathway.MetabolicPathway
Metabolic map (picture/graph)	Field not mandatory in the study record. This information shall be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Image	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.ProposedMetabolicPathway.MetabolicMapPictureGraph
Appendix: Metabolites and their parents in treatment groups	Field not mandatory in the study record. This information shall be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Header 2	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.AppendixMetabolitesAndTheirParentsInTreatmentGroups
Any other information on results incl. tables	Field not mandatory in the study record. In this field, you can enter any other remarks on results. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. Note: One rich text editor field each is provided for the MATERIALS AND METHODS and	Header 2	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables

	RESULTS section. In addition, the fields 'Overall remarks' and 'Executive summary' allow rich text entry.		
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.OverallRemarksAttachments
Overall remarks	In this field, you can enter any overall remarks or transfer free text from other databases. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. You can also upload any htm or html document. If you entered the study in the MSS composer and/or if the XML-file created with the MSS-composer is available to you, please generate a word report from the MSS-composer (using the adequate feature in the MSS-composer software) and copy/paste the content of this report in this field. Additional text can be added to complement the basic report generated by the MSS-composer.	Rich text area	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.OverallRemarksAttachments.RemarksOnResults
Attachments	Attach any background document that cannot be inserted in any rich text editor field, particularly image files		ENDPOINT_STUDY_RECORD.MetabolismInLivestock.OverallRem

	(e.g. an image of a structural formula).		arksAttachments.Attachment
Illustration (picture/graph)		Image	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.OverallRemarksAttachments.IllustrationPicGraph
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ApplicantSummaryAndConclusion
Conclusions	Mandatory field in the study record. Write here the Applicant's conclusion of the metabolism study in context of the application.	Text area	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ApplicantSummaryAndConclusion.Conclusions
Executive summary	Mandatory field in the study record. Briefly summarise the relevant aspects of the study including the conclusions reached in the context of the application.	Rich text area	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ApplicantSummaryAndConclusion.ExecutiveSummary

Links to support material:

Please find specific instructions on how to structure the results of metabolism studies plants and livestock under the following link:

<https://www.efsa.europa.eu/en/applications/pesticides/tools>

From the page, users will find all instructions to download the MSS composer (part of the Metapath software package), link to the technical manual for the MSS-composer, detailed information on the data flow for metabolism studies and access to the databases of metapath files.

Specific instructions on the process workflow for metabolism data (including the list of mandatory fields in the MSS composer) are available in the following document:
<https://zenodo.org/record/4785179#.YMjEe6gzbd4>

6.3 Magnitude of residues in plants – Endpoint summary

Endpoint summary for “PRIMARY CROPS”:

Purpose:

To provide a summary overview of the residue levels of all components of monitoring (MO) and risk assessment (RA) residue definitions (RD) in the relevant commodities for the critical GAP(s), to summarize risk assessment values and the MRL proposals and to conclude whether the magnitude of residues in plant (primary crops) was sufficiently elucidated in the context of the present dossier.

ENDPOINT_SUMMARY.MagnitudeResiduesPlants v.2.3 (Final)			
Name	Instructions	Type	Field path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.AdministrativeDataSummary
		Confidentiality	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.AdministrativeDataSummary.DataProtection
Description of key information	<p>Enter a short description of the most relevant endpoint data.</p> <p>Only information on studies for primary crops should be described here. Information on rotational crops should be reported in a separate endpoint summary record.</p>	Header 1	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.KeyInformation
	<p>Please make a statement whether the magnitude of residues in plant (primary crops) was sufficiently elucidated in the context of the present dossier (according to the relevant data requirements and to OECD TG No 509) and highlight data gap(s) and the non-standard uncertainty(ies), if any. Respective detailed parameters on the available key trials used for risk assessment should be reported in the repeatable block "Summary of residues data from the supervised residue</p>	Rich text area	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.KeyInformation.KeyInformation

	trials”, following the instructions below.		
Endpoint	From the picklist select the relevant endpoint addressed by this summary. Here: “residue in crops (field trials)”.	Closed list with remarks	ENDPOINT_SUMMARY. MagnitudeResiduesPlans.KeyInformation.Endpoint
Summary of residues data from the supervised residue trials	Repeat this block to create one “new item” per relevant GAP under assessment.		ENDPOINT_SUMMARY. MagnitudeResiduesPlans.KeyInformation.SummaryResiduesData
Study name / type	Provide here the link to the relevant study(ies) used to derive the endpoints (HR, STMR, MRL...) reported in this table.	Endpoint reference list	ENDPOINT_SUMMARY. MagnitudeResiduesPlans.KeyInformation.SummaryResiduesData.Link
Relevant GAP	This entry refers to GAP linked to the endpoint values reported in this table. Please note that cross-link to GAP is not possible. Therefore, the exact name of the GAP document as reported in the product dataset should be reported in the text box. Enter the document name/s of the GAP document/s from the product dataset in the text box.	MultiLineText2000	ENDPOINT_SUMMARY. MagnitudeResiduesPlans.KeyInformation.SummaryResiduesData.RelevantGap
Plant back interval (PBI)	Not relevant for primary crops. If the endpoint selected is “residue in crops (field trials)”, this field does not appear.	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY. MagnitudeResiduesPlans.KeyInformation.SummaryResiduesData.PlantBackIntervalPBI
Commodity(ies) for which MRL and risk assessment values are derived	Indicate the commodity(ies) for which MRL and risk assessment values are derived. In case of extrapolation, indicate all extrapolated commodities (e.g. apples, pears, quinces, etc.). Please select from the picklist the	Multiselect open list	ENDPOINT_SUMMARY. MagnitudeResiduesPlans.KeyInformation.SummaryResiduesData.CommodityForMrl

	<p>commodity(ies) of plant origin to which MRLs apply according to Part A of Annex I of Regulation (EC) 396/2005.</p> <p>The picklist contains also relevant feed items, to be selected when residue trials provide data on residues in feed items.</p>		
Commodity(ies) used in the residue trials	<p>Please select from the picklist the commodity(ies) of plant origin according to Part A and B of Annex I of Regulation (EC) 396/2005 on which the residue trials were performed (multi-selection is possible)</p> <p>The picklist contains also relevant feed items, to be selected when residue trials provide data on residues in feed items, used to derive STMR, HR and CF for feed items. For feed items not listed, select `Other` and specify.</p>	Multi select open list	ENDPOINT_SUMMARY. MagnitudeResiduesPlans.KeyInformation.SummaryResiduesData.Commodity
Residue levels: RD RA	<p>Report here all results from supervised residue trials for one crop raw agricultural commodity (RAC), e.g. for wheat grain, including the components of the residue definition for risk assessment (RA). Values should be separated by semicolon and sorted by magnitude starting with the lowest value. The residue values below LOQ shall be indicated. For chemicals, values are reported under the default unit [mg/kg].</p>	Multi-line text	ENDPOINT_SUMMARY. MagnitudeResiduesPlans.KeyInformation.SummaryResiduesData.ResidueLevelsRiskAssessment

	For example: <0.01; <0.01; 0.01; 0.05; 0.05; 0.05; 0.05; 0.05 mg/kg.		
Residue levels: RD MO	If residue definition (RD) for risk assessment (RA) and RD for monitoring are different, please report here all results from supervised residue trials relevant for each RAC, e.g. for wheat grain, including the components of the residue definition for monitoring. Values should be separated by semicolon and sorted by magnitude starting with the lowest value. The residue values below LOQ shall be indicated. For chemicals, values are reported under the default unit [mg/kg]. For example: <0.01; <0.01; 0.01; 0.05; 0.05; 0.05; 0.05; 0.05 mg/kg.	Multi-line text	ENDPOINT_SUMMARY. MagnitudeResiduesPlans.KeyInformation.SummaryResiduesData.ResidueLevelsMonitoring
Conversion factor	If RD for RA differ from RD for monitoring insert here the mean conversion factor (CF). CF= [residue concentration] according to RD-RA / [residue concentration] according RD-MO To derive the mean CF, you need to derive the CF for each pair of results (RD-RA/RD-MO) individually and to calculate the average of the series of values.	Decimal	ENDPOINT_SUMMARY. MagnitudeResiduesPlans.KeyInformation.SummaryResiduesData.MeanConversionFactor
Highest residue RD-RA	Enter the supervised trials highest residue value (HR) [default unit is mg/kg] according to	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY. MagnitudeResiduesPlans.KeyInformation.Sum

	the residue definition for risk assessment.		maryResiduesData.HighestResidue
STMR RD-RA	Enter the supervised trials median residue value (STMR) [default unit is mg/kg] according to the residue definition for risk assessment.	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.KeyInformation.SummaryResiduesData.Stmr
Highest residue RD-Mo	Enter the supervised trials highest residue value (HR) [default unit is mg/kg] according to the residue definition for monitoring.	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.KeyInformation.SummaryResiduesData.HighestResidueRDMo
STMR RD-Mo	Enter supervised trails median residue value (STMR) [default unit is mg/kg] according to the residue definition for monitoring.	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.KeyInformation.SummaryResiduesData.STMRRDMo
MRL derived	<p>Enter here the MRL as derived from the submitted residue trials for the commodity(ies) listed under `Commodity(ies) for which MRL and risk assessment values are derived`.</p> <p>Not mandatory for commodities exclusively used as feed items (e.g. wheat straw).</p>	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.KeyInformation.SummaryResiduesData.MrIderived
Provisional	Specify if proposed MRL and risk assessment values are provisional: "yes" or "no"? If "yes", clarify the reason in the remark field..	Closed list with remarks (2000)	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.KeyInformation.SummaryResiduesData.Provisional
Remarks	Please insert here any other remarks, if necessary, relevant for the residue trials data. If the results reported in the block refer to	Text area	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.KeyInformation.SummaryResiduesData.Remarks

	single trial results for pulp (e.g. orange pulp), this should be specified here in the remarks: e.g. "detailed results and risk assessment values derived from pulp". In such a case, no MRL needs to be derived.		
Summary of residues data from the supervised residue trials			
Additional information	Discussion(Header 1) – common block	Header 1	ENDPOINT_SUMMARY. MagnitudeResiduesPlans.Discussion
	Use this field to add any additional useful text on this section. If there is no additional information to be reported this field may be left empty.	Rich text area	ENDPOINT_SUMMARY. MagnitudeResiduesPlans.Discussion.Discussion
Attached background material	Add any additional document that support the above key results (e.g. calculation tables, graphs).		ENDPOINT_SUMMARY. MagnitudeResiduesPlans.Discussion.AttachedBackgroundMaterial
Attached confidential document	The original file only needs to be attached here if it differs from the file in Attached (sanitised) documents for publication.	Single file attachment	ENDPOINT_SUMMARY. MagnitudeResiduesPlans.Discussion.AttachedBackgroundMaterial.AttachedDocument
Attached (sanitised) documents for publication	Add any additional document that support the above key results (e.g. calculation tables, graphs). In support of the MRLs calculated for plant commodities, please also attach here the OECD calculator Excel, available for single and multiple data sets here: https://www.oecd.org/env/ehs/pesticides-biocides/oecdmaximumresiduelimitcalculator.htm .	Attachments list	ENDPOINT_SUMMARY. MagnitudeResiduesPlans.Discussion.AttachedSanitisedDocsForPublication

	<p>If additional calculators (e.g. Kruskal-Wallis.xls to compare dataset) were used in the assessment, they should also be uploaded here</p> <p>The uploaded file should not contain confidential material.</p>		
Remarks		Text	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.Discussion.AttachedBackgroundMaterial.Remarks
Attached background material			

Endpoint summary for “ROTATIONAL CROPS”:

Purpose:

Provide a summary overview of the residue levels of all components of monitoring (MO) and risk assessment (RA) residue definitions (RD) in the relevant rotational crops at various plant back intervals (PBI) covering the maximum soil concentration expected for the active substance (and its soil metabolites) for the use pattern on primary crop under assessment, to summarize risk assessment values and the MRL proposals (if relevant) and to conclude whether the magnitude of residues in rotational crops was sufficiently elucidated in the context of the present dossier and whether restrictions in crop rotation are required.

ENDPOINT_SUMMARY.MagnitudeResiduesPlants v.1.2 (Final)			
Name	Instructions	Type	Field path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.AdministrativeDataSummary
		Confidentiality	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.AdministrativeDataSummary.DataProtection

Description of key information	Enter a short description of the most relevant endpoint data. Only information on studies for rotational crops should be described here. Information on primary crops should be reported in a separate endpoint summary record	Header 1	ENDPOINT_SUMMARY. MagnitudeResiduesPlans.KeyInformation
	Please make a statement whether the magnitude of residues in rotational crops was sufficiently elucidated in the context of the present dossier (according to the current data requirements and to OECD TG 504) and highlight data gap(s) and the non-standard uncertainty(ies), if any. Please indicate here: 1) Whether significant residues are expected in rotational crops, in the context of the present application (i.e. based on the GAP on primary crops under assessment). If no: please provided rationale. If yes: please specify if specific studies investigating the magnitude of residues in rotational crops were reported. 2) If specific studies on the magnitude of residues in rotational crops were reported, please make a statement: - as to whether the study parameters cover	Rich text area	ENDPOINT_SUMMARY. MagnitudeResiduesPlans.KeyInformation.KeyInformation

	<p>the maximum soil concentration expected for the active substance (and its soil metabolites), considering the use pattern on primary crop under assessment.</p> <p>- as to whether those studies can be used to derive MRL and risk assessment values (HR and STMR).</p> <p>Respective detailed parameters and results on the eventual available key trials used for risk assessment should be reported in the detailed table below.</p>		
Endpoint	From the picklist select the relevant endpoint addressed by this summary. Here: "residues in rotational crops (limited field studies)"	Closed list with remarks	ENDPOINT_SUMMARY. MagnitudeResiduesPlans.KeyInformation.Endpoint
Summary of residues data from the supervised residue trials	Repeat this block to create one box per crop group for which risk assessment values and MRLs may be derived from rotational crops.		ENDPOINT_SUMMARY. MagnitudeResiduesPlans.KeyInformation.SummaryResiduesData
Study name / type	Provide here the link to the relevant study(ies) used to derive the endpoints (HR, STMR, MRL...) reported in this table.	Endpoint reference list	ENDPOINT_SUMMARY. MagnitudeResiduesPlans.KeyInformation.SummaryResiduesData.Link
Relevant GAP	<p>This entry refers to GAP linked to the endpoint values reported in this table.</p> <p>As the endpoints values are for residues in rotational crops, the "relevant GAP" here is the primary GAP leading to residues in soil. Please note that cross-link to GAP is not</p>	MultiLineText2000	ENDPOINT_SUMMARY. MagnitudeResiduesPlans.KeyInformation.SummaryResiduesData.RelevantGap

	possible. Therefore, the exact name of the GAP document as reported in the product dataset should be reported in the text box. Enter the document name/s of the GAP document/s from the product dataset in the text box.		
Plant back interval (PBI)	This field appears only if the endpoint selected is "residues in rotational crops (limited field studies)". For rotational crops trials, specify at which PBI (typically 30d, 120d or 365d) the residue results are considered.	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY. MagnitudeResiduesPlans.KeyInformation.SummaryResiduesData.PlantBackIntervalPBI
Commodity(ies) for which MRL and risk assessment values are derived	Indicate the commodity(ies) for which MRL and risk assessment values are derived. Please select from the picklist the commodity of plant origin to which MRLs apply according to Part A of Annex I of Regulation (EC) 396/2005. The picklist contains also relevant feed items, to be selected when residue trials provide data on residues in feed items. For feed items not listed, select 'Other' and specify.	Multi select open list	ENDPOINT_SUMMARY. MagnitudeResiduesPlans.KeyInformation.SummaryResiduesData.CommodityForMrl
Commodity(ies) used in the residue trials	Please select from the picklist the commodity of plant origin according to Part A and B of Annex I of Regulation (EC) 396/2005 on which the residue trials were performed.	Multi select open list	ENDPOINT_SUMMARY. MagnitudeResiduesPlans.KeyInformation.SummaryResiduesData.Commodity

	The picklist contains also relevant feed items, to be selected when residue trials provide residue data in feed items, used to derive STMR, HR and CF for feed items. For feed items not listed, select `Other` and specify.		
Residue levels: RD RA	Report here all results from supervised residue trials for one crop RAC, e.g. for wheat grain, including the components of the residue definition for risk assessment. Values should be separated by semicolon and sorted by magnitude starting with the lowest value. The residue values below LOQ shall be indicated. Values are reported under the default unit [mg/kg]. For example: <0.01; <0.01; 0.01; 0.05; 0.05; 0.05; 0.05; 0.05 mg/kg.	Multi-line text	ENDPOINT_SUMMARY. MagnitudeResiduesPlants.KeyInformation.SummaryResiduesData.ResidueLevelsRiskAssessment
Residue levels: RD MO	If RD for RA and RD for monitoring differ report here all results from supervised residue trials for one crop RAC, e.g. for wheat grain, including the components of the residue definition for monitoring. Values should be separated by semicolon and sorted by magnitude starting with the lowest value. The residue values below LOQ shall be indicated (for example, <0.01 mg/kg). Values	Multi-line text	ENDPOINT_SUMMARY. MagnitudeResiduesPlants.KeyInformation.SummaryResiduesData.ResidueLevelsMonitoring

	are reported under the default unit [mg/kg]. For example: <0.01; <0.01; 0.01; 0.05; 0.05; 0.05; 0.05; 0.05 mg/kg.		
Conversion factor	If RD for RA differ from RD for monitoring insert here the mean conversion factor (CF). CF= [residue concentration] according to RD-RA / [residue concentration] according RD-MO To derive the mean CF, you need to derive the CF for each pair of results (RD-RA/RD-MO) individually and to calculate the average of the series of values.	Decimal	ENDPOINT_SUMMARY. MagnitudeResiduesPlans.KeyInformation.SummaryResiduesData.MeanConversionFactor
Highest residue RD-RA	Enter the supervised trials highest residue value (HR) [default unit is mg/kg] according to the residue definition for risk assessment.	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY. MagnitudeResiduesPlans.KeyInformation.SummaryResiduesData.HighestResidue
STMR RD-RA	Enter the supervised trials median residue value (STMR) [default unit is mg/kg] according to the residue definition for risk assessment.	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY. MagnitudeResiduesPlans.KeyInformation.SummaryResiduesData.Stmr
Highest residue RD-Mo	Enter the supervised trials highest residue value (HR) [default unit is mg/kg] according to the residue definition for monitoring.	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY. MagnitudeResiduesPlans.KeyInformation.SummaryResiduesData.HighestResidueRDMo
STMR RD-Mo	Enter the supervised trails median residue value (STMR) [default unit is mg/kg] according to the residue definition for monitoring.	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY. MagnitudeResiduesPlans.KeyInformation.SummaryResiduesData.STMRDMo

MRL derived	<p>If MRL is derived, please enter here the MRL as derived from the submitted residue trials for the commodity(ies) listed under `Commodity(ies)` for which MRL and risk assessment values are derived`.</p> <p>Not mandatory for commodities exclusively used as feed items (e.g. wheat straw).</p>	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.MagnitudeResiduesPlans.KeyInformation.SummaryResiduesData.MrId derived
Provisional	<p>Specify if proposed MRL and risk assessment values are provisional:"yes" or "no"? If "yes", clarify the reason in the remark field.</p>	Closed list with remarks (2000)	ENDPOINT_SUMMARY.MagnitudeResiduesPlans.KeyInformation.SummaryResiduesData.Prov isional
Remarks	<p>Please insert here any other remarks, if necessary.</p> <p>Please specify which eventual mitigation measures were considered to derive the endpoints above.</p> <p>Indicate whether a rotational crop was planted/sown following a treatment and harvest of primary crop.</p> <p>Indicate whether the proportionality principle was applied to derive the key endpoints (HR, STMR, MRL) and how the scaling factors were derived (e.g. based on soil samples analysis compared to plateau expected concentration (PEC) calculated for the critical GAPs under assessment).</p> <p>Please elaborate on the approach used to derive the MRL proposal and risk</p>	Text area	ENDPOINT_SUMMARY.MagnitudeResiduesPlans.KeyInformation.SummaryResiduesData.Rem arks

	assessment values for rotational crops and indicate if any extrapolations are proposed.		
Summary of residues data from the supervised residue trials			
Additional information	Discussion(Header 1) – common block	Header 1	ENDPOINT_SUMMARY. MagnitudeResiduesPlans.Discussion
	Possibility to add any additional useful text on this section. If there is no additional information to be reported this field may be left empty.	Rich text area	ENDPOINT_SUMMARY. MagnitudeResiduesPlans.Discussion.Discussion
Attached background material	Add any additional document that support the above key results (e.g. calculation tables, graphs).		ENDPOINT_SUMMARY. MagnitudeResiduesPlans.Discussion.AttachedBackgroundMaterial
Attached confidential document	The original file only needs to be attached here if it differs from the file in Attached (sanitised) documents for publication.	Single file attachment	ENDPOINT_SUMMARY. MagnitudeResiduesPlans.Discussion.AttachedBackgroundMaterial.AttachedDocument
Attached (sanitised) documents for publication	Add any additional document that support the above key results (e.g. calculation tables, graphs). In support of the MRLs calculated for plant commodities, please also attach here the OECD calculator Excel, available for single and multiple data sets here: https://www.oecd.org/env/ehs/pesticides-biocides/oecdmaximumresiduelimitcalculator.htm The uploaded file should not contain confidential material.	Attachments list	ENDPOINT_SUMMARY. MagnitudeResiduesPlans.Discussion.AttachedSanitisedDocsForPublication

Remarks		Text	ENDPOINT_SUMMARY. MagnitudeResiduesPlan ts.Discussion.AttachedB ackgroundMaterial.Rem arks
Attached background material			

6.3 Magnitude of residues in plants – Endpoint study record

Purpose:

- Primary crops: Magnitude of residue trials in plants shall allow to quantify the highest likely residue levels of all components of the different residue definitions in treated crops at harvest or outloading from store, in accordance with the proposed GAP, and, to determine, where appropriate, the decline rate of plant protection product residues in plants.
- Rotational crops: Magnitude of residue trials in rotational crops shall permit an evaluation of the magnitude of residues in rotational crops, to decide on restrictions in crop rotation, provide information for assessing the overall relevancy of the residues for dietary risk assessment and to decide on the necessity of MRLs for rotational crops

ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops v.7.2 (Final)			
Name	Instructions	Type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.AdministrativeData
	Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	Confidentiality	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.AdministrativeData.DataProtection
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.DataSource
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods
Product type	Field not mandatory. The product type is already reported in Section 3.2 (Effect on harmful organism,	Open list with remarks	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.ProductType

	function, mode of action and possible resistance). This field is optional.		
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.TestMaterials
Analytical methods		Header 2	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.AnalyticalMethods
Analytical method	<p>"This block of fields can be repeated to cover each analytical methods used to analyse samples (including soil). All combinations of:</p> <ul style="list-style-type: none"> - analytical method - analysed matrix and - analysed substance <p>should be defined to use them in block "Residue".</p>		ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.AnalyticalMethods.AnalyticalMethod
Method ID	<p>Create an ID for the method. This ID should be used in the summary of the residue trials to unambiguously refer to the method used in the trial.</p> <p>In the field "related information", please create a link towards the study record of the used analytical method and its validation. If the study record referred to is duly compiled and contain the data on method validation, the rest of this block is not required.</p>	Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.AnalyticalMethods.AnalyticalMethod.MethodID
Related information	Select the record containing the related	Endpoint reference field	ENDPOINT_STUDY_RECORD.ResiduesInRotati

	<p>study summary of the used analytical method and its validation data are described, thus creating a link.</p> <p>If the study record referred to was duly compiled and contain the data on method validation, further information is not required</p>		<p>onalCrops.MaterialsAndMethods.AnalyticalMethods.AnalyticalMethod.RelatedInformation</p>
Details on analytical methods	<p>Describe methods fully or reference them if previously submitted. It may be sensible to outline the analytical methodology in chapter 'Analytical methods' and include a reference to that method description in field 'Cross-reference to same study'.</p> <p>Use freetext template and delete/add elements as appropriate, or upload predefined table(s), if any, in rich text field 'Any other information on materials and methods incl. tables' or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').</p> <p>The following information should be addressed: Method validation data,</p>	Text template	<p>ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.AnalyticalMethods.AnalyticalMethod.DetailsOnAnalyticalMethods</p>

	<p>recovery and method sensitivity data. Preparation and handling of the sample throughout the method described in detail. Note that methods for metabolites may also be needed. Recovery data should be obtained concurrently with the residue analyses to validate the method and establish its sensitivity (lowest reliable quantification limit). State the LOD and LOQ. Experimental design of these validation studies described including: (1) Identity of the test compounds and crop substrates, (2) Magnitudes of fortification levels, (3) Number of replicates per test compound per level. Identify instrumentation, equipment and reagents used and the operating conditions of the instrumentation. If the extraction/clean-up procedure is complex, a flow diagram should be submitted.</p>		
Combinations of substance and analysed sample portion	Define for each analytical method all relevant combinations of analysed substance and - analysed matrix		ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.AnalyticalMethods.AnalyticalMethod.CombinationsOfSubstanceAndSamplePortion

	to use them in block "Residue levels".		
Analyte identity	<p>Click the Link button to navigate to the Substances Inventory and select the relevant substance name for indicating the identity (i.e. CAS number, CAS name, IUPAC name, SMILES code, molecular formula, structural formula etc.). If not available in the inventory, create a new one. Once stored in the Substances Inventory a reference substance can be re-used in the data set. Depending on the user interface of the software used the identity of the reference substance may only be displayed in a shortened form (e.g. comprising the CAS and IUPAC name), with a link for navigating to the actual record containing the reference substance information.</p> <p>If several compounds are directly analysed together by the analytical method (e.g. a common moiety method), a specific reference substance (being directly a sum of analytes) should be created and referred to. In this case, the results can be directly reported</p>	Entity reference field	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.AnalyticalMethods.AnalyticalMethod.CombinationsOfSubstanceAndSamplePortion.AnalyteIdentity

	<p>for the sum of compounds.</p> <p>In case of isomers please specify if the analyte measured is the sum of isomers (without distinction of isomers) or if specific isomer(s) were analysed separately. A corresponding reference substance may need to be created.</p>		
Analysed sample portion ID	Enter applicants internal code for the analysed sample portion.	Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.AnalyticalMethods.AnalyticalMethod.CombinationsOfSubstanceAndSamplePortion.AnalysedSamplePortionID
Analysed sample portion description	Include a description of the for the analysed sample portion. Field sample may be separated into several analysis samples, e.g., whole orange may be separated into a peel sample and a pulp sample for analysis (in that case also give weights of peel and pulp), aspirated grain fractions are separated from grain.	Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.AnalyticalMethods.AnalyticalMethod.CombinationsOfSubstanceAndSamplePortion.AnalysedSamplePortionDescription
Fortification	This block of fields can be repeated to cover each 'Fortification level'.		ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.AnalyticalMethods.AnalyticalMethod.CombinationsOfSubstanceAndSamplePortion.Fortification
Fortification level	Enter the fortification level.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAnd

			Methods.AnalyticalMethods.AnalyticalMethod.CombinationsOfSubstanceAndSamplePortion.Fortification.FortificationLevel
Recovery (%)	Enter the percentage of recovery.	Decimal	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.AnalyticalMethods.AnalyticalMethod.CombinationsOfSubstanceAndSamplePortion.Fortification.Recovery
Fortification			
Combinations of substance and analysed sample portion			
Analytical method			
Residue trials	This field contains detailed information of supervised residue trials on primary crops performed according to the critical GAP. For rotational crops the residue trials reflect the accumulation of residues in rotational crops via soil uptake following the realistic agricultural practices on primary crops.	Header 2	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern
Trial ID no.	Insert the trial specific, unequivocal identification code For example, Company Internal Code	Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialIdNo
Trial information	This block of fields can be repeated to cover each trial. It includes the nested repeatable block 'Plot' which in turn includes the repeatable blocks 'Application' and 'Sampling'.		ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation

	Please use the repeatable block to report individual trial information. Copy this block of fields for recording the results of each sampling. This option could be deployed in case of small data sets.		
Geographic location and soil characteristics		Header 3	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics
Test site type	Select the type of test site or test facility where the crops were grown, normally 'greenhouse', 'growth chamber' or 'outdoor test plot' for crop study or 'field site' for crop rotation study. If not listed, select 'other:' and specify.	Open list	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.TestSiteType
Geographic location	Trial specific information.	Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.GeographicLocation
Trial deviation	List any deviations which may impact the trial results or study conclusions.	Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.TrialDeviation
Year	Indicate the year in which the first GLP data are collected in trial.	Integer	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.Geo

	Trial may extend over several years.		graphicLocationAndSoil Characteristics.Year
Country or territory	Select the country or the territory of the test site. The names of countries and territories are those prevailing at OECD for names used in lists available on the OECD website or in an OECD document. The codes mentioned between square brackets correspond to the 2-letter ISO codes.	Open list	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAnd Methods.StudyUsePattern.TrialInformation.GeographicLocationAndSoil Characteristics.Country
Geographic region	Select the geographic region of the country.	Closed list	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAnd Methods.StudyUsePattern.TrialInformation.GeographicLocationAndSoil Characteristics.GeographicRegion
State/Province	Select the state/province as applicable depending on the selected country or territory.	Open list	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAnd Methods.StudyUsePattern.TrialInformation.GeographicLocationAndSoil Characteristics.StateProvince
County	Indicate the county as applicable.	Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAnd Methods.StudyUsePattern.TrialInformation.GeographicLocationAndSoil Characteristics.County
City	Indicate the city and the postal code as applicable.	Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAnd Methods.StudyUsePattern.TrialInformation.GeographicLocationAndSoil Characteristics.City

GPS coordinates	<p>Provide the GPS coordinates as applicable. Use any of the following units and formats to specify the latitude and longitude:</p> <ul style="list-style-type: none"> - sexagesimal degree (degrees, minutes, and seconds): e.g. 50° 26' 46" N 80° 58' 56" W - degrees and decimal minutes: e.g. 50° 26.767' N 80° 58.933' W - decimal degrees: e.g. 50.446° N 80.982° W 	Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.GPSCoordinates
Type of crop	For crop rotation studies indicate whether the crop information entered in this field block refers to the primary crop or the rotational crop.	Open list with remarks	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.TypeOfCrop
Type of trial	For residues in crops (field trials) studies indicate type of trial, i.e. decline trial, harvest trial, reverse decline trial, post-harvest trial, seed treatment trial, single unit variability trial, or other:.	Open list with remarks	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.TypeOfTrial
Crop grouping (primary)		Open list	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.CropGroupingPrimary
Crop group	Select the crop group from drop-down list. If	Open list with remarks	ENDPOINT_STUDY_RECORD.ResiduesInRotati

	not listed, select 'other fruit:', 'other vegetables:' or 'other:' and specify.		onalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.CropGroup
Crop	Enter the EPPO name of crop, see EPPO Plant Protection Thesaurus. at http://eppt.eppo.org	Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.Crop
Crop code	Enter the EPPO Code, see EPPO Plant Protection Thesaurus. at http://eppt.eppo.org	Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.CropCode
Crop variety	Specify the crop variety used in the study, e.g. blood orange.	Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.CropVariety
Replant no. (1, 2)	List the consecutive numbers of the replanting. i.e. 1st crop replant = 1, 2nd crop replant = 2.	Integer	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.ReplantNo
Date of planting	Enter the date of planting.	Date	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.DateOfPlanting
Date of seeding	Enter the date of planting.	Date	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoil

			Characteristics.DateOfSeedling
Date of flowering (beginning)	Enter the date of the beginning of flowering.	Date	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.DateOfFloweringBeginning
Date of flowering (end)	Enter the date of the end of flowering.	Date	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.DateOfFloweringEnd
Date of harvest (beginning)	Enter the date of the beginning of harvest.	Date	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.DateOfHarvestBegin
Date of harvest (end)	Enter the date of the end of harvest.	Date	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.DateOfHarvestEnd
Crop plant back interval	Specify the time in days after application.	Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.CropPlantBackInterval
Crop information / history	All cultural information pertaining to planting, culture and trial-history of primary crop(s) or rotational crops, planting dates, rainfall and irrigation (accumulated from	Text template	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.CropInformation

	application), temperature data.		
Soil characterization	Describe the soil type.	Multi-line text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.SoilCharacterization
Other details on test crops	Include other details on test crops.	Text area	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.OtherDetailsOnTestCrops
Plot description		Header 3	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription
Plot	This block of fields can be repeated to cover each plot. It includes the nested repeatable blocks 'Application' and 'Sampling'.		ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot
Plot ID	Unequivocal plot identification e.g. consecutive number.	Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.PlotID
Control plot	Indicate if this plot is a "control plot".	Closed list	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.ControlPlot
Corresponding control plot ID	Plot ID of the corresponding control plot. A control plot	Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.Plot

	could be used in different test plots.		Description.Plot.CorrespondingControlPlotID
Plot description	Describe plot specific information which are not described in other sections in detail, e.g. plot size or area, row spacing, plant spacing, plants/area, crop height, seeding rates, number of seeds/area, leaf wall area (LWA, applicable for high crops only), etc.	Multi-line text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.PlotDescription
Environmental conditions	Describe environmental conditions information which are not described in other sections in detail eg. abnormal weather conditions, soil properties, any other environmental effect that might have had an impact on the results observed in this study.	Multi-line text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.EnvironmentalConditions
Other details on test site	Describe details on testing environment information which are not described in other sections in detail including crop and pesticide history on the trial site for the three years preceding the study, rationale for selection of trial site, location of test and control sites (as appropriate attach map of test plots indicating their location, topography, and location and size of of control plots in relation	Text template	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.DetailsOnTestSite

	to test plots), environmental conditions experienced during the course of the study (i.e., temperature, rainfall, sunlight), and soil characteristics (not required for materials applied to foliage) at the testing site such as soil type, % sand, % silt, % clay,% organic matter, cation exchange capacity and pH. Use freetext template and delete/add elements as appropriate or upload predefined table(s), if any, in rich text field 'Any other information on materials and methods incl. tables' or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').		
Application		Header 4	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.Application
Application	This block of fields can be repeated to cover each application of a given plot.		ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.Application.Application
Application no. (1, 2)	List the consecutive numbers of the applications. i.e. 1st	Integer	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAnd

	crop replant = 1, 2nd crop replant = 2. In the case of seed treatment, the sowing of the seeds is the first application.		Methods.StudyUsePattern.TrialInformation.PlotDescription.Plot.Application.Application.ApplicationNo
Bare soil	For crop rotational studies indicate if the application was on bare soil or not.	Closed list	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.Application.Application.BareSoil
Growth stage code (BBCH) at application	Enter the code of the BBCH-scale system or an interval of two codes separated by "-" eg. 99 or 99-99.	Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.Application.Application.GrowthStageCode
Growth stage description at application	Enter the description of the growth stage at application.	Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.Application.Application.GrowthStage
Date of application	Enter the date of application.	Date	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.Application.Application.DateOfApplication
Method of application	Select the method of application.	Open list	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.Application.Application.MethodOfApplication
Seeding rate	Enter the seeding rate.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.Plot

			Description.Plot.Applica tion.Application.Seeding Rate
Thousand grain weight	Enter the thousand grain weight.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RE CORD.ResiduesInRotati onalCrops.MaterialsAnd Methods.StudyUsePatte rn.TrialInformation.Plot Description.Plot.Applica tion.Application.Thousa ndGrainWeight
Applied test material	This block of fields can be repeated to cover each test material for a given application. Because products applied for crop maintenance should have no effect on the residue of interest, these products do not need to be reported in this block.		ENDPOINT_STUDY_RE CORD.ResiduesInRotati onalCrops.MaterialsAnd Methods.StudyUsePatte rn.TrialInformation.Plot Description.Plot.Applica tion.Application.TestIte m
Test material information	Select the appropriate TMI record. If not available in the repository, create a new one. You may also copy an existing TMI record, edit it and store it as new TMI.	Entity reference field	ENDPOINT_STUDY_RE CORD.ResiduesInRotati onalCrops.MaterialsAnd Methods.StudyUsePatte rn.TrialInformation.Plot Description.Plot.Applica tion.Application.TestIte m.TestMaterialInformat ion
Description of test item	Add additional information which was not part of the universal Test material information block (TMI). Information regarding tested pesticide product, end-use product, formulation, treated/dressed seed, tank mix adjuvants etc. used in the test item applied to the trial plot, crop, and/or the harvested commodity.	Multi-line text	ENDPOINT_STUDY_RE CORD.ResiduesInRotati onalCrops.MaterialsAnd Methods.StudyUsePatte rn.TrialInformation.Plot Description.Plot.Applica tion.Application.TestIte m.DescriptionOfTestIte m
Formulation type	Select the formulation type.	Open list	ENDPOINT_STUDY_RE CORD.ResiduesInRotati onalCrops.MaterialsAnd

			Methods.StudyUsePattern.TrialInformation.PlotDescription.Plot.Application.Application.TestItem.FormulationType
Trade name	Provide the trade name, company developmental code or other.	Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.Application.Application.TestItem.TradeName
Active ingredients (a.i.)	This block of fields can be repeated to cover each test item for a given application.		ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.Application.Application.TestItem.ActiveIngredients
Related substance information	Each component should be cross referenced to a 'Real' Substance definition in IUCLID.	Entity reference field	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.Application.Application.TestItem.ActiveIngredients.RelatedSubstanceInfo
Name of a.i.	Indicate the name of the active ingredient, trade name or company developmental code or other.	Multi-line text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.Application.Application.TestItem.ActiveIngredients.NameOfAI
Nominal a.i. content	Indicate the nominal a.i. content of the test substance.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.Application.Application.TestItem.ActiveIngredients.NominalAIContent
Applied amount (actual)	State the actual application rate, anticipated/targeted use rate (label rate) of	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePatte

	the test material (formulated product).		rn.TrialInformation.PlotDescription.Plot.Application.Application.TestItem.ActiveIngredients.AppliedAmountActual
Amount a.i./seed (actual)	Indicate the amount a.i./seed (actual).	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.Application.Application.TestItem.ActiveIngredients.AmountAISEedActual
Applied amount (cumulative nominal)	State the cumulative amount of test substance a.i. actually applied to the plot with all applications so far. For instance if this is the third application, add amounts applied in application 1 + application 2 + application 3. The Rate a.i./area has to be taken into consideration if seed treatment is involved along with additional foliar applications.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.Application.Application.TestItem.ActiveIngredients.AppliedAmountCumulative
Adjuvant added	Indicate the additive type, additive name, content added in spray volume (%), actual additive amount.	Multi-line text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.Application.Application.TestItem.ActiveIngredients.AdjuvantAdded
Amount of water used in spray application (nominal)	Indicate the amount of water used in spray application (nominal).	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.Application.Application.TestItem.ActiveIngredients.AmountOfWaterUsedInSpray
Active ingredients (a.i.)			

Applied test material			
Application			
Other details on application	Include other details on preharvest interval(s), post-treatment crop maintenance and in the case of fruit tree treatments the height of crown and the application rate per meter height of crown.	Text	ENDPOINT_STUDY_ROTATIONALCROPS.MATERIALSANDMETHODS.StudyUsePattern.TrialInformation.PlotDescription.Plot.Application.OtherDetailsOnApplication
Sampling		Header 4	ENDPOINT_STUDY_ROTATIONALCROPS.MATERIALSANDMETHODS.StudyUsePattern.TrialInformation.PlotDescription.Plot.SamplingAndAnalyticalMethodology
Details on sample collection	Include details on sampling time which are not reported in detail in the section "Summary of residues" (age of crop in days) for rotational crop RACs; stages of crop development at each sampling point (e.g., at forage hay and grain stages), number of samples/replicates. Use free text template and delete/add elements as appropriate.	Text template	ENDPOINT_STUDY_ROTATIONALCROPS.MATERIALSANDMETHODS.StudyUsePattern.TrialInformation.PlotDescription.Plot.SamplingAndAnalyticalMethodology.DetailsOnSampleCollection
Details on sample handling and preparation	Details on sample handling and preparation which are not reported in detail in the section "Summary of residues".	Text template	ENDPOINT_STUDY_ROTATIONALCROPS.MATERIALSANDMETHODS.StudyUsePattern.TrialInformation.PlotDescription.Plot.SamplingAndAnalyticalMethodology.DetailsOnSampleHandlingAndPreparation

Sampling and analysis of soil		Header 4	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.SamplingAndAnalysisOfSoil
Details on sampling of soil	If soil residues were determined, include details on the sampling, sampling method and handling and preparation of samples. Use freetext template and delete/add elements as appropriate, or upload predefined table(s), if any, in rich text field 'Any other information on materials and methods incl. tables' or adapt table(s) from study report.	Text template	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.SamplingAndAnalysisOfSoil.DetailsOnSamplingOfSoil
Details on analytical methodology for soil residues	If soil residues were determined, include details on the analytical methodology applied for the identification and characterisation of the residues. Use freetext template and delete/add elements as appropriate, or upload predefined table(s), if any, in rich text field 'Any other information on materials and methods incl. tables' or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1'). The following	Text template	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.SamplingAndAnalysisOfSoil.DetailsOnAnalyticalMethodologyForSoilResidues

	<p>information should be addressed:</p> <p>ANALYTICAL METHODOLOGY</p> <ul style="list-style-type: none"> - Description of instrumentation, equipment and reagents used for determining total radioactivity in each sample. Give a detailed description of the analytical method employed to measure residues and listing of which chemical species were measured (parent pesticide, metabolites). If the methodology is described in chapter 'Analytical methods', you can include a cross-reference to that record in field 'Cross-reference to other study'. - Description of the extraction schemes: state 'see graphic attached' if a figure is attached in field 'Illustration (picture/graph)' in 'Overall remarks, attachments'. - Description of extraction and fractionation of radioactivity in each matrix - Chromatographic and spectroscopic behaviour of radioactive residues in extracts of animal matrices, parent, metabolites, and reference standards <p>t analytical methods if</p>		
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	<p>reported in this report. As appropriate, upload predefined table(s), if any, in rich text field 'Any other information on results incl. tables' or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').</p>		
Plot			
Trial information			
Any other information on materials and methods incl. tables	<p>Any other information on materials and methods incl. tables - (H2) – common block</p> <p>In this field, you can enter any information on materials and methods, for which no distinct field is available You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document. For example, tables summarizing the details on sampling time (age of crop in days) for rotational crop RACs; stages of crop development at each sampling point (e.g., at forage hay and grain stages), number of samples/replicates. For rotational crop trials if soil residues were determined, in `Sampling and analysis of soil` include details</p>	Header 2	<p>ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables</p>

	on the sampling, sampling method and handling and preparation of soil samples.		
	In this field, you can enter any information on materials and methods, for which no distinct field is available, or transfer free text from other databases. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. You can also upload any htm or html document. Note: One rich text editor field each is provided for the MATERIALS AND METHODS and RESULTS section. In addition the fields 'Overall remarks' and 'Executive summary' allow rich text entry.	Rich text area	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables.OtherInformation
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion
Storage stability of residues (Sample integrity)	Where samples were not analysed within 30 days, provide evidence showing that the storage did not affect the results of the study. Provide here the information on how long the residue field	Text area	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.StorageStability

	<p>samples were stored prior to analysis and under which conditions. Specify whether the conditions of storage of the samples of the present studies are covered by the most limiting storage conditions for which stability of the relevant residues has been demonstrated. Provide justification for deviations, if any. Typically, reference should be made to Section 6.1 where storage stability data showing the behaviour of residues as a function of time in plant commodities have been reported. By reference to the endpoint summary on storage stability (Section 6.1), please specify whether the conditions of storage of the samples of the present studies are covered by the most limiting storage conditions for which stability of the relevant residues has been demonstrated.</p>		
Summary of residues	<p>Please use the repeatable block to report individual results, for each sampling and for each relevant analyte. Copy this block of fields for recording the results of each sampling. This option could be deployed in case of small data sets.</p>	Header 2	<p>ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops</p>
Sampling and residues	<p>Enter a consecutive sampling number and</p>		<p>ENDPOINT_STUDY_RECORD.ResiduesInRotati</p>

	describe the sampled material. Specify the residue level of each analyte determined for each sampling instance. Copy this block of fields for recording the results of multiple samplings.		onalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues
Trial ID no.	Trial specific, unequivocal identification code. For example, Company Internal Code.	Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.TrialIDNo
Plot ID	Unequivocal plot identification, e.g. consecutive number (already used in block "Plot description").	Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.PlotID
Sampling ID	Unique sample identification code.	Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.SamplingID
Sampling timing	Provide any information regarding the timing of the sampling, e.g. relation to application events, days after last application, etc.	Open list with remarks	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.SamplingTiming
Growth stage code (BBCH) at sampling	Enter the code of the BBCH-scale system or an interval of two codes separated by "-" eg. 99 or 99-99.	Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.GrowthStageCode
Growth stage description at sampling	Enter the code of the BBCH-scale system and a description of the growth stage at application.	Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops

			ps.SamplingAndResidue s.GrowthStage
Date of sampling	Enter the date of sampling.	Date	ENDPOINT_STUDY_RE CORD.ResiduesInRotati onalCrops.ResultsAndDi scussion.SummaryOfRa dioactiveResiduesInCro ps.SamplingAndResidue s.DateOfSampling
Sampling information	Description of sampling method, special remark (e.g. cabbage was harvested according to agricultural practice, 1st set of outer leaves were removed), sample handling (e.g. samples were frozen within 24 hours).	Multi-line text	ENDPOINT_STUDY_RE CORD.ResiduesInRotati onalCrops.ResultsAndDi scussion.SummaryOfRa dioactiveResiduesInCro ps.SamplingAndResidue s.SamplingInformation
Sampled material / commodity (Field RAC sample) code	Specify the sampled material / commodity (field RAC sample). Raw agricultural commodity (RAC) means the product in or nearly in its natural state intended for sale or consumption without further processing, or for processing into food for sale to the consumer. It includes irradiated primary food commodities and products after removal of certain parts of the plant. The term RAC means the same as "primary food commodity" or "primary feed commodity". The codes and names of raw agricultural commodities contained in the picklist are extracted from the Codex Classification of Foods and Animal Feeds, issued by the Joint FAO/WHO Food Standards Programme. The following Classes	Open list	ENDPOINT_STUDY_RE CORD.ResiduesInRotati onalCrops.ResultsAndDi scussion.SummaryOfRa dioactiveResiduesInCro ps.SamplingAndResidue s.SampledMaterialCom modity

	<p>and Types are included with all their groups:</p> <ul style="list-style-type: none"> - Class A Primary Food Commodities of Plant Origin; -Type 1 Fruits; - Type 2 Vegetables; - Type 3 Grasses; -Type 4 Nuts and seeds; Type 5 Herbs and spices (Codes starting with FB, FC, FI, FP, FS, FT, GC, GS, HH, HS, SB, SO, TN, VA, VB, VC, VD, VL, VO, VP, VR and VS) - Class C Primary Feed Commodities; Type 11 Primary feed commodities of plant origin (Codes starting with AL, AF, AM, AS and AV). <p>The field should be empty, if no appropriate Sampled material / commodity could be found in the Codex Classification of Foods and Animal Feeds.</p>		
Sampled material / commodity (Field RAC sample) description	Specify the sampled material / commodity.	Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.SampledMaterialCommodityDescription
Residue levels	Specify residue level of each analyte determined for this sampling instance. Copy this block of fields for recording the results of repetitions and for multiple analytes.		ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.ResidueLevels
Method ID	Identify the analytical method that was used to obtain this result. This should cross-reference with Method	Link to repeatable entry	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidue

	ID in the block "Analytical methods".		s.ResidueLevels.Method ID
Analyte identity	<p>Click the Link button to navigate to the Substances Inventory and select the relevant substance name for indicating the identity (i.e. CAS number, CAS name, IUPAC name, SMILES code, molecular formula, structural formula etc.). If not available in the inventory, create a new one.</p> <p>Once stored in the Substances Inventory a reference substance can be re-used in the data set.</p> <p>Depending on the user interface of the software used the identity of the reference substance may only be displayed in a shortened form (e.g. comprising the CAS and IUPAC name), with a link for navigating to the actual record containing the reference substance information.</p> <p>If several compounds are directly analysed together by the analytical method (e.g. a common moiety method), a specific reference substance (being directly a sum of analytes) should be created and referred to. In this case, the results can be directly reported for the sum of compounds.</p>	Entity reference field	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.ResidueLevels.Analyte Identity

	In case of isomers please specify if the analyte measured is the sum of isomers (without distinction of isomers) or if specific isomer(s) were analysed separately. A corresponding reference substance may need to be created.		
Analysis sample portion ID	Include "Analysed sample portion ID" which was defined in block "Analytical methods".	Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.ResidueLevels.AnalysisSampleDescription
Extraction date	Enter the date of extraction.	Date	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.ResidueLevels.ExtractionDate
Analysis date	Enter the date of analysis.	Date	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.ResidueLevels.AnalysisDate
Storage stability factor	Factor that allows for the correction of residue results in cases where analytes are not stable throughout the duration of the study. Depending on the relevant regulation corrected data may be provided in addition, but not instead of measured data. This refers also to data	Decimal	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.ResidueLevels.StorageStabilityFactor

	which are corrected for recovery.		
Use of storage stability factor	e.g., linear, first-order, etc	Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.ResidueLevels.UseOfFactor
Correction by storage stability	Nor relevant for PPP applications. The correction by Storage Stability Factor was done?	Closed list	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.ResidueLevels.CorrectionByStorageStability
Recovery	Nor relevant for PPP applications. List the average recovery that was obtained for this analyte in this matrix. This allows for the correction of the analytical results for the recovery, if desired	Decimal	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.ResidueLevels.Recovery
Correction by recovery	Nor relevant for PPP applications. The correction by recovery was done?	Closed list	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.ResidueLevels.CorrectionByRecovery
Reference portion	Specify for which part of plant or commodity the residue is calculated	Multi-line text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.ResidueLevels.ReferencePortion
Residue level (measured)	Enter the result as measured (i.e. based on the measured analyte), without recalculation and correction for storage stability.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues

	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.		s.ResidueLevels.ResidueLevelMeasured
Calculated analyte identity	Click the Link button to navigate to the Substances Inventory and select the relevant substance name for indicating the identity (i.e. CAS number, CAS name, IUPAC name, SMILES code, molecular formula, structural formula etc.). If not available in the inventory, create a new one. Once stored in the Substances Inventory a reference substance can be re-used in the data set. Depending on the user interface of the software used the identity of the reference substance may only be displayed in a shortened form (e.g. comprising the CAS and IUPAC name), with a link for navigating to the actual record containing the reference substance information.	Entity reference field	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.ResidueLevels.CalculatedAnalyteIdentity
Residue level (calculated)	Enter the result expressed as the calculated analyte (e.g. acid expressed as carboxylic ester), without correction for storage stability or recovery.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.ResidueLevels.ResidueLevelCalculated

	<p>Note: Depending on the relevant regulation corrected data may be provided in addition, but not instead of measured data. This refers also to data which are corrected for recovery.</p> <p>Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.</p>		
Residue level (calculated and corrected)	<p>Not relevant for PPP applications.</p> <p>Enter the result expressed as the calculated analyte (e.g. acid expressed as carboxylic ester), after correction for storage stability and/or recovery.</p> <p>Depending on the relevant regulation corrected data may be provided in addition, but not instead of measured data. This refers also to data which are corrected for recovery.</p> <p>Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.</p>	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.ResidueLevels.ResidueLevelCorrected

Residue levels			
Total / mean	Specify the total (mean) of the parent compound and eventual metabolite(s), if for instance it is relevant for the residue definition for risk assessment purpose.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.TotalMean
Sampling and residues			
Any other information on results incl. tables	In this field, you can enter any information on materials and methods, for which no distinct field is available, or transfer free text from other databases. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document.	Header 2 Applicants summary and conclusion – common block	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
		Rich text area	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables.OtherInformation
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.OverallRemarksAttachments
Applicant's summary and conclusion		Header 1	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ApplicantSummaryAndConclusion
Interpretation of results	Select applicable conclusion from the picklist	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ApplicantSummaryAndConclusion.InterpretationOfResults
Conclusions	The assessment and conclusion of the applicant should be reported here.	Text area	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ApplicantSu

			mmaryAndConclusion.C onclusions
Executive summary	<p>The assessment and conclusion of the applicant should be reported here.</p> <p>Briefly summarise the relevant aspects of the study(ies) including the conclusions reached. If a specific format is prescribed, copy it from the corresponding document or upload it if provided as htm or html document.</p> <p>Example for supervised residue trials on primary crops: [Number] field trials for [active ingredient] on [crop(s)] were conducted in [country] during the [year] growing season. At each trial location, [describe timing and method of application; formulation used, rate, treatment interval and seasonal application rates of [xx] g ai/ha]. An adjuvant [was or was not] added to the spray mixture for all applications. [Crops] were harvested at a preharvest interval (PHI) of [xx] days. In [one] trial, samples were collected at different time intervals (PHIs of x, xx, xxx days) to monitor residue decline. All samples were maintained frozen at the testing facility, during shipping to the laboratory, and were stored frozen until analysis. The</p>	Rich text area	ENDPOINT_STUDY_RE CORD.ResiduesInRotati onalCrops.ApplicantSu mmaryAndConclusion.E xecutiveSummary

	<p>maximum storage interval for samples between harvest and analysis was [xx] days/months. Residues of [active ingredient] have been shown to be stable in [crops] for up to [xx] days under frozen conditions. Adequate storage stability data are therefore available to support the storage conditions and intervals for samples in the current trials. Samples in the current study were analyzed using Method [Method ID], a [describe method] to determine residues of [list analytes]. Acceptable [method validation and] concurrent recoveries were reported for [matrices] samples at fortification levels of [xx] mg/kg, thus validating the method. The limit of quantitation (LOQ) was [xx] per analyte for [matrices]. Individual sample (and per-trial average) residues in [matrix] ranged from [xx] mg/kg to [yy] mg/kg. [Include for each matrix and/or variation in use pattern in the study]. Residue decline data show that residues of [active ingredient/metabolite] [increase/decrease/are unchanged/are too variable to assess decline] in</p>		
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	<p>[commodities] with increasing PHIs.</p> <p>Example for rotational crop field trials: [Number] field trials for [active ingredient] on [crop(s)] as rotational crops were conducted in [country] during the [year] growing season. At each trial location, [describe timing and method of application (specify bare soil or primary crop); formulation used, rate, treatment interval and seasonal application rates of [xx] g ai/ha). An adjuvant [was or was not] added to the spray mixture for all applications. [Describe growth/maintenance of primary crop, if applicable]. [Crops] were planted into treated plots at plant-back intervals (PBIs) of [xx, yy, and zz] days. Crops were harvested at maturity and prepared for residue analysis. All samples were maintained frozen at the testing facility, shipped and stored frozen until analysis. The maximum storage duration for samples between harvest and analysis was [xx] days/months. Residues of [active ingredient] have been shown to be stable in [crops] for up to [xx] days under frozen conditions. Adequate storage stability data are</p>		
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	<p>therefore available to support the storage conditions and intervals for samples in the current trials. Samples in the current study were analyzed using Method [Method ID], a [describe method] to determine residues of [list analytes]. Acceptable [method validation and] concurrent recoveries were reported for [matrices] samples at fortification levels of [xx] mg/kg, thus validating the method. The limit of quantitation (LOQ) was [xx] mg/kg per analyte for [matrices]. The results from these trials show that quantifiable residues of [list analytes] are not expected to occur at PBIs greater than [xx] days. At a PBI of [yy] days, individual sample residues ranged from [xx] ppm to [yy] ppm (Crop 1), [xx] ppm to [yy] ppm (Crop 2), and [xx] ppm to [yy] ppm (Crop 3). [Address other PBIs as needed.]</p>		
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6.4 Feeding studies – Flexible summary

Purpose:

Summary overview of the residue levels of all components in products of animal origin which result from residues in feed.

Information on the relevant animal matrix for the calculated animal burdens in order to summarise the risk assessment values and the proposals for MRLs and to determine whether the magnitude of residues in products of animal origin has been sufficiently elucidated in the context of the present dossier.

Note: Feeding studies shall be provided where metabolism studies indicate that residues at levels of above 0,01 mg/kg may occur in edible animal tissue, milk, eggs or fish, taking into account the residue levels in potential feeding stuffs, obtained at the 1 × dose rate, calculated on the dry weight basis. Feeding studies shall not be required where intake is below 0,004 mg/kg bw/day, except in cases where the residue, that is to say the active substance, its metabolites or breakdown products, as defined in the residue definition for risk assessment, tends to accumulate.

FLEXIBLE_SUMMARY.ResiduesInLivestock– v.1.2 (Final)			
Name	Instructions	Data type	Field path
Administrative data	Administrative data summary – common block	Header 1	FLEXIBLE_SUMMARY.ResiduesInLivestock.AdministrativeDataSummary
Description of the key informations	Enter a short description of the most relevant endpoint data derived from the livestock feeding studies and the calculated dietary burdens.	Text area	
Key value for chemical safety assessment		Header 1	FLEXIBLE_SUMMARY.ResiduesInLivestock.KeyValueForChemicalSafetyAssessment
Dietary burden	Provide here the results of the calculated livestock dietary burden for each relevant species (one new item per species). Repeat the block for each species. The dietary burden results reported here are the ones used to derive the MRL and risk assessment values in animal commodities that are reported in the second part of the present document.		FLEXIBLE_SUMMARY.ResiduesInLivestock.KeyValueForChemicalSafetyAssessment.DietaryBurden
RD RA (plant/feed)	Provide the plant risk assessment residue definition (valid for all plants including feed and processed feed item) for which this dietary burden is calculated.	Multi-line text	FLEXIBLE_SUMMARY.ResiduesInLivestock.KeyValueForChemicalSafetyAssessment.DietaryBurden.RDRAPlantFeed
Animal species	Select the animal species, which the calculated dietary burden refers to.	Closed list	FLEXIBLE_SUMMARY.ResiduesInLivestock.KeyValueForChemicalSafetyAssessment.DietaryBurden.AnimalSpecies
Median dietary burden (mg/kg bw per day)	Report the Median dietary burden (mg/kg bw per day) calculated for the selected animal species.	Unit measure with Closed List (Decimal)	FLEXIBLE_SUMMARY.ResiduesInLivestock.KeyValueForChemicalSafetyAssessment.DietaryBurden.MedianDietaryBurdenMgKgBwPerDay

Maximal dietary burden (mg/kg bw per day)	Report the Maximal dietary burden (mg/kg bw per day) calculated for the selected animal species.	Unit measure with Closed List (Decimal)	FLEXIBLE_SUMMARY.ResiduesInLivestock.KeyValueForChemicalSafetyAssessment.DietaryBurden.MaximalDietaryBurdenMgKgBwPerDay
Median dietary burden (mg/kg DM)	Report the Median dietary burden (mg/kg dry matter) calculated for the selected animal species.	Unit measure with Closed List (Decimal)	FLEXIBLE_SUMMARY.ResiduesInLivestock.KeyValueForChemicalSafetyAssessment.DietaryBurden.MedianDietaryBurdenMgKgDM
Maximal dietary burden (mg/kg DM)	Report the Maximal dietary burden (mg/kg dry matter) calculated for the selected animal species.	Unit measure with Closed List (Decimal)	FLEXIBLE_SUMMARY.ResiduesInLivestock.KeyValueForChemicalSafetyAssessment.DietaryBurden.MaximalDietaryBurdenMgKgDM
Trigger exceeded?	Conclude ("Yes" or "No") whether the trigger value is exceeded according to the relevant data requirement.	Closed list	FLEXIBLE_SUMMARY.ResiduesInLivestock.KeyValueForChemicalSafetyAssessment.DietaryBurden.TriggerExceeded
Remarks	Additional remarks on the calculated dietary burden result for the given species.	Text area	FLEXIBLE_SUMMARY.ResiduesInLivestock.KeyValueForChemicalSafetyAssessment.DietaryBurden.Remarks
Dietary burden			
Summary of residues data from feeding studies	Expected key information: MRL derived, median and highest residue levels (STMR and HR) for each animal matrix (i.e. muscle, fat, liver, kidney, milk, eggs, etc.) based on the results of the feeding studies and comparison with dietary burden calculations. MRL and risk assessment values reported here are derived from the dietary burden results reported above. Repeat the block for each animal tissue.		FLEXIBLE_SUMMARY.ResiduesInLivestock.KeyValueForChemicalSafetyAssessment.SummaryOfResiduesDataFromFeedingStudies
Link to relevant study record(s)	Link to the relevant study record.	Endpoint reference list	FLEXIBLE_SUMMARY.ResiduesInLivestock.KeyValueForChemicalSafetyAssessment.SummaryOfResiduesDataFromFeedingStudies.LinkToRelevantStudyRecordS
Highest residue RD-RA	Enter the highest residue according to the residue definition for risk assessment. [default unit "mg/kg"]	Unit measure with	FLEXIBLE_SUMMARY.ResiduesInLivestock.KeyValueForChemicalSafetyAssessment

		Closed List (Decimal)	essment.SummaryOfResiduesDataFromFeedingStudies.HighestResidueRDRA
STMR RD-RA	Enter supervised trails median residue value according to the residue definition for risk assessment. [default unit "mg/kg"]	Unit measure with Closed List (Decimal)	FLEXIBLE_SUMMARY.ResiduesInLivestock.KeyValueForChemicalSafetyAssessment.SummaryOfResiduesDataFromFeedingStudies.STMRRDRA
Highest residue RD-Mo	Enter the highest residue according to the residue definition for monitoring. [default unit "mg/kg"]	Unit measure with Closed List (Decimal)	FLEXIBLE_SUMMARY.ResiduesInLivestock.KeyValueForChemicalSafetyAssessment.SummaryOfResiduesDataFromFeedingStudies.HighestResidueRD Mo
STMR RD-Mo	Enter supervised trails median residue value according to the residue definition for monitoring. [default unit "mg/kg"]	Unit measure with Closed List (Decimal)	FLEXIBLE_SUMMARY.ResiduesInLivestock.KeyValueForChemicalSafetyAssessment.SummaryOfResiduesDataFromFeedingStudies.STMRRDMo
MRL derived Provisional	<p>This field refers to the MRL which is derived from the dietary burden reported in the present document. MRL is always expressed according to the residue definition for monitoring [default unit "mg/kg"].</p> <p>All MRLs should be listed as basis for the decision on the MRL proposal to be reported in the summary report MRL.</p>	Unit measure with Closed List (Decimal)	FLEXIBLE_SUMMARY.ResiduesInLivestock.KeyValueForChemicalSafetyAssessment.SummaryOfResiduesDataFromFeedingStudies.MRLDerived
	If proposed MRL and risk assessment values are provisional ("yes"), clarify the reason in the additional remark field .	Closed list with remarks (2000)	FLEXIBLE_SUMMARY.ResiduesInLivestock.KeyValueForChemicalSafetyAssessment.SummaryOfResiduesDataFromFeedingStudies.Provisional
Remarks	<p>Specify here the animal tissue or product (e.g. cattle muscle/fat/liver/kidney, sheep muscle/fat/liver/kidney, poultry cattle muscle/fat/liver/kidney, cattle milk, sheep milk, poultry eggs...) for which MRL and risk assessment values were calculated in this block.</p> <p>This field can also be used to report any further additional remark regarding the calculated MRL and</p>	Text area	FLEXIBLE_SUMMARY.ResiduesInLivestock.KeyValueForChemicalSafetyAssessment.SummaryOfResiduesDataFromFeedingStudies.Remarks

	risk assessment values, that could not be reported in the above table.		
Conversion factor (CF)	Conversion factor between enforcement and risk assessment derived from the results of the feeding study.	Decimal	FLEXIBLE_SUMMARY.ResiduesInLivestock.KeyValueForChemicalSafetyAssessment.SummaryOfResiduesDataFromFeedingStudies.ConversionFactorCF
Summary of residues data from feeding studies			
Additional information	Discussion (Header 1) – common block Provide additional information related to the endpoint, for example: <ul style="list-style-type: none"> - information on the potential data gaps - relevance of the results for the risk assessment 	Header 1	FLEXIBLE_SUMMARY.ResiduesInLivestock.Discussion

6.4 Feeding studies – Endpoint study record

Purpose:

Residues in Livestock studies are conducted in order to quantify levels of residues in meat, milk, eggs and edible meat by-products (e.g. fat, liver, kidney), following the use of a pesticide product on feed plant commodities. The studies are conducted according to OECD TG 505 and provide data on the quantitative transfer of residues, i.e. factor between residue level in the diet and residue levels in edible commodities (milk, eggs, tissues).

Residues in Livestock studies are typically conducted in ruminants (cattle) and poultry (laying hen). In general, the results of cattle feeding studies may be extrapolated to other domestic animals (ruminants, horses, pigs, rabbits and others) and laying hen feeding studies to other types of poultry (turkey, goose, duck and others). Please create one Endpoint study record per feeding study. Extrapolations should be specified in the endpoint summary above.

If feeding studies are not required in the context of the present application, please specify

NB: If you used a metabolism study as a proxy to conclude that residues exceeding the LOQ are expected in some matrices or if the calculated intakes indicate that existing MRLs have to be changed, additional calculations based on the livestock feeding study data have to be performed in order to set/update the MRL values for products of animal origin.

ENDPOINT_STUDY_RECORD.ResiduesInLivestock v.7.2(Final)			
Name	Instructions	Type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.AdministrativeData

	See Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	Confidentiality	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.AdministrativeData.DataProtection
Endpoint	<p>Select relevant endpoint from picklist, here: "Residues in livestock". In some cases there is only one endpoint title, which may be entered automatically depending on the software application. If multiple study types are covered by the same data entry form, the specific study type should be selected. If none matches, select the more generic endpoint description '<Generic endpoint>', other' (e.g. Skin irritation / corrosion, other) and give an explanation in the adjacent text field. The generic endpoint title reflects the title of the corresponding OECD Harmonised Template (OHT).</p> <p>Please note: For (Q)SAR studies the generic endpoint title should be selected, normally with no need to fill in the adjacent text field, as '(Q)SAR' needs to be indicated in field 'Type of information' and the model should be described in field 'Justification of non-standard information' or 'Attached justification'. A specific endpoint title may be used, if addressed by</p>	Closed list with remarks	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.AdministrativeData.Endpoint

	<p>the (Q)SAR information, i.e. the model behind has been validated by experimental data addressing this endpoint.</p> <p>Note: For the purpose of OHTs, an 'endpoint' is defined in the rather broad sense as an observable or measurable inherent property of a chemical substance which may be specified by the relevant regulatory framework as 'information requirement' (e.g. Boiling point, Sub-chronic toxicity: oral, Fish early-life stage toxicity). In a narrower sense, the term '(eco)toxicity endpoint' refers to an outcome or effect observed in a study.</p>		
Type of information	<p>Select the appropriate type of information, e.g. ' experimental study', ' experimental study planned' or, if alternatives to testing apply, '(Q)SAR', 'read-across ...'. In the case of calculated data, the value 'calculation (if not (Q)SAR)' should only be chosen if the study report does not clearly indicate whether it is based on '(Q)SAR'. If the information is taken from a handbook or review article, select the relevant item, e.g. 'experimental study', if this is provided in the information source.</p>	Open list with remarks	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.AdministrativeData.StudyResultType

	<p>Otherwise select 'not specified'. Please note: In field 'Reference type' the option 'review article or handbook' should be selected. In general, the option 'not specified' should be selected if the submitter lacks the knowledge of the type of information. The option 'other:' can be used if another than a pre-defined item applies.</p> <p>In the case of read-across, follow the instructions related to the relevant legislation, for instance as to whether the (robust) study summary should be entered in a separate data set defined for the read-across (source) substance and referenced in the target substance dataset.</p> <p>If 'experimental study planned' or 'experimental study planned (based on read-across)' is indicated (in some legislations also defined as 'testing proposal' or 'undertaking of intended submission'), the submitter should include as much information as possible on the planned study in order to support the evaluation of the proposal. Typically, this would include at least</p>		
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	<p>the test guideline, information on the test material, the species and the route of administration in the corresponding distinct fields, as appropriate. Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on whether specific fields should be completed and/or further details should be attached in field 'Attached background material'.</p>		
Adequacy of study	<p>Indicate the adequacy of a (robust) study summary in terms of usefulness for hazard/risk assessment purposes depending on the relevant legislation. Note: This field is only applicable (or active) if neither 'waiving of standard information' nor 'experimental study planned' has been selected in field 'Type of information'. Explanation:</p> <ul style="list-style-type: none"> - key study: In general, a key study is the study that has been identified as most suitable to describe an endpoint from the perspective of quality, completeness and representativity of data. - supporting study: Any other adequate study that is considered supportive for the key 	Closed list	<p>ENDPOINT_STUDY_RECORD.ResiduesInLivestock.AdministrativeData.PurposeFlag</p>

	<p>study or key studies.</p> <ul style="list-style-type: none"> - weight of evidence: A record that contributes to a weight of evidence justification for the non-submission of a particular (adequate) study. The weight of evidence justification is normally endpoint-related, i.e. based on all available records included in the weight of evidence evaluation. A short reasoning for why a given record is used in this respect can be provided in field 'Detailed justification / remarks'. - disregarded due to major methodological deficiencies: study that demonstrates a higher concern than the key study/ies, but is not used as key study because of flaws in the methodology or documentation. This phrase should be selected for justifying why a potentially critical result has not been used for the hazard assessment. The lines of argumentation should be provided in field 'Rationale for reliability incl. deficiencies', accompanied by the appropriate reliability score. - other information: any other non-relevant information which does not need to be flagged 		
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	<p>specifically as 'disregarded due to major methodological deficiencies'.</p> <p>Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field.</p>		
Robust study summary	<p>Set this flag if relevant for the respective regulatory programme or if otherwise useful as filter for printing or exporting records flagged as 'Robust Study Summary' or in combination with 'Adequacy of study'.</p> <p>Explanation: The term 'Robust Study Summary' is actually used only to describe the technical content of a very detailed summary of an experimental study or of any other relevant information. It is a priori no synonym with the term 'Key study', although a key study should usually be submitted in the form of Robust Study Summary. However, a Robust Summary may also be useful for other adequate studies that are considered supportive of the key study or even for inadequate studies if they can be used for a weight-of-evidence analysis. Also for</p>	Check box	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.AdministrativeData.RobustStudy

	<p>studies that are flawed, but indicate critical results, Robust Study Summaries highlighting the weaknesses of the studies need to be elaborated.</p> <p>Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field.</p>		
Used for classification	<p>Set this flag if relevant for the respective regulatory programme or if otherwise useful as filter for printing or exporting records flagged as 'Used for classification'.</p> <p>Explanation: In some use cases it may be necessary to indicate those records that are used for the classification of that substance, e.g. according to UN GHS. If not relevant, disregard this field.</p> <p>Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field.</p>	Check box	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.AdministrativeData.UsedForClassification
Used for SDS	<p>Set this flag if relevant for the respective regulatory programme or if otherwise useful as filter for printing or exporting records flagged as 'SDS information'.</p>	Check box	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.AdministrativeData.UsedForMSDS

	<p>Explanation: 'SDS' stands for Safety Data Sheet. In some use cases it may be necessary to indicate those records that are used for the compilation of SDS information. If not relevant, disregard this field.</p> <p>Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field.</p>		
Study period	<p>If applicable indicate the period during which the study was conducted, i.e. start and end date, using an unambiguous date format, e.g. 'From 12 MAY 1999 to 15 AUG 2000' or 'From May 12, 1999 to Aug. 15, 2000'.</p> <p>Note: Independent of the study period the in-life period (i.e. the phase of a study following treatment in which the test system is alive/growing) may have to be specified for some toxicology endpoints.</p>	Text	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.AdministrativeData.StudyPeriod
Reliability	<p>Enter an appropriate reliability score, according to Klimisch et al. (1997):</p> <p>1 = reliable without restrictions: "studies or data [...] generated according to generally</p>	Open list	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.AdministrativeData.Reliability

	<p>valid and/or internationally accepted testing guidelines (preferably performed according to GLP) or in which the test parameters documented are based on a specific (national) testing guideline [...] or in which all parameters described are closely related/comparable to a guideline method."</p> <p>2 = reliable with restrictions: "studies or data [...] (mostly not performed according to GLP), in which the test parameters documented do not totally comply with the specific testing guideline, but are sufficient to accept the data or in which investigations are described which cannot be subsumed under a testing guideline, but which are nevertheless well documented and scientifically acceptable."</p> <p>3 = not reliable: "studies or data [...] in which there were interferences between the measuring system and the test substance or in which organisms/test systems were used which are not relevant in relation to the exposure (e.g. non-physiological</p>		
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	<p>pathways of application) or which were carried out or generated according to a method which is not acceptable, the documentation of which is not sufficient for assessment and which is not convincing for an expert judgment.”</p> <p>4 = not assignable: “studies or data [...] which do not give sufficient experimental details and which are only listed in short abstracts or secondary literature (books, reviews, etc.).”</p> <p>The 'other:' option may be selected if a different scoring system is used. Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field.</p> <p>Note: This field is only applicable (or active) if neither 'waiving of standard information' nor 'experimental study planned' has been selected in field 'Type of information'.</p> <p>Note: The term reliability defines the inherent quality of a test report or publication relating to preferably standardised</p>		
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	methodology and the way the method and results are described. More detailed criteria can be selected in field 'Justification'.		
Rationale for reliability incl. deficiencies	<p>Select an appropriate standard justification from the picklist, e.g. 'Comparable to guideline study with acceptable restrictions'. Additional explanations (e.g. deficiencies observed) can be entered in the related supplementary text field. Particularly if reliability scores 2 or 3 are assigned, indicate the concrete arguments for defending a study or relevant deficiencies.</p> <p>For QSAR results (i.e. 'Type of information' is '(Q)SAR') some pre-defined phrases are provided for indicating if the prediction results are considered reliable based on the scientific validity of the (Q)SAR model used, its applicability to the query substance, and the adequacy of reporting. Please note: If (Q)SAR results are flagged as key study in field 'Adequacy of study', the relevance of the model used for the regulatory endpoint should be documented in the field where the (Q)SAR model is described, i.e.</p>	Open list with remarks (32000)	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.AdministrativeData.RationalReliability

	'Justification for type of information', 'Attached justification' or 'Cross-reference'.		
Data waiving	<p>If appropriate, indicate here that the study has been waived, i.e. not performed. Select the basis from the picklist (e.g. 'study technically not feasible' or 'other justification'). Include a more detailed justification in the field 'Justification for data waiving' and, as needed, in field 'Justification for type of information', 'Attached justification' and/or 'Cross-reference'.</p> <p>Please note: the option 'study scientifically not necessary / other information available' covers cases where it can be justified that performance of a specific study prescribed by the relevant legislation is scientifically not necessary because reliable information is provided in other part(s) of the submission document. The option 'study waived due to provisions of other regulation' can be used for indicating that another, overlapping regulation allows or requires the waiving of a specific information requirement. This should then be detailed</p>	Closed list	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.AdministrativeData.DataWaiving

	<p>in the justification fields.</p> <p>If waiving is based on several lines of argumentation (e.g. 'exposure considerations' and 'study scientifically not necessary / other information available'), create separate records for each.</p> <p>Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use data waivers.</p>		
Justification for data waiving	<p>In addition to the more generic justification selected in the preceding field 'Data waiving', it is highly recommended to provide a detailed justification. To this end you can either select one or multiple specific standard phrase(s) if it/they give an appropriate rationale of the description given in the preceding field 'Data waiving' or 'other:' and enter free text. Additional specific explanations should be provided if the pre-defined phrase(s) do not sufficiently describe the justification.</p> <p>More details can be provided using the following fields:</p> <ul style="list-style-type: none"> - Text field adjacent to this field 'Justification for data waiving' 	Multi select open list with remarks (32000)	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.AdministrativeData.DataWaivingJustification

	<p>(available after selecting any picklist item in this field);</p> <ul style="list-style-type: none"> - Field 'Justification for type of information'; - Field 'Attached justification'; - Cross-reference (for referencing / linking to a justification or information referred to in the justification which is stored in another record, e.g. a record describing physico-chemical properties information used to support a data waiver) <p>Please note: The pre-defined phrases are not necessarily exhaustive and may not always apply. Consult the guidance documents and waiving options in the relevant regulatory frameworks. If no suitable phrase is available from the picklist, enter a free text justification using the 'other:' option.</p>		
Justification for type of information	<p>This field can be used for entering free text. As appropriate, one of the freetext templates can be selected (e.g. Justification for read-across (analogue)) to use pre-defined headers and bulleted elements. Delete/add elements as appropriate.</p> <p>Consult any programme-specific</p>	Text template	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.AdministrativeData.JustificationForTypeOfInformation

	<p>guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on what should be taken into account when providing justifications or whether specific reporting formats should be used.</p> <p>Explanations:</p> <p>Option 1: Type 'Waiving of standard information':</p> <p>This field should be used for entering any further lines of argumentation, if necessary, in addition to those provided in the field 'Justification for data waiving'.</p> <p>Option 2: Type 'Experimental study planned / Testing proposal':</p> <p>Further details can be entered here on the study design / methodology proposed in addition to details given in the distinct fields on test guideline, test material, species, route of administration and other relevant fields.</p> <p>Option 3: Type 'QSAR prediction':</p> <p>Based on this freetext template details on the</p>		
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	<p>QSAR model used can be given, in addition to the information provided in field 'Principles of method if other than guideline'.</p> <p>Please note: Any information that can be re-used for several study summaries can be entered once and then assigned to the relevant studies using either the 'Attached justification' or 'Cross-reference' feature.</p> <p>Option 4: Type 'Read-across (analogue)' and Option 5: Type 'Read-across (category)'</p> <p>This freetext template can be used and modified as appropriate for providing a justification for read-across, particularly if it is endpoint-specific.</p> <p>Please note: Any information that can be re-used for several study summaries can be entered once and then assigned to the relevant studies using either the 'Attached justification' or 'Cross-reference' feature.</p>		
Attached justification	<p>The Attached justification feature can be used in case the justification is best provided in form of attached document(s). Copy this block of fields</p>		<p>ENDPOINT_STUDY_RECORD.ResiduesInLivestock.AdministrativeData.AttachedJustification</p>

	for attaching more than one file. Refer to the relevant legislation-specific guidance document as to the recommended use of the Attached justification feature.		
Attached justification	Upload file by clicking the upload icon.	Single file attachment	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.AdministrativeData.AttachedJustification.AttachedJustification
Reason / purpose	Indicate the reason for / purpose of the attached document. Select the relevant item from the picklist or, if none applies, select 'justification, other:' and specify.	Closed list with remarks	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.AdministrativeData.AttachedJustification.ReasonPurpose
Attached justification			
Cross-reference	The cross-reference feature can be used to refer to related information that is provided in another record of the dataset. This can be done either by entering just free text in the 'Remarks' field or by creating a link to the relevant record. The field 'Reason / purpose' allows for selecting a standard reason from the picklist and optionally to add free text explanation in the related supplementary text field. Refer to the relevant legislation-specific guidance document as		ENDPOINT_STUDY_RECORD.ResiduesInLivestock.AdministrativeData.CrossReference

	to the recommended use of cross-references.		
Reason / purpose for cross-reference	<p>Select the appropriate reason of the cross-reference, i.e.</p> <ul style="list-style-type: none"> - assessment report (for referring to a record that contains an assessment report as attachment) - data waiving: supporting information (for referring to a record containing relevant endpoint information that is used to justify a data waiver) - exposure-related information (for referring to a record containing exposure-related information that is used for instance to justify a data waiver) - read-across source (for linking to another study summary used for read-across. This can be useful in cases where results are derived from one or several read-across sources and recorded in a separate (target) study summary.) - read-across supporting information (for linking to another record which contains read-across justification that applies also for the current study summary) - (Q)SAR model reporting (OMRF) (for referring to a record containing the relevant 	Open list with remarks	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.AdministrativeData.CrossReference.Reason Purpose

	<p>model description. Note: The (Q)SAR prediction should be reported specifically for each endpoint in the field 'Justification for type of information'.)</p> <ul style="list-style-type: none"> - reference to other assay used for intermediate effect derivation (for optional indication in a study summarising 'intermediate effects' if reference is made to the outcome of another assay) - reference to same study (e.g. if different species were tested and the results recorded in different records), - reference to other study (e.g. if another study is considered relevant in the interpretation of the test results), - other: (to be specified). 		
Related information	As appropriate, select the record containing the related information, thus creating a link.	Endpoint reference field	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.AdministrativeData.CrossReference.RelatedInformation
Remarks	This field can be used for including any remarks.	Text area	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.AdministrativeData.CrossReference.Remarks
Cross-reference			
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.DataSource

Reference	<p>Indicate the bibliographic reference of the study report or publication the study summary is based on. Provide general information such as Title, Author, Year, Bibliographic source, Testing Facility, Report Number, Study number, Report date etc., as requested in the core template for literature search (http://www.oecd.org/ehs/templates/Generic%20elements%20for%20all%20OHTs%20(added%20online%20Feb%202017).zip).</p> <p>Always enter the primary reference in the first block of fields or sort it to the first position, if there are more than one reference to be cited. Copy this block of fields for specifying any other references related to this record (e.g. report of a preliminary study or other documentation). If results of a study report have been published, indicate the full citation of that publication(s) in addition to the reference of the original study.</p>	Literature reference list	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.DataSource.Reference
Data access	Select appropriate indication for data access. Enter 'Not applicable' if the summary consists of	Open list with remarks	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.DataSource.DataAccess

	<p>information that is commonly accessible such as guidance on safe use.</p> <p>Select 'data submitter has permission to refer' if the information requirement can be covered based on a permission to refer to old data as issued by the relevant regulatory agency. In addition, provide, in the adjacent free-text field, the statement according to instructions you received from the relevant regulatory authority together with the permission to refer.</p>		
Data protection claimed	<p>Indicate as appropriate. Note: 'yes' should be selected only if 'Data submitter is data owner' or 'Data submitter has Letter of Access'. Options 'yes, but willing to share' or 'yes, but not willing to share' may be relevant for specific regulatory programmes where the submitter is requested to indicate whether he is willing to share studies conducted (e.g. with vertebrates). In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. 'for</p>	Closed list with remarks	<p>ENDPOINT_STUDY_RECORD.ResiduesInLivestock.DataSource.DataProtectionClaimed</p>

	justification see attached document X')		
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods
Background information	Use this field to include any background information, if required, or any relevant introductory remarks on the study summary. Leave field empty if not applicable. Do not include information for which specific fields are provided. For instance, include any background information on the test substance in fields on 'Test materials'.	Multi-line text	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.BackgroundInformation
Product type	introduction	Open list with remarks	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.ProductType
Type of study	<p>Indicate the type of study in terms of exposure source. Select either 'livestock feeding', 'direct animal treatment', 'livestock feeding and direct animal treatment', 'animal premise treatment' or 'other:' (specify). In the supplementary remarks field, you can add explanations as appropriate.</p> <p>Most frequent options in the context EU PPP assessments: "livestock feeding"</p>	Open list	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.TypeOfStudy

Test guideline	Material and methods – common block		ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.Guideline
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.TestMaterials
Test animals		Header 2	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.TestAnimals
Species	Select name of species. Multiple selection is possible, but it is strongly recommended to use separate records for each animal species studied. You can include a cross-reference, in field 'Same study also described in chapter:', to the record where the methodology is described in detail.	Multi select open list	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.TestAnimals.Species
Details on housing conditions and test animals	Include details on housing conditions and test animals. Use free text template and delete/add elements as appropriate, or upload predefined table(s), if any, in rich text field 'Any other information on materials and methods incl. tables' or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1'). The following information should be addressed: HOUSING / HOLDING AREA: Describe the test facilities, i.e. animal	Text template	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.TestAnimals.DetailsOnHousingConditionsAndTestAnimals

	<p>housing including size of enclosures, individual vs. group housing, food and water containers, temperature, lighting, and waste handling.</p> <p>TEST ANIMALS: Include information on breed, age, weight, stage of development, health status and condition of test animals.</p>		
Details on dietary regime	<p>Include details on dietary regime. Use free text template and delete/add elements as appropriate, upload predefined table(s), if any, in rich text field 'Any other information on materials and methods incl. tables' or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').</p> <p>The following information should be addressed:</p> <ul style="list-style-type: none"> - Composition of diet: Describe the diet of animals during acclimation and the dosing period regarding: <ul style="list-style-type: none"> (1) Types of feed (e.g., corn grain, layers mash, alfalfa pellets) and liquids; (2) Quantities provided (i.e., specific amounts or ad libitum). - Feed consumption: Report the feed consumption (dry weight for ruminants) on an individual or 	Text template	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.TestAnimals.DetailsOnDietaryRegime

	<p>treatment group basis throughout the study.</p> <ul style="list-style-type: none"> - Water: Report water consumption - Acclimation period: specify 		
Administration / exposure		Header 2	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.AdministrationExposure
Treatment type (route of exposure)	<p>Select the treatment type used which determines the primary route of exposure in the study. Multiple selection is possible if, in specific situations, direct application of a product to livestock was studied in addition to exposure through feeding of treated crops.</p> <p>Most frequent options in the context EU PPP assessments:</p> <p>Oral: "capsule" or "applied on feed"</p>	Multi select open list	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.AdministrationExposure.TreatmentTypeRouteOfExposure
Frequency of dosing	<p>The frequency of application / dosing if the test material is not incorporated into the total diet or feed.</p> <p>Note: Reporting of the dates of the initial and final doses/applications may also be required. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.</p>	Multi-line text	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.AdministrationExposure.FrequencyOfDosing
Dosing duration	<p>Indicate the total length of the dosing period (e.g. 20 days).</p>	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.AdministrationExposure.DosingDuration

Doses / concentrations	Indicate the dose rates (feeding levels) as "mg/kg bw per day" (also possible mg/kg diet, mg/animal/day). If diet is the route of administration, the level of the test material in the total diet may be reported in parts per million (mg/kg feed) (dry weight basis for ruminants).	Multi-line text	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.AdministrationExposure.DosesConcentrations
Dose / conc.	Enter numeric value with unit (recommended "mg/kg bw/day".	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.DoseConc
Remarks	Enter any remarks related to dose / concentration values, e.g. feeding level.	Multi-line text	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.Remarks
Doses / concentrations			
Details on dosing	Include further details on the preparation of dose and the dosing regimen. If diet is the route of administration, use free text template (delete/add elements as appropriate) or formulate otherwise or upload predefined table(s), if any, in rich text field 'Any other information on materials and methods incl. tables' or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').	Text template	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.AdministrationExposure.DetailsOnDosing

	<p>PREPARATION OF DOSE: Describe the method of preparation of the dose (mixing with feed or concentrate ration, gelatine capsule, bolus, etc.). Indicate the date of dose preparation and storage conditions prior to its administration.</p> <p>RATIONALE FOR SELECTION OF DOSE LEVELS: Briefly describe, i.e. Level of intake expected, Exaggerated levels. Provide justification for other than the recommended dosing scheme.</p> <p>ANALYSIS OF SPIKED FEED: Describe the method used to analyse spiked feeds and the results of such analyses. If the methodology is described in chapter 'Analytical methods', you can include a cross-reference to that record in the block 'Cross-reference'.</p> <p>DOSING REGIME: Using an appropriate predefined table indicate the dosing regimen used.</p>		
No. of animals per dose group	Report the number of animals per dose group, e.g. "3 cows per feeding level".	Multi-line text	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.AdministrationExposure.NoOfAnimalsPerDoseGroup
Control animals	Indicate whether and what type of concurrent control groups were used. Multiple selection is possible. If not listed, select 'other' and specify.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.AdministrationExposure.ControlAnimals

Further details on study design		Header 2	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.FurtherDetailsOnStudyDesign
Further details on study design	Include any further relevant details on the study design.	Text area	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.FurtherDetailsOnStudyDesign.FurtherDetailsOnStudyDesign
Details on sampling and analytical methods	<p>Include details on the sampling, handling and preparation of samples and the analytical methodology applied. Use freetext template and delete/add elements as appropriate, or upload predefined table(s), if any, in rich text field 'Any other information on materials and methods incl. tables' or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').</p> <p>The following information should be addressed:</p> <p>IN-LIFE SAMPLING</p> <ul style="list-style-type: none"> - Milk / eggs collected: Explain the collection of milk and eggs with any deviations from normal practice explained. Note compositing or pooling of samples; no pooling of milk from animals within a dosage group. - Amount of milk and number of eggs 	Text template	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.FurtherDetailsOnStudyDesign.DetailsOnSamplingAndAnalyticalMethods

	<p>produced during normal production: Provide data as indicated.</p> <p>- Urine, faeces, cage wash collected: For feed-through pesticides, include data on urine, feces and cage wash.</p> <p>POST-SLAUGHTER SAMPLING</p> <p>- Mode of sacrifice: Describe</p> <p>- Interval from last dose or treatment to sacrifice: Describe the time interval in hours or days between time of sacrifice and administration of last dose or application of final treatment. Give an explanation of intervals longer than 24 hours and consideration of their effect on residues.</p> <p>- Tissue harvested and their weights: Indicate the tissues taken after sacrifice, their type (e.g., thigh muscle, omental fat, etc.), and their weights.</p> <p>- Specification of and combining of samples from different animals: Indicate if pooling was done (usually acceptable for poultry, but not ruminants).</p> <p>SAMPLE HANDLING AND PREPARATION: Describe the handling of tissues, eggs and milk between sample</p>		
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	<p>collection and storage addressing at least following items:</p> <ul style="list-style-type: none"> - Sample preparation prior to storage: e.g., chopping - Containers - Storage temperature - Length of storage: Include dates of collection, shipping, analysis, etc. - Mode of shipping, if applicable: <p>ANALYTICAL METHODOLOGY</p> <p>The method and its validation should be reported in Section 4 of the dossier 'Analytical methods', using a specific study record. Please cross-refer to the analytical methods and its validation using the "cross reference" block (see instructions in common block). If the study record referred to was duly compiled and contain the data on method validation, further information is not required in the present document.</p> <p>In the study record created for this method (and its validation) in Section 4 of the dossier, the following information is expected:</p>		
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	<ul style="list-style-type: none"> - Description of instrumentation, equipment and reagents used: Give a detailed description of the analytical method employed to measure residues and listing of which chemical species were measured (parent pesticide, metabolites). If the methodology is described in chapter 'Analytical methods', you can include a cross-reference to that record in the block 'Cross-reference'. - Extraction schemes: state 'see graphic attached' if a figure is attached in field 'Illustration (picture/graph)' in 'Overall remarks, attachments'. - Description of extraction and fractionation of radioactivity in each matrix - Chromatographic and spectroscopic behaviour of radioactive residues in extracts of animal matrices, parent, metabolites, and reference standards - The LOQ for all animal matrices analysed and, if available, the LOD and a description of how the LOQ and LOD were determined. 		
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Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
	In this field, you can enter any information on materials and methods, for which no distinct field is available, or transfer free text from other databases. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. You can also upload any htm or html document.	Rich text area	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables.OtherInformation
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ResultsAndDiscussion
Storage stability	Provide storage stability data showing the behavior of residues as a function of time in tissues, milk, and eggs. Where samples were not analysed within 30 days, provide evidence showing that the storage did not affect the results of the study. Typically, reference should be made to Section 6.1 where storage stability data showing the behaviour of residues as a function of time in tissues, milk, and eggs have been reported. By reference to the endpoint summary on	Text area	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ResultsAndDiscussion.StorageStability

	storage stability (Section 6.1), please specify whether the conditions of storage of the samples of the present studies are covered by the most limiting storage conditions for which stability of the relevant residues has been demonstrated.		
Residue data	<p><u>Enter a consecutive sampling number and specify the matrix / tissue sampled, sampling time and dose/feeding level. In a nested repeatable block, multiple analytes and repetitions can be recorded with the residue levels.</u></p> <p><u>Copy this block of fields for each different sampling instance.</u></p>		ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ResultsAndDiscussion.ResidueData
Sampling no.	<p>Important clarification: Please note that detailed sampling numbers should be reported in the nested blocks below, for each analytical repetition of each analyte. Therefore, this field is not relevant for reporting sampling numbers.</p> <p>Instead, this field should be used to indicate the animal number to which the residue data summarised in this repeatable block refers. For example, if three different goats were used in a lactating goat</p>	Multi select closed list	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ResultsAndDiscussion.ResidueData.SamplingNo

	feeding study, please indicate if the block refers to Animal #1, Animal #2 or Animal #3. Although multiple numbers can be selected, this function should not be used.		
Matrix / tissue sampled	Select the matrix / tissue analysed from the drop-down list. Further details can be entered as free text in the related supplementary text field, for instance the animal number. If not listed, select 'other:' and specify.	Open list with remarks	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ResultsAndDiscussion.ResidueData.MatrixTissueSampled
Sampling date	Report the days after the first dose or the actual date in ISO 8601 format (e.g. 2021-05-22).	Text	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ResultsAndDiscussion.ResidueData.SamplingDate
Sampling time	Report phase of the day the sampling took place, for milk/egg sampling.	Open list	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ResultsAndDiscussion.ResidueData.SamplingTime
Slaughter interval	Report time between last dose and sacrifice, for tissue.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ResultsAndDiscussion.ResidueData.SlaughterInterval
Additional information on the sampling procedure	Report any additional information regarding the sampling procedure, if applicable.	Multi-line text	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ResultsAndDiscussion.ResidueData.AdditionalInformationOnTheSamplingProcedure
Feeding level	Specify the feeding level, typically 1, 2 or 3.	Integer	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ResultsAndDiscussion

			on.ResidueData.FeedingLevel
Dose (mg/kg bw)	Specify the dose in mg/kg bw.	Decimal	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ResultsAndDiscussion.ResidueData.DoseFeedingLevel
Analyte measured	Specify residue level of each analyte determined for this sampling instance. Copy this block of fields only if there is a need for recording the results for multiple analytes. If only one analyte (e.g. parent compound) was analysed in the study, no need to repeat this block.		ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ResultsAndDiscussion.ResidueData.AnalyteMeasured
Analyte identity	Click the Link button to navigate to the Substances Inventory and select the relevant substance name for indicating the identity (i.e. CAS number, CAS name, IUPAC name, SMILES code, molecular formula, structural formula etc.). If not available in the inventory, create a new one. Once stored in the Substances Inventory a reference substance can be re-used in the data set. Depending on the user interface of the software used the identity of the reference substance may only be displayed in a shortened form (e.g. comprising the CAS and IUPAC name), with a link for navigating to the actual record containing the	Entity reference field	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ResultsAndDiscussion.ResidueData.ResidueLevels.AnalyteIdentity

	<p>reference substance information.</p> <p>If several compounds are directly analysed together by the analytical method (e.g. a common moiety method), a specific reference substance (being directly a sum of analytes) should be created and referred to. In this case, the results can be directly reported for the sum of compounds.</p> <p>In case of isomers please specify if the analyte measured is the sum of isomers (without distinction of isomers) or if specific isomer(s) were analysed separately. A corresponding reference substance may need to be created.</p>		
Residue level	<p>Enter the result as measured (i.e. based on the measured analyte), without recalculation and correction for storage stability.</p> <p>Copy this block of fields for recording the results of analytical repetitions. The mean calculated from all analytical repetitions should be reported after this repeatable block.</p>		ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ResultsAndDiscussion.ResidueData.AnalyteMeasured.ResidueLevel

Analysed sample ID	Report the sample number/ID that was measured.	Text	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ResultsAndDiscussion.ResidueData.AnalyteMeasured.ResidueLevel.AnalysedSampleID
Residue level	Report the measured level of the residue mentioned afore. [Typical unit :“mg/kg”]	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ResultsAndDiscussion.ResidueData.AnalyteMeasured.ResidueLevel.ResidueLevel
Residue level			
Mean residue level	Enter the mean residue level of the replicates data provided above [Typical unit :“mg/kg”]	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ResultsAndDiscussion.ResidueData.AnalyteMeasured.MeanResidueLevel
Remarks	Enter any additional information, e.g. the storage stability factor and how it was used in cases the residue level is based on a corrected value. Also correction by recovery if any can be indicated.	Text	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ResultsAndDiscussion.ResidueData.ResidueLevels.Remarks
Analyte measured			
Total / mean	Specify the total (mean) of the relevant analytes reported above. Typically: sum of the parent compound and relevant metabolite(s), if for instance this calculated result is in line with the residue definition. If only one analyte (e.g. parent compound) was analysed in the	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ResultsAndDiscussion.ResidueData.TotalMean

	study, please ignore this field..		
Residue data			
Recoveries	Provide recovery percentages (all values, not just averages or ranges) for the test substance and/or its metabolites for tissues, milk, and eggs fortified with these compounds. If the method is described in another record, you can include a reference to that method description using the 'Cross-reference' feature. As appropriate, upload predefined table(s), if any, in rich text field 'Any other information on results incl. tables' or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').	Text area	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ResultsAndDiscussion.Recoveries
Depuration	Provide the results of depuration studies, if any. If a separate depuration study was done, you can include a reference to that record using the 'Cross-reference' feature. As appropriate, upload predefined table(s), if any, in rich text field 'Any other information on results incl. tables' or adapt table(s) from study report. Use table numbers in the sequence in which you	Text area	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ResultsAndDiscussion.Depuration

	refer to them in the text (e.g. '... see Table 1').		
Residue transfer	Outline the conclusion reached as to whether residues of the pesticide transfer from feed items, direct application to meat, milk and eggs. If so, discuss the extent of transfer. Indicate the time needed to reach a plateau level in eggs and milk, respectively. The results can be summarized in a table (the preferable format) showing either the ranges or maximum residues in type each of sample for each feeding level. As appropriate, upload predefined table(s), if any, in rich text field 'Any other information on results incl. tables' or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').	Text area	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ResultsAndDiscussion.ResidueTransfer
Any other information on results incl. tables		Header 2	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
	In this field, you can enter any other remarks on results. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was	Rich text area	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables.OtherInformation

	converted to the HTML format.		
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ApplicantSummaryAndConclusion
Conclusions	Enter any conclusions if applicable in addition to the information given in fields 'Key results' and 'Interpretation of results' (if any).	Text area	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ApplicantSummaryAndConclusion.Conclusions
Executive summary	<p>Briefly summarise the relevant aspects of the study including the conclusions reached. Example: [Active ingredient] was administered [method of administration] to [number and breed] of [animal] for [duration] consecutive days. Dosing was made at [list dosing levels in mg/kg feed]. [Report details on depuration study, if applicable.]</p> <p>Milk/egg samples were collected twice daily [provide details on sampling method]. Animals were sacrificed on Day xx within [xx] hours of last dose. Tissue samples of [liver, kidney, muscle, and fat] were taken from each sacrificed animal. All samples were maintained frozen at the testing facility, during shipping to the laboratory and were stored frozen until</p>	Rich text area	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ApplicantSummaryAndConclusion.ExecutiveSummary

	<p>analysis. The maximum storage interval for samples between collection and analysis was [xx] days/months. Residues of [active ingredient] have been shown to be stable in [livestock matrices] for up to [xx] days under frozen conditions. Adequate storage stability data are therefore available to support the storage conditions and intervals for samples in the current study.</p> <p>Samples in the current study were analysed using Method [Method ID], a [describe method] to determine residues of [list analytes]. Acceptable [method validation and] concurrent recoveries were reported for [matrices] samples at fortification levels of [xx] ppm, thus validating the method. The limit of quantitation (LOQ) was [xx] ppm per analyte for [matrices].</p> <p>Following a pre-slaughter interval of [xx] hours, individual sample residues ranged from xx ppm to yy ppm [list matrices and residue levels]. [Describe, qualitatively and quantitatively, the relationship between residue levels and dosing levels for the matrices addressed in the study.] Depuration</p>		
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	results indicated that residues of [analytes(s)] will [describe depuration results, noting especially matrices where there appears to be little reduction of residues with time.]		
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6.5 Effects of processing – Endpoint summary

Purpose:

Purpose of document on the effects of processing on the nature of residues: To provide a summary on the nature of the active substance/metabolites under standard hydrolysis study and to conclude whether or not breakdown or reaction products arise from residues in the raw agricultural commodity (RAC) during processing, which may require a separate risk assessment.

Purpose of document on the effects of processing on the magnitude of residues: To provide an overview on the quantitative distribution of residues in various processed commodities (PC) and the derived processing factors (PF). Pesticide residues to be measured in processing studies are determined by the residue definition which is derived from studies on the nature of the residue in processing and/or in plant and livestock.

ENDPOINT_SUMMARY.NatureMagnitudeResiduesProcessedCommodities v.2.4 (Final)			
Name	Instructions	Type	Field path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.NatureMagnitudeResiduesProcessedCommodities.AdministrativeDataSummary
	See Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	Confidentiality	ENDPOINT_SUMMARY.NatureMagnitudeResiduesProcessedCommodities.AdministrativeDataSummary.DataProtection
Description of key information		Header 1	ENDPOINT_SUMMARY.NatureMagnitudeResiduesProcessedCommodities.KeyInformation
	Please make a statement whether: 1) the nature of residues in processed commodities was sufficiently investigated	Rich text area	ENDPOINT_SUMMARY.NatureMagnitudeResiduesProcessedCommodities.KeyInformation.KeyInformation

	<p>in the context of the present dossier (according to current data requirements and OECD Guideline No 507) and highlight data gap(s) and the non-standard uncertainty(ies), if any. Please also clarify if the reported conclusions on stability/non stability of the residues under hydrolytic conditions refer to the parent compound only and/or to any relevant metabolites found in plant and animals. In the latter case, please create the endpoint summary in the metabolite data set and specify the metabolites covered by this conclusion.</p> <p>2) the magnitude of residues in processed commodities was sufficiently investigated in the context of the present dossier (according to current data requirements and to OECD Guideline No 508) and highlight data gap(s) and the non-standard uncertainty(ies), if any.</p> <p>Key results used for the risk assessment should be reported in the detailed tables below.</p>		
Nature of residues in processed commodities	Repeat this block to create one row per key result (e.g. one row for each hydrolytic condition investigated by the study/ies).		ENDPOINT_SUMMARY. NatureMagnitudeResiduesProcessedCommodities.KeyInformation.ResidueNatureProcessedCommodities

Relevant studies	Provide here the link to the most relevant study(ies) from which the key results for nature of residues in processed commodities.	Endpoint reference list	ENDPOINT_SUMMARY. NatureMagnitudeResiduesProcessedCommodities.KeyInformation.ResidueNatureProcessedCommodities.RelevantStudies
Conditions	Select the standard hydrolysis conditions (e.g. sterilisation) for which a conclusion can be derived.	Multi select open list with remarks (2000)	ENDPOINT_SUMMARY. NatureMagnitudeResiduesProcessedCommodities.KeyInformation.ResidueNatureProcessedCommodities.Conditions
Stable	Select a statement whether the residues are stable or not when undergoing hydrolytic conditions mentioned above. Please use the field "remark" to further specify the conclusion (e.g. if the answer is "no", please specify which are the main degradation products expected, e.g. if the answer is "inconclusive", please specify the eventual data gaps).	Closed list with remarks (2000)	ENDPOINT_SUMMARY. NatureMagnitudeResiduesProcessedCommodities.KeyInformation.ResidueNatureProcessedCommodities.Stable
Nature of residues in processed commodities	Repeat this block to create one row per key result (e.g. one row for each hydrolytic condition investigated by the study/ies).		
Processing factors	<p>Repeat this block to create one box per combination raw agricultural commodity (RAC)/processed commodity (PC) for which processing factors could be derived.</p> <p>This section can also be used to capture the distribution of residues in peel/pulp by derivation of process factor pulp/RAC.</p>		ENDPOINT_SUMMARY. NatureMagnitudeResiduesProcessedCommodities.KeyInformation.ProcessingFactors

Relevant studies	Provide here the link to the most relevant study(ies) from which the key values (e.g. processing factors) for magnitude of residues in process commodities are derived.	Endpoint reference list	ENDPOINT_SUMMARY. NatureMagnitudeResiduesProcessedCommodities.KeyInformation.ProcessingFactors.RelevantStudies
Raw agricultural commodity (RAC)	<p>Raw agriculture commodity (RAC) means the product in or nearly in its natural state intended for sale or consumption without further processing. The term RAC means the same as "primary food commodity" or "primary feed commodity".</p> <p>Indicate the raw agricultural commodity (RAC) for which the processing factor is derived (e.g. apple).</p> <p>If not available, select 'other:' and specify.</p>	Open list with remarks (2000)	ENDPOINT_SUMMARY. NatureMagnitudeResiduesProcessedCommodities.KeyInformation.ProcessingFactors.RawCommodity
Processed commodity (PC)	Processed commodity (PC) means the products - resulting from the application of physical, chemical or biological processes or combinations of these to a "primary food commodity" - intended for direct sale to the consumer, for direct use as an ingredient in the manufacture of food or for further processing. A primary processed commodity is derived from mechanical or chemical processing of the RAC and is not a multicomponent product.	Open list with remarks (2000)	ENDPOINT_SUMMARY. NatureMagnitudeResiduesProcessedCommodities.KeyInformation.ProcessingFactors.ProcessedCommodity

	Indicate the processed commodity (PC) for which the processing factor is derived (e.g. apple juice). If not available, select 'other:' and specify.		
Number of trials	Indicate here the number of independent tests used to derive processing factors.	Integer	ENDPOINT_SUMMARY. NatureMagnitudeResiduesProcessedCommodities.KeyInformation.ProcessingFactors.NoTrials
Median processing factor: RD MO	<p>Processing factor (PF) is the ratio of the residue level identified in the processed commodity according to the residue definition for enforcement (RD MO) and the residue level identified in the raw agricultural commodity according to enforcement residue definition (RD MO):</p> $PF\ MO = \frac{[residue\ concentration\ in\ Processed\ Com]\ RD\ MO}{[residue\ concentration\ in\ RAC]\ RD\ MO}$ <p>This factor is valid for the combination `procedure/commodity`, which was investigated in the processing study.</p> <p>Insert here the mean (of two studies) or median (of more than 2 studies) value of all available processing factors for a given combination raw agricultural commodity (RAC)/processed commodity (PC).</p>	Decimal	ENDPOINT_SUMMARY. NatureMagnitudeResiduesProcessedCommodities.KeyInformation.ProcessingFactors.ProcessingFactorMo

	<p>If the residue definition for enforcement purposes in processed products differs from the residue definition in the RAC, the processing factor should be calculated taking into account the molecular weights of the different substances. If that is not feasible, the processing factors shall reflect the enforcement residue definition in processed commodity.</p>		
<p>Median processing factor: RD RA</p>	<p>Insert here the mean (of two studies) or median (of more than 2 studies) value of all available processing factors for a given combination raw agricultural commodity (RAC)/processed commodity (PC) according to following formula:</p> $PF\ RA = \frac{[residue\ concentration\ in\ Processed\ Com]\ RD\ RA}{[residue\ concentration\ in\ RAC]\ RD\ MO.}$ <p>If the residue definition for risk assessment purposes in processed products differs from that in the RAC, the processing factor should be calculated taking into account the molecular weights of the different substances. If that is not feasible, the processing factors shall reflect the risk assessment residue</p>	Decimal	<p>ENDPOINT_SUMMARY. NatureMagnitudeResiduesProcessedCommodities.KeyInformation.ProcessingFactors.ProcessingFactorRa</p>

	definition in processed commodity.		
Remarks	Please enter any additional remark for the processing factor, for example if the processing factor is tentative.	Multi-line text	ENDPOINT_SUMMARY.NatureMagnitudeResiduesProcessedCommodities.KeyInformation.ProcessingFactors.Remarks
Processing factors			
Additional information	Discussion(Header 1) – common block	Header 1	ENDPOINT_SUMMARY.NatureMagnitudeResiduesProcessedCommodities.Discussion

6.5.1 Nature of the residue – Endpoint study record

Purpose:

Studies concerning the nature of the residue to establish whether or not breakdown or reaction products arise from residues in the raw agricultural commodity (RAC) during processing, which may require a separate risk assessment.

ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod v.5.2 (Final)			
Name	Instructions	Type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.AdministrativeData
	See Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	Confidentiality	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.AdministrativeData.DataProtection
Endpoint	Select relevant endpoint from picklist: - Nature of the residues in processed commodities: high temperature hydrolysis. Or - Nature of the residues in processed commodities: other.	Closed list with remarks	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.AdministrativeData.Endpoint

	<p>If `other` is selected, please specify in the remark field the type of the study.</p> <p>From the picklist select the relevant endpoint addressed by this study summary. In some cases there is only one endpoint title, which may be entered automatically depending on the software application. If multiple study types are covered by the same data entry form, the specific study type should be selected. If none matches, select the more generic endpoint description '<Generic endpoint>', other' (e.g. Skin irritation / corrosion, other) and give an explanation in the adjacent text field. The generic endpoint title reflects the title of the corresponding OECD Harmonised Template (OHT).</p> <p>Please note: For (Q)SAR studies the generic endpoint title should be selected, normally with no need to fill in the adjacent text field, as '(Q)SAR' needs to be indicated in field 'Type of information' and the model should be described in field 'Justification of non-standard information' or 'Attached justification'. A specific endpoint title may be used, if addressed by</p>		
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	<p>the (Q)SAR information, i.e. the model behind has been validated by experimental data addressing this endpoint.</p> <p>Note: For the purpose of OHTs, an 'endpoint' is defined in the rather broad sense as an observable or measurable inherent property of a chemical substance which may be specified by the relevant regulatory framework as 'information requirement' (e.g. Boiling point, Sub-chronic toxicity: oral, Fish early-life stage toxicity). In a narrower sense, the term '(eco)toxicity endpoint' refers to an outcome or effect observed in a study.</p>		
Type of information	<p>Select the appropriate type of information, e.g. ' experimental study', ' experimental study planned' or, if alternatives to testing apply, '(Q)SAR', 'read-across ...'. In the case of calculated data, the value 'calculation (if not (Q)SAR)' should only be chosen if the study report does not clearly indicate whether it is based on '(Q)SAR'.</p> <p>If the information is taken from a handbook or review article, select the relevant item, e.g. 'experimental study', if this is provided in the information source. Otherwise select 'not</p>	Open list with remarks	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.AdministrativeData.StudyResultType

	<p>specified'. Please note: In field 'Reference type' the option 'review article or handbook' should be selected. In general, the option 'not specified' should be selected if the submitter lacks the knowledge of the type of information. The option 'other:' can be used if another than a pre-defined item applies.</p> <p>In the case of read-across, follow the instructions related to the relevant legislation, for instance as to whether the (robust) study summary should be entered in a separate data set defined for the read-across (source) substance and referenced in the target substance dataset.</p> <p>If 'experimental study planned' or 'experimental study planned (based on read-across)' is indicated (in some legislations also defined as 'testing proposal' or 'undertaking of intended submission'), the submitter should include as much information as possible on the planned study in order to support the evaluation of the proposal. Typically, this would include at least the test guideline, information on the test material, the species and the route of administration in the</p>		
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	<p>corresponding distinct fields, as appropriate. Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on whether specific fields should be completed and/or further details should be attached in field 'Attached background material'.</p>		
Adequacy of study	<p>Indicate the adequacy of a (robust) study summary in terms of usefulness for hazard/risk assessment purposes depending on the relevant legislation. Note: This field is only applicable (or active) if neither 'waiving of standard information' nor 'experimental study planned' has been selected in field 'Type of information'. Explanation:</p> <ul style="list-style-type: none"> - key study: In general, a key study is the study that has been identified as most suitable to describe an endpoint from the perspective of quality, completeness and representativity of data. - supporting study: Any other adequate study that is considered supportive for the key study or key studies. - weight of evidence: A record that contributes to a weight of evidence justification for the non-submission of a particular (adequate) study. The weight of evidence justification is 	Closed list	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.AdministrativeData.PurposeFlag

	<p>normally endpoint-related, i.e. based on all available records included in the weight of evidence evaluation. A short reasoning for why a given record is used in this respect can be provided in field 'Detailed justification / remarks'.</p> <p>- disregarded due to major methodological deficiencies: study that demonstrates a higher concern than the key study/ies, but is not used as key study because of flaws in the methodology or documentation. This phrase should be selected for justifying why a potentially critical result has not been used for the hazard assessment. The lines of argumentation should be provided in field 'Rationale for reliability incl. deficiencies', accompanied by the appropriate reliability score.</p> <p>- other information: any other non-relevant information which does not need to be flagged specifically as 'disregarded due to major methodological deficiencies'. Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field.</p>		
Robust study summary	Set this flag if relevant for the respective	Check box	ENDPOINT_STUDY_RECORD.NatureResiduesI

	<p>regulatory programme or if otherwise useful as filter for printing or exporting records flagged as 'Robust Study Summary' or in combination with 'Adequacy of study'. Explanation: The term 'Robust Study Summary' is actually used only to describe the technical content of a very detailed summary of an experimental study or of any other relevant information. It is a priori no synonym with the term 'Key study', although a key study should usually be submitted in the form of Robust Study Summary. However, a Robust Summary may also be useful for other adequate studies that are considered supportive of the key study or even for inadequate studies if they can be used for a weight-of-evidence analysis. Also for studies that are flawed, but indicate critical results, Robust Study Summaries highlighting the weaknesses of the studies need to be elaborated. Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field.</p>		nProcessedCommod.AdministrativeData.Robust Study
Used for classification	Set this flag if relevant for the respective regulatory programme	Check box	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.AdministrativeData.Robust Study

	<p>or if otherwise useful as filter for printing or exporting records flagged as 'Used for classification'.</p> <p>Explanation: In some use cases it may be necessary to indicate those records that are used for the classification of that substance, e.g. according to UN GHS. If not relevant, disregard this field.</p> <p>Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field.</p>		administrativeData.UsedForClassification
Used for SDS	<p>Set this flag if relevant for the respective regulatory programme or if otherwise useful as filter for printing or exporting records flagged as 'SDS information'.</p> <p>Explanation: 'SDS' stands for Safety Data Sheet. In some use cases it may be necessary to indicate those records that are used for the compilation of SDS information. If not relevant, disregard this field.</p> <p>Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field.</p>	Check box	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.AdministrativeData.UsedForMSDS
Study period	<p>If applicable indicate the period during which the study was conducted, i.e. start</p>	Text	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.AdministrativeData.UsedForMSDS

	<p>and end date, using an unambiguous date format, e.g. 'From 12 MAY 1999 to 15 AUG 2000' or 'From May 12, 1999 to Aug. 15, 2000'. Note: Independent of the study period the in-life period (i.e. the phase of a study following treatment in which the test system is alive/growing) may have to be specified for some toxicology endpoints.</p>		administrativeData.StudyPeriod
Reliability	<p>Enter an appropriate reliability score, according to Klimisch et al. (1997):</p> <p>1 = reliable without restrictions: "studies or data [...] generated according to generally valid and/or internationally accepted testing guidelines (preferably performed according to GLP) or in which the test parameters documented are based on a specific (national) testing guideline [...] or in which all parameters described are closely related/comparable to a guideline method."</p> <p>2 = reliable with restrictions: "studies or data [...] (mostly not performed according to GLP), in which the test parameters documented do not totally comply with the specific testing guideline, but are sufficient to accept the data or in which</p>	Open list	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.AdministrativeData.Reliability

	<p>investigations are described which cannot be subsumed under a testing guideline, but which are nevertheless well documented and scientifically acceptable.”</p> <p>3 = not reliable: “studies or data [...] in which there were interferences between the measuring system and the test substance or in which organisms/test systems were used which are not relevant in relation to the exposure (e.g. non-physiological pathways of application) or which were carried out or generated according to a method which is not acceptable, the documentation of which is not sufficient for assessment and which is not convincing for an expert judgment.”</p> <p>4 = not assignable: “studies or data [...] which do not give sufficient experimental details and which are only listed in short abstracts or secondary literature (books, reviews, etc.).”</p> <p>The 'other:' option may be selected if a different scoring system is used. Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH)</p>		
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	<p>on how to use this field.</p> <p>Note: This field is only applicable (or active) if neither 'waiving of standard information' nor 'experimental study planned' has been selected in field 'Type of information'.</p> <p>Note: The term reliability defines the inherent quality of a test report or publication relating to preferably standardised methodology and the way the method and results are described. More detailed criteria can be selected in field 'Justification'.</p>		
Rationale for reliability incl. deficiencies	<p>Select an appropriate standard justification from the picklist, e.g. 'Comparable to guideline study with acceptable restrictions'. Additional explanations (e.g. deficiencies observed) can be entered in the related supplementary text field. Particularly if reliability scores 2 or 3 are assigned, indicate the concrete arguments for defending a study or relevant deficiencies.</p> <p>For QSAR results (i.e. 'Type of information' is '(Q)SAR') some pre-defined phrases are provided for indicating if the prediction results are considered reliable based on the scientifically validity of the (Q)SAR model</p>	Open list with remarks (32000)	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.AdministrativeData.RationalReliability

	<p>used, its applicability to the query substance, and the adequacy of reporting. Please note: If (Q)SAR results are flagged as key study in field 'Adequacy of study', the relevance of the model used for the regulatory endpoint should be documented in the field where the (Q)SAR model is described, i.e. 'Justification for type of information', 'Attached justification' or 'Cross-reference'.</p>		
Data waiving	<p>If appropriate, indicate here that the study has been waived, i.e. not performed. Select the basis from the picklist (e.g. 'study technically not feasible' or 'other justification'). Include a more detailed justification in the field 'Justification for data waiving' and, as needed, in field 'Justification for type of information', 'Attached justification' and/or 'Cross-reference'. Please note: the option 'study scientifically not necessary / other information available' covers cases where it can be justified that performance of a specific study prescribed by the relevant legislation is scientifically not necessary because reliable information is provided in other part(s) of the submission document.</p>	Closed list	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.AdministrativeData.DataWaiving

	<p>The option 'study waived due to provisions of other regulation' can be used for indicating that another, overlapping regulation allows or requires the waiving of a specific information requirement. This should then be detailed in the justification fields.</p> <p>If waiving is based on several lines of argumentation (e.g. 'exposure considerations' and 'study scientifically not necessary / other information available'), create separate records for each.</p> <p>Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use data waivers.</p>		
Justification for data waiving	<p>In addition to the more generic justification selected in the preceding field 'Data waiving', it is highly recommended to provide a detailed justification. To this end you can either select one or multiple specific standard phrase(s) if it/they give an appropriate rationale of the description given in the preceding field 'Data waiving' or 'other:' and enter free text. Additional specific explanations should be provided if the pre-defined phrase(s) do not</p>	Multi select open list with remarks (32000)	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.AdministrativeData.DataWaivingJustification

	<p>sufficiently describe the justification.</p> <p>More details can be provided using the following fields:</p> <ul style="list-style-type: none"> - Text field adjacent to this field 'Justification for data waiving' (available after selecting any picklist item in this field); - Field 'Justification for type of information'; - Field 'Attached justification'; - Cross-reference (for referencing / linking to a justification or information referred to in the justification which is stored in another record, e.g. a record describing physico-chemical properties information used to support a data waiver) <p>Please note: The pre-defined phrases are not necessarily exhaustive and may not always apply. Consult the guidance documents and waiving options in the relevant regulatory frameworks. If no suitable phrase is available from the picklist, enter a free text justification using the 'other:' option.</p>		
Justification for type of information	<p>This field can be used for entering free text. As appropriate, one of the freetext templates can be selected (e.g. Justification for read-across (analogue)) to use pre-defined headers and bulleted elements. Delete/add</p>	Text template	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.AdministrativeData.JustificationForTypeOfInformation

	<p>elements as appropriate.</p> <p>Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on what should be taken into account when providing justifications or whether specific reporting formats should be used.</p> <p>Explanations:</p> <p>Option 1: Type 'Waiving of standard information':</p> <p>This field should be used for entering any further lines of argumentation, if necessary, in addition to those provided in the field 'Justification for data waiving'.</p> <p>Option 2: Type 'Experimental study planned / Testing proposal':</p> <p>Further details can be entered here on the study design / methodology proposed in addition to details given in the distinct fields on test guideline, test material, species, route of administration and other relevant fields.</p> <p>Option 3: Type 'QSAR prediction':</p>		
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	<p>Based on this freetext template details on the QSAR model used can be given, in addition to the information provided in field 'Principles of method if other than guideline'.</p> <p>Please note: Any information that can be re-used for several study summaries can be entered once and then assigned to the relevant studies using either the 'Attached justification' or 'Cross-reference' feature.</p> <p>Option 4: Type 'Read-across (analogue)' and Option 5: Type 'Read-across (category)'</p> <p>This freetext template can be used and modified as appropriate for providing a justification for read-across, particularly if it is endpoint-specific.</p> <p>Please note: Any information that can be re-used for several study summaries can be entered once and then assigned to the relevant studies using either the 'Attached justification' or 'Cross-reference' feature.</p>		
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.DataSource
Product type	Indicate the product type addressed by the information entered in this record. Leave field empty if not applicable.	Open list with remarks	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.MaterialsAndMethods.ProductType

Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.MaterialsAndMethods
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.MaterialsAndMethods.TestMaterials
Radiolabelling	Select the appropriate product from the picklist (yes; no; other;; not specified). Indicate if labelled or non-labelled test material was used. Details on labelled material to be described in field 'Specific details on test material'. Any other useful information to include in the remark field.	Open list with remarks	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.MaterialsAndMethods.TestMaterials.Radiolabelling
Study design		Header 2	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.MaterialsAndMethods.StudyDesign
Test strategies	Brief description of testing guideline conditions used.	Text area	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.MaterialsAndMethods.StudyDesign.TestStrategies
Experimental procedure	Describe experimental procedure applied by using the existing templates. Brief outline of study design, i.e. test facility, environmental/hydrolytic conditions, amount and concentrations of test substance applied, use of solvent, etc. Use freetext template and delete/add elements as appropriate. If applicable, discuss unusual experimental problems encountered,	Text template	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.MaterialsAndMethods.StudyDesign.ExperimentalProcedure

	attempts made to alleviate these problems which resulted in deviations from the intended test protocol and the effects, if any, of those deviations on the results of the study.		
Sampling and analytical methodology		Header 2	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.MaterialsAndMethods.SamplingAndAnalyticalMethodology
Details on sample handling and storage conditions	Include details on the sampling, sample handling and storage conditions. The following information should be addressed: handling and shipping of commodities, storage conditions, length of storage, any preparation done prior to extraction. Use the existing templates to report the necessary information.	Text template	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.MaterialsAndMethods.SamplingAndAnalyticalMethodology.DetailsOnSampleHandlingAndStorageConditions
Details on analytical methodology	Describe methods fully or reference them if previously submitted. It may be sensible to outline the analytical methodology in chapter 'Analytical methods' and include a reference to that method description using the 'Cross-reference' feature. If the method has been reported in Section 4 of the dossier 'Analytical methods', please refer to it, using the cross reference block. If the study record referred to was duly compiled and contain the data on	Text template	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.MaterialsAndMethods.SamplingAndAnalyticalMethodology.DetailsOnAnalyticalMethodology

	<p>method validation, further information is not required.</p> <p>If no study record was created for this method (and its validation) in Section 4 of the dossier, please use the existing templates to report the details on analytical method. The following information should be addressed: method validation data, recovery and method sensitivity data. Preparation and handling of the sample throughout the method described in detail. Note that methods for metabolites may also be needed. Recovery data should be obtained concurrently with the residue analyses to validate the method and establish its sensitivity (lowest reliable quantification limit). State the LOD and LOQ. Experimental design of these validation studies described including: (1) Identity of the test compounds and crop substrates, (2) Magnitudes of fortification levels, (3) Number of replicates per test compound per level. Identify instrumentation, equipment and reagents used and the operating conditions of the instrumentation. If the extraction/clean-up procedure is complex, a</p>		
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	<p>flow diagram should be submitted.</p> <p>Use freetext template and delete/add elements as appropriate, or upload predefined table(s), if any, in rich text field 'Any other information on materials and methods incl. tables' or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').</p>		
Any other information on materials and methods incl. tables	<p>Any other information on materials and methods incl. tables - (H2) – common block</p> <p>In this field, you can enter any information on materials and methods, for which no distinct field is available, or transfer free text from other databases. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document.</p>	Header 2	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
		Rich text area	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables.OtherInformation
Results and discussion	Identify all major components of TRR and specify the	Header 1	ENDPOINT_STUDY_RECORD.NatureResiduesI

	quantity expressed both as mg/L active ingredient equivalents and %TRR. Copy this block of fields for recording the results for each analyte found under each test condition.		nProcessedCommod.ResultsAndDiscussion
Total radioactive residues (TRR)	Use the repeatable block to report individual results for each identified compound per test condition. Copy this block of fields for recording the results for each test compound per test condition.		ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.ResultsAndDiscussion.TotalRadioactiveResiduesTRR
TRR component no.	<u>Enter consecutive numbering of the components of TRR.</u>	Closed list	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.ResultsAndDiscussion.TotalRadioactiveResiduesTRR.TRRComponentNo
Sample ID	Please report here the sampled ID.	Text area	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.ResultsAndDiscussion.StorageStability
Storage stability (Sample Integrity)	Please provide a statement on the sample integrity against storage conditions. Provide storage stability data for all major components of the total radioactive residues, including conditions and length of storage of samples following receipt in laboratory and conditions and length of storage of extracts prior to identification of residues (Note: Handling, pre-shipping storage and shipping	Text area	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.ResultsAndDiscussion.TotalRadioactiveResiduesTRR.StorageStability

	<p>procedures for harvested samples to be described in field 'Details on sampling handling and storage conditions'.</p> <p>As appropriate, upload predefined table(s), if any, in rich text field 'Any other information on results incl. tables' or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').</p> <p>Note: Specific tables may be required. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.</p>		
Test conditions	<p>Specify the test / environmental conditions for the TRR result recorded, using the predefined picklist. If conditions other than "baking, brewing and boiling", "pasteurisation" or sterilisation" have been tested, please use other and specify the conditions in the free text field.</p>	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.ResultsAndDiscussion.TotalRadioactiveResiduesTRR.TestConditions
Identity of TRR component	<p>Click the Link button to navigate to the Substances Inventory and select the relevant substance name for indicating the identity (i.e. CAS number, CAS name, IUPAC name, SMILES code, molecular formula, structural</p>	Entity reference field	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.ResultsAndDiscussion.TotalRadioactiveResiduesTRR.IdentityOfTRRComponent

	<p>formula etc.). If not available in the inventory, create a new one.</p> <p>Once stored in the Substances Inventory a reference substance can be re-used in the data set.</p> <p>Depending on the user interface of the software used the identity of the reference substance may only be displayed in a shortened form (e.g. comprising the CAS and IUPAC name), with a link for navigating to the actual record containing the reference substance information.</p>		
TRR concentration	Enter the concentration of the component expressed as active ingredient equivalents (preferably use mg/L).	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.ResultsAndDiscussion.TotalRadioactiveResiduesTRR.TRRConcentration
TRR (%)	Enter the percentage of the component (%TRR).	Decimal	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.ResultsAndDiscussion.TotalRadioactiveResiduesTRR.TRRPercentage
Fortification level	Enter the concentration of the sample before hydrolysis (preferably use mg/L).	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.ResultsAndDiscussion.TotalRadioactiveResiduesTRR.FortificationLevel
TRR (%) prior hydrolysis	Enter the percentage of the initial TRR concentration of the sample before hydrolysis. Calculation based on field 'Fortification Level'.	Decimal	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.ResultsAndDiscussion.TotalRadioactiveResiduesTRR.TRRPriorHydrolysis
Total radioactive residues (TRR)			

Other details on TRRs	Provide any other relevant details related to the characterisation and/or identification and distribution of TRRs. As appropriate, upload predefined table(s), if any, in rich text field 'Any other information on results incl. tables' or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').	Text area	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.ResultsAndDiscussion.OtherDetailsOnTRRs
Metabolic pathway	Discuss the routes of degradation observed and describe the metabolic pathways and/or attach figures in field "Illustration (picture/graph)"	Rich text area	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.ResultsAndDiscussion.MetabolicPathway
Any other information on results incl. tables		Header 2	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
	In this field, you can enter any other remarks on results. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. If you did not use the option 1 to report the detailed results for each analyte determined for given processing condition, please report it in one/several table(s) of results.	Rich text area	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables.OtherInformation

	Note: One rich text editor field each is provided for the MATERIALS AND METHODS and RESULTS section. In addition the fields 'Overall remarks' and 'Executive summary' allow rich text entry.		
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.ApplicantSummaryAndConclusion
Conclusions	The assessment and conclusion of the applicant should be reported here. Enter any conclusions if applicable in addition to the information given in fields 'Key results' and 'Interpretation of results' (if any).	Text area	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.ApplicantSummaryAndConclusion.Conclusions
Executive summary	If relevant for the respective regulatory programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, copy it from the corresponding document or upload it if provided as htm or html document. Consult the programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) thereof.Example: The effect of processing on the nature of [active	Rich text area	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.ApplicantSummaryAndConclusion.ExecutiveSummary

	<p>substance/metabolite] was investigated in standard hydrolysis study simulating [include here the process, temperature, pH] conditions.</p> <p>The results showed that the [active substance/metabolite] is hydrolytically stable OR progressively degrades to [indicate degradation product, % applied radioactivity, amount in mg/kg] OR almost totally degraded to [indicate degradation product, % applied radioactivity, amount in mg/kg] under [indicate processing condition]. Further considerations on the nature of identified degradation products, if any, could be provided here.</p>		
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6.5.3 Magnitude of residues in processed commodities – Endpoint study record

Purpose:

Studies concerning the effects of processing on the magnitude of residues in processed commodities to determine the quantitative distribution of residues in the various processed commodities used as food or feed, to estimate processing factors and to allow a more realistic estimation of dietary intake of residues.

ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm v.4.3 (Final)			
Name	Instructions	Type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.AdministrativeData
		Confidentiality	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.AdministrativeData.DataProtection
Endpoint	Select relevant endpoint from picklist: magnitude of residues in processed commodities	Closed list with remarks	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.AdministrativeData.Endpoint

Type of information		Open list with remarks	ENDPOINT_STUDY_RE CORD.MagnitudeResidI nProcessedComm.Admi nistrativeData.StudyRes ultType
Adequacy of study		Closed list	ENDPOINT_STUDY_RE CORD.MagnitudeResidI nProcessedComm.Admi nistrativeData.PurposeF lag
Robust study summary		Check box	ENDPOINT_STUDY_RE CORD.MagnitudeResidI nProcessedComm.Admi nistrativeData.RobustSt udy
Used for classification		Check box	ENDPOINT_STUDY_RE CORD.MagnitudeResidI nProcessedComm.Admi nistrativeData.UsedFor Classification
Used for SDS		Check box	ENDPOINT_STUDY_RE CORD.MagnitudeResidI nProcessedComm.Admi nistrativeData.UsedFor MSDS
Study period		Text	ENDPOINT_STUDY_RE CORD.MagnitudeResidI nProcessedComm.Admi nistrativeData.StudyPeri od
Reliability		Open list	ENDPOINT_STUDY_RE CORD.MagnitudeResidI nProcessedComm.Admi nistrativeData.Reliability
Rationale for reliability incl. deficiencies		Open list with remarks (32000)	ENDPOINT_STUDY_RE CORD.MagnitudeResidI nProcessedComm.Admi nistrativeData.RationalR eliability
Data waiving		Closed list	ENDPOINT_STUDY_RE CORD.MagnitudeResidI nProcessedComm.Admi nistrativeData.DataWai ving
Justification for data waiving		Multi select open list with remarks (32000)	ENDPOINT_STUDY_RE CORD.MagnitudeResidI nProcessedComm.Admi nistrativeData.DataWai vingJustification
Justification for type of information		Text template	ENDPOINT_STUDY_RE CORD.MagnitudeResidI nProcessedComm.Admi

			nistrativeData.JustificationForTypeOfInformation
Attached justification			ENDPOINT_STUDY_RECORD.MagnitudeResidualProcessedComm.AdministrativeData.AttachedJustification
Attached justification		Single file attachment	ENDPOINT_STUDY_RECORD.MagnitudeResidualProcessedComm.AdministrativeData.AttachedJustification.AttachedJustification
Reason / purpose		Closed list with remarks	ENDPOINT_STUDY_RECORD.MagnitudeResidualProcessedComm.AdministrativeData.AttachedJustification.ReasonPurpose
Attached justification			
Cross-reference			ENDPOINT_STUDY_RECORD.MagnitudeResidualProcessedComm.AdministrativeData.CrossReference
Reason / purpose for cross-reference		Open list with remarks	ENDPOINT_STUDY_RECORD.MagnitudeResidualProcessedComm.AdministrativeData.CrossReference.ReasonPurpose
Related information		Endpoint reference field	ENDPOINT_STUDY_RECORD.MagnitudeResidualProcessedComm.AdministrativeData.CrossReference.RelatedInformation
Remarks		Text area	ENDPOINT_STUDY_RECORD.MagnitudeResidualProcessedComm.AdministrativeData.CrossReference.Remarks
Cross-reference			
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.MagnitudeResidualProcessedComm.Data Source
Reference		Literature reference list	ENDPOINT_STUDY_RECORD.MagnitudeResidualProcessedComm.Data Source.Reference

Data access		Open list with remarks	ENDPOINT_STUDY_RECORD.MagnitudeResidualProcessedComm.DataSource.DataAccess
Data protection claimed		Closed list with remarks	ENDPOINT_STUDY_RECORD.MagnitudeResidualProcessedComm.DataSource.DataProtectionClaimed
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.MagnitudeResidualProcessedComm.MaterialsAndMethods
Product type	Field not mandatory. The product type is already reported in Section 3.2 (Effect on harmful organism, function, mode of action and possible resistance). This field is optional.	Open list with remarks	ENDPOINT_STUDY_RECORD.MagnitudeResidualProcessedComm.MaterialsAndMethods.ProductType
Test guideline			ENDPOINT_STUDY_RECORD.MagnitudeResidualProcessedComm.MaterialsAndMethods.Guideline
Qualifier		Closed list	ENDPOINT_STUDY_RECORD.MagnitudeResidualProcessedComm.MaterialsAndMethods.Guideline.Qualifier
Guideline		Open list	ENDPOINT_STUDY_RECORD.MagnitudeResidualProcessedComm.MaterialsAndMethods.Guideline.Guideline
Version / remarks		Multi-line text	ENDPOINT_STUDY_RECORD.MagnitudeResidualProcessedComm.MaterialsAndMethods.Guideline.VersionRemarks
Deviations		Closed list with remarks	ENDPOINT_STUDY_RECORD.MagnitudeResidualProcessedComm.MaterialsAndMethods.Guideline.Deviation
Test guideline			

Principles of method if other than guideline		Text template	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.MaterialsAndMethods.MethodNoGuideline
GLP compliance		Closed list with remarks	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.MaterialsAndMethods.GLPComplianceStatement
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.MaterialsAndMethods.TestMaterials
Test material information		Entity reference field	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Specific details on test material used for the study		Text template	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.MaterialsAndMethods.TestMaterials.SpecificDetailsOnTestMaterialUsedForTheStudy
Specific details on test material used for the study (confidential)		Text template	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.MaterialsAndMethods.TestMaterials.SpecificDetailsOnTestMaterialUsedForTheStudyConfidential
Study design		Header 2	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.MaterialsAndMethods.StudyDesign
Bulk raw agricultural commodity (RAC)	Raw agriculture commodity (RAC) means the product in or nearly in its natural state intended for sale or consumption without further processing, or for processing into food for sale to the consumer. The term RAC means the same as "primary food"	Open list	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.MaterialsAndMethods.StudyDesign.BulkRawAgriculturalCommodity

	appropriate. The following information should be addressed: handling and shipping of commodities, storage conditions, length of storage, any preparation done prior to extraction.		ology.DetailsOnSample HandlingAndPreparation
Details on analytical methodology	<p>The analytical method and its validation should be reported in a specific study record, created in Section 4 of the dossier 'Analytical methods'. Please refer to it, providing the UUID of study record of the used analytical method and its validation. If the study record referred to was duly compiled and contain the data on method validation, further information is not required.</p> <p>Please make sure that the following details on analytical method are duly reported: method validation data, recovery and method sensitivity data. Preparation and handling of the sample throughout the method described in detail. Note that methods for metabolites may also be needed. Recovery data should be obtained concurrently with the residue analyses to validate the method and establish its sensitivity (lowest reliable quantification limit). State the LOD and LOQ. Experimental design of these</p>	Text template	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.MaterialsAndMethods.SamplingAndAnalyticalMethodology.DetailsOnAnalyticalMethodology

	validation studies described including: (1) Identity of the test compounds and crop substrates, (2) Magnitudes of fortification levels, (3) Number of replicates per test compound per level. Identify instrumentation, equipment and reagents used and the operating conditions of the instrumentation. If the extraction/clean-up procedure is complex, a flow diagram should be submitted.		
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.MagnitudeResidueInProcessedComm.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
	In this field, you can enter any information on materials and methods, for which no distinct field is available, or transfer free text from other databases. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document. Please report here the details on the analytical methods that could not be reported in Section 4. Please use the recommended formats as available in [cf. residue Template 6.1 (http://doi.org/10.5281/zenodo.4621833), Table 6.5].	Rich text area	ENDPOINT_STUDY_RECORD.MagnitudeResidueInProcessedComm.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables.OtherInformation

Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion
Storage stability of residues (Sample integrity)	Provide storage stability data for all major residues, including conditions and length of storage of samples following receipt in laboratory and conditions and length of storage of extracts prior to identification of residues (Note: Handling, pre-shipping storage and shipping procedures for harvested samples to be described in field 'Details on sampling and analytical methodology').	Text area	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.StorageStabilityOfResiduesSampleIntegrity
Residues in RAC prior to processing		Header 2	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInRACPriorToProcessing
Bulk RAC sub-sample sample no.	Option 1: possibility to use the repeatable block to report individual results for each RAC. Copy this block of fields for recording the results for each test compound per test condition. This option could be deployed in case of small data sets. Option 2: report directly the detailed information on the results in RAC in the Excel file Processing trials table [cf. residue Template 6.5 (http://doi.org/10.5281/zenodo.4621130)] to be attached in the field		ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInRACPriorToProcessing.BulkRACSubSamplesSampleNo

	below "Attached background material"		
Date of sub-sample		Date	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInRACPriorToProcessing.BulkRACSubSampleSampleNo.DateOfSubSample
Analysis sample ID		Text	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInRACPriorToProcessing.BulkRACSubSampleSampleNo.AnalysisSampleID
Analysis sample description		Text	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInRACPriorToProcessing.BulkRACSubSampleSampleNo.AnalysisSampleDescription
Analyte measured			ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInRACPriorToProcessing.BulkRACSubSampleSampleNo.AnalyteMeasured
Analyte identity		Entity reference field	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInRACPriorToProcessing.BulkRACSubSampleSampleNo.AnalyteMeasured.AnalyteIdentity
Extraction date		Date	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInRACPriorToProcessing.BulkRACSubSampleSampleNo.AnalyteMeasured.ExtractionDate
Analysis date		Date	ENDPOINT_STUDY_RECORD.MagnitudeResidI

			nProcessedComm.ResultsAndDiscussion.ResiduesInRACPriorToProcessing.BulkRACSubSampleSampleNo.AnalyteMeasured.AnalysisDate
Method ID		Text	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInRACPriorToProcessing.BulkRACSubSampleSampleNo.AnalyteMeasured.MethodID
Storage stability factor		Decimal	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInRACPriorToProcessing.BulkRACSubSampleSampleNo.AnalyteMeasured.StorageStabilityFactor
Use of factor		Text	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInRACPriorToProcessing.BulkRACSubSampleSampleNo.AnalyteMeasured.UseOfFactor
Correction by storage stability		Closed list	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInRACPriorToProcessing.BulkRACSubSampleSampleNo.AnalyteMeasured.CorrectionByStorageStability
Recovery		Decimal	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInRACPriorToProcessing.BulkRACSubSampleSampleNo.AnalyteMeasured.Recovery
Correction by recovery		Closed list	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.Residu

			esInRACPriorToProcessing.BulkRACSubSampleSampleNo.AnalyteMeasured.CorrectionByRecovery
Reference portion		Multi-line text	ENDPOINT_STUDY_RECORD.MagnitudeResidueInProcessedComm.ResultsAndDiscussion.ResiduesInRACPriorToProcessing.BulkRACSubSampleSampleNo.AnalyteMeasured.ReferencePortion
Residue level (measured)		Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.MagnitudeResidueInProcessedComm.ResultsAndDiscussion.ResiduesInRACPriorToProcessing.BulkRACSubSampleSampleNo.AnalyteMeasured.ResidueLevelMeasured
Residue level (calculated)	Not needed	Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.MagnitudeResidueInProcessedComm.ResultsAndDiscussion.ResiduesInRACPriorToProcessing.BulkRACSubSampleSampleNo.AnalyteMeasured.ResidueLevelCalculated
Residue level (calculated and corrected)	Not needed	Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.MagnitudeResidueInProcessedComm.ResultsAndDiscussion.ResiduesInRACPriorToProcessing.BulkRACSubSampleSampleNo.AnalyteMeasured.ResidueLevelCalculatedAndCorrected
Analyte measured			
Bulk RAC sub-sample sample no.			
Residues in processed fractions (PF) and aspirated grain fractions (AGF)		Header 2	ENDPOINT_STUDY_RECORD.MagnitudeResidueInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF
Processing information	Description of processing method(s).	Multi-line text	ENDPOINT_STUDY_RECORD.MagnitudeResidueInProcessedComm.ResultsAndDiscussion.ResiduesInRACPriorToProcessing.BulkRACSubSampleSampleNo.AnalyteMeasured.CorrectionByRecovery

	<p>Processed fraction: Special attention should be given to, but not limited to, processing order, pressures, temperatures, and the corresponding yield-weights of each fraction. Processed fraction handling (e.g. samples were frozen within 24 hours after processing). A description of the process method is necessary and the use of flow chart diagrams is helpful.</p>		nProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.ProcessingInformation
Processed fraction	<p>Option 1: possibility to use the repeatable block to report individual results for each processed commodity/fraction. Copy this block of fields for recording the results for each test compound per test condition. This option could be deployed in case of small data sets.</p> <p>Option 2: report directly the detailed information on the results for each processed commodity/fraction in the Excel file Processing trials table [cf. residue Template 6.5 (http://doi.org/10.5281/zenodo.4621130)] for residues in processed commodities to be attached in the field below "Attached sanitized documents"</p>		ENDPOINT_STUDY_RECORD.MagnitudeResidueInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.ProcessedFraction
Processed fraction (PF sample)		Open list	ENDPOINT_STUDY_RECORD.MagnitudeResidueInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractions

			PFAAndAspiratedGrainFractionsAGF.ProcessedFraction.ProcessedFractionPFSample
PF sample no.		Text	ENDPOINT_STUDY_RECORD.MagnitudeResidualInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAAndAspiratedGrainFractionsAGF.ProcessedFraction.PFSampleNo
Date of processing		Date	ENDPOINT_STUDY_RECORD.MagnitudeResidualInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAAndAspiratedGrainFractionsAGF.ProcessedFraction.DateOfProcessing
Analysis sample ID		Text	ENDPOINT_STUDY_RECORD.MagnitudeResidualInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAAndAspiratedGrainFractionsAGF.ProcessedFraction.AnalysisSampleID
Analysis sample description		Text	ENDPOINT_STUDY_RECORD.MagnitudeResidualInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAAndAspiratedGrainFractionsAGF.ProcessedFraction.AnalysisSampleDescription
Analyte measured			ENDPOINT_STUDY_RECORD.MagnitudeResidualInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAAndAspiratedGrainFractionsAGF.ProcessedFraction.AnalyteMeasured
Analyte identity		Entity reference field	ENDPOINT_STUDY_RECORD.MagnitudeResidualInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractions

			PFAAndAspiratedGrainFractionsAGF.ProcessedFraction.AnalyteMeasured.AnalyteIdentity
Extraction date		Date	ENDPOINT_STUDY_RECORD.MagnitudeResidueInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAAndAspiratedGrainFractionsAGF.ProcessedFraction.AnalyteMeasured.ExtractionDate
Analysis date		Date	ENDPOINT_STUDY_RECORD.MagnitudeResidueInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAAndAspiratedGrainFractionsAGF.ProcessedFraction.AnalyteMeasured.AnalysisDate
Method ID		Text	ENDPOINT_STUDY_RECORD.MagnitudeResidueInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAAndAspiratedGrainFractionsAGF.ProcessedFraction.AnalyteMeasured.MethodID
Storage stability factor		Decimal	ENDPOINT_STUDY_RECORD.MagnitudeResidueInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAAndAspiratedGrainFractionsAGF.ProcessedFraction.AnalyteMeasured.StorageStabilityFactor
Use of factor		Text	ENDPOINT_STUDY_RECORD.MagnitudeResidueInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAAndAspiratedGrainFractionsAGF.ProcessedFraction.AnalyteMeasured.UseOfFactor
Correction by storage stability		Closed list	ENDPOINT_STUDY_RECORD.MagnitudeResidueInProcessedComm.Result

			tsAndDiscussion.ResiduesInProcessedFractionsPFAAndAspiratedGrainFractionsAGF.ProcessedFraction.AnalyteMeasured.CorrectionByStorageStability
Recovery		Decimal	ENDPOINT_STUDY_RECORD.MagnitudeResidueInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAAndAspiratedGrainFractionsAGF.ProcessedFraction.AnalyteMeasured.Recovery
Correction by recovery		Closed list	ENDPOINT_STUDY_RECORD.MagnitudeResidueInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAAndAspiratedGrainFractionsAGF.ProcessedFraction.AnalyteMeasured.CorrectionByRecovery
Reference portion		Multi-line text	ENDPOINT_STUDY_RECORD.MagnitudeResidueInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAAndAspiratedGrainFractionsAGF.ProcessedFraction.AnalyteMeasured.ReferencePortion
Residue level (measured)		Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.MagnitudeResidueInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAAndAspiratedGrainFractionsAGF.ProcessedFraction.AnalyteMeasured.ResidueLevelMeasured
Residue level (calculated)	Not needed	Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.MagnitudeResidueInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAAndAspiratedGrainFractionsAGF.ProcessedFraction.AnalyteMeasured.ResidueLevelCalculated

Residue level (calculated and corrected)	Not needed	Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.ProcessedFraction.AnalyteMeasured.ResidueLevelCalculatedAndCorrected
Analyte measured			
Processed fraction			
Aspirated grain fractions (AGF sample)	Option 1: possibility to use the repeatable block to report individual results for each AGF sample. Copy this block of fields for recording the results for each test compound per test condition. This option could be deployed in case of small data sets. Option 2: report directly the detailed information on the results for each AGF sample in the Excel file Processing trials table [cf. residue Template 6.5 (http://doi.org/10.5281/zenodo.4621130)] for residues in processed commodities to be attached in the field below "Attached sanitized documents".		ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.AspiratedGrainFractionsAGFSample
AGF analysis sample		Text	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.AspiratedGrainFractionsAGFSample.AGFAnalysisSample
Date of AGF sample		Date	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.Residu

			esInProcessedFractions PFAAndAspiratedGrainFr actionsAGF.AspiratedGr ainFractionsAGFSample. DateOfAGFSample
Analysis sample ID		Text	ENDPOINT_STUDY_RE CORD.MagnitudeResidI nProcessedComm.Result sAndDiscussion.Residu esInProcessedFractions PFAAndAspiratedGrainFr actionsAGF.AspiratedGr ainFractionsAGFSample. AnalysisSampleID
Analyte measured			ENDPOINT_STUDY_RE CORD.MagnitudeResidI nProcessedComm.Result sAndDiscussion.Residu esInProcessedFractions PFAAndAspiratedGrainFr actionsAGF.AspiratedGr ainFractionsAGFSample. AnalyteMeasured
Analyte identity		Entity reference field	ENDPOINT_STUDY_RE CORD.MagnitudeResidI nProcessedComm.Result sAndDiscussion.Residu esInProcessedFractions PFAAndAspiratedGrainFr actionsAGF.AspiratedGr ainFractionsAGFSample. AnalyteMeasured.Analyt eIdentity
Extraction date		Date	ENDPOINT_STUDY_RE CORD.MagnitudeResidI nProcessedComm.Result sAndDiscussion.Residu esInProcessedFractions PFAAndAspiratedGrainFr actionsAGF.AspiratedGr ainFractionsAGFSample. AnalyteMeasured.Extrac tionDate
Analysis date		Date	ENDPOINT_STUDY_RE CORD.MagnitudeResidI nProcessedComm.Result sAndDiscussion.Residu esInProcessedFractions PFAAndAspiratedGrainFr actionsAGF.AspiratedGr ainFractionsAGFSample.

			AnalyteMeasured.AnalysisDate
Method ID		Text	ENDPOINT_STUDY_RECORD.MagnitudeResidueInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAAndAspiratedGrainFractionsAGF.AspiratedGrainFractionsAGFSample.AnalyteMeasured.MethodID
Storage stability factor		Decimal	ENDPOINT_STUDY_RECORD.MagnitudeResidueInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAAndAspiratedGrainFractionsAGF.AspiratedGrainFractionsAGFSample.AnalyteMeasured.StorageStabilityFactor
Use of factor		Text	ENDPOINT_STUDY_RECORD.MagnitudeResidueInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAAndAspiratedGrainFractionsAGF.AspiratedGrainFractionsAGFSample.AnalyteMeasured.UseOfFactor
Correction by storage stability		Closed list	ENDPOINT_STUDY_RECORD.MagnitudeResidueInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAAndAspiratedGrainFractionsAGF.AspiratedGrainFractionsAGFSample.AnalyteMeasured.CorrectionByStorageStability
Recovery		Decimal	ENDPOINT_STUDY_RECORD.MagnitudeResidueInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAAndAspiratedGrainFractionsAGF.AspiratedGrainFractionsAGFSample.AnalyteMeasured.Recovery

Correction by recovery		Closed list	ENDPOINT_STUDY_RECORD.MagnitudeResidueInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPAndAspiratedGrainFractionsAGF.AspiratedGrainFractionsAGFSample.AnalyteMeasured.CorrectionByRecovery
Residue level (measured)		Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.MagnitudeResidueInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPAndAspiratedGrainFractionsAGF.AspiratedGrainFractionsAGFSample.AnalyteMeasured.ResidueLevelMeasured
Residue level (calculated)		Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.MagnitudeResidueInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPAndAspiratedGrainFractionsAGF.AspiratedGrainFractionsAGFSample.AnalyteMeasured.ResidueLevelCalculated
Residue level (calculated and corrected)		Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.MagnitudeResidueInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPAndAspiratedGrainFractionsAGF.AspiratedGrainFractionsAGFSample.AnalyteMeasured.ResidueLevelCalculatedAndCorrected
Analyte measured			
Aspirated grain fractions (AGF sample)			
Distribution of residues	Report quantitative information on the recovery of the residue from the processed commodities.	Text area	ENDPOINT_STUDY_RECORD.MagnitudeResidueInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPAndAspiratedGrainFr

			actionsAGF.DistributionOfResidues
Any other information on results incl. tables	In this field, you can enter any other remarks on results. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format.	Header 2	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
		Rich text area	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables.OtherInformation
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.OverallRemarksAttachments
Overall remarks		Rich text area	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.OverallRemarksAttachments.RemarksOnResults
Attached background material			ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.OverallRemarksAttachments.AttachedBackgroundMaterial
Attached document		Single file attachment	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.OverallRemarksAttachments.AttachedBackgroundMaterial.AttachedDocument
Remarks		Text	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.OverallRemarksAttachments.AttachedBackgroundMaterial.Remarks
Attached background material			

Attached full study report		Attachments list	ENDPOINT_STUDY_RECORD.MagnitudeResidualProcessedComm.OverallRemarksAttachments.AttachedStudyReport
Illustration (picture/graph)		Image	ENDPOINT_STUDY_RECORD.MagnitudeResidualProcessedComm.OverallRemarksAttachments.IllustrationPicGraph
Attached (sanitised) documents for publication	Please upload here the Excel file Processing trials table. An empty Excel file to report Residues in Processed commodities is available on the 'knowledge junction' [cf. residue Template 6.5 (http://doi.org/10.5281/zenodo.4621130)]. The uploaded file should not contain confidential material.	Attachments list	ENDPOINT_STUDY_RECORD.MagnitudeResidualProcessedComm.OverallRemarksAttachments.AttachedSanitisedDocsForPublication
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.MagnitudeResidualProcessedComm.ApplicantSummaryAndConclusion
Conclusions	The assessment and conclusion of the applicant should be reported here.	Text area	ENDPOINT_STUDY_RECORD.MagnitudeResidualProcessedComm.ApplicantSummaryAndConclusion.Conclusions
Executive summary	Briefly summarise the relevant aspects of the study including the conclusions reached. Example: [crop] field trial for [active ingredient] was conducted in [country, location] during the [year] growing season. [Active ingredient, % ai, formulation type] was applied to [crop] at [rate of application (xx g ai/ha)] and harvested xx days after final	Rich text area	ENDPOINT_STUDY_RECORD.MagnitudeResidualProcessedComm.ApplicantSummaryAndConclusion.ExecutiveSummary

	<p>treatment. The [RAC samples] were processed into [processed food/feed fractions] using [simulated commercial practices].</p> <p>All samples were frozen at the testing facility and remained frozen during shipping and storage prior to processing and analysis. The maximum storage interval for samples was [xx] days/months [specify period from harvest to processing and from processing to analysis]. Storage conditions and durations are supported by studies showing that residues of [active ingredient] are stable in [crops/processed commodities] for up to [xx] days under frozen conditions.</p> <p>Samples in the current study were analyzed using Method [Method ID], a [describe method] method to determine residues of [list analytes]. Acceptable [method validation and] concurrent recoveries were reported for [matrices] samples at fortification levels of [xx] mg/kg, thus validating the method. The limit of quantitation (LOQ) was [xx] mg/kg per analyte for [matrices].</p>		
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	A comparison of the residues in the raw agricultural commodity (RAC) with those in each processed fraction resulted in processing factors of [processing factors] for [processed fractions], respectively. These processing factors [conform/did not conform] with the theoretical concentration factors.		
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6.7 Proposed residue definitions and maximum residue levels

6.7.1 Proposed residue definitions – Endpoint summary

Purpose:

provide a summary overview on the residue definitions for commodities of plant and animal origin as derived on the basis of available metabolism studies in plant, livestock and processed commodities; and to provide conclusions on which compounds are to be included in the residue definitions for enforcement and risk assessment. In this endpoint summary, you should also highlight the provisional (i.e. tentative) residue definitions and their relevant data gaps.

ENDPOINT_SUMMARY.ResidueFood v.2.1 (Final)			
Name	Instructions	Type	Field path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.ResidueFood.AdministrativeDataSummary
	See Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	Confidentiality	ENDPOINT_SUMMARY.ResidueFood.AdministrativeDataSummary.Data Protection
Description of key information		Header 1	ENDPOINT_SUMMARY.ResidueFood.KeyInformation
	Optional text box to specify any particular issue related to the residue definitions, that could not be reported in the following tables.	Rich text area	ENDPOINT_SUMMARY.ResidueFood.KeyInformation.KeyInformation

Food / feed of plant origin residue definition risk assessment	Use the repeatable block to create as many rows as necessary to reflect the residue definition(s) for risk assessment for each combination "crop group/metabolism group/treatment type/provisional or not". Please make sure that a residue definition for risk assessment is proposed for all combinations that are relevant for this application		ENDPOINT_SUMMARY. ResidueFood.KeyInformation.FoodFeedPlantOriginResidueRa
Crop group	Indicate if the residue definition covers primary crops and/or processed commodities and/or rotational crops. Please make sure that a residue definition for risk assessment is proposed for each item of the picklist, unless not required (e.g. not relevant for rotational crops)	Multi select closed list with remarks	ENDPOINT_SUMMARY. ResidueFood.KeyInformation.FoodFeedPlantOriginResidueRa.CropGroup
Metabolism group	If the residue definition is for primary crops or rotational crops, then select the metabolism group(s) for which the RD is applicable (from list OECD list Crops and Crop Groups for Purposes of Metabolism in Crops Studies)	Multi select open list with remarks	ENDPOINT_SUMMARY. ResidueFood.KeyInformation.FoodFeedPlantOriginResidueRa.MetabolismGroup
Treatment type	Indicate the type(s) of treatment for which the RD is applicable (e.g. seed treatment or foliar application)	Multi select open list with remarks	ENDPOINT_SUMMARY. ResidueFood.KeyInformation.FoodFeedPlantOriginResidueRa.TreatmentType
Residue definition risk assessment	Write here the full name of the residue definition for risk assessment; please use the exact wording in line with the current standards (e.g. sum of	Multi-line text	ENDPOINT_SUMMARY. ResidueFood.KeyInformation.FoodFeedPlantOriginResidueRa.ResidueDefinitionRisk

	parent and metabolite 01, expressed as parent).		
Residue definition risk assessment components	Select the substance(s) (parent and/or metabolites/breakdown products) that is/are part of the residue definition written above	Entity reference list	ENDPOINT_SUMMARY. ResidueFood.KeyInformation.FoodFeedPlantOriginResidueRa.ResidueDefinitionRiskComp
Provisional	Indicate if the residue definition for risk assessment is provisional, if yes a remark field will open where the data gaps should be reported. Please note that if there is a data gap, the RD should be considered provisional.	Closed list with remarks (2000)	ENDPOINT_SUMMARY. ResidueFood.KeyInformation.FoodFeedPlantOriginResidueRa.Provisional
Remarks	Any additional remarks regarding the proposed RD for risk assessment (e.g. common RD with other substances, RD1 associated with tox references value of compound 1, RD2 associated with tox references value of compound 2...).	Multi-line text	ENDPOINT_SUMMARY. ResidueFood.KeyInformation.FoodFeedPlantOriginResidueRa.Remarks
Food / feed of plant origin residue definition risk assessment			
Food / feed of plant origin residue definition for monitoring	Use the repeatable block to create as many rows as necessary to reflect the residue definition(s) for monitoring for each combination "metabolism group/provisional or not". Please note that for monitoring RD, no distinction be made between primary and rotational crops.		ENDPOINT_SUMMARY. ResidueFood.KeyInformation.FoodFeedPlantOriginMonitoring
Metabolism group	Select the metabolism group(s) for which the RD is applicable (from	Multi select open list with remarks	ENDPOINT_SUMMARY. ResidueFood.KeyInformation.FoodFeedPlantOr

	list OECD list Crops and Crop Groups for Purposes of Metabolism in Crops Studies)		iginMonitoring.MetabolismGroup
Residue definition monitoring	Write here the full name of the residue definition for monitoring; please use the exact wording in line with the current standards (e.g. sum of parent and metabolite 01, expressed as parent).	Multi-line text	ENDPOINT_SUMMARY. ResidueFood.KeyInformation.FoodFeedPlantOriginMonitoring.ResidueDefinitionMonitoring
Residue definition monitoring components	Select the substance(s) (parent and/or metabolites/breakdown products) that is/are part of the residue definition written above	Entity reference list	ENDPOINT_SUMMARY. ResidueFood.KeyInformation.FoodFeedPlantOriginMonitoring.ResidueDefinitionMonitoringComponent
Monitoring residue definition LOQ (mg/kg)	Limit of quantification (LOQ) for the residue definition for monitoring and enforcement	Decimal	ENDPOINT_SUMMARY. ResidueFood.KeyInformation.FoodFeedPlantOriginMonitoring.MonitoringResidueDefinitionLoq
Provisional	Indicate if the residue definition for monitoring is provisional, if yes describe a remark field will open where the data gap(s) should be reported. Please note that if there is a data gap, the RD should be considered provisional.	Closed list with remarks (2000)	ENDPOINT_SUMMARY. ResidueFood.KeyInformation.FoodFeedPlantOriginMonitoring.Provisional
Remarks	Any additional remarks regarding the proposed RD monitoring (e.g. common RD with other substance(s)...))	Multi-line text	ENDPOINT_SUMMARY. ResidueFood.KeyInformation.FoodFeedPlantOriginMonitoring.Remarks
Validated method	Indicate if a validated method for Monitoring (including inter-laboratory validation ILV) is available for the proposed residue definition.	Check box	ENDPOINT_SUMMARY. ResidueFood.KeyInformation.FoodFeedPlantOriginMonitoring.ValidateMethod
Link to validated method	Link to the study describing method for monitoring and its validation	Endpoint reference field	ENDPOINT_SUMMARY. ResidueFood.KeyInformation.FoodFeedPlantOr

			iginMonitoring.LinkToValidatedMethod
Food / feed of plant origin residue definition for monitoring			
Food of animal origin residue definition risk assessment	Use the repeatable block to create as many rows as necessary to reflect the residue definition(s) for risk assessment for each combination "animal commodity/provisional or not".		ENDPOINT_SUMMARY. ResidueFood.KeyInformation.AnimalFoodFeedPlantOriginRa
Animal	Select the animal group(s) (e.g. ruminants) for which the proposed residue definition is applicable. If the same residue definition is applicable to several animals (e.g. ruminants and pigs), multi-selection feature can be used.	Open list with remarks	ENDPOINT_SUMMARY. ResidueFood.KeyInformation.AnimalFoodFeedPlantOriginRa.Animal
Commodity	Select the animal product(s) (e.g. liver or eggs) for which the proposed residue definition is applicable. Please make sure that a residue definition for risk assessment is proposed for each item of the picklist. If the same residue definition is applicable to several commodities (e.g. for all tissues of ruminants and pigs), multi-selection feature can be used.	Multi select open list with remarks	ENDPOINT_SUMMARY. ResidueFood.KeyInformation.AnimalFoodFeedPlantOriginRa.Commodity
Residue definition risk assessment	Write here the full name of the residue definition for risk assessment; please use the exact wording in line with the current standards (e.g. sum of parent and metabolite	Multi-line text	ENDPOINT_SUMMARY. ResidueFood.KeyInformation.AnimalFoodFeedPlantOriginRa.ResidueDefinitionRiskAssessment

	01, expressed as parent).		
Residue definition risk assessment components	Select the substance(s) (parent and/or metabolites/breakdown products) that is/are part of the residue definition written above	Entity reference list	ENDPOINT_SUMMARY. ResidueFood.KeyInformation.AnimalFoodFeedPlantOriginRa.ResidueDefinitionRiskAssessmentComponents
Provisional	Indicate if the residue definition for risk assessment is provisional, if yes a remark field will open where the data gaps should be reported. Please note that if there is a data gap, the RD should be considered provisional.	Closed list with remarks (2000)	ENDPOINT_SUMMARY. ResidueFood.KeyInformation.AnimalFoodFeedPlantOriginRa.Provisional
Remarks	Any additional remarks regarding the proposed RD for risk assessment (e.g. common RD with other substances, RD1 associated with tox references value of compound 1, RD2 associated with tox references value of compound 2...).	Multi-line text	ENDPOINT_SUMMARY. ResidueFood.KeyInformation.AnimalFoodFeedPlantOriginRa.Remarks
Food of animal origin residue definition risk assessment			
Food of animal origin residue definition monitoring	Use the repeatable block to create as many rows as necessary to reflect the residue definition(s) for monitoring for each combination "animal commodity/provisional or not".		ENDPOINT_SUMMARY. ResidueFood.KeyInformation.AnimalFoodFeedPlantOriginMonitoring
Animal	Select the animal group(s) (e.g ruminants) for which the proposed residue definition is applicable. If the same residue definition is applicable to several animals (e.g. ruminants and pigs),	Open list	ENDPOINT_SUMMARY. ResidueFood.KeyInformation.AnimalFoodFeedPlantOriginMonitoring.Animal

	multi-selection feature can be used.		
Commodity	Select the animal product(s) (e.g. liver or eggs) for which the proposed residue definition is applicable. If the same residue definition is applicable to several commodities (e.g. r all tissues of ruminants and pigs), multi-selection feature can be used.	Multi select open list with remarks	ENDPOINT_SUMMARY. ResidueFood.KeyInformation.AnimalFoodFeedPlantOriginMonitoring.Commodity
Residue definition monitoring	Write here the full name of the residue definition for risk assessment; please use the exact wording in line with the current standards (e.g. sum of parent and metabolite 01, expressed as parent).	Multi-line text	ENDPOINT_SUMMARY. ResidueFood.KeyInformation.AnimalFoodFeedPlantOriginMonitoring.ResidueDefinitionMonitoring
Residue definition monitoring components	Select the substance(s) (parent and/or metabolites/breakdown products) that is/are part of the residue definition written above	Entity reference list	ENDPOINT_SUMMARY. ResidueFood.KeyInformation.AnimalFoodFeedPlantOriginMonitoring.ResidueDefinitionMonitoringComp
Monitoring residue definition LOQ (mg/kg)	Limit of quantification (LOQ) for the residue definition for monitoring and enforcement	Decimal	ENDPOINT_SUMMARY. ResidueFood.KeyInformation.AnimalFoodFeedPlantOriginMonitoring.MonitoringResidueDefinitionLoq
Provisional	Indicate if the residue definition for monitoring is provisional, if yes describe a remark field will open where the data gap(s) should be reported. Please note that if there is a data gap, the RD should be considered provisional.	Closed list with remarks (2000)	ENDPOINT_SUMMARY. ResidueFood.KeyInformation.AnimalFoodFeedPlantOriginMonitoring.Provisional
Remarks	Any additional remarks regarding the proposed RD monitoring (e.g. common RD with other substance(s)...)	Multi-line text	ENDPOINT_SUMMARY. ResidueFood.KeyInformation.AnimalFoodFeedPlantOriginMonitoring.Remarks

Validated method	Indicate if a validated method for Monitoring (including inter-laboratory validation ILV) is available for the proposed residue definition.	Check box	ENDPOINT_SUMMARY.ResidueFood.KeyInformation.AnimalFoodFeedPlantOriginMonitoring.ValidatedMethod
Link to validated method	Link to the study describing method for monitoring and its validation	Endpoint reference field	ENDPOINT_SUMMARY.ResidueFood.KeyInformation.AnimalFoodFeedPlantOriginMonitoring.LinkToValidatedMethod
Food of animal origin residue definition monitoring			
Additional information	Discussion(Header 1) – common block	Header 1	ENDPOINT_SUMMARY.ResidueFood.Discussion

6.7.2 Proposed maximum residue levels and justification – Flexible summary

Purpose:

provide a summary overview on the proposed MRLs for commodities of plant and animal origin as derived on the basis of supervised residue field trials (for plants) or from livestock feeding studies (for animal commodities). In this endpoint summary, you should also highlight the tentative/indicative MRLs and their relevant data gaps, indicate the proposed extrapolations and discuss the eventual non-standard uncertainty.

FLEXIBLE_SUMMARY.MRLProposal v2.3 (Final)			
Name	Instructions	Type	Field path
Administrative data	Administrative data summary – common block	Header 1	FLEXIBLE_SUMMARY.MRLProposal.AdministrativeDataSummary
		Confidentiality	FLEXIBLE_SUMMARY.MRLProposal.AdministrativeDataSummary.DataProtection
Description of key information		Header 1	FLEXIBLE_SUMMARY.MRLProposal.KeyInformation
	Optional text box to specify any particular issue related to the proposed MRL(s), that could not be reported in the following table.	Rich text area	FLEXIBLE_SUMMARY.MRLProposal.KeyInformation.KeyInformation
Maximum residue level	Use the repeatable block to create as many		FLEXIBLE_SUMMARY.MRLProposal.KeyInforma

	<p>rows as necessary to report each MRL proposed in this application. Please report only one MRL proposal per combination "commodity/residue definition for monitoring". If for a given plant commodity, different MRLs could be derived in section 6.3 (based different GAPs), please only report the MRL to be proposed for inclusion in the Regulation (i.e. highest MRL for which no safety concerns are identified). Also note that only MRLs fully supported by data are expected to be reported in this table. A MRL proposal should be linked to a GAP, to at least one commodity and to a residue definition for monitoring (RD MO). If more than one RD MO are derived for this active substance, please propose one MRL per RD MO.</p>		<p>tion.MaximumResidueLevel</p>
Rationale for MRL proposal	<p>Please indicate the reason why a new MRL is proposed, by choosing one or more rationale(s). Repeat this action for each MRL proposed in this table. Examples: - if an MRL on wheat grain is directly derived from a GAP on wheat, please select "use on primary crop". - If an MRL on commodity of animal origin is derived because the GAP on</p>	<p>Open list with remarks (2000)</p>	<p>FLEXIBLE_SUMMARY.MRLProposal.KeyInformation.MaximumResidueLevel.RationaleForMrl</p>

	wheat leads to a significant increase of the dietary burden, please select "increase of the livestock dietary burden".		
Critical GAP	<p>This entry refers to the critical GAP(s), on which the MRL proposal is based.</p> <p>Please note that cross-link to GAP is not possible. Therefore, the exact name of the GAP document as reported in the product dataset should be reported in the text box.</p> <p>If rationale for the MRL proposal is "use on primary crop", please enter the document name/s of the corresponding GAP document/s from the product dataset in the text box. The corresponding GAP is/are the critical GAP(s), on which the MRL proposal is based.</p> <p>In case of several GAPs for the same commodity/crop (e.g. SEU, NEU, indoor, third countries) only the GAP resulting in the highest MRL proposal (not leading to consumer safety concerns) should be reported here. If the MRL proposal is based on a combined dataset linked to several GAPs, all these GAP should be reported here. If rationale for MRL proposal is "residue in rotational crops from soil uptake", report</p>	MultiLineText2000	FLEXIBLE_SUMMARY.MRLProposal.KeyInformation.MaximumResidueLevel.CriticalGap

	here the GAP leading to highest residue in soil.		
Commodity	<p>The picklist contain all commodities of plant and animal origin to which MRLs apply according to Annex I of Reg. (EC) No 396/2005, plus products or part of products exclusively used for animal feed production.</p> <p>Indicate the commodity(ies) for which MRL is/are derived. Please repeat this block for each MRL. In case of extrapolation with similar MRL for different commodities, the extrapolated commodities can be selected using the multi-selection (e.g. apples, pears, quinces).</p>	Multi select open list	FLEXIBLE_SUMMARY.MRLProposal.KeyInformation.MaximumResidueLevel.Commodity
MRL proposal	<p>This field refers to the MRL proposal (in mg/kg) in the commodity(ie)y of plant or animal origin. In case of multiple GAPs, the highest MRL (expressed on RD for monitoring) and not leading to consumer safety concerns should be inserted here. Only MRLs fully supported by data are expected to be reported in this table. Therefore, provisional MRLs are not expected to be reported in this table.</p>	Unit measure with Closed List (Decimal)	FLEXIBLE_SUMMARY.MRLProposal.KeyInformation.MaximumResidueLevel.MrlProposal
Residue definition monitoring	<p>Enter the monitoring residue definition relevant for the selected commodities of plant or animal origin. This is the residue definition on</p>	Multi-line text	FLEXIBLE_SUMMARY.MRLProposal.KeyInformation.MaximumResidueLevel.ResidueDefinitionMonitoring

	which the MRL is derived.		
MRL at LOQ	Tick this box to indicate if the MRL is proposed at the enforcement LOQ (equivalent to symbol * in the EU MRL database).	Check box	FLEXIBLE_SUMMARY.MRLProposal.KeyInformation.MaximumResidueLevel.MrlLoq
Remarks	Any additional remarks linked to the MRL derived.	Multi-line text	FLEXIBLE_SUMMARY.MRLProposal.KeyInformation.MaximumResidueLevel.Remarks
Maximum residue level			
Additional information	Discussion(Header 1) – common block	Header 1	FLEXIBLE_SUMMARY.MRLProposal.Discussion
	<p>Provide any additional information related to the MRL proposal(s), e.g., cases where MRL proposal are based on results from other crops.</p> <p>In support of the MRLs proposed for plant commodities, please attach here the OECD calculator Excel file, available on https://www.oecd.org/env/ehs/pesticides-biocides/oecdmaximumresiduelimitcalculator.htm, including the residue values used to derive the MRL proposal(s). The MRLs proposed for animal commodities, should be justified by the Animal Calculator Excel, which is uploaded in the endpoint summary of Section 6.4 (Feeding studies). The uploaded file should not contain confidential material.</p> <p>Upload this information into the Attached</p>	Rich text area	FLEXIBLE_SUMMARY.MRLProposal.Discussion.Discussion

	(sanitised) documents for publication field		
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Maximum residue level + New item 📄 Import file ▼						
#	Rationale for MRL propo...	Critical GAP	Commodity	MRL proposal	Residue definition m...	MRL at LOQ
1	use on primary crop	Citrus_SEU.002 UUID752403c0- ee82-4c0c- a195-2e1c158951e 1	✓ 0110050 - Mandarins (0100000 - Fruits, fresh or frozen; tree nuts > 0110000 - Citrus fruits > 0110050 - Mandarins)	2 mg/kg	parent	<input type="checkbox"/>

6.9 Estimation of the potential and actual exposure through diet and other sources – Flexible summary

Purpose:

To provide an overview of the estimated potential or actual exposure to the active substance/metabolite(s) to humans through the intake of food and other means from the uses under consideration (e.g. representative/intended GAP and/or MRLs) and highlighting whether a risk for consumer is expected. In the long-term (chronic) risk assessment, the estimated chronic dietary exposure is compared with the acceptable daily intake (ADI) value which gives the concentration of a chemical that can be consumed over a long period without unacceptable negative health effects. For the short-term (acute) risk assessment, the Acute Reference Dose (ARfD) is used to identify possible consumer health risks. The ARfD gives the concentration of a chemical that can be ingested over a short period of time (one meal, one day) without appreciable risks. EFSA PRIMo (Pesticide Residue Intake Model), an Excel-based calculation spreadsheet, is the standard tool used at EU level to perform the dietary risk assessment for pesticide residues in the framework of setting and reviewing of maximum residue levels for pesticides under Regulation(EC) No 396/2005 and in the peer review of pesticides under Regulation (EU) No 1107/2009. EFSA guidance on the Use of EFSA PRIMo rev 3, available <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2018.5147>.

FLEXIBLE_SUMMARY.ExpectedExposure v.2.2 (Final)			
Name	Instructions	Type	Field path
Administrative data		Header 1	FLEXIBLE_SUMMARY.ExpectedExposure.AdministrativeDataSummary
	See Confidentiality Requests Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	Confidentiality	FLEXIBLE_SUMMARY.ExpectedExposure.AdministrativeDataSummary.DataProtection
Description of key information		Header 1	FLEXIBLE_SUMMARY.ExpectedExposure.KeyInformation

	<p>Optional text box to specify any issue related to the exposure assessment that could not be reported in the following tables. Make reference to the risk assessment residue definition reported in the Proposed residue definitions document, the toxicological reference values reported in the Toxicological reference values document and Processing/peeling factors reporting in the Nature and magnitude of residues in processed commodities document.</p> <p>When estimating the exposure, it shall be born in mind that the risk assessment has to take into account the residue definition established for risk assessment.</p> <p>Describe if relevant, the possible presence of pesticide residues arising from sources other than current plant protection uses of active substances (for example use of active substances resulting in common metabolites, use as biocide or veterinary drug), and how their aggregate exposure shall be taken into account.</p> <p>Describe the method and results, if cumulative exposure to more</p>	Rich text area	<p>FLEXIBLE_SUMMARY.ExpectedExposure.KeyInformation.KeyInformation</p>
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	<p>than one active substance has been performed.</p> <p>If different exposure scenario are performed in the dossier, this should be reflected in different endpoint summaries. Please create on endpoint summary per scenario. Similarly, if both TMDI and IEDI are calculated to assess the chronic exposure, this should be reported in separate documents.</p>		
Exposure from dietary sources	Summarize results from PRIMO such as TMDI/IEDI (% ADI), IESTI (% ARfD) indicating the uses under consideration (e.g. representatives and/or MRLs) and highlighting whether a risk for consumer is expected.	Header 2	FLEXIBLE_SUMMARY.ExpectedExposure.KeyInformation.ExposureDietarySources
Model	Select PRIMO version (e.g. "PRIMo 3.1") if 'other' is selected provide details in the remarks	Open list with remarks	FLEXIBLE_SUMMARY.ExpectedExposure.KeyInformation.ExposureDietarySources.Model
Residue definition(s) for risk assessment	Specify the compound(s), e.g., parent + metabolite(s), that are considered in the present exposure assessment.	Text	FLEXIBLE_SUMMARY.ExpectedExposure.KeyInformation.ExposureDietarySources.ResidueDefinitionSForRiskAssessment
Toxicological reference values	Please select the document (from the mammalian toxicology section) where are reported the toxicological reference values (ADI and ARfD) relevant for this risk assessment.	Endpoint reference field	FLEXIBLE_SUMMARY.ExpectedExposure.KeyInformation.ExposureDietarySources.ToxicologicalReferenceValues
Chronic exposure		Header 3	FLEXIBLE_SUMMARY.ExpectedExposure.KeyInformation.ExposureDiet

			arySources.ChronicExposure
TMDI or IEDI	Specify if TMDI or IEDI calculations.	Open list with remarks	FLEXIBLE_SUMMARY.ExpectedExposure.KeyInformation.ExposureDietarySources.ChronicExposure.TMDIOrIEDI
Assumptions	Specify the scenario under assessment and the assumptions taken for the chronic exposure calculations: e.g. if possible exposure from other sources were considered such as non-EU PPP compounds (e.g. biocide or veterinary drug), other active substances resulting in common metabolites; if residues from rotational crops were considered; if Codex MRLs were considered; if any risk mitigation measures are applied; if other non-standard factors affecting the calculation are applied.	Multi-line text	FLEXIBLE_SUMMARY.ExpectedExposure.KeyInformation.ExposureDietarySources.ChronicExposure.Assumptions
Toxicological reference value (ADI) (converted)	[Only if needed]: If the TRV taken from the TRV document can directly be considered without conversion, this field is not relevant. If there is a need to convert the TRV to match with the expression of the RDA (e.g. if the TRV is expressed for the variant but the RDA is expressed as acid), please report the converted value of the TRV here and explain the rationale for the conversion (incl. the factors used).	Unit measure with Open List (Decimal)	FLEXIBLE_SUMMARY.ExpectedExposure.KeyInformation.ExposureDietarySources.ChronicExposure.ToxicologicalReferenceValueADIConverted

Total exposure (absolute value)	Please report the absolute value of the highest calculated chronic exposures among all surveys/populations.	Unit measure with Open List (Decimal)	FLEXIBLE_SUMMARY.ExpectedExposure.KeyInformation.ExposureDietarySources.ChronicExposure.TotalExposureAbsoluteValue
Total exposure (% of ADI)	Please report the value of the highest calculated chronic (among all surveys/populations) as % of ADI.	Decimal	FLEXIBLE_SUMMARY.ExpectedExposure.KeyInformation.ExposureDietarySources.ChronicExposure.TotalExposureOfADI
Population / Survey	Please report the name of the survey/population for which the highest chronic exposure was identified. This information is available in PRIMo excel file.	Open list with remarks	FLEXIBLE_SUMMARY.ExpectedExposure.KeyInformation.ExposureDietarySources.ChronicExposure.PopulationSurvey
Contribution of commodities			FLEXIBLE_SUMMARY.ExpectedExposure.KeyInformation.ExposureDietarySources.ChronicExposure.ContributionOfCommodities
Commodity - chronic exposure	Commodities of plant and animal origin available for the PRIMo calculations (to assess the chronic exposure):	Open list	FLEXIBLE_SUMMARY.ExpectedExposure.KeyInformation.ExposureDietarySources.ChronicExposure.ContributionOfCommodities.Commodity
Chronic exposure from this commodity (absolute value)	Please report the absolute value of the chronic exposure due to the above mentioned commodity (highest calculated chronic exposures among all surveys/populations).	Unit measure with Open List (Decimal)	FLEXIBLE_SUMMARY.ExpectedExposure.KeyInformation.ExposureDietarySources.ChronicExposure.ContributionOfCommodities.ChronicExposureFromThisCommodityAbsoluteValue
Chronic exposure from this commodity (% of ADI)	Please report the value of the highest calculated chronic (among all surveys/populations) as % of ADI. Please report the value of the chronic exposure due to the above mentioned commodity as % of ADI (highest	Decimal	FLEXIBLE_SUMMARY.ExpectedExposure.KeyInformation.ExposureDietarySources.ChronicExposure.ContributionOfCommodities.ChronicExposureFromThisCommodityOfADI

	calculated chronic exposures among all surveys/populations).		
Population / Survey	Please report the name of the survey/population for which the highest chronic exposure was identified. This information is available in PRIMo excel file.	Open list with remarks	FLEXIBLE_SUMMARY.ExpectedExposure.KeyInformation.ExposureDietarySources.ChronicExposure.ContributionOfCommodities.PopulationSurvey
Contribution of commodities			
Acute exposure		Header 3	FLEXIBLE_SUMMARY.ExpectedExposure.KeyInformation.ExposureDietarySources.AcuteExposure
Assumptions	Specify the scenario under assessment and the assumptions taken for the acute exposure calculations: e.g., if possible exposure from other sources were considered such as non-EU PPP compounds (e.g. biocide or veterinary drug), other active substances resulting in common metabolites; if residues from rotational crops were considered; if Codex MRLs were considered; if any risk mitigation measures are applied; if other non-standard factors affecting the calculation are applied.	Multi-line text	FLEXIBLE_SUMMARY.ExpectedExposure.KeyInformation.ExposureDietarySources.AcuteExposure.Assumptions
Toxicological reference value (ARfD) (converted)	[Only if needed]: If the TRV taken from the TRV document can directly be considered without conversion, this field is not relevant. If there is a need to convert the TRV to match with the expression of the RD RA (e.g., if the tRV is	Unit measure with Open List (Decimal)	FLEXIBLE_SUMMARY.ExpectedExposure.KeyInformation.ExposureDietarySources.AcuteExposure.ToxicologicalReferenceValueARfDConverted

	expressed for the variant but the RD RA is expressed as acid), please report the converted value of the TRV here and explain the rational for the conversion (incl. the factors used).		
Acute exposure			FLEXIBLE_SUMMARY.ExpectedExposure.KeyInformation.ExposureDietarySources.AcuteExposure.AcuteExposure
Commodity - acute exposure	Commodities of plant and animal origin for which an acute exposure can be calculated in PRIMo:	Open list	FLEXIBLE_SUMMARY.ExpectedExposure.KeyInformation.ExposureDietarySources.AcuteExposure.AcuteExposure.Commodity
Exposure (absolute value)	Please report the absolute value of the acute exposure calculated for the commodity(ies) under assessment. Please report the highest IESTI.	Unit measure with Open List (Decimal)	FLEXIBLE_SUMMARY.ExpectedExposure.KeyInformation.ExposureDietarySources.AcuteExposure.AcuteExposure.ExposureAbsoluteValue
Exposure (% of ARfD)	Please report the acute exposure as % of ARfD calculated for the commodity(ies) under assessment. Please report the highest IESTI	Decimal	FLEXIBLE_SUMMARY.ExpectedExposure.KeyInformation.ExposureDietarySources.AcuteExposure.AcuteExposure.ExposureOfARfD
Acute exposure			
Exposure from other sources (drinking water)		Header 2	FLEXIBLE_SUMMARY.ExpectedExposure.KeyInformation.ExposureOtherSources
	Exposure from other sources (drinking water). Please report in the Table the additional contribution to consumer intake through drinking water resulting from groundwater	Rich text area	FLEXIBLE_SUMMARY.ExpectedExposure.KeyInformation.ExposureOtherSources.field4124

	<p>metabolites expected to be present above 0.75 µg/L. Indicate any metabolites included in the exposure assessment. Report PE Cgw or make reference to the information reported in Estimation of concentrations in ground water. Please use the recommended formats, available on knowledge junction [cf. residue Template 6.1 (http://doi.org/10.5281/zenodo.4621833)], Table 6.9]. Please repeat the tables as much as necessary.</p>		
Additional information	<p>Discussion(Header 1) – common block</p> <p>Please upload here the PRIMo calculation. In case different scenarios are assessed, please repeat the block as much as necessary and explain the different scenarios in the remark field.</p> <p>An empty template of the PRIMo file is available on `knowledge junction (Residue Template 6.6: PRIMo rev.3.: http://doi.org/10.5281/zenodo.1137758).</p> <p>The uploaded file should not contain confidential material.</p>	Header 1	FLEXIBLE_SUMMARY.ExpectedExposure.Discussion

Links to support material:

FAO Manual (FAO, 2016): <http://www.fao.org/3/i5452e/i5452e.pdf>

6.10 Other studies – Endpoint summary

ENDPOINT_SUMMARY.AdditionalInformationOnResiduesInFoodAndFeedingstuffs v.6.3 (Final)			
Name	Instructions	Type	Field path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.AdditionalInformationOnResiduesInFoodAndFeedingstuffs.AdministrativeDataSummary
		Confidentiality	ENDPOINT_SUMMARY.AdditionalInformationOnResiduesInFoodAndFeedingstuffs.AdministrativeDataSummary.DataProtection
Link to relevant study record(s)		Header 1	ENDPOINT_SUMMARY.AdditionalInformationOnResiduesInFoodAndFeedingstuffs.LinkToRelevantStudyRecord
Study name / type		Endpoint reference list	ENDPOINT_SUMMARY.AdditionalInformationOnResiduesInFoodAndFeedingstuffs.LinkToRelevantStudyRecord.Link
Description of key information		Header 1	ENDPOINT_SUMMARY.AdditionalInformationOnResiduesInFoodAndFeedingstuffs.KeyInformation
		Rich text area	ENDPOINT_SUMMARY.AdditionalInformationOnResiduesInFoodAndFeedingstuffs.KeyInformation.KeyInformation
Additional information	Discussion(Header 1) – common block	Header 1	ENDPOINT_SUMMARY.AdditionalInformationOnResiduesInFoodAndFeedingstuffs.Discussion
	Provide a brief description of additional study(ies) and of the key conclusions derived from this/these study(ies).	Rich text area	ENDPOINT_SUMMARY.AdditionalInformationOnResiduesInFoodAndFeedingstuffs.Discussion.Discussion
Attached background material	Provide the original version of any additional useful document that contains confidential material		ENDPOINT_SUMMARY.AdditionalInformationOnResiduesInFoodAndFeedingstuffs.Discussion.

			AttachedBackgroundMaterial
Attached document	The original file only needs to be attached here if it differs from the file in Attached (sanitised) documents for publication.	Single file attachment	ENDPOINT_SUMMARY. AdditionalInformationOnResiduesInFoodAndFeedingstuffs.Discussion. AttachedBackgroundMaterial.AttachedDocument
Remarks		Text	ENDPOINT_SUMMARY. AdditionalInformationOnResiduesInFoodAndFeedingstuffs.Discussion. AttachedBackgroundMaterial.Remarks
Attached background material			
Attached (sanitised) documents for publication	Provide any document for publication	Attachments list	ENDPOINT_SUMMARY. AdditionalInformationOnResiduesInFoodAndFeedingstuffs.Discussion. AttachedSanitisedDocsForPublication

6.10 Other studies – Endpoint study record

Purpose:

Use this section to report any study that does not fit into other specific endpoints study records or endpoints study summaries of the Section 6 (e.g. specific studies used to refine the consumer risk assessment such studies on variability factors).

ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood v.6.3 (Final)			
Name	Instructions	Type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.AdministrativeData
		Confidentiality	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.AdministrativeData.DataProtection
Endpoint	Select from picklist 'additional information on residue chemistry'	Closed list with remarks	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.AdministrativeData.Endpoint

Type of information		Open list with remarks	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.AdministrativeData.StudyResultType
Adequacy of study		Closed list	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.AdministrativeData.PurposeFlag
Robust study summary		Check box	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.AdministrativeData.RobustStudy
Used for classification		Check box	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.AdministrativeData.UsedForClassification
Used for SDS		Check box	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.AdministrativeData.UsedForMSDS
Study period		Text	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.AdministrativeData.StudyPeriod
Reliability		Open list	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.AdministrativeData.Reliability
Rationale for reliability incl. deficiencies		Open list with remarks (32000)	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.AdministrativeData.RationalReliability
Data waiving		Closed list	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.AdministrativeData.DataWaiving
Justification for data waiving		Multi select open list with remarks (32000)	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.AdministrativeData.DataWaivingJustification

Justification for type of information		Text template	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.AdministrativeData.JustificationForTypeOfInformation
Attached justification			ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.AdministrativeData.AttachedJustification
Attached justification		Single file attachment	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.AdministrativeData.AttachedJustification.AttachedJustification
Reason / purpose		Closed list with remarks	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.AdministrativeData.AttachedJustification.ReasonPurpose
Attached justification			
Cross-reference			ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.AdministrativeData.CrossReference
Reason / purpose for cross-reference		Open list with remarks	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.AdministrativeData.CrossReference.ReasonPurpose
Related information		Endpoint reference field	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.AdministrativeData.CrossReference.RelatedInformation
Remarks		Text area	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.AdministrativeData.CrossReference.Remarks
Cross-reference			
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.DataSource

Reference		Literature reference list	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.DataSource.Reference
Data access		Open list with remarks	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.DataSource.DataAccess
Data protection claimed		Closed list with remarks	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.DataSource.DataProtectionClaimed
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.MaterialsAndMethods
Background information		Multi-line text	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.MaterialsAndMethods.BackgroundInformation
Product type	Field not mandatory. The product type is already reported in Section 3.2 (Effect on harmful organism, function, mode of action and possible resistance). This field is optional.	Open list with remarks	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.MaterialsAndMethods.ProductType
Test guideline			ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.MaterialsAndMethods.Guideline
Qualifier		Closed list	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.MaterialsAndMethods.Guideline.Qualifier
Guideline		Open list	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.MaterialsAndMethods.Guideline.Guideline
Version / remarks		Multi-line text	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.MaterialsAndMethods.Guideline.VersionRemarks

Deviations		Closed list with remarks	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.MaterialsAndMethods.Guideline.Deviation
Test guideline			
Principles of method if other than guideline		Text template	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.MaterialsAndMethods.MethodNoGuideline
GLP compliance		Closed list with remarks	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.MaterialsAndMethods.GLPComplianceStatement
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.MaterialsAndMethods.TestMaterials
Test material information		Entity reference field	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Specific details on test material used for the study		Text template	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.MaterialsAndMethods.TestMaterials.SpecificDetailsOnTestMaterialUsedForTheStudy
Specific details on test material used for the study (confidential)		Text template	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.MaterialsAndMethods.TestMaterials.SpecificDetailsOnTestMaterialUsedForTheStudyConfidential
Study design		Header 2	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.MaterialsAndMethods.StudyDesign

Details on study design		Text area	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.MaterialsAndMethods.StudyDesign.FurtherDetailsOnStudyDesign
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block In this field, you can enter any information on materials and methods, for which no distinct field is available, or transfer free text from other databases. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. You can also upload any htm or html document. Note: One rich text editor field each is provided for the MATERIALS AND METHODS and RESULTS section. In addition, the fields 'Overall remarks' and 'Executive summary' allow rich text entry.	Header 2	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
		Rich text area	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables.OtherInformation
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.ResultsAndDiscussion

Details on results	Provide any other relevant details if not entered in the specific "Description" fields for the examined parameters.	Text area	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.ResultsAndDiscussion.DetailsOnResults
Any other information on results incl. tables	In this field, you can enter any other remarks on results. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. Note: One rich text editor field each is provided for the MATERIALS AND METHODS and RESULTS section. In addition, the fields 'Overall remarks' and 'Executive summary' allow rich text entry.	Header 2	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
		Rich text area	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables.OtherInformation
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.ApplicationSummaryAndConclusion
Conclusions	The assessment and conclusion of the applicant should be reported here.	Text area	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.ApplicationSummaryAndConclusion.Conclusions

Executive summary	Briefly summarise the relevant aspects of the study including the conclusions reached.	Rich text area	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.ApplicationSummaryAndConclusion.ExecutiveSummary
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6.10.1 Effect on the residue level in pollen and bee products – Endpoint summary

Purpose:

provide a summary overview on the transfer of residues into pollen and bee products when active substance is applied on melliferous crop according to the intended/critical use pattern and whether any adverse risk to bee health was observed in the context of the present dossier.

Please report the key results on the residue levels in pollen and bee products for human consumption resulting from residues taken up by honeybees from crops at blossom.

ENDPOINT_SUMMARY.SupplementaryStudies v.2.1 (Final)			
Name	Instructions	Type	Field path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.SupplementaryStudies.AdministrativeDataSummary
	See Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	Confidentiality	ENDPOINT_SUMMARY.SupplementaryStudies.AdministrativeDataSummary.DataProtection
Link to relevant study record(s)		Header 1	ENDPOINT_SUMMARY.SupplementaryStudies.LinkToRelevantStudyRecord
Study name / type	Provide here the link to the most relevant study(ies) from which the key values for magnitude of residues in honey and setting of MRLs in honey are derived.	Endpoint reference list	ENDPOINT_SUMMARY.SupplementaryStudies.LinkToRelevantStudyRecord.Link
Results		Read-only	ENDPOINT_SUMMARY.SupplementaryStudies.LinkToRelevantStudyRecord.Results

Description of key information		Header 1	ENDPOINT_SUMMARY. SupplementaryStudies. KeyInformation
	<p>Please make a statement whether the magnitude residues in bee products was sufficiently investigated (according the current data requirements and to the latest version of the Technical Guideline SANTE/11956/2016) in the context of the present dossier and highlight data gap(s) and the non-standard uncertainty(ies), if any. Please report here the type of the experimental study according to the latest version of the Technical Guideline SANTE/11956/2016 (e.g., experimental studies via syrup feeding, field residue trials or tunnel trials), which was designed with an objective to determine the inadvertent residue in honey arising from pesticide use, in order to allow a dietary risk assessment and to establish scientifically-based MRLs.</p> <p>The relevance of results should be discussed in relation to the proposed uses of the plant protection product, including a critical appraisal of the study and its results. In particular the following points must be addressed:</p> <ul style="list-style-type: none"> - A residue at or above the LOQ (a value of 0.05 mg/kg or lower is 	Rich text area	ENDPOINT_SUMMARY. SupplementaryStudies. KeyInformation.KeyInformation

	favoured) in control samples - Adverse effects on health of the honeybees - MRL proposal and risk assessment values If studies reported in this summary are not guideline or GLP compliant, if deviation from guidance are observed (e.g. not validated analytical method), please report it here.		
Additional information	Discussion(Header 1) – common block	Header 1	ENDPOINT_STUDY_RECORD.SupplementaryStudies.Discussion

6.10.1 Effect on the residue level in pollen and bee products – Endpoint study record

Purpose:

Studies to determine the residue in pollen and bee products for human consumption resulting from residues taken up by honeybees from crops at blossom.

ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities v.2.3(Final)			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.AdministrativeData
	See Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	Confidentiality	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.AdministrativeData.DataProtection
Endpoint	Select relevant endpoint from picklist: - residues in honey - residues in pollen - residues in other bee products Once selected the endpoint, in the Remark field indicate	Closed list with remarks	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.AdministrativeData.Endpoint

	the type of experimental study, according to the latest version of the Technical Guideline SANTE/11956/2016, i.e., - Experimental study via syrup feeding - Experimental field data - Experimental tunnel data		
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.DataSource
Reference	Literature reference v.5.1 (Final)	Literature reference list	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.DataSource.Reference
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.MaterialsAndMethods
Test guideline	Indicate according to which test guideline the study was conducted. (There are two options referring to the same guideline "Residue Levels in honey SANTE/11956/2016 rev. 9" and "Technical Guidelines for determining the magnitude of pesticide residues in honey and setting Maximum Residues Levels in honey". If the study was performed according to this guideline, by convention please select "Residue Levels in honey		ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.MaterialsAndMethods.Guideline

	<p>SANTE/11956/2016 rev. 9").</p> <p>If no test guideline was explicitly followed, but the methodology used is equivalent or similar to a specific guideline, you can indicate so in the 'Qualifier' subfield preceding the field 'Guideline'. Copy this block of fields for specifying more than one guideline (e.g. US EPA in addition to OECD guideline).</p>		
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.MaterialsAndMethods.TestMaterials
Specific details on test material used for the study	<p>Please describe here any information relevant to a specific experimental study not mentioned elsewhere as required according to the latest version of the Technical Guideline SANTE/11956/2016. You can report data according to two options:</p> <p>Option 1: use the free text to describe specific experimental study, or</p> <p>Option 2: to report data in a table format to be inserted in the section` Any other information on materials and methods incl. tables`, ensuring that the following information is reported:</p> <p>For the experimental study via syrup feeding please provide the information on the formulation type, the content of a.s. in</p>	Text template	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.MaterialsAndMethods.TestMaterials.SpecificDetailsOnTestMaterialUsedForTheStudy

	<p>feeding solution [g/L], water solubility, LogPow, photolytic degradation, content of sugar in feeding solution [g/L], application method and test duration, incl. period prior to feeding. Information on the matrix used (feeding solution), sampling method, dates of sampling, number of replicates, sugar content in nectar/honey (% BRIX), water content in nectar/honey (%), days from start of feeding until honey shall also be reported. For the experimental study field test /tunnel test ("semi-field test") please provide information on the number of bee colonies (for tunnel trials), number of bee hives (for field trials), health effects on honeybees, formulation type, content of active substance in the formulation, water solubility, LogPow, photolytic degradation, the crop/variety, date of flowering, date of application, site parameters, including crops growing in the surroundings, method of application, application details and rate per treatment (kg a.s./ha), weather data for the application, growth rate of the crop (BBCH stage), species tested, duration of bee's exposure (days).</p>		
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	<p>Information on the matrix (e.g. plant, flower), sampling date, sampling method, days after last treatment (DALA), growth stage of crop (e.g. BBCH) at sampling, sugar content in nectar/honey (% BRIX), water content in nectar/honey (%) shall be also reported here. Additionally, please provide information related to sampling (sample material, weight, periods of drying, sugar content (%)), and storage of field samples (duration, temperature, storage conditions, honey conditioning, etc. For details of the analytical method validation data, please make a reference to Section 4 of the dossier 'Analytical methods' and leave this field empty. Reference to the corresponding endpoint study record should be done using the cross reference box (see instructions in the common block).</p>		
Specific details on test material used for the study (confidential)		Text template	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.MaterialsAndMethods.TestMaterials.SpecificDetailsOnTestMaterialUsedForTheStudyConfidential
Any other information on materials and methods incl. tables	<p>Any other information on materials and methods incl. tables - (H2) – common block</p> <p>In this field, you can enter any information</p>	Header 2	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables

	<p>on materials and methods, for which no distinct field is available, or transfer free text from other databases. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document.</p> <p>If you did not use the option 1 to report the detailed information for each experimental study, please report it here in one/several table(s).</p> <p>For the analytical method validation data: the method should be reported in Section 4 of the dossier 'Analytical methods'. Please refer to it, using the cross reference box and an referring to the corresponding study record (analytical method and its validation data). If the study record referred to was duly compiled and contain the data on method validation, further information is not required.</p>		
		Rich text area	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables.OtherInformation
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.ResultsAndDiscussion

Any other information on results incl. tables	<p>Discuss and evaluate the reported measurements and the relevance of results in relation to the proposed uses of the PPP, including a critical appraisal of the study and its results.</p> <p>The results of the study can be also presented in a table format.</p> <p>In particular the following points must be addressed:</p> <ul style="list-style-type: none"> - a residue at or above the LOQ (a value of 0.05 mg/kg or lower is favoured) in control samples. - MRL proposal, with reasoning, and derived risk assessment values. 	Header 2	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
		Rich text area	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables.OtherInformation
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.ApplicationSummaryAndConclusion
Key result		Read-only	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.ApplicationSummaryAndConclusion.KeyResult
Conclusions	The assessment and conclusion of the applicant should be reported here.	Text area	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.ApplicationSummaryAndConclusion.Conclusions
Executive summary	Briefly summarise the relevant aspects of the study including the	Rich text area	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.Applica

	<p>conclusions reached. In case new compounds have been identified in bee product, which are not included in the risk assessment residue definition in plant commodities please report this information here. Example:</p> <p>In case of field test/tunnel test: The residue trials for the determination of residues of [test substance] in [bee product] from [name crop] were conducted in [country, location] during the [year] growing season. [Active ingredient, % ai, formulation type] was applied to [crop] at [rate of application (xx g ai/ha)] under [specify trial conditions (field/tunnel)].</p> <p>In case of syrup feeding study: [residue of concern] was administered via syrup [application method] to bees for [duration] consecutive days. Dosing was made at [list dosing levels in mg/kg feed].</p> <p>[Bee product] samples were collected at [conditions of sampled product (maturity, water content (%) etc.] at [crop growth stage].</p> <p>Residues of [active substance/metabolites] were present at the level of [xx] mg/kg in control samples of [bee</p>		ntSummaryAndConclusion.ExecutiveSummary
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	<p>product]/not present in control samples of [bee product] above the LOQ of [xx] mg/kg in control samples.</p> <p>In [bee product] the residues of [active substance/metabolites] were present at the level of [xx] mg/kg.</p> <p>All samples were frozen at the testing facility and remained frozen during shipping and storage prior to processing and analysis. The maximum storage interval for samples was [xx] days/months [specify period from harvest to processing and from processing to analysis]. Storage conditions and durations are supported by studies showing that residues of [active ingredient] are stable in [crops/processed commodities] for up to [xx] days under frozen conditions.</p> <p>Samples in the current study were analyzed using Method [Method ID], a [describe method] method to determine residues of [list analytes]. Acceptable [method validation and] concurrent recoveries were reported for [matrices] samples at fortification levels of [xx] mg/kg, thus validating the method. The limit of quantitation (LOQ) was</p>		
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	[xx] mg/kg per analyte for [matrices].		
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7. Fate and behaviour in the environment

Purpose:

Provide summary information of the most relevant study(-ies) from which the key value for assessment is extrapolated. Provide only the most relevant details related to:

Mobility

Microorganisms: Persistence and multiplication (competitiveness) in soil, water and air

Chemicals: Fate and behavior in soil, water and air

This document can be used to summarize information from a range of different studies to conclude on specific aspects of fate and behavior or persistence and multiplication in the environment

This document can be used to provide an overarching discussion of the data and how it was handled for the purposes of establishing endpoints.

ENDPOINT_SUMMARY.EnvironmentalFateAndPathways v.5.0 (Final)			
Name	Instructions	Type	Field path
Administrative data	Administrative data summary – common block Description of key information: Enter a short description of the most relevant endpoint data. The short description could include for example: -the test guideline used, -the test organism, -the exposure duration, -the contextual information of the origin of the value, -qualitative characterization of some properties	Header 1	ENDPOINT_SUMMARY.EnvironmentalFateAndPathways.AdministrativeDataSummary
Additional information	Discussion (Header 1) – common block Data analysis file (calculation of parameters) can be uploaded in Attached (sanitised) documents for publication, the original file should be	Header 1	ENDPOINT_SUMMARY.EnvironmentalFateAndPathways.Discussion

	uploaded in Attached document only if it differs from the sanitised version		
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7.1 Fate and behaviour in soil

7.1.1 Route and rate of degradation in soil, aerobic and anaerobic (laboratory studies) - Endpoint Summary

Purpose:

Summarise the results of the laboratory studies on the rate of degradation in soil reporting all relevant information on the properties of the soils, the rates of degradation for persistence and modelling for active substance and its metabolites, and the correspondent kinetic models used.

ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP - v.3.5 (Final)			
Name	Instructions	Type	Field Path
Administrative data	Administrative data summary – common block Report Information to support the persistence /rate of degradation in soil. Make reference to the studies used to conclude on the rate of degradation in soil. Multiple endpoint summaries can be created where different DegT50 values are defined at different pH values. The pH should be specified in the 'Description of key information field	Header 1	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa
Persistence / rate of degradation in soil	Click on 'add new item' to repeat this block of fields for each relevant compound, soil and test conditions		ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.PersistenceDegradationSoil

Parent / metabolite	Indicate whether the DT50 is reported for parent or metabolite.	Closed list	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.PersistenceDegradationSoil.ParentMetabolite
Substance	Select the substance for the DT50 value.	Entity reference field	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.PersistenceDegradationSoil.Substance
Test conditions	Select the test conditions, e.g.: aerobic or anaerobic	Closed list	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.PersistenceDegradationSoil.TestConditions
Soil type	Enter the type of soil used in the laboratory test system.	Text	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.PersistenceDegradationSoil.SoilType
pH	Enter the pH value of the soil in the laboratory test system.	Decimal	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.PersistenceDegradationSoil.Ph
measured in	Indicate the medium (e.g. calcium chloride solution, water) in which the soil pH was measured.	Multi-line text	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.PersistenceDegradationSoil.MeasuredIn
Soil moisture	EU PPP: Biodegradation summary block (Key statistics)-common block Enter the soil moisture at which the incubation was carried out (e.g.: maximum water holding capacity (%) or pF2 (%) or pF2.5 (%) values).	UnitMeasure	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.PersistenceDegradationSoil.SoilMoisture
Half-life in soil (DT50)	Enter the DT50 value (d) for persistence.	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.PersistenceDegradationSoil.HalfLifeSoil
DT90 in soil	Enter the DT90 value (d) for persistence.	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.PersistenceDegradationSoil.DtNinetySoil
at the temperature of	Enter the temperature of the soil in the laboratory test system.	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.PersistenceDegradationSoil.Temperature
Chi-square (x2) error	Enter the Chi-square error of the kinetic model (reported in the field "Method of calculation") used for deriving the	Decimal	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.PersistenceDegradationSoil.ChiSquare

	degradation rates for persistence.		
Method of calculation	Enter the kinetic model (e.g. SFO, FOMC, DFOP, HS) used for deriving the degradation endpoints (DT50 and DT90) for persistence.	Text	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.PersistenceDegradationSoil.CalculationMethod
Kinetic parameters	Where the rate of degradation endpoints result from a biphasic fit (e.g.: FOMC, DFOP) enter the values of the proper kinetic parameters (e.g.: alpha, beta, k1, k2 and g).	Multi select open list with remarks	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.PersistenceDegradationSoil.KineticParameters
Kinetic formation fraction	Enter the kinetic formation fraction (f. f. kf/kdp) of transformation products.	Decimal	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.PersistenceDegradationSoil.KineticFormationFraction
Precursor	For metabolites, when relevant, select the precursor substance (e.g. the active substance or another metabolite).	Entity reference field	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.PersistenceDegradationSoil.Precursor
Remarks	Provide any additional information needed to interpret the reported results	Text area	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.PersistenceDegradationSoil.Remarks
Persistence / rate of degradation in soil			
Modelling / rate of degradation in soil	Click on 'add new item' to repeat this block of fields for each relevant compound, soil and test conditions		ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.ModellingDegradationSoil
Parent / metabolite	Indicate whether the DT50 is reported for parent or metabolite.	Closed list	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.ModellingDegradationSoil.ParentMetabolite
Substance	Select the substance for the DT50 value.	Entity reference field	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.ModellingDegradationSoil.Substance

Test conditions	Select the test conditions, e.g.: aerobic or anaerobic	Closed list	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.ModellingDegradationSoil.TestConditions
Soil type	Enter the type of soil used in the laboratory test system.	Text	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.ModellingDegradationSoil.SoilType
pH	Enter the pH value of the soil in the laboratory test system.	Decimal	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.ModellingDegradationSoil.Ph
measured in	Indicate the medium (e.g. calcium chloride solution, water) in which the soil pH was measured.	Multi-line text	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.ModellingDegradationSoil.MeasuredIn
Soil moisture	EU PPP: Biodegradation summary block (Key statistics)-common block Enter the soil moisture at which the incubation was carried out (e.g.: maximum water holding capacity (%) or pF2 (%) or pF2.5 (%) values)	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.ModellingDegradationSoil.SoilMoisture
Normalised (DT 50)	Enter the DT50 value (d) for modelling normalized at 20°C and pF2/10kPa using a Q10 of 2.58 and Walker equation coefficient of 0.7.	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.ModellingDegradationSoil.NormalisedDtFifty
Chi-square (χ^2) error	Enter the Chi-square error of the kinetic model (reported in the field "Method of calculation") used for deriving the degradation rates for modelling.	Decimal	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.ModellingDegradationSoil.ChiSquare
Method of calculation	Enter the kinetic model (e.g. SFO, FOMC, DFOP, HS) used for deriving modelling endpoint (normalised DT50); when biphasic kinetic	Text	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.ModellingDegradationSoil.CalculationMethod

	model is used, it should be specified how the DT50 was derived (DT90 FOMC/3.32, DFOP slow phase, etc...).		
Kinetic parameters	Where the rate of degradation endpoints result from a biphasic fit (e.g.: FOMC, DFOP) enter the values of the proper kinetic parameters (e.g.: alpha, beta, k1, k2 and g).	Multi select open list with remarks	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.ModellingDegradationSoil.KineticParameters
Kinetic formation fraction	Enter the kinetic formation fraction (f. f. kf/kdp) of transformation products.	Decimal	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.ModellingDegradationSoil.KineticFormationFraction
Precursor	For metabolites, when relevant, select the precursor substance (e.g. the active substance or another metabolite).	Entity reference field	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.ModellingDegradationSoil.Precursor
Remarks	Provide any additional information needed to interpret the reported results.	Text area	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.ModellingDegradationSoil.Remarks
Modelling / rate of degradation in soil			
Key value for safety assessment			ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.KeyValueCsa
Parent / metabolite	Indicate whether the DT50 is reported for the parent or the metabolite.	Closed list	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.KeyValueCsa.ParentMetabolite
Substance	Select the substance for the DT50 value.	Entity reference field	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.KeyValueCsa.Substance
Half-life in soil (DT50)	Indicate the geometric mean (if not pH dependent) of the normalised DT50 values (d). If pH dependence is identified, values other than the geometric	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.KeyValueCsa.HalfLifeSoil

	mean can be reported according to the pH dependency evaluation (please select "yes" in the "pH dependence" field).		
Mean formation fraction	Indicate the arithmetic mean of the formation fraction (f.f. kf/kdp) values for the metabolite.	Decimal	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.KeyValueCsa.FormationFraction
pH dependence	Select 'yes' or 'no' to indicate whether the result is pH dependent	Closed list	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.KeyValueCsa.PhDependence
Remarks		Text area	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.KeyValueCsa.Remarks
Key value for safety assessment			
Additional information	Discussion(Header 1) – common block	Header 1	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.Discussion

7.1.1 Route and rate of degradation in soil, aerobic and anaerobic (laboratory studies) - Endpoint summary

Purpose:

Summarize the results of studies on the aerobic and anaerobic route of degradation in soil and identify the metabolites requiring further consideration for risk assessment.

ENDPOINT_SUMMARY.RouteDegSoil_EU_PPP – v.1.3 (Final)			
Name	Instructions	Type	Field Path
Administrative data	Administrative data summary – common block Provide a brief description of relevant studies and metabolites that should be considered for risk assessment	Header 1	ENDPOINT_SUMMARY.RouteDegSoil_EU_PPP.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.RouteDegSoil_EU_PPP.KeyValueCsa

Route of degradation in soil	The route of degradation consists in: 1) determining the amount mineralization; 2) determining the amount of non-extractable residues; 3) identifying metabolites above the regulatory trigger.		ENDPOINT_SUMMARY.RouteDegSoil_EU_PPP.KeyValueCsa.Degradati onSoil
Parent / metabolite	Rows should be created for the active substance and each metabolite	Closed list	ENDPOINT_SUMMARY.RouteDegSoil_EU_PPP.KeyValueCsa.Degradati onSoil.ParentMetabolite
Substance	Select the relevant labelled parent or metabolite.	Entity reference field	ENDPOINT_SUMMARY.RouteDegSoil_EU_PPP.KeyValueCsa.Degradati onSoil.Substance
Test conditions	Indicate whether the results are for aerobic conditions, anaerobic conditions. A summary can be completed for each type of test condition.	Closed list	ENDPOINT_SUMMARY.RouteDegSoil_EU_PPP.KeyValueCsa.Degradati onSoil.TestConditions
Sterile conditions	Indicate if the results were obtained under sterile conditions	Check box	ENDPOINT_SUMMARY.RouteDegSoil_EU_PPP.KeyValueCsa.Degradati onSoil.SterileConditions
Mineralisation (%)	Indicate the mineralization percentage after 100 days.	Range (Decimal)	ENDPOINT_SUMMARY.RouteDegSoil_EU_PPP.KeyValueCsa.Degradati onSoil.Mineralisation
Non extractable residues (%)	Indicate the non-extractable residues percentage after 100 days.	Range (Decimal)	ENDPOINT_SUMMARY.RouteDegSoil_EU_PPP.KeyValueCsa.Degradati onSoil.NonExtractableR esidues
Maximum occurrence (%)	Indicate the maximum occurrence of each metabolite (X% after Y days) observed in the parent-dosed study.	Decimal	ENDPOINT_SUMMARY.RouteDegSoil_EU_PPP.KeyValueCsa.Degradati onSoil.MaximumOccurr ence
Day maximum occurrence observed (days)	Report the time point in days when the maximum occurrence was observed.	Integer	ENDPOINT_SUMMARY.RouteDegSoil_EU_PPP.KeyValueCsa.Degradati onSoil.DayMaximumOcc urence
Actual duration (days)	Report the duration of the study in days.	Integer	ENDPOINT_SUMMARY.RouteDegSoil_EU_PPP.

			KeyValueCsa.Degradati onSoil.ActualDuration
Radio label	Provide information on the radio labelling used to obtain these results	Text	ENDPOINT_SUMMARY. RouteDegSoil_EU_PPP. KeyValueCsa.Degradati onSoil.RadioLabel
Number soils	Report the number of soil analysed to obtain these results	Integer	ENDPOINT_SUMMARY. RouteDegSoil_EU_PPP. KeyValueCsa.Degradati onSoil.NumberSoils
Remarks		Text area	ENDPOINT_SUMMARY. RouteDegSoil_EU_PPP. KeyValueCsa.Degradati onSoil.Remarks
Route of degradation in soil			
Additional information	Discussion(Header 1) – common block	Header 1	ENDPOINT_SUMMARY. RouteDegSoil_EU_PPP. Discussion

Links to support material:

DG SANCO Working Document on "Evidence Needed to Identify POP, PBT and vPvB Properties for Pesticides" (25.09.2012 – rev. 3)

ECHA Guidance on information requirements and chemical safety assessment Chapter R 11: PBT Assessment (revision 1)

7.1.1 Route and rate of degradation in soil, aerobic and anaerobic (laboratory studies)-Endpoint study record

Purpose:

These experiments are performed to determine the route and the rate of transformation of the test substance in soil, and to determine the nature and rates of formation of transformation products.

Principle of the study:

- The microbial biomass of soils used for laboratory degradation studies shall be determined immediately before the commencement and at the end of the study.
- The soils used for degradation studies shall be representative of the range of agricultural soils typical of the various regions of the Union where use exists or is anticipated.
- The soils shall fulfil the following conditions: they shall cover a range of organic carbon content, particle size distribution and where on the basis of other information, degradation is expected to be pH dependent, they shall cover approximately the following pH (preferably measured in CaCl₂) ranges: 5 to 6, 6 to 7 and 7 to 8.
- Soils used shall, wherever possible, be freshly sampled. If use of stored soils is unavoidable, storage shall be carried out for a limited time (at the most three months) under defined and reported conditions, which are adequate to maintain soil microbial viability. Soils stored for longer periods of time may only be used for adsorption/desorption studies.
- A soil having extreme characteristics with respect to parameters such as particle size distribution, organic carbon content and pH shall not be used.

ENDPOINT_STUDY_RECORD.BiodegradationInSoil – v7.2			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.DataSource
Materials and methods	Material and methods – common block Applicable test guideline: Microbial Pesticide Test Guidelines OPPTS 885.5200 Expression in a Terrestrial Environment	Header 1	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods
Test type	Indicate whether the study was a field trial or laboratory study.	Open list	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.TestType
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.TestMaterials
Radiolabelling	Indicate if labelled or non-labelled test material was used. Details on labelled material to be described in field 'Details on test material'.	Closed list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.TestMaterials.Radiolabelling
Study design		Header 2	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign
Oxygen conditions	Indicate whether test was performed under aerobic or anaerobic conditions. Include any explanations in the supplementary remarks field as appropriate.	Open list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.OxygenConditions
Soil classification	Select as cited in the study report. If not available from picklist, select 'other:' and specify.	Open list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.SoilClassification
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field 'Report date'.	Integer	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.Year

Soil properties	Repeat this block of fields for each different soil used as indicated by the Soil No. Enter soil type as cited in the study report and the respective soil properties.		ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.SoilProperties
Soil no.	Select a consecutive soil number from drop-down list if more than one soil types were used.	Close d list	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.SoilProperties.Soi lNo
Soil type	Select from drop-down list.	Open list	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.SoilProperties.Soi lType
% Clay	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.SoilProperties.Cla y
% Silt	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.SoilProperties.Silt
% Sand	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.SoilProperties.Sa nd
% Org. C	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.SoilProperties.Or gC
pH	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.SoilProperties.Ph
CEC	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.SoilProperties.CE C

Bulk density (g/cm³)	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.SoilProperties.BulkDensityGCm
% Moisture content	Moisture content of the soil (at pF 2 or at Maximum Water Holding Capacity). Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.SoilProperties.MoistureContent
Soil properties			
Details on soil characteristics	For each soil type, specify soil collection and storage and properties of the soil as far as not indicated in the defined fields. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.DetailsOnSoilCharacteristics
Duration of test (contact time)	Specify duration of test in terms of contact time. Repeat block for each soil type. If different test runs have different durations, enter lower and upper value in respective subfields.		ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.DurationOfTestContactTime
Soil No.	Select a consecutive soil number from drop-down list if more than one soil types were used.	Close d list	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.DurationOfTestContactTime.SoilNo
Duration	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.DurationOfTestContactTime.Duration
Duration of test (contact time)			
Initial test substance concentration	Specify the initial test concentration applied. If different concentrations were used in different test runs, copy this block of fields accordingly. If a range of concentrations is reported, include the lower and upper values in the numeric range field. If appropriate copy this block of fields for indicating different parameters the initial concentration is based on (e.g. COD and test substance).		ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.InitialTestSubstanceConcentration

Soil No.	Select a consecutive soil number from drop-down list if more than one soil types were used.	Close d list	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.InitialTestSubstanceConcentration.SoilNo
Initial conc.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.InitialTestSubstanceConcentration.InitialConc
Based on	From drop-down list, select the parameter on which the initial concentration is based.	Open list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.InitialTestSubstanceConcentration.BasedOn
Initial test substance concentration			
Parameter followed for biodegradation estimation	Indicate the parameter used to measure biodegradation. Copy field for more than one parameter as appropriate. In supplementary remarks field, give relevant details on the method. For radiochemical measurement or test substance analysis use freetext template in field 'Details on analytical methods'.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.ParameterFollowed
Details on analytical methods	If the amount of test material in the test solutions was monitored, enter any details on the analytical methods used. Use freetext template and delete/add elements as appropriate. Copy any subheading(s) under IDENTIFICATION AND QUANTIFICATION OF PARENT COMPOUND to include the respective information for transformation products and/or non-extractable residues.	Text templ ate	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.DetailsOnAnalyticalMethods
Experimental conditions	For each soil type, indicate the environmental conditions during the test if available or assumed in the model, if estimated.		ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.ExperimentalConditions
Soil No.	Select a consecutive soil number from drop-down list if more than one soil types were used.	Close d list	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDes

			ign.ExperimentalCon ditions.SoilNo
Temp.	Specify test temperature including mean and range values during test if available or temperature assumed in the model, if estimated. Use °C; convert other units and indicate original data in parentheses if applicable.	Text	ENDPOINT_STUDY_ RECORD.Biodegrada tionInSoil.MaterialsA ndMethods.StudyDes ign.ExperimentalCon ditions.Temp
Humidity	Indicate soil humidity in % moisture content or g water/100g soil dry weight.	Text	ENDPOINT_STUDY_ RECORD.Biodegrada tionInSoil.MaterialsA ndMethods.StudyDes ign.ExperimentalCon ditions.Humidity
Microbial biomass	Indicate initial and final microbial biomass / microbial population of control and treated soil, if provided. Specify unit, e.g., mg biomass/100 g soil dry weight or µg C/g soil.	Text	ENDPOINT_STUDY_ RECORD.Biodegrada tionInSoil.MaterialsA ndMethods.StudyDes ign.ExperimentalCon ditions.MicrobialBiom ass
Experime ntal condition s			
Details on experime ntal condition s	Include Soil No. in parentheses if conditions were not identical for all soil types tested. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text templ ate	ENDPOINT_STUDY_ RECORD.Biodegrada tionInSoil.MaterialsA ndMethods.StudyDes ign.DetailsOnExperi mentalConditions
Any other informati on on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Heade r 2	ENDPOINT_STUDY_ RECORD.Biodegrada tionInSoil.MaterialsA ndMethods.AnyOther InformationOnMateri alsAndMethodsInclT ables
Results and discussio n		Heade r 1	ENDPOINT_STUDY_ RECORD.Biodegrada tionInSoil.ResultsAnd Discussion
Material (mass) balance	If applicable, indicate mean total recovery of test material as percentage of applied amount +/- standard deviation. Copy this block of fields for each soil type as appropriate.		ENDPOINT_STUDY_ RECORD.Biodegrada tionInSoil.ResultsAnd Discussion.MaterialM assBalance
Soil No.	Select a consecutive soil number from drop-down list if more than one soil types were used.	Close d list	ENDPOINT_STUDY_ RECORD.Biodegrada tionInSoil.ResultsAnd

			Discussion.MaterialMassBalance.SoilNo
Sampling date	Enter the date the sample was taken	Date	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.MaterialMassBalance.SamplingDate
Sampling day(s)	Enter sampling time in days.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.MaterialMassBalance.SamplingDays
% Total extractable	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.MaterialMassBalance.TotalExtractable
% Non extractable	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.MaterialMassBalance.NonExtractable
% CO2	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.MaterialMassBalance.CO2
% Other volatiles	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.MaterialMassBalance.OtherVolatiles
% Recovery	Enter numeric value.	Decimal	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.MaterialMassBalance.Recovery
St. dev.	Enter numeric value.	Decimal	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.MaterialMassBalance.StDev

Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.MaterialMassBalance.RemarksOnResults
Material (mass) balance			
% Degradation	For each soil type, indicate percentage of degradation of test substance including standard deviation at the end of the study period. Also indicate on what parameter the degradation rate is based on (e.g. 'radiochemical measurement'). If required, copy block of fields to include values based on different parameters.		ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.Degradation
Parent/product	Indicate if the result reported is for the active substance/parent or the product/metabolite. The identify of the substance can be selected below	Close d list	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.Degradation.ParentProduct
Name or code for product	Click the Link button to navigate to the Substances Inventory and select the relevant substance name. If not available in the inventory, create a new one.	Entity reference field	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.Degradation.NameOrCodeForProduct
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.Degradation.KeyResult
Soil No.	Select a consecutive soil number from drop-down list if more than one soil types were used.	Close d list	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.Degradation.SoilNo
Sampling date	Enter date when the sample was taken	Date	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.Degradation.SamplingDate
% Degr.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.Degradation.Degr
St. dev.	Enter numeric value.	Decimal	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAnd

			Discussion.Degradation.StDev
Parameter	From drop-down list, select the parameter on which the percentage is based. Further information can be given in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.Degradation.Parameter
Sampling time	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.Degradation.SamplingTime
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.Degradation.RemarksOnResults
% Degradation			
Half-life / dissipation time of parent compound	For each soil type, include value (or range if reported so) of half-life and indicate the type of half-life (For first order kinetics DT50 = half-life).		ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.HalfLifeOfParentCompound
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.HalfLifeOfParentCompound.KeyResult
Soil No.	Select a consecutive soil number from drop-down list if more than one soil types were used.	Closed list	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.HalfLifeOfParentCompound.SoilNo
DT50	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.HalfLifeOfParentCompound.HalfLife

St. dev.	Enter numeric value.	Decimal	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.HalfLifeOfParentCompound.StDev
Type	Select from drop-down list.	Open list	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.HalfLifeOfParentCompound.Type
Temp.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.HalfLifeOfParentCompound.Temp
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.HalfLifeOfParentCompound.RemarksOnResults
Half-life / dissipation time of parent compound			
Transformation products	Indicate whether transformation products occurred. If yes, provide the identified transformation products in following block of fields. Any further details can be entered in field 'Any other information on results incl. tables'. Not relevant for microorganisms	Closed list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.TransformationProducts
Identity of transformation products	Indicate the identity of the transformation products using an appropriate identifier, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields for each relevant substance. Any further details on transformation products can be provided in field 'Any other information on materials and methods incl. tables'.		ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.IdentityTransformation
No.	For easier distinction select a consecutive number for each transformation product from drop-down list if more than one transformation product is entered. If the same substance is identified by more than one identifiers (e.g.	Closed list	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.IdentityTransformation.No

	by CAS name and Common name), make sure that the same number is allocated to these entries.		
Reference substance	Click the Link button to navigate to the Substances Inventory and select the relevant substance name. If not available in the inventory, create a new one.	Entity reference field	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.IdentityTransformation.ReferenceSubstance
Identity of transformation products			
Details on transformation products	Indicate any relevant supplementary information on transformation products. Use freetext template and delete/add items as appropriate. If useful attach a figure in the corresponding field.	Text template	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.TransformationProductsDetails
Evaporation of parent compound	Indicate whether evaporation of the parent compound occurred or not. Include any explanations in field 'Details on results' as appropriate. 'Yes' should be selected when CO ₂ has been detected in volatile traps.	Close d list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.EvaporationOfParentCompound
Volatile metabolites	Indicate whether volatile metabolites were found or not. Include any explanations in field 'Details on results' as appropriate.	Close d list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.VolatileMetabolites
Residues	Indicate whether residues were found or not. Include any explanations in field 'Details on results' as appropriate.	Close d list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.Residues
Details on results	Indicate any further relevant details of test results. Use freetext template and delete/add elements as appropriate. As appropriate or requested by the regulatory programme include table(s) with raw data in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1'). In field 'Attached background material', attach graph(s) with the full degradation or elimination curves. TEST CONDITIONS: If the test conditions were not maintained, describe any anomalies or problems encountered. MAJOR / MINOR TRANSFORMATION PRODUCTS: Indicate concentration ranges of the transformation products specified in the defined field 'Identity of transformation products' or specify if no major	Text template	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.DetailsOnResults

	transformation products were detected. Tabulate comprehensive data and refer to respective table no. (use predefined table if any) or other appropriate table. STERILE TREATMENTS: If used, report the transformation of the parent, and compare the results with those of the non-sterile treatments: SUPPLEMENTARY EXPERIMENT: Briefly describe the results of the supplementary experiment, if any.		
Results with reference substance	Indicate whether the results with the reference substance(s) are valid.	Multi-line text	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.ResultsWithReferenceSubstance
Any other information on results incl. tables	Any other information on results incl. tables Block For Microorganisms the tables in the results and discussion section do not need to be reported unless suitable data is available. However Tabulation/graphs of population dynamics and Discussion of test results should be provided in this field.	Header 2	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block Data analysis file (calculation of parameters) can be uploaded in Attached (sanitised) documents for publication, the original file should be uploaded in Attached document only if it differs from the sanitised version	Header 1	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.OverallRemarksAttachments
Kinetic evaluation	The filled "Template 7.1 - template for presentation of kinetic fitting" (https://doi.org/10.5281/zenodo.4557253) shall be uploaded here to report the visual and statistical kinetic evaluation.	Attachments list	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.OverallRemarksAttachments.KineticEvaluation
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ApplicantSummaryAndConclusion

7.1.2 Route and rate of degradation in soil

7.1.2.1 Route of degradation in soil (soil photolysis) – Endpoint summary

Purpose:

Summarize the results of the route and rate of degradation in soil photolysis studies (DegT50) and identify the metabolites requiring further consideration for risk assessment.

Provide only the most relevant details related to the viability/population dynamics in soil and persistence in the terrestrial environment.

Provide only the most relevant details, which could be:

- amounts of test substance given as % of applied initial amount, and as mg·kg⁻¹ soil
- transformation half-life or DT50 and DT90
- if available, any transformation product / metabolite (identity and concentration)
- details on test soil

The document should contain the information needed to be reported according to the list of end points for degradation in soil (SANCO/12592/2012-rev. 2, 22 March 2019).

ENDPOINT_SUMMARY.PhototransformationInSoil – v.5.0 (Final)			
Name	Instructions	Type	Field Path
Administrative data	Administrative data summary – common block Provide a brief description of relevant studies and effects. In study name/type the type of soil used in the laboratory test system should be provided	Header 1	ENDPOINT_SUMMARY.PhototransformationInSoil.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.PhototransformationInSoil.KeyValueForChemicalSafetyAssessment
Half-life in soil		Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.PhototransformationInSoil.KeyValueForChemicalSafetyAssessment.HalfLifeInSoil
Additional information	Discussion(Header 1) – common block For the DT50 value reported above include information on the conditions e.g. soil type, pH, temperature. The method of calculation should also be described. Table in the format of the List of Endpoints: Rate of degradation on soil (photolysis) laboratory active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.3) is recommended	Header 1	ENDPOINT_SUMMARY.PhototransformationInSoil.Discussion

7.1.2.1 Route of degradation in soil (soil photolysis) – Endpoint study record

Purpose:

The soil photolysis study determining the route and rate of the active substance and the nature and rates of formation of transformation products shall be provided and the related DegT50 value reported.

In case the deposition of the active substance on the soil surface is unlikely to occur (not significant) or in case photolysis is not expected to contribute significantly to the degradation of the active substance in soil,

e.g. due to low light absorbance of the active substance, a detailed justification shall be provided instead of a soil photolysis study.

Any major metabolites (or other degradation products that at any sampling time during the studies account for more than 10% of the active substance added) should be identified and their degradation rates should be studied.

The recommended methods given in OECD test guideline 307 are appropriate to almost all chemical substances for which an analytical method with sufficient accuracy and sensitivity is available. The test should not be applied to highly volatile chemicals since they cannot be kept in soil under the experimental conditions of this test.

Any deviation from the guideline method used (and reasons for it) or any other special consideration should be reported.

ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil – v.7.3 (Final)			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.DataSource
Materials and methods	Material and methods – common block Applicable test guideline: OECD Test Guideline 307: Aerobic and anaerobic transformation in soil Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU - Final Report of the Ground Water Work Group of FOCUS (Sanco/13144/2010, version 3, 10 October 2014) Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration - Final Report of the Work Group on Degradation Kinetics of FOCUS (Sanco/10058/2005, version 2.0, June 2006) EFSA (2007). Scientific Opinion on a request from EFSA related to the default Q10 value used to describe the temperature effect on transformation rates of pesticides in soil. The EFSA Journal (2007) 622, 1-32.	Header 1	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.TestMaterials

Radiolabelling	Indicate if labelled or non-labelled test material was used. Details on labelled material should be described in field 'Details on test material'.	Close d list with remar ks	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.TestMaterials.Radiolabelling
Study design		Head er 2	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign
Analytical monitoring	Indicate whether test substance was monitored in the test solutions. For robust study summaries or as requested by the regulatory programme, provide further details on sampling and analytical methods in the corresponding free text fields.	Close d list with remar ks	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign.AnalyticalMonitoring
Analytical method	Reference to the Analytical Method endpoint study record describing the method can be included in the remarks	Multi select open list with remar ks	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign.AnalyticalMethod
Details on sampling	Enter details on sampling regime and method. Use free text template as appropriate.	Text templ ate	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign.DetailsOnSampling
Details on analytical methods	If the amount of test material in the test solutions was monitored, enter any details on the analytical methods used. Use free text template and delete/add elements as appropriate. Copy any subheading(s) under IDENTIFICATION AND QUANTIFICATION OF PARENT COMPOUND to include the respective information for transformation products.	Text templ ate	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign.DetailsOnAnalyticalMethods
Details on soil	Using free text template give details on the soil used. As an alternative option, attach a document e.g. excerpt from the study report. Note: If applicable, indicate the title and year of the soil classification system used after the respective prompt, i.e. Canadian System of Soil Classification / DIN 19863 (Deutsche Industrie-Norm) / NF X31-107 (Norme française) / USDA (US Department of Agriculture) / WRB (World Reference Base for Soil Resources) / or other (to be specified).	Text templ ate	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign.DetailsOnSoil
Light source	Select light source used.	Open list with remar ks	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign.LightSource
Light spectrum :	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a	Rang e	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAn

wavelength in nm	range use both numeric fields together with the appropriate qualifier(s) if applicable.	(Decimal)	dMethods.StudyDesign.LightSpectrumWavelengthInNm
Relative light intensity	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign.RelativeLightIntensity
Details on light source	Enter any relevant details on the light source. Use either of the two free text templates as appropriate. As an alternative option, attach a document e.g. excerpt from the study report.	Text template	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign.DetailsOnLightSource
Details on test conditions	Use free text template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign.DetailsOnTestConditions
Duration of test at given test condition	Indicate the test duration and % moisture, temperature, and initial test substance concentration at which test was conducted. If test runs with different conditions and durations were performed, copy this block of fields as appropriate.		ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign.DurationOfTestAtGivenTestCondition
Duration	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign.DurationOfTestAtGivenTestCondition.Duration
% Moisture	Enter numeric value.	Decimal	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign.DurationOfTestAtGivenTestCondition.Moisture
Temp.	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign.DurationOfTestAtGivenTestCondition.Temp
Initial conc. measured	Enter numeric value.	Unit measure with	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign

		Open List (Decimal)	.DurationOfTestAtGivenTestCondition.InitialConcMeasured
Duration of test at given test condition			
Reference substance	Indicate if test(s) with a substance with known photolysis was performed. If yes, report the identity of the substance in the supplementary remarks field.	Closed list with remarks	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign.ReferenceSubstance
Dark controls	Indicate if dark, i.e. negative controls were used in parallel studies. Remarks can be included in the supplementary remarks field.	Closed list with remarks	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign.DarkControls
Computational methods	Enter details on computational methods used to calculate relevant parameters.	Multi-line text	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign.ComputationalMethods
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion
Preliminary study	Describe results from preliminary study performed, if any (e.g., adsorption of test material to the walls of the test container).	Multi-line text	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.PreliminaryStudy
Test performance	Report on any unusual observations during test, deviations from test procedure or any other information affecting results.	Multi-line text	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.TestPerformance
Spectrum of substance	Select spectral parameter from picklist and enter value in the subsequent subfield. Any notes can be included in subfield 'Remarks'. Copy block of fields for each parameter cited in the study report.		ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.Spectrum

	If the substance absorbs light at wavelengths >295 nm, give the wavelength (lambda value) of maximum absorption at wavelengths >295 nm and the maximum molar absorption (extinction) coefficient (epsilon value). If there is no absorption maximum at >295 nm, give the molar extinction coefficient at 295 nm. An alternative to the above is to attach a file that depicts graphically or in tabular form the complete UV/VIS absorption spectrum (include reference to respective Figure or Table No. in subfield 'Remarks').		
Parameter	Select parameter from drop-down list and enter the corresponding value or range with unit (unless dimensionless) in the related text field, together with any explanation if necessary, e.g. on the study group the result refers to. Explanations: AUC: Area under the plasma (blood) level vs. time curve from zero up to a certain measured time point (specify the time); Cmax: Maximum (peak) concentration; C(time): Maximum concentration at a specified time after administration of a given dose; Tmax: Time to reach peak or maximum concentration following administration.	Open list	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.Spectrum.Parameter
Value	Enter numeric value.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.Spectrum.Value
Remarks	Enter any remarks related to the recorded value as appropriate.	Text	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.Spectrum.Remarks
Spectrum of substance			
% Degradation	Specify percentage of degradation or range and sampling time. Copy this block of fields for recording results at different test conditions.		ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.Degradation
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.Degradation.KeyResult
% Degr.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the	Range	ENDPOINT_STUDY_RECORD.PhotoTransform

	second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	(Decimal)	ationInSoil.ResultsAndDiscussion.Degradation.DegradationPercent
St. dev.	Enter numeric value.	Decimal	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.Degradation.StDev
Sampling time	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.Degradation.TimePoint
Test condition	If results at different test conditions are reported, specify test condition (e.g. different temperatures). Otherwise leave this subfield empty.	Text	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.Degradation.TestCondition
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.Degradation.RemarksOnResults
% Degradation			
Quantum yield (for direct photolysis)	Give the reaction quantum yield of the test substance (values between 0 and 1).	Decimal	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.QuantumYield
Dissipation half-life of parent compound	Provide the half-life / DT50 or range as appropriate. Copy this block of fields for recording results at different test conditions.		ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.DissipationHalfLife
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Checkbox	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.DissipationHalfLife.KeyResult
DT50	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a	Range with closed	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAnd

	range use both numeric fields together with the appropriate qualifier(s) if applicable.	list (Decimal)	Discussion.DissipationHalfLife.HalfLife
Test condition	If results at different test conditions are reported, specify test condition (e.g. different temperatures). Otherwise leave this subfield empty.	Text	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.DissipationHalfLife.TestCondition
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.DissipationHalfLife.RemarksOnResults
Dissipation half-life of parent compound			
Transformation products	Indicate whether transformation products occurred. If yes, provide the identified transformation products in following block of fields. Any further details can be entered in field 'Any other information on results incl. tables'.	Closed list with remarks	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.TransformationProducts
Identity of transformation products	Indicate the identity of the transformation products using an appropriate identifier, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields for each relevant substance. Any further details on transformation products can be provided in field 'Any other information on materials and methods incl. tables'.		ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.IdentityTransformation
No.	For easier distinction select a consecutive number for each transformation product from drop-down list if more than one transformation product is entered. If the same substance is identified by more than one identifiers (e.g. by CAS name and Common name), make sure that the same number is allocated to these entries.	Closed list	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.IdentityTransformation.No
Reference substance	Click the Link button to navigate to the Substances Inventory and select the relevant substance name. If not available in the inventory, create a new one.	Entity reference field	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.IdentityTransformation.ReferenceSubstance
Identity of transfor			

mation products			
Details on results	<p>Indicate any further relevant details of test results. Use free text template and delete/add elements as appropriate. As appropriate or requested by the regulatory programme include table(s) with raw data in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').</p> <p>Explanations on free text prompts:</p> <p>TEST CONDITIONS: If the test conditions were not maintained, describe any anomalies or problems encountered.</p> <p>HALF-LIFE: Include a table with detailed results for dark and irradiated samples including Regression equation, r^2 and DT90 if available.</p> <p>MAJOR / MINOR TRANSFORMATION PRODUCTS: Indicate concentration ranges of the transformation products specified in the defined field 'Identity of transformation products' or specify if no major transformation products were detected. Tabulate comprehensive data and refer to respective table no. (use predefined table if any) or another appropriate table. Distinguish between dark and irradiated samples; compare the transformation products formed in the dark and irradiated samples and identify and quantify the products that are formed by photo transformation only.</p> <p>As appropriate attach Figure showing the pathway of photo transformation of the test substance.</p> <p>SUPPLEMENTARY EXPERIMENT: Briefly describe the results of the supplementary experiment, if any.</p>	Text template	ENDPOINT_STUDY_RE CORD.PhotoTransform ationInSoil.ResultsAnd Discussion.ResultsDeta ils
Results with reference substance	Indicate whether the results with the reference substance(s) are valid.	Multi-line text	ENDPOINT_STUDY_RE CORD.PhotoTransform ationInSoil.ResultsAnd Discussion.ResultsRefe renceSubstance
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RE CORD.PhotoTransform ationInSoil.ResultsAnd Discussion.AnyOtherInf ormationOnResultsIncl Tables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RE CORD.PhotoTransform ationInSoil.OverallRem arksAttachments

Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ApplicantSummaryAndConclusion
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7.1.2.1 Route of degradation in soil (soil photolysis) – Endpoint study record

Purpose:

The soil photolysis study determining the route and rate of the active substance and the nature and rates of formation of transformation products shall be provided and the related DegT50 value reported.

In case the deposition of the active substance on the soil surface is unlikely to occur (not significant) or in case photolysis is not expected to contribute significantly to the degradation of the active substance in soil, e.g. due to low light absorbance of the active substance, a detailed justification shall be provided instead of a soil photolysis study.

Any major metabolites (or other degradation products that at any sampling time during the studies account for more than 10% of the active substance added) should be identified and their degradation rates should be studied.

The recommended methods given in OECD test guideline 307 are appropriate to almost all chemical substances for which an analytical method with sufficient accuracy and sensitivity is available. The test should not be applied to highly volatile chemicals since they cannot be kept in soil under the experimental conditions of this test.

Any deviation from the guideline method used (and reasons for it) or any other special consideration should be reported.

ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil – v.7.3 (Final) [September 2020]			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.DataSource
Materials and methods	Material and methods – common block Applicable test guideline:	Header 1	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods

	<p>OECD Test Guideline 307: Aerobic and anaerobic transformation in soil</p> <p>Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU - Final Report of the Ground Water Work Group of FOCUS (Sanco/13144/2010, version 3, 10 October 2014) Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration - Final Report of the Work Group on Degradation Kinetics of FOCUS (Sanco/10058/2005, version 2.0, June 2006)</p> <p>EFSA (2007). Scientific Opinion on a request from EFSA related to the default Q10 value used to describe the temperature effect on transformation rates of pesticides in soil. The EFSA Journal (2007) 622, 1-32.</p>		
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.TestMaterials
Radiolabelling	Indicate if labelled or non-labelled test material was used. Details on labelled material should be described in field 'Details on test material'.	Closed list with remarks	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.TestMaterials.Radiolabelling
Study design		Header 2	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign
Analytical monitoring	Indicate whether test substance was monitored in the test solutions. For robust study summaries or as requested by the regulatory programme, provide further details on sampling and analytical methods in the corresponding free text fields.	Closed list with remarks	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign.AnalyticalMonitoring
Analytical method	Reference to the Analytical Method endpoint study record describing the method can be included in the remarks	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign.AnalyticalMethod
Details on sampling	Enter details on sampling regime and method. Use free text template as appropriate.	Text template	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign.DetailsOnSampling
Details on analytical	If the amount of test material in the test solutions was monitored, enter any details on the analytical methods used. Use free text template and delete/add elements	Text template	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAn

I methods	as appropriate. Copy any subheading(s) under IDENTIFICATION AND QUANTIFICATION OF PARENT COMPOUND to include the respective information for transformation products.		dMethods.StudyDesign .DetailsOnAnalyticalMethods
Details on soil	Using free text template give details on the soil used. As an alternative option, attach a document e.g. excerpt from the study report. Note: If applicable, indicate the title and year of the soil classification system used after the respective prompt, i.e. Canadian System of Soil Classification / DIN 19863 (Deutsche Industrie-Norm) / NF X31-107 (Norme française) / USDA (US Department of Agriculture) / WRB (World Reference Base for Soil Resources) / or other (to be specified).	Text template	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign .DetailsOnSoil
Light source	Select light source used.	Open list with remarks	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign .LightSource
Light spectrum : wavelength in nm	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign .LightSpectrumWavelengthInNm
Relative light intensity	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign .RelativeLightIntensity
Details on light source	Enter any relevant details on the light source. Use either of the two free text templates as appropriate. As an alternative option, attach a document e.g. excerpt from the study report.	Text template	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign .DetailsOnLightSource
Details on test conditions	Use free text template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign .DetailsOnTestConditions
Duration of test at given test condition	Indicate the test duration and % moisture, temperature, and initial test substance concentration at which test was conducted. If test runs with different conditions and durations were performed, copy this block of fields as appropriate.		ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign .DurationOfTestAtGivenTestCondition
Duration	Enter numeric value.	Unit measure with Close	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign .DurationOfTestAtGive

		d List (Decimal)	nTestCondition.Duration
% Moisture	Enter numeric value.	Decimal	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign.DurationOfTestAtGivenTestCondition.Moisture
Temp.	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign.DurationOfTestAtGivenTestCondition.Temp
Initial conc. measured	Enter numeric value.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign.DurationOfTestAtGivenTestCondition.InitialConcMeasured
Duration of test at given test condition			
Reference substance	Indicate if test(s) with a substance with known photolysis was performed. If yes, report the identity of the substance in the supplementary remarks field.	Closed list with remarks	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign.ReferenceSubstance
Dark controls	Indicate if dark, i.e. negative controls were used in parallel studies. Remarks can be included in the supplementary remarks field.	Closed list with remarks	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign.DarkControls
Computational methods	Enter details on computational methods used to calculate relevant parameters.	Multi-line text	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign.ComputationalMethods
Any other information on materials	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.AnyOtherInf

and methods incl. tables			ormationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion
Preliminary study	Describe results from preliminary study performed, if any (e.g., adsorption of test material to the walls of the test container).	Multi-line text	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.PreliminaryStudy
Test performance	Report on any unusual observations during test, deviations from test procedure or any other information affecting results.	Multi-line text	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.TestPerformance
Spectrum of substance	Select spectral parameter from picklist and enter value in the subsequent subfield. Any notes can be included in subfield 'Remarks'. Copy block of fields for each parameter cited in the study report. If the substance absorbs light at wavelengths >295 nm, give the wavelength (lambda value) of maximum absorption at wavelengths >295 nm and the maximum molar absorption (extinction) coefficient (epsilon value). If there is no absorption maximum at >295 nm, give the molar extinction coefficient at 295 nm. An alternative to the above is to attach a file that depicts graphically or in tabular form the complete UV/VIS absorption spectrum (include reference to respective Figure or Table No. in subfield 'Remarks').		ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.Spectrum
Parameter	Select parameter from drop-down list and enter the corresponding value or range with unit (unless dimensionless) in the related text field, together with any explanation if necessary, e.g. on the study group the result refers to. Explanations: AUC: Area under the plasma (blood) level vs. time curve from zero up to a certain measured time point (specify the time); Cmax: Maximum (peak) concentration; C(time): Maximum concentration at a specified time after administration of a given dose; Tmax: Time to reach peak or maximum concentration following administration.	Open list	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.Spectrum.Parameter
Value	Enter numeric value.	Unit measure with Open List	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.Spectrum.Value

		(Decimal)	
Remarks	Enter any remarks related to the recorded value as appropriate.	Text	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.Spectrum.Remarks
Spectrum of substance			
% Degradation	Specify percentage of degradation or range and sampling time. Copy this block of fields for recording results at different test conditions.		ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.Degradation
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Checkbox	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.Degradation.KeyResult
% Degr.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.Degradation.DegradationPercent
St. dev.	Enter numeric value.	Decimal	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.Degradation.StDev
Sampling time	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.Degradation.TimePoint
Test condition	If results at different test conditions are reported, specify test condition (e.g. different temperatures). Otherwise leave this subfield empty.	Text	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.Degradation.TestCondition
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.Degradation.RemarksOnResults

% Degradation			
Quantum yield (for direct photolysis)	Give the reaction quantum yield of the test substance (values between 0 and 1).	Decimal	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.QuantumYield
Dissipation half-life of parent compound	Provide the half-life / DT50 or range as appropriate. Copy this block of fields for recording results at different test conditions.		ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.DissipationHalfLife
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Checkbox	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.DissipationHalfLife.KeyResult
DT50	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.DissipationHalfLife.HalfLife
Test condition	If results at different test conditions are reported, specify test condition (e.g. different temperatures). Otherwise leave this subfield empty.	Text	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.DissipationHalfLife.TestCondition
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.DissipationHalfLife.RemarksOnResults
Dissipation half-life of parent compound			
Transformation products	Indicate whether transformation products occurred. If yes, provide the identified transformation products in following block of fields. Any further details can be entered in field 'Any other information on results incl. tables'.	Closed list with remarks	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.TransformationProducts
Identity of	Indicate the identity of the transformation products using an appropriate identifier, e.g. CAS number, CAS		ENDPOINT_STUDY_RECORD.PhotoTransform

transformation products	name, IUPAC name. Copy this block of fields for each relevant substance. Any further details on transformation products can be provided in field 'Any other information on materials and methods incl. tables'.		ationInSoil.ResultsAndDiscussion.IdentityTransformation
No.	For easier distinction select a consecutive number for each transformation product from drop-down list if more than one transformation product is entered. If the same substance is identified by more than one identifiers (e.g. by CAS name and Common name), make sure that the same number is allocated to these entries.	Close d list	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.IdentityTransformation.No
Reference substance	Click the Link button to navigate to the Substances Inventory and select the relevant substance name. If not available in the inventory, create a new one.	Entity reference field	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.IdentityTransformation.ReferenceSubstance
Identity of transformation products			
Details on results	<p>Indicate any further relevant details of test results. Use free text template and delete/add elements as appropriate. As appropriate or requested by the regulatory programme include table(s) with raw data in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').</p> <p>Explanations on free text prompts:</p> <p>TEST CONDITIONS: If the test conditions were not maintained, describe any anomalies or problems encountered.</p> <p>HALF-LIFE: Include a table with detailed results for dark and irradiated samples including Regression equation, r^2 and DT90 if available.</p> <p>MAJOR / MINOR TRANSFORMATION PRODUCTS: Indicate concentration ranges of the transformation products specified in the defined field 'Identity of transformation products' or specify if no major transformation products were detected. Tabulate comprehensive data and refer to respective table no. (use predefined table if any) or another appropriate table. Distinguish between dark and irradiated samples; compare the transformation products formed in the dark and irradiated samples and identify and quantify the products that are formed by photo transformation only.</p> <p>As appropriate attach Figure showing the pathway of</p>	Text templ ate	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.ResultsDetails

	photo transformation of the test substance. SUPPLEMENTARY EXPERIMENT: Briefly describe the results of the supplementary experiment, if any.		
Results with reference substance	Indicate whether the results with the reference substance(s) are valid.	Multi-line text	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.ResultsReferenceSubstance
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ApplicantSummaryAndConclusion

7.1.2.2 Rate of degradation in soil (field studies) – Endpoint summary

Purpose:

Summarize the results of the field studies providing information on the transformation of the active substance, and if required its metabolites, under representative actual use conditions.

ENDPOINT_SUMMARY.FieldStudies – v.3.0 (Final) [July 2020]			
Name	Instructions	Type	Field Path
Administrative data	Administrative data summary – common block Provide a brief description of relevant studies and effects. Information on the following aspects of behavior in soil can be described in this document; investigation of pH dependence of degradation based on	Header 1	ENDPOINT_SUMMARY.FieldStudies.AdministrativeDataSummary

	<p>field data, cross walk exercise to determine if a field study conducted in the US is relevant for the EU, comparison of field and laboratory DT50 values.</p> <p>Multiple endpoint summaries can be created where different DegT50 values are defined at different pH values. The pH should be specified in the 'Description of key information field.</p>		
Additional information	<p>Discussion(Header 1) – common block</p> <p>Table in the format specified in The list of Endpoints Rate of degradation field soil dissipation studies (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.2.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.2.1) is recommended.</p> <p>The EFSA DegT50Endpoint Selector excel file can be uploaded here.</p>	Header 1	ENDPOINT_SUMMARY.F ieldStudies.Discussion

Links to support material:

FOCUS Group (2006). Generic guidance for estimating persistence and degradation kinetics from environmental fate studies on pesticides in EU registration. (SANCO/ 10058/2005-v. 2.0, 434 pp Version 1.1, 18 December 2014)

EFSA European Food Safety Authority, 2014. EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil. EFSA Journal 2014;12(5):3662, 37 pp., [doi:10.2903/j.efsa.2014.3662](https://doi.org/10.2903/j.efsa.2014.3662)

7.1.2.2 Rate of degradation in soil (field studies) – Endpoint study record

Purpose:

The soil dissipation studies shall provide estimates of the time required for dissipation of 50 % and 90 % (DisT50field and DisT90field) and, if possible, of the time required for degradation of 50 % and 90 %

(DegT50_{field} and DegT90_{field}), of the active substance under field conditions. Where relevant, information on metabolites, breakdown and reaction products shall be provided.
Information on non-experimental studies e.g. comparison of extraction methods or soil storage stability can be reported in this endpoint study.

ENDPOINT_STUDY_RECORD.FieldStudies – v.6.3 (Final) [September 2020]			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.FieldStudies.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.FieldStudies.DataSource
Materials and methods	Material and methods – common block In test guideline indicate according to which test guideline the study was conducted: US EPA, (2009) OCSPP 836.6100 Terrestrial field dissipation document or OECD Guidance Document If no test guideline was explicitly followed, but the methodology used is equivalent or similar to a specific guideline, you can indicate so in the 'Qualifier' subfield preceding the field 'Guideline'. Copy this block of fields for specifying more than one guideline. Applicable test guideline (guideline field): OECD Test Guideline 232: Guidance document for conducting pesticide terrestrial field dissipation studies.	Header 1	ENDPOINT_STUDY_RECORD.FieldStudies.MaterialsAndMethods
Type of measurement	Indicate the type of measurement applied.	Multi-line text	ENDPOINT_STUDY_RECORD.FieldStudies.MaterialsAndMethods.TypeOfMeasurement
Media	Indicate the media investigated.	Multi-line text	ENDPOINT_STUDY_RECORD.FieldStudies.MaterialsAndMethods.Media

Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.FieldStudies.MaterialsAndMethods.TestMaterials
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block In this field, you can enter any information on materials and methods, for which no distinct field is available, or transfer free text from other databases. See Appendix A of EFSA guidance on the estimation of degradation rates Page 35 (DegT50matrix) from field experiments in the soil compartment EFSA (2014) You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. You can also upload any htm or html document. Note: One rich text editor field each is provided for the MATERIALS AND METHODS and RESULTS section. In addition the fields 'Overall remarks' and 'Executive summary' allow rich text entry.	Header 2	ENDPOINT_STUDY_RECORD.FieldStudies.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.FieldStudies.ResultsAndDiscussion
Any other information on results incl. tables	Any other information on results incl. tables Block For chemicals the table presenting the kinetic fitting must be included here The following information should be included Substance, Soil, Kinetic model, Mo, χ^2 , %-	Header 2	ENDPOINT_STUDY_RECORD.FieldStudies.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables

	<p>error, Prob>t, Lower CI, Upper CI, DT50 and DT90</p> <p>An example of the table format is available here The filled "Template 7.1 - template for presentation of kinetic fitting" (https://doi.org/10.5281/zenodo.4557253)</p>		
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.FieldStudies.OverallRemarksAttachments
Kinetic evaluation		Attachments list	ENDPOINT_STUDY_RECORD.FieldStudies.OverallRemarksAttachments.KineticEvaluation
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.FieldStudies.ApplicantSummaryAndConclusion

Links to support material:

FOCUS (1997). Soil persistence models and Eu registration

FOCUS (2006). Generic guidance for estimating persistence and degradation kinetics from environmental fate studies on pesticides in EU registration (SANCO/ 10058/2005-v. 2.0, 434 pp Version 1.1, 18 December 2014).

EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil <https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2014.3662>

7.1.3 Adsorption and desorption in soil – Endpoint summary

Purpose:

Summarize the results of the adsorption/desorption studies to provide the adsorption coefficients of the active substance and its metabolite in the soil.

ENDPOINT_SUMMARY.AdsorptionDesorption v.6.0 (Final)			
Name	Instructions	Type	Field Path
Administrative data	Administrative data summary – common block Provide a brief description of relevant studies and effects.	Header 1	ENDPOINT_SUMMARY.AdsorptionDesorption.AdministrativeDataSummary

	Reference can also be made to the results of aged sorption studies if available.		
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.AdsorptionDesorption.KeyValueForChemicalSafetyAssessment
Koc at 20 °C	Report the organic carbon adsorption coefficient (Koc)	Decimal	ENDPOINT_SUMMARY.AdsorptionDesorption.KeyValueForChemicalSafetyAssessment.KocAt20 Celsius
Other adsorption coefficients	If the value for Koc is missing, provide information on other adsorption coefficients.		ENDPOINT_SUMMARY.AdsorptionDesorption.KeyValueForChemicalSafetyAssessment.OtherAdsorptionCoefficients
Type	Select additional adsorption coefficients. Other can be used in case of a coefficient value which is not in the list	Open list	ENDPOINT_SUMMARY.AdsorptionDesorption.KeyValueForChemicalSafetyAssessment.OtherAdsorptionCoefficients.Type
Value in L/kg		Decimal	ENDPOINT_SUMMARY.AdsorptionDesorption.KeyValueForChemicalSafetyAssessment.OtherAdsorptionCoefficients.TypeValue
at the temperature of		Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.AdsorptionDesorption.KeyValueForChemicalSafetyAssessment.OtherAdsorptionCoefficients.AtTheTemperatureOf
Other adsorption coefficients			
Additional information	Discussion(Header 1) – common block Provide the original version of any document that contains confidential material. A table in the format from the List of Endpoints Soil adsorption active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.3.1.1 and Regulation (EU) N°	Header 1	ENDPOINT_SUMMARY.AdsorptionDesorption.Discussion

	284/2013, Annex Part A, point 9.1.2.1) is recommended.		
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Links to support material:

European Commission. Scientific Committee on plants SCP/KOC/002-Final. Opinion of the Scientific Committee on Plants on methods for the determination of the organic carbon adsorption coefficient (Koc) for a plant protection product active substance in the context of Council Directive 91/414/EEC (18 July 2002)[3]

Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU - Final Report of the Ground Water Work Group of FOCUS (Sanco/13144/2010, version 3, 10 October 2014)

EFSA (2017). Technical report on the outcome of the pesticides peer review meeting on the OECD 106 evaluators checklist. EFSA supporting publication 2017:EN-1326

7.1.3.1 Adsorption and desorption – Endpoint study record

Purpose:

Adsorption/desorption studies give information on the mobility of active substance and its metabolites in soil.

Studies on adsorption and desorption of the active substance shall be provided, except where the nature and manner of use of plant protection products containing the active substance preclude soil contamination such as indoor uses on stored products or brush applied wound healing treatments for trees

ENDPOINT_STUDY_RECORD.AdsorptionDesorption – v.6.3 (Final)			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.DataSource
Materials and methods	Material and methods – common block Applicable test guideline: OECD Test Guideline 106: Adsorption - desorption using a batch equilibrium method. Indicate the type of method used regardless of whether it is already specified in the guideline, as this	Header 1	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods

	field can be used for query purposes.		
Media	Indicate the medium (i.e. soil, sediment or sewage sludge) for which the adsorption (desorption) determination was made. For the HPCL estimation method, select 'soil/sewage sludge'. For any other, select 'other' and specify.	Open list	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.Media
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.TestMaterials
Radiolabelling	Indicate if labelled or non-labelled test material was used. Details on labelled material to be described in field 'Details on test material'.	Closed list with remarks	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.TestMaterials.Radiolabelling
Study design		Header 2	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign
Test temperature	Indicate test temperature values measured during test. Include range, mean, standard deviation and unit.	Multi-line text	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.TestTemperature
HPLC method		Header 3	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.HPLCMethod
Details on study design: HPLC method	For the HPLC method only, enter any details on the study design that could be relevant for evaluating this study summary. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.HPLCMethod.DetailsOnStudyDesignHplcMethod
Batch equilibrium or other method		Header 3	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod
Analytical monitoring	Indicate whether test substance was monitored in the test solutions. For robust study summaries or as requested by the regulatory programme, provide further details	Closed list with remarks	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.AnalyticalMonitoring

	on sampling and analytical methods in the corresponding freetext fields.		
Details on sampling	If the amount of test material in the test solutions was monitored, enter details on sampling. Use freetext template as appropriate and delete/add elements as appropriate.	Text template	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.DetailsOnSampling
Details on analytical methods	If the amount of test material in the test solutions was monitored, enter any details on the analytical methods used. Use freetext template and delete/add elements as appropriate. Reference Analytical method endpoint study record can be included here	Text template	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.DetailsOnAnalyticalMethods
Matrix properties	Repeat this block of fields for each different matrix type used as indicated by the Matrix no. Specify the type of soil, sediment or sludge.		ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.MatrixProperties
Matrix no.	Select a consecutive number from drop-down list if more than one matrix type were used.	Closed list	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.MatrixProperties.MatrixNo
Matrix type	Select from drop-down list.	Open list	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.MatrixProperties.MatrixType
% Clay	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.MatrixProperties.Clay
% Silt	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together	Range (Decimal)	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.MatrixProperties.Silt

	with the appropriate qualifier(s) if applicable.		
% Sand	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECO RD.AdsorptionDesorption. MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.MatrixProperties.Sand
% Org. carbon	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECO RD.AdsorptionDesorption. MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.MatrixProperties.OrgCarbon
pH	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECO RD.AdsorptionDesorption. MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.MatrixProperties.Ph
CEC	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECO RD.AdsorptionDesorption. MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.MatrixProperties.CEC
Bulk density (g/cm³)	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECO RD.AdsorptionDesorption. MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.MatrixProperties.BulkDensityGCM
Matrix properties			
Details on matrix	Depending on the test system, i.e. water-soil or water-sediment or water-activated sludge simulation system, include details on either the soil, sediment or sludge solids used in the study. Select respective freetext template and delete/add elements as appropriate. As an alternative	Text template	ENDPOINT_STUDY_RECO RD.AdsorptionDesorption. MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.DetailsOnMatrix

	option, include or attach an excerpt from the study report.		
Details on test conditions	Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. As appropriate or requested by the regulatory programme include tables in the rich text field 'Any other information on results incl. tables' summarising the study design for the adsorption and desorption phase. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').	Text template	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.DetailsOfTestConditions
Duration of adsorption equilibration	Indicate sample number (if multiple types of soil/sediment/sludge were used), indicate temperature and initial pH and test substance concentration at which adsorption was conducted and the respective test duration. If test runs with different conditions and durations were performed, copy this block of fields as appropriate.		ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.DurationOfAdsorptionEquilibration
Sample No.	Select a consecutive sample number from drop-down list if more than one matrix types were used. Create a new row for each sample/soil tested	Closed list	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.DurationOfAdsorptionEquilibration.SampleNo
Duration	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.DurationOfAdsorptionEquilibration.Duration
Initial conc. measured	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.Duration

	with the appropriate qualifier(s) if applicable.		nOfAdsorptionEquilibratio n.InitialConcMeasured
pH	Enter the initial pH.	Decimal	ENDPOINT_STUDY_RECO RD.AdsorptionDesorption. MaterialsAndMethods.Stu dyDesign.BatchEquilibriu mOrOtherMethod.Duratio nOfAdsorptionEquilibratio n.Ph
Temp.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with closed list (Decimal)	ENDPOINT_STUDY_RECO RD.AdsorptionDesorption. MaterialsAndMethods.Stu dyDesign.BatchEquilibriu mOrOtherMethod.Duratio nOfAdsorptionEquilibratio n.Temp
Remarks	Enter any remarks related to the duration of the adsorption equilibration.	Text	ENDPOINT_STUDY_RECO RD.AdsorptionDesorption. MaterialsAndMethods.Stu dyDesign.BatchEquilibriu mOrOtherMethod.Duratio nOfAdsorptionEquilibratio n.Remarks
Duration of adsorption equilibration			
Duration of desorption equilibration	Indicate sample number (if multiple types of soil/sediment/sludge were used), temperature and amount of test substance concentration in the adsorbed state and the respective test duration. If test runs with different conditions and durations were performed, copy this block of fields as appropriate.		ENDPOINT_STUDY_RECO RD.AdsorptionDesorption. MaterialsAndMethods.Stu dyDesign.BatchEquilibriu mOrOtherMethod.Duratio nOfDesorptionEquilibratio n
Sample no.	Select a consecutive sample number from drop-down list if more than one matrix types were used. Create a new row for each sample/soil tested	Closed list	ENDPOINT_STUDY_RECO RD.AdsorptionDesorption. MaterialsAndMethods.Stu dyDesign.BatchEquilibriu mOrOtherMethod.Duratio nOfDesorptionEquilibratio n.SampleNo
Duration	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECO RD.AdsorptionDesorption. MaterialsAndMethods.Stu dyDesign.BatchEquilibriu mOrOtherMethod.Duratio nOfDesorptionEquilibratio n.Duration

Conc. of adsorbed test mat.	Enter a numeric value.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.DurationOfDesorptionEquilibration.ConcOfAdsorbedTestMat
pH	Enter the initial pH.	Decimal	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.DurationOfDesorptionEquilibration.Ph
Temp.	Enter a numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.DurationOfDesorptionEquilibration.Temp
Remarks	Enter any remarks related to the duration of the adsorption equilibration.	Text	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.DurationOfDesorptionEquilibration.Remarks
Duration of desorption equilibration			
Computational methods	Enter details on computational methods used to calculate relevant parameters. Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from the study report.	Text template	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.ComputationalMethods
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion
Adsorption coefficient			ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.AdsorptionCoefficient

Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECO RD.AdsorptionDesorption. ResultsAndDiscussion.Ads orptionCoefficient.KeyRes ult
Sample No.	Select a consecutive sample number from drop-down list if more than one matrix types were used.	Closed list	ENDPOINT_STUDY_RECO RD.AdsorptionDesorption. ResultsAndDiscussion.Ads orptionCoefficient.Sample No
Type	Either of the following parameters can be selected from the drop-down list: adsorption coefficient Koc or log Koc, distribution constant Kd or log Kd. Include any explanations in the supplementary remarks field as appropriate. For reporting partition coefficients (Kp / log Kp) please use the next block of fields 'Partition coefficients'.	Open list with remarks	ENDPOINT_STUDY_RECO RD.AdsorptionDesorption. ResultsAndDiscussion.Ads orptionCoefficient.Type
Value	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECO RD.AdsorptionDesorption. ResultsAndDiscussion.Ads orptionCoefficient.Value
pH	Enter numeric value.	Decimal	ENDPOINT_STUDY_RECO RD.AdsorptionDesorption. ResultsAndDiscussion.Ads orptionCoefficient.Ph
Temp.	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECO RD.AdsorptionDesorption. ResultsAndDiscussion.Ads orptionCoefficient.Temp
Matrix	This free text field can be used to specify the matrix tested if several types were used, e.g. 'Soil no. 1: clay', 'sediment type ...' etc.	Text	ENDPOINT_STUDY_RECO RD.AdsorptionDesorption. ResultsAndDiscussion.Ads orptionCoefficient.Matrix
% Org. carbon	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECO RD.AdsorptionDesorption. ResultsAndDiscussion.Ads orptionCoefficient.Percent ageOfOrganicCarbon
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived;	Open list with remarks (2000)	ENDPOINT_STUDY_RECO RD.AdsorptionDesorption. ResultsAndDiscussion.Ads

	<ul style="list-style-type: none"> - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:' 		orptionCoefficient.RemarksOnResults
Adsorption coefficient			
Partition coefficients	Include any relevant solids-water partition coefficient Kp or log Kp for the compartment-water system covered (e.g. log Kp solids-water in soil). If required, copy block of fields to include several parameters.		ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.AdsorptionOther
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.AdsorptionOther.KeyResult
Sample No.	Select a consecutive sample number from drop-down list if more than one matrix types were used.	Closed list	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.AdsorptionOther.SampleNo
Phase system	Indicate the compartment-water system or select 'other:' and specify.	Open list with remarks	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.AdsorptionOther.PhaseSystem
Type	Select 'Kp' or 'log Kp' from the drop-down list. Include any explanations in the supplementary remarks field as appropriate.	Open list with remarks	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.AdsorptionOther.Type
Value	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.AdsorptionOther.Value
Temp.	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.AdsorptionOther.Temp
pH	Enter numeric value.	Decimal	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.AdsorptionOther.Ph

Matrix	This free text field can be used to specify the matrix tested if several types were used, e.g. 'Soil no. 1: clay', 'sediment type ...' etc.	Text	ENDPOINT_STUDY_RECO RD.AdsorptionDesorption. ResultsAndDiscussion.Ads orptionOther.Matrix
% Org. carbon	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECO RD.AdsorptionDesorption. ResultsAndDiscussion.Ads orptionOther.OrgCarbon
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECO RD.AdsorptionDesorption. ResultsAndDiscussion.Ads orptionOther.RemarksOnR esults
Partition coefficients			
Results: HPLC method		Header 2	ENDPOINT_STUDY_RECO RD.AdsorptionDesorption. ResultsAndDiscussion.Res ultsHplcMethod
Details on results (HPLC method)	For the HPLC method only, include further data as indicated in the freetext template.	Text template	ENDPOINT_STUDY_RECO RD.AdsorptionDesorption. ResultsAndDiscussion.Res ultsHplcMethod.DetailsOn ResultsHplcMethod
Results: Batch equilibrium or other method		Header 2	ENDPOINT_STUDY_RECO RD.AdsorptionDesorption. ResultsAndDiscussion.Res ultsBatchEquilibriumOrOth erMethod
Adsorption and desorption constants	For each soil used provide adsorption and desorption constants including data on the slope of Freundlich adsorption/desorption isotherms (1/N) and regression coefficient of Freundlich equation (R2). Upload predefined table as appropriate or requested by the regulatory programme in the rich text field 'Any other information on results incl. tables' or adapt table(s) from	Multi-line text	ENDPOINT_STUDY_RECO RD.AdsorptionDesorption. ResultsAndDiscussion.Res ultsBatchEquilibriumOrOth erMethod.AdsorptionAndD esorptionConstants

	study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').		
Recovery of test material	Indicate recovery of test material in supernatant solution and solid phase as well as non-extractable residues after adsorption/desorption, including mean standard deviation. Upload predefined table as appropriate or requested by the regulatory programme in the rich text field 'Any other information on results incl. tables' or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').	Multi-line text	ENDPOINT_STUDY_RECO RD.AdsorptionDesorption. ResultsAndDiscussion. ResultsBatchEquilibriumOrOtherMethod.RecoveryOfTest Material
Concentration of test substance at end of adsorption equilibration period	Give concentration of test substance in solid and liquid phases at the end of adsorption equilibration period and percent adsorbed test material of applied, including standard deviation; indicate whether the amount on sorbent residue is measured by sorbent residue analysis or calculated by difference (total applied - concentration in solution). Upload predefined table as appropriate or requested by the regulatory programme in the rich text field 'Any other information on results incl. tables' or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').	Multi-line text	ENDPOINT_STUDY_RECO RD.AdsorptionDesorption. ResultsAndDiscussion. ResultsBatchEquilibriumOrOtherMethod.ConcentrationOf TestSubstanceAtEndOfAdsorptionEquilibrationPeriod
Concentration of test substance at end of desorption equilibration period	Give concentration of test substance in solid and liquid phases at the end of desorption equilibration period and percent desorbed test material of adsorbed, including standard deviation; indicate whether the amount on sorbent residue is measured by sorbent residue analysis or calculated by difference (total applied - concentration in solution). Upload predefined table as appropriate or requested by the	Multi-line text	ENDPOINT_STUDY_RECO RD.AdsorptionDesorption. ResultsAndDiscussion. ResultsBatchEquilibriumOrOtherMethod.ConcentrationOf TestSubstanceAtEndOfDesorptionEquilibrationPeriod

	regulatory programme in the rich text field 'Any other information on results incl. tables' or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').		
Mass balance (%) at end of adsorption phase	Indicate sample number (if multiple types of soil/sediment/sludge were used), duration of end of adsorption phase and include the respective mass balance as % of the applied test substance. For indicating values for different soil (samples), copy this block of fields as appropriate.		ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.ResultsBatchEquilibriumOrOtherMethod.MassBalanceAtEndOfAdsorptionPhase
Sample no.	Select a consecutive sample number from drop-down list if more than one matrix types were used.	Closed list	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.ResultsBatchEquilibriumOrOtherMethod.MassBalanceAtEndOfAdsorptionPhase.SampleNo
Duration	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.ResultsBatchEquilibriumOrOtherMethod.MassBalanceAtEndOfAdsorptionPhase.Duration
% Adsorption	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.ResultsBatchEquilibriumOrOtherMethod.MassBalanceAtEndOfAdsorptionPhase.AdsorptionPercentage
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:', e.g. details on soil.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.ResultsBatchEquilibriumOrOtherMethod.MassBalanceAtEndOfAdsorptionPhase.RemarksOnResults

Mass balance (%) at end of adsorption phase			
Mass balance (%) at end of desorption phase	Indicate sample number (if multiple types of soil/sediment/sludge were used), duration of end of desorption phase and include the respective mass balance as % of the applied test substance. For indicating values for different soil (samples), copy this block of fields as appropriate.		ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.ResultsBatchEquilibriumOrOtherMethod.MassBalanceAtEndOfDesorptionPhase
Sample no.	Select a consecutive sample number from drop-down list if more than one matrix types were used.	Closed list	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.ResultsBatchEquilibriumOrOtherMethod.MassBalanceAtEndOfDesorptionPhase.SampleNo
Duration	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.ResultsBatchEquilibriumOrOtherMethod.MassBalanceAtEndOfDesorptionPhase.Duration
% Desorption	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.ResultsBatchEquilibriumOrOtherMethod.MassBalanceAtEndOfDesorptionPhase.DesorptionPercentage
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:', e.g. details on soil.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.ResultsBatchEquilibriumOrOtherMethod.MassBalanceAtEndOfDesorptionPhase.RemarksOnResults
Mass balance (%) at end of desorption phase			

Transformation products	Indicate whether transformation products occurred. If yes, provide the identified transformation products in following block of fields. Any further details can be entered in field 'Any other information on results incl. tables'.	Closed list with remarks	ENDPOINT_STUDY_RECO RD.AdsorptionDesorption. ResultsAndDiscussion. ResultsBatchEquilibriumOrOtherMethod.Transformation Products
Identity of transformation products	Indicate the identity of the transformation products using an appropriate identifier, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields for each relevant substance. Any further details on transformation products can be provided in field 'Any other information on materials and methods incl. tables'.		ENDPOINT_STUDY_RECO RD.AdsorptionDesorption. ResultsAndDiscussion. ResultsBatchEquilibriumOrOtherMethod.IdentityTransformation
No.	For easier distinction select a consecutive number for each transformation product from drop-down list if more than one transformation product is entered. If the same substance is identified by more than one identifiers (e.g. by CAS name and Common name), make sure that the same number is allocated to these entries.	Closed list	ENDPOINT_STUDY_RECO RD.AdsorptionDesorption. ResultsAndDiscussion. ResultsBatchEquilibriumOrOtherMethod.IdentityTransformation.No
Reference substance	Click the Link button to navigate to the Substances Inventory and select the relevant substance name. If not available in the inventory, create a new one.	Entity reference field	ENDPOINT_STUDY_RECO RD.AdsorptionDesorption. ResultsAndDiscussion. ResultsBatchEquilibriumOrOtherMethod.IdentityTransformation.ReferenceSubstance
Identity of transformation products			
Details on results (Batch equilibrium method)	Indicate any further relevant details of test results. Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from the study report.	Text template	ENDPOINT_STUDY_RECO RD.AdsorptionDesorption. ResultsAndDiscussion. ResultsBatchEquilibriumOrOtherMethod.DetailsOnResultsBatchEquilibriumMethod
Statistics	Indicate the parameters analyzed, the statistical method used and the statistical test performed.	Multi-line text	ENDPOINT_STUDY_RECO RD.AdsorptionDesorption. ResultsAndDiscussion. ResultsBatchEquilibriumOrOtherMethod.Statistics
Any other information on results incl. tables		Header 2	ENDPOINT_STUDY_RECO RD.AdsorptionDesorption. ResultsAndDiscussion.Any

			OtherInformationOnResultsInclTables
	In this field, you can enter any other remarks on results. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. The filled in table of Template 7.2 (Template for presenting the results of the OECD 106 evaluators checklist" should be pasted here. Note: One rich text editor field each is provided for the MATERIALS AND METHODS and RESULTS section. In addition the fields 'Overall remarks' and 'Executive summary' allow rich text entry.	Rich text area	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables.OtherInformation
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ApplicantSummaryAndConclusion

Links to support material:

European Commission. Scientific Committee on plants SCP/KOC/002-Final. Opinion of the Scientific Committee on Plants on methods for the determination of the organic carbon adsorption coefficient (Koc) for a plant protection product active substance in the context of Council Directive 91/414/EEC (18 July 2002)[3]

Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU - Final Report of the Ground Water Work Group of FOCUS (Sanco/13144/2010, version 3, 10 October 2014)

EFSA (2017). Technical report on the outcome of the pesticides peer review meeting on the OECD 106 evaluators checklist. EFSA supporting publication 2017:EN-1326

7.1.3.2 Aged sorption – Endpoint study record

Purpose:

As a higher tier option, information on aged sorption may be provided. Time dependent sorption studies should be reported in this document

ENDPOINT_STUDY_RECORD.AgedSorption – v.2.1 (Final)			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.AgedSorption.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.AgedSorption.DataSource
Materials and methods	Material and methods – common block Applicable test guideline: European Commission, 2014. Assessing potential for movement of active substances and their metabolites to ground water in the EU. Report of the FOCUS Workgroup. EC Document Reference SANCO/13144/2010-v. 3,613 pp., as outlined in Generic guidance for tier 1 FOCUS groundwater assessment, v. 2.2, May 2014. ; OECD 307; OECD 106; European Commission, 2021. Guidance on how aged sorption studies for pesticides should be conducted, analyzed and used in regulatory assessments. EC Document Reference SANTE/12586/2020 – REV 0 26 January 2021	Header 1	ENDPOINT_STUDY_RECORD.AgedSorption.MaterialsAndMethods
Type of study	Include only information that does not fit into any of the	Open list	ENDPOINT_STUDY_RECORD.AgedSorption.Ma

	<p>specific chapters. Indicate the type of information, e.g. 'Soil leaching'. If not available from the picklist, use 'other:' and include an appropriate description.</p> <p>Include any relevant information from a study report or publication in fields 'Any other information on materials and methods incl. tables', 'Any other information on results incl. tables' or 'Overall remark' as appropriate.</p> <p>Fill in fields for Administrative data and Data source as appropriate.</p>		terialsAndMethods.TypeOfStudy
Media	Indicate the media addressed.	Open list	ENDPOINT_STUDY_RECORD.AgedSorption.MaterialsAndMethods.Media
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.AgedSorption.MaterialsAndMethods.TestMaterials
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.AgedSorption.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.AgedSorption.ResultsAndDiscussion
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.AgedSorption.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.AgedSorption.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.AgedSorption.Ap

			plicantSummaryAndConclusion
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7.1.4 Mobility in soil, leaching and lysimeter studies – Endpoint summary

Purpose:

Chemicals: conclude on the mobility and leaching potential of the active substance, metabolites, breakdown and reaction products

Microorganisms: Provide sufficient data to evaluate the mobility of the micro-organism and its degradation products in relevant environmental compartments.

Where studies are provided for more than one endpoint separate summaries can be created for each endpoint.

ENDPOINT_SUMMARY.OtherDistributionData – v.3.0 (Final) [July 2020]			
Name	Instructions	Type	Field Path
Administrative data	Administrative data summary – common block Provide a brief description of relevant studies and effects.	Header 1	ENDPOINT_SUMMARY.OtherDistributionData.AdministrativeDataSummary
Additional information	Discussion (Header 1) – common block Provide additional information related to the endpoint. Presentation of the results in the tabular format of the List of Endpoints Mobility in soil column leaching active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.4.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1) and Lysimeter / field leaching studies (Regulation (EU) N° 283/2013, Annex Part A, points 7.1.4.2 /	Header 1	ENDPOINT_SUMMARY.OtherDistributionData.Discussion

	<p>7.1.4.3 and Regulation (EU) N° 284/2013, Annex Part A, points 9.1.2.2 / 9.1.2.3) is recommended</p> <p>If there is no additional information to be reported this field may be left empty.</p>		
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Links to support material:

Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU - Final Report of the Ground Water Work Group of FOCUS (Sanco/13144/2010, version 3, 10 October 2014)

7.1.4 Mobility in soil, leaching and lysimeter studies – Endpoint study records

Purpose:

Chemicals/Microorganisms: Provide sufficient data to evaluate the mobility and leaching potential of metabolites, breakdown, and reaction products.

ENDPOINT_STUDY_RECORD.OtherDistributionData -v.6.3 (Final) [September 2020]			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.OtherDistributionData.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.OtherDistributionData.DataSource
Materials and methods	Material and methods – common block Applicable test guideline: OECD Test Guideline 312: Leaching in Soil Columns.	Header 1	ENDPOINT_STUDY_RECORD.OtherDistributionData.MaterialsAndMethods
Type of study	Include only information that does not fit into any of the specific chapters. Indicate the type of information, e.g. 'Soil leaching'. If not available from the	Open list	ENDPOINT_STUDY_RECORD.OtherDistributionData.MaterialsAndMethods.TypeOfStudy

	<p>picklist, use 'other:' and include an appropriate description.</p> <p>Include any relevant information from a study report or publication in fields 'Any other information on materials and methods incl. tables', 'Any other information on results incl. tables' or 'Overall remark' as appropriate.</p> <p>Fill in fields for Administrative data and Data source as appropriate.</p>		
Media	Indicate the media addressed.	Open list	ENDPOINT_STUDY_RECORD.OtherDistributionData.MaterialsAndMethods.Media
Test material	Test material – common block	Header 2	ENDPOINT_STUDY_RECORD.OtherDistributionData.MaterialsAndMethods.TestMaterials
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.OtherDistributionData.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.OtherDistributionData.ResultsAndDiscussion
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.OtherDistributionData.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.OtherDistributionData.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.OtherDistributionData.ApplicantSummaryAndConclusion

Links to support material:

OECD Guidance Document 22: Guidance Document for the Performance Of Out-door Monolith Lysimeter Studies <https://doi.org/10.1787/20777876>

9. Literature data – Flexible record

Purpose:

Description of the methodology used for the search for all relevant data from scientific peer reviewed open literature.

List of all relevant studies retrieved

FLEXIBLE_RECORD.LiteratureSearch – v.5.0 (Final)			
Name	Instructions	Type	Field Path
Administrative data	See Confidentiality Requests Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	Header 1	FLEXIBLE_RECORD.LiteratureSearch.AdministrativeData
		Confidentiality	FLEXIBLE_RECORD.LiteratureSearch.AdministrativeData.DataProtection
Link to relevant studies	<p>Link to all Literature Reference entities that were retrieved from the literature search and are considered relevant and reliable after the full text screening step.</p> <p>An appropriate Endpoint Study Record should be completed for each relevant study and the literature reference included in the data source section.</p>	Header 1	FLEXIBLE_RECORD.LiteratureSearch.RelevantStudies
Literature reference(s)		Literature reference list	FLEXIBLE_RECORD.LiteratureSearch.RelevantStudies.LiteratureReference
Description of key information	Summary of all relevant data from the scientific peer reviewed open literature on the active substance, metabolites and breakdown or reaction products and	Rich text area	FLEXIBLE_RECORD.LiteratureSearch.RelevantStudies.KeyInformationDesc

	plant protection products containing the active substance and dealing with side-effects on health, the environment and non-target species		
Overall summary of the literature search	<p>Summary of the methodology used to retrieve relevant studies on side-effects on health, the environment and non-target species.</p> <p>Report the criteria used to classify the references as being clearly non-relevant (e.g. not related to pesticides).</p> <p>Report the criteria used to assess the reliability of the studies.</p>	Rich text area	FLEXIBLE_RECORD.LiteratureSearch.RelevantStudies.SearchSummary
Search strategy	Indicate how the literature search was carried out.	Header 1	FLEXIBLE_RECORD.LiteratureSearch.SearchStrategy
Bibliographic databases used in the literature review and search results	A description each of the search strategies used in the literature review		FLEXIBLE_RECORD.LiteratureSearch.SearchStrategy.DatabasesUsed
Online search service	Select the database/source where the search was performed. Use other to indicate a database/source that is not included in the list. The remarks field should contain the justification for selecting the database/source. More information on databases/sources is provided in the supporting materials below	Open list with remarks	FLEXIBLE_RECORD.LiteratureSearch.SearchStrategy.DatabasesUsed.SearchService
Date of search	Provide the date when the search was	Date	FLEXIBLE_RECORD.LiteratureSearch.SearchStr

	performed using the database.		ategy.DatabasesUsed.D ate
Time window of the literature search	The period covered in the literature search e.g. 2010 to 2020	Text	FLEXIBLE_RECORD.Lite ratureSearch.SearchStr ategy.DatabasesUsed.Ti meWindow
Search string(s) used	The search strings used to retrieve the records e.g. 1. ts=Chlorpyrifos 2. ts=(Brodan or Detmol or Dowco 179 or Dursban or eradex or Lorsban or Paqeant or Piridane) 3. ts=((scout or stipend or empire) and (pesticide* or insect*)) 4. #3 OR #2 OR #1 More examples are provided in the supporting materials below	Multi-line text	FLEXIBLE_RECORD.Lite ratureSearch.SearchStr ategy.DatabasesUsed.S trings
Filters	Indicate if filters were applied in the search. If yes is selected the filters applied must be described	Closed list with remarks	FLEXIBLE_RECORD.Lite ratureSearch.SearchStr ategy.DatabasesUsed.Fi lters
Limits	Indicate if any limits were applied in the search, for example only studies in English. If yes is the limits applied must be described	Closed list with remarks	FLEXIBLE_RECORD.Lite ratureSearch.SearchStr ategy.DatabasesUsed.Li mits
Number of hits	The number of hits for the search in each database/source	Integer	FLEXIBLE_RECORD.Lite ratureSearch.SearchStr ategy.DatabasesUsed.N oHits
Number of hits after refinement	The number of hits after refinement, if applicable	Integer	FLEXIBLE_RECORD.Lite ratureSearch.SearchStr ategy.DatabasesUsed.N oHitsRefinement
Number of hits after duplicate removal	The number of hits after duplicate removal	Integer	FLEXIBLE_RECORD.Lite ratureSearch.SearchStr ategy.DatabasesUsed.N oHitsDuplicate
Bibliographic databases used in			

the literature review and search results			
Evaluation of the review		Header 1	FLEXIBLE_RECORD.LiteratureSearch.EvaluationOfTheReview
Records retrieved	The number of records retrieved when the results for the searches above were combined	Integer	FLEXIBLE_RECORD.LiteratureSearch.EvaluationOfTheReview.RecordsRetrieved
Records after removal of duplicates	Total number of summary records retrieved after removing duplicates from all database searches	Integer	FLEXIBLE_RECORD.LiteratureSearch.EvaluationOfTheReview.NoAfterDuplicates
Records after rapid assessment	Report the number of records retained after title/abstract screening	Integer	FLEXIBLE_RECORD.LiteratureSearch.EvaluationOfTheReview.NoRapidAssessment
Records after detailed assessment	Report the number of records retained after full text screening	Integer	FLEXIBLE_RECORD.LiteratureSearch.EvaluationOfTheReview.NoDetailedAssessment
Reliable studies	Report the number of records retained after the reliability assessment	Integer	FLEXIBLE_RECORD.LiteratureSearch.EvaluationOfTheReview.ReliableStudies
Evaluated studies	Number of studies included in the dossier, reported in an endpoint study record and used as supporting information. These studies should be listed in the Literature reference(s) field and the number should be the same.	Integer	FLEXIBLE_RECORD.LiteratureSearch.EvaluationOfTheReview.EvaluatedStudies
Publications excluded from the risk assessment after detailed assessment of full-text documents	For each of the studies excluded on the basis of relevance or reliability link to the Literature Reference entity and describe the reason for exclusion		FLEXIBLE_RECORD.LiteratureSearch.EvaluationOfTheReview.ExcludedPublications
Literature reference	Link a reference to the excluded publication.	Literature reference list	FLEXIBLE_RECORD.LiteratureSearch.EvaluationOfTheReview.ExcludedPublications.LiteratureReference

Exclusion reason	Reason for not including publication in dossier (based on relevance and reliability criteria).	Multi-line text	FLEXIBLE_RECORD.LiteratureSearch.EvaluationOfTheReview.ExcludedPublications.ExclusionReason
Publications excluded from the risk assessment after detailed assessment of full-text documents	For each of the studies excluded on the basis of relevance or reliability link to the Literature Reference entity and describe the reason for exclusion		
Additional information		Header 1	FLEXIBLE_RECORD.LiteratureSearch.AdditionalInformation
Additional information	Any other information needed to interpret the results for the literature research	Rich text area	FLEXIBLE_RECORD.LiteratureSearch.AdditionalInformation.AdditionalInfo
Attached background material	Upload supporting files e.g bibliographic metadata		FLEXIBLE_RECORD.LiteratureSearch.AdditionalInformation.BackgroundMaterial
Attached document	Upload file by clicking the upload icon. The bibliographic results of literature searches can be uploaded here in RIS format or as an Excel table containing bibliographic information.	Single file attachment	FLEXIBLE_RECORD.LiteratureSearch.AdditionalInformation.BackgroundMaterial.Attachment
Remarks	Indicate the source of the contents of the file and the format type.	Text	FLEXIBLE_RECORD.LiteratureSearch.AdditionalInformation.BackgroundMaterial.Remarks
Attached background material			

Link to support material:

[Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation \(EC\) No 1107/2009](#)

[Further guidance on performing and presenting the literature search](#)

[Inventory of Sources of Scientific Evidence Relevant to EFSA's Risk](#)

[Technical Manual for Performing Electronic Literature Searches in Food and Feed Safety](#)

11. Summary and evaluation

11.1 Assessment from other authorities – Flexible record

Purpose:

Provide information on previous assessments of the active substance, as a pesticide or under other regulatory processes, both within Europe and outside of Europe.

Listing of EU MRLs (Document E1)

List of MRLs established in exporting countries or in non-EU OECD countries (Document E2)

FLEXIBLE_RECORD.AssessmentOtherAuthorities – v 1.3 (Final)			
Name	Instructions	Type	Field Path
Administrative data	See Administrative data	Header 1	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AdministrativeDataSummary
	Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	Confidentiality	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AdministrativeDataSummary.DataProtection
Assessments in Europe	In this section, provide information on previous or ongoing evaluations in Europe.	Header 1	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsEurope
Biocide	Indicate if this active substance has been or is being assessed under the Biocidal Products Regulation (BPR, Regulation (EU) 528/2012) Select the status of the application and provide details on the nature of the application	Open list with remarks (2000)	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsEurope.Biocide
Veterinary medicine	Indicate if this active substance has been or is being assessed under the veterinary medicinal products Regulation (EU) 2019/6. Select the status of the application and provide details on the nature of the application	Open list with remarks (2000)	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsEurope.VeterinaryMedicine
Other product safety assessments	In this section provide information on previous or ongoing evaluations in Europe under regulations other than Biocides or Veterinary Medicines		FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsEurope.OtherProductSafetyAssessments
Evaluation	If this active substance has been or is being assessed under any other product or food safety	Open list	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsEurope.Oth

	regulations indicate the context of the evaluation.		erProductSafetyAssessments.Evaluation
Status	Select the status of the application and provide details on the nature of the application	Open list with remarks (2000)	FLEXIBLE_RECORD.Asse ssmentOtherAuthorities. AssessmentsEurope.Oth erProductSafetyAssessm ents.Status
Other product safety assessments			
Existing residue definitions		Header 2	FLEXIBLE_RECORD.Asse ssmentOtherAuthorities. AssessmentsEurope.Exis tingResidues
Monitoring purposes (plant)	<p>Check the current existing RD in the EU MRL data base.</p> <p>The field refers to the enforcement residue definition of plant commodity/ies for which the MRL application is submitted. An EU Pesticides data base could be consulted</p> <p>If different enforcement residue definitions are set in different commodities under consideration, this shall be indicated.</p>	Multi-line text	FLEXIBLE_RECORD.Asse ssmentOtherAuthorities. AssessmentsEurope.Exis tingResidues.Monitoring PurposesPlant
Risk assessment (plant)	<p>The field refers to the risk assessment residue definitions for plant commodity/ies for which the MRL application is submitted.</p> <p>If different risk assessment residue definitions are set in different plant commodities under consideration, this shall be indicated.</p> <p>If for processed commodities residue definitions differ from residue definitions in raw agricultural commodity (RAC), this shall be indicated.</p> <p>If for rotational crops the residue definition differs from the residue definition in primary crops, this shall be indicated.</p>	Multi-line text	FLEXIBLE_RECORD.Asse ssmentOtherAuthorities. AssessmentsEurope.Exis tingResidues.RiskAssess mentPlant

	Available in EFSA ccl and Registration reports		
Monitoring purposes (animal)	<p>The field refers to the enforcement residue definitions for animal commodity/ies for which the MRL application is submitted. An EU Pesticides data base could be consulted</p> <p>If different enforcement residue definitions are set in different commodities under consideration, this shall be indicated.</p> <p>Please check the current existing RD in the EU MRL data base.</p>	Multi-line text	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsEurope.ExistingResidues.MonitoringPurposesAnimal
Risk assessment (animal)	<p>The field refers to the risk assessment residue definitions for animal commodity/ies for which the MRL application is submitted.</p> <p>If different risk assessment residue definitions are set in different commodities under consideration, this shall be indicated.</p> <p>Available in EFSA ccl and Registration reports</p>	Multi-line text	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsEurope.ExistingResidues.RiskAssessmentAnimal
Remarks	Any comment on the existing RD for risk assessment (e.g. provisional, clarify the source, data gaps, ...)	Multi-line text	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsEurope.ExistingResidues.Remarks
EFSA paramCode			FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsEurope.ExistingResidues.EfsaParamCode
RD paramCode	<p>Enter one or more EFSA param codes to identify the substance/s which comprise the residue definition for monitoring purpose (as used for reporting pesticide residue monitoring data)</p> <p>EFSA paramCodes can be downloaded or accessed by the EFSA catalogue browser application</p>	Text	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsEurope.ExistingResidues.EfsaParamCode.RdParamCode
EFSA paramCode			

Existing MRL		Header 2	FLEXIBLE_RECORD.Asse ssmentOtherAuthorities. AssessmentsEurope.Exis tingMrl
EU MRL	List the existing EU MRLs for this active substance		FLEXIBLE_RECORD.Asse ssmentOtherAuthorities. AssessmentsEurope.Exis tingMrl.EuMrl
Commodity	Select the commodity The picklist comprises commodities as listed in Part A of Annex I to Reg. 396/2005 and in addition feed commodities.	Multi select closed list with remarks	FLEXIBLE_RECORD.Asse ssmentOtherAuthorities. AssessmentsEurope.Exis tingMrl.EuMrl.Commodit y
MRL value	Enter the MRL value in mg/kg	Unit measure with Closed List (Decimal)	FLEXIBLE_RECORD.Asse ssmentOtherAuthorities. AssessmentsEurope.Exis tingMrl.EuMrl.MrlValue
Residue definition monitoring	Enter the enforcement residue definition in the commodity/ies for the MRL	Multi-line text	FLEXIBLE_RECORD.Asse ssmentOtherAuthorities. AssessmentsEurope.Exis tingMrl.EuMrl.ResidueMo nitoring
Remarks	Any comment on the existing MRL (provisional, confirmatory data required.)	Multi-line text	FLEXIBLE_RECORD.Asse ssmentOtherAuthorities. AssessmentsEurope.Exis tingMrl.EuMrl.Remarks
EU MRL			
Assessments outside Europe	In this section provide information on previous or ongoing evaluations outside of Europe	Header 1	FLEXIBLE_RECORD.Asse ssmentOtherAuthorities. AssessmentsOutsideEuro pe
Biocide	Indicate if this active substance has been or is being assessed for use as a biocide outside of Europe. Select the status of the application and provide details on the nature of the application	Open list with remarks (2000)	FLEXIBLE_RECORD.Asse ssmentOtherAuthorities. AssessmentsOutsideEuro pe.Biocide
Veterinary medicine	Indicate if this active substance has been or is being assessed for use as a veterinary medicine outside of Europe Select the status of the application and provide details on the nature of the application	Open list with remarks (2000)	FLEXIBLE_RECORD.Asse ssmentOtherAuthorities. AssessmentsOutsideEuro pe.VeterinaryMedicine
Other product safety assessments	In this section provide information on previous or ongoing evaluations outside Europe under regulations other than Biocides or Veterinary Medicines		FLEXIBLE_RECORD.Asse ssmentOtherAuthorities. AssessmentsOutsideEuro pe.OtherProductSafetyAs sessments

Evaluation	If this active substance has been or is being assessed under any other product or food safety regulations indicate the context of the evaluation.	Open list	FLEXIBLE_RECORD.Asse ssmentOtherAuthorities. AssessmentsOutsideEuro pe.OtherProductSafetyAs sessments.Evaluation
Status	Indicate if this active substance has been or is being assessed under any other product or food safety regulations. If yes provide details on the nature and status of the application	Open list with remarks (2000)	FLEXIBLE_RECORD.Asse ssmentOtherAuthorities. AssessmentsOutsideEuro pe.OtherProductSafetyAs sessments.Status
Other product safety assessments			
Existing residue definitions	Enter the enforcement residue definitions for the MRL in the exporting country if they differ from those listed above	Header 2	FLEXIBLE_RECORD.Asse ssmentOtherAuthorities. AssessmentsOutsideEuro pe.ExistingResidues
Monitoring purposes (plant)	<p>The field refers to the enforcement residue definition in the exporting country for plant commodity /-ies for which the MRL application is submitted.</p> <p>If different enforcement residue definitions are set in different commodities under consideration, this shall be indicated.</p>	Multi-line text	FLEXIBLE_RECORD.Asse ssmentOtherAuthorities. AssessmentsOutsideEuro pe.ExistingResidues.Mon itoringPurposesPlant
Risk assessment (plant)	<p>The field refers to the risk assessment residue definition in the exporting country in the plant commodity for which the MRL application is submitted.</p> <p>If different risk assessment residue definitions are set in different commodities under consideration, this shall be indicated.</p> <p>If the MRL application is submitted to account for residues in rotational crops and the residue definition in rotational crops differs from the residue definition in primary crops, this shall be indicated.</p>	Multi-line text	FLEXIBLE_RECORD.Asse ssmentOtherAuthorities. AssessmentsOutsideEuro pe.ExistingResidues.Risk AssessmentPlant
Monitoring purposes (animal)	The field refers to the enforcement residue definition in the exporting country for the animal	Multi-line text	FLEXIBLE_RECORD.Asse ssmentOtherAuthorities. AssessmentsOutsideEuro

	commodity/ies for which the MRL application is submitted. If different enforcement residue definitions are set in different commodities under consideration, this shall be indicated.		pe.ExistingResidues.MonitoringPurposesAnimal
Risk assessment (animal)	The field refers to the risk assessment residue definition in the exporting country for the animal commodity for which the MRL application is submitted. If different risk assessment residue definitions are set in different commodities under consideration, this shall be indicated.	Multi-line text	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsOutsideEurope.ExistingResidues.RiskAssessmentAnimal
Remarks	Any comment on the existing RD for risk assessment (e.g., provisional, clarify the source, data gaps, ...)	Multi-line text	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsOutsideEurope.ExistingResidues.Remarks
Existing MRL in the exporting country		Header 2	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsOutsideEurope.MrlExportingCountries
Exporting country MRL			FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsOutsideEurope.MrlExportingCountries.ExportingCountryMrl
Country	Select the exporting country from the list	Multi select open list	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsOutsideEurope.MrlExportingCountries.ExportingCountryMrl.Country
Commodity	The commodity plant parts which were analyzed for and for which results should be reported in this table. The picklist comprised commodities as listed in Part A of Annex I to Reg. 396/2005 and in addition feed commodities. ONLY in case the tested commodity is not present in the picklist choose "other" and enter manually.	Multi select open list with remarks	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsOutsideEurope.MrlExportingCountries.ExportingCountryMrl.Commodity

MRL value	<p>If MRL setting processes are established in exporting countries.</p> <p>If MRL setting processes are not established in exporting countries, specify if Codex residue limit (CXL) is applicable.</p> <p>If there are no CXL and no MRL in the exporting country, report 'not relevant' and specify the reason in remark box.</p>	Unit measure with Closed List (Decimal)	FLEXIBLE_RECORD.Asse ssmentOtherAuthorities. AssessmentsOutsideEuro pe.MrlExportingCountrie s.ExportingCountryMrl.M rlValue
Residue definition monitoring	Enter the enforcement residue definition of plant commodity/ies for the MRL	Multi-line text	FLEXIBLE_RECORD.Asse ssmentOtherAuthorities. AssessmentsOutsideEuro pe.MrlExportingCountrie s.ExportingCountryMrl.R esidueMonitoring
Remarks	<p>Any additional remark on the MRL in the exporting country.</p> <p>If MRL setting processes are not established in exporting countries, specify if Codex residue limit (CXL) is applicable.</p> <p>If no CXL and no MRL in the exporting country, report 'not relevant' and specify the reason in remark box.</p>	Multi-line text	FLEXIBLE_RECORD.Asse ssmentOtherAuthorities. AssessmentsOutsideEuro pe.MrlExportingCountrie s.ExportingCountryMrl.R emarks
Exporting country MRL			
Additional information	This section is only relevant for MRL applications	Header 1	FLEXIBLE_RECORD.Asse ssmentOtherAuthorities. AdditionalInformation
Evidence of registration in the exporting country	Please confirm with this checkbox that the evidence of the registration in the exporting country and, if available, the registered use pattern in the exporting country were attached.	Check box	FLEXIBLE_RECORD.Asse ssmentOtherAuthorities. AdditionalInformation.Re gistrationInExportingCou ntry
Evidence of registration in the exporting country (remark)	Clarification should be given in remark field if no evidence can be provided.	Multi-line text	FLEXIBLE_RECORD.Asse ssmentOtherAuthorities. AdditionalInformation.Re gistrationInExportingCou ntryRemark
Evidence of registration in the exporting country attached	Upload attachments with evidence of registration in the exporting country (these attachments will be published and should not contain confidential information)	Attachments list	FLEXIBLE_RECORD.Asse ssmentOtherAuthorities. AdditionalInformation.Re gistrationInExportingCou ntryAttachment

Registered use pattern in the exporting country	Please confirm with this checkbox that the registered use pattern has been entered in the Good agricultural practices (GAP) document has been completed. Product Section 2	Attachments list	FLEXIBLE_RECORD.Asse ssmentOtherAuthorities. AdditionalInformation.Re gistrationInExportingCou ntryUsePattern
Legislation in the exporting country concerning the MRL	Please confirm with this checkbox that the Legislation in the exporting country concerning the MRL attached.	Check box	FLEXIBLE_RECORD.Asse ssmentOtherAuthorities. AdditionalInformation.Le gislationInExportingCoun try
Legislation in the exporting country concerning the MRL (remark)	Clarification should be given if no MRLs are established in the originating country.	Multi-line text	FLEXIBLE_RECORD.Asse ssmentOtherAuthorities. AdditionalInformation.Le gislationExportingCountr yRemark
Legislation in the exporting country concerning the MRL attached	Upload copies of the Legislation in the exporting country concerning the MRL	Attachments list	FLEXIBLE_RECORD.Asse ssmentOtherAuthorities. AdditionalInformation.Le gislationExportingCountr yAttachment

Links to support material:

<https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=homepage&language=EN>

European Food Safety Authority. (2020). Harmonized terminology for scientific research [Data set]. Zenodo. <http://doi.org/10.5281/zenodo.3243215>

EFSA Catalogue Browser User Guide 10.2903/sp.efsa.2019.EN-1726
<https://github.com/openefsa/catalogue-browser/releases>

11.2 Other reports – Flexible summary

Purpose:

Summarise the overall conclusions for the substance or mixture.

Provide a place to upload files or reports which could not be attached in other sections but are used to support the evaluation.

FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP – v.1.1 (Final) [October 2020]			
Name	Instructions	Data type	Field path
Administrative data	See administrative data	Header 1	FLEXIBLE_SUMMARY.S ummaryEvaluation_EU_ PPP.AdministrativeData Summary

	Use this field to set flags for confidentiality and regulatory purpose(s). Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	Confidentiality	FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP.AdministrativeDataSummary.DataProtection
Reports and administrative information		Header 1	FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP.ReportsAdministrativeInfo
Reports and administrative information			FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP.ReportsAdministrativeInfo.ReportsAdministrativeInfo
Type of report	Indicate the type of document that has been uploaded e.g. 'Document C Existing or proposed labels'	Multi-line text	FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP.ReportsAdministrativeInfo.ReportsAdministrativeInfo.TypeOfReport
Attached confidential document	The original file only needs to be attached here if the non-confidential file uploaded under "Attached (sanitised) documents for publication" contains redactions. If a file is uploaded under this field, (a) confidentiality request(s) must be submitted for each part of the file considered confidential and the information claimed confidential must be clearly boxed or earmarked consistently with the redactions applied in the corresponding non-	Single file attachment	FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP.ReportsAdministrativeInfo.ReportsAdministrativeInfo.AttachedDocument

	confidential file. This file will not be published.		
Attached (sanitised) document for publication	<p>Any document uploaded here must be uploaded in their public (non-confidential) version. The public version will be published once the dossier has been considered valid/admissible. All elements therein claimed confidential should be sanitised. Save for the elements blackened, if applicable, content and layout-wise the public version must be fully identical with the confidential version. Upon conclusion of the confidentiality assessment, if applicable, a revised public version removing the redactions relating to confidentiality requests that were rejected in part or in full must be uploaded here.</p>	Single file attachment	FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP.ReportsAdministrativeInfo.ReportsAdministrativeInfo.SanitisedDocument
Reports and administrative information			
Other references (including SDS)	Link to other reports not referenced in the endpoint study records needed to support the assessment. The	Header 1	FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP.OtherReferencesIncludingSDS

	<p>bibliographic information should be completed and the PDF uploaded in the literature reference entity</p> <p>This would include</p> <p>'Safety datasheets'</p> <p>'Scientific opinions of national/international regulatory bodies'</p>		
References		Literature reference list	FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP.OtherReferencesIncludingSDS.References
Additional information		Header 1	FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP.AdditionalInformation
Additional information	Overall summary of the main conclusions for the substance or mixture can be entered here	Rich text area	FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP.AdditionalInformation.AdditionalInformation

Additional considerations

The applicant must ensure that terms and conditions asserted by any copyright holder of publications or information submitted to EFSA are fully satisfied. The applicant should consult with copyright licensing authorities (i.e. at national level) for guidance on purchasing copyright licenses to reproduce any publications provided to EFSA. The applicant remains solely responsible and liable for obtaining all necessary authorisations and rights to use, reproduce and share the publications provided to EFSA

11.3 Relevance of metabolites in ground water – Flexible summary

Purpose:

Chemical active substance: For all metabolites, breakdown or reaction products identified as a part of the residue definition for risk assessment with respect to groundwater a PECGW calculation shall be required for assessing their relevance. Where identified metabolites, breakdown or reaction products are found to occur in concentrations above 0,1 µg/L in the leachate, an assessment of their relevance shall be required.

FLEXIBLE_SUMMARY.RelevantMetabolitesGroundWater v2.1 (Final)			
Name	Instructions	Data Type	Field path
Administrative data	The general rules on confidentiality requests apply in setting the flags (Administrative data summary – common block). See section on Confidentiality of dossiers	Header 1	FLEXIBLE_SUMMARY.RelevantMetabolitesGroundWater.AdministrativeDataSummary
		Confidentiality	FLEXIBLE_SUMMARY.RelevantMetabolitesGroundWater.AdministrativeDataSummary.DataProtection
Link to relevant biodegradation studies	Provide link to relevant endpoint study records on biodegradation used to conclude on the occurrence of metabolites in groundwater	Endpoint reference list	FLEXIBLE_SUMMARY.RelevantMetabolitesGroundWater.AdministrativeDataSummary.RelevantBiodegradationStudies
Link to relevant lysimeter studies	Insert link to relevant endpoint study records on lysimeter studies used to conclude on the occurrence of metabolites in groundwater	Endpoint reference list	FLEXIBLE_SUMMARY.RelevantMetabolitesGroundWater.AdministrativeDataSummary.RelevantLysimeterStudies
Description of key information	See the Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council Directive 91/414/EEC.	Header 1	FLEXIBLE_SUMMARY.RelevantMetabolitesGroundWater.DescriptionKeyInfo

		Rich text area	FLEXIBLE_SUMMARY.RelevantMetabolitesGroundWater.DescriptionKeyInfo.field436
Step 1: Exclusion of degradation products of no concern	<p>This step applies to all metabolites. A degradation product which may be expected to occur in groundwater as a result of a soil degradation study or a lysimeter study will require further assessment unless one of the following conditions apply: a) it is CO₂ or an inorganic compound, not containing a heavy metal; or, b) it is an organic compound of aliphatic structure, with a chain length of 4 or less, which consists only of C, H, N or O atoms and which has no "alerting structures" such as epoxide, nitrosamine, nitrile or other functional groups of known toxicological concern. c) it is a substance, which is known to be of no toxicological or ecotoxicological concern, and which is naturally occurring at much higher concentrations in the respective compartment. If condition a), b) or c) is met, the degradation product is considered to be a degradation product of no concern and no additional data are required.</p>	Header 2	FLEXIBLE_SUMMARY.RelevantMetabolitesGroundWater.DescriptionKeyInfo.StepOne
		Rich text area	FLEXIBLE_SUMMARY.RelevantMetabolitesGroundWater.DescriptionKeyInfo.StepOne.field8430

Step 2: Quantification of potential groundwater contamination	All metabolites not excluded in Step 1 that are found in soil degradation and/or available lysimeter or field leaching studies should in principle be characterised and identified by the notifiers to the extent that is technically feasible, as outlined above in the introductory remarks to this chapter. This is particularly the case for those metabolites which are predicted to be present in the leachate leaving the upper soil layer at an annual to triannual average flux (as defined by FOCUS5) concentration exceeding 0.1 µg/L. For these metabolites the predicted environmental concentration in groundwater needs to be estimated with the highest feasible accuracy and validity.	Header 2	FLEXIBLE_SUMMARY.RelevantMetabolitesGroundWater.DescriptionKeyInfo.StepTwo
		Rich text area	FLEXIBLE_SUMMARY.RelevantMetabolitesGroundWater.DescriptionKeyInfo.StepTwo.field 247
Stage 1 of Step 3: Screening for biological activity	Active substances of plant protection products are defined according to Art. 2 of the Directive on the basis of their biological activity against plants or harmful organisms (in the context of this document defined as the "biological activity"). The same criterion is used here to identify those breakdown products, which – from a regulatory perspective - should be treated in the same way as	Header 2	FLEXIBLE_SUMMARY.RelevantMetabolitesGroundWater.DescriptionKeyInfo.StageOneStep Three

	<p>active substances with respect to groundwater protection. The goal is to identify metabolites, which have a comparable target activity as the parent active ingredient, and to deal with cases where the parent molecule is a precursor of the active substance. Efficacy testing should be focused on this question of comparing the activity against the biological target. However, for parent compounds with a known range of activities, or for a compound belonging to a totally new group, it may be necessary to test a metabolite in a more extensive screening battery. Structure-activity relationships may be considered on the basis of the mode of activity of the parent molecule (i.e. usually the active substance). In many cases for compounds belonging to a well defined group of active substances (e.g. sulfonyl thiourea herbicides) this may already provide useful and sufficient information for the assessment of this question in the absence of experimental data.</p>		
		Rich text area	FLEXIBLE_SUMMARY.RelevantMetabolitesGroundWater.DescriptionKeyInfo.StageOneStepThree.field3368
Stage 2 of Step 3: Screening for genotoxicity	All metabolites that have passed step 1, step 2 and stage 1 of step 3 should be screened for their genotoxic	Header 2	FLEXIBLE_SUMMARY.RelevantMetabolitesGroundWater.DescriptionKeyInfo.StageTwoStepThree

	<p>activity by at least the following package of in vitro genotoxicity studies: Ames test, gene mutation test with mammalian cells, and chromosome aberration test. Equivocal results in in vitro studies should be substantiated by in vivo experiments. Mutagenic metabolites (any category) are considered relevant.</p>		
		Rich text area	FLEXIBLE_SUMMARY.RelevantMetabolitesGroundWater.DescriptionKeyInfo.StageTwoStepThree.field957
Stage 3 of Step 3: Screening for toxicity	<p>Stage 3 of Step 3 is aimed at the question of whether a metabolite has certain toxicological properties, which - from a regulatory perspective - qualify for considering it "relevant". A metabolite is considered "relevant" if its toxicological properties lead to a classification as toxic of very toxic (T or T+) according to Directive 67/548/EEC. Reflecting the general concept of this document, the toxicity classification of the parent active substance as determined according to Directive 67/548/EEC is used for pragmatic reasons as a starting point to focus the screening activity.</p>	Header 2	FLEXIBLE_SUMMARY.RelevantMetabolitesGroundWater.DescriptionKeyInfo.StageThreeStepThree
		Rich text area	FLEXIBLE_SUMMARY.RelevantMetabolitesGroundWater.DescriptionKeyInfo.StageThreeStepThree.field2883

Step 4: Exposure assessment - threshold of concern approach	Metabolites which have not been identified as being relevant according to the hazard screening outlined in Step 3, should be further tested in an exposure assessment to make sure that any contamination of groundwater will not lead to unacceptable exposure of consumers via their drinking water.	Header 2	FLEXIBLE_SUMMARY.RelevantMetabolitesGroundWater.DescriptionKeyInfo.StepFour
		Rich text area	FLEXIBLE_SUMMARY.RelevantMetabolitesGroundWater.DescriptionKeyInfo.StepFour.field 992
Step 5: Refined risk assessments for non-relevant metabolites	Metabolites which have passed steps 1 to 3 and for which levels of estimated concentrations of metabolites in groundwater (as defined in Step 2) lie between 0.75 µg/L (from Step 4) and 10 µg/L ¹² will require a refined assessment of their potential toxicological significance for consumers. All such metabolites, which are estimated to occur at levels exceeding the toxicological threshold for unknown substances, must be fully identified and also synthesised by the notifier, if necessary to allow their further testing.	Header 2	FLEXIBLE_SUMMARY.RelevantMetabolitesGroundWater.DescriptionKeyInfo.StepFive
		Rich text area	FLEXIBLE_SUMMARY.RelevantMetabolitesGroundWater.DescriptionKeyInfo.StepFive.field 9341
Additional information	Discussion (Header 1) – common block	Header 1	FLEXIBLE_SUMMARY.RelevantMetabolitesGroundWater.Discussion

	<p>Provide additional information related to the endpoint, for example:</p> <ul style="list-style-type: none"> - information on the potential data gaps - relevance of the results for the risk assessment - the rationale for the choice of the key study(ies) and the choice for the key value that characterises the endpoint - the rationale for any user-derived values for the sake of transparency -the possible reasons for differentiating results when several studies were identified to be relevant for the assessment. <p>If there is no additional information to be reported this field may be left empty.</p>		
	Provide any additional information related to the endpoint.	Rich text area	FLEXIBLE_SUMMARY.RelevantMetabolitesGroundWater.Discussion.Discussion
Attached background material	<p>Attach any background document that cannot be inserted in any rich text editor field, particularly image files (e.g. an image of a structural formula). Copy this block of fields for attaching more than one file.</p>		FLEXIBLE_SUMMARY.RelevantMetabolitesGroundWater.Discussion.AttachedBackgroundMaterial
Attached confidential document	<p>The original file only needs to be attached here if it differs from the non-confidential file uploaded under "Attached (sanitised) documents for publication". If a file is uploaded under this field a confidentiality claim must be submitted for each part of the file considered confidential.</p>	Single file attachment	FLEXIBLE_SUMMARY.RelevantMetabolitesGroundWater.Discussion.AttachedBackgroundMaterial.AttachedDocument

	<p>Provide any additional documents relevant for the submission, not already provided under the methods or results section or in the full study report.</p> <p>Examples are:</p> <ul style="list-style-type: none"> - Scientific publication - GLP documentation - (Q)SAR: supporting information - Data analysis file (calculation of parameters) - Data supporting the reliability and sensitivity of the method - Specific information on the test material or test system - Justification - Other <p>For test guidelines that provide a reporting template (data analysis file), that file must be completed and can be uploaded here if not yet done in the results section.</p>		
Attached (sanitised) documents for publication	A non-confidential version of any submitted background material must be uploaded here. These will be published once the dossier has been considered valid/admissible.	Single file attachment	FLEXIBLE_SUMMARY.RelevantMetabolitesGroundWater.Discussion.AttachedBackgroundMaterial.AttachedSanitisedDocsForPublication

	All elements therein claimed confidential should be sanitised. Upon conclusion of the confidentiality assessment, if applicable, a revised non-confidential version removing the redactions relating to confidentiality requests that were rejected in part or in full must be uploaded here.		
Remarks	As appropriate, include remarks, e.g. a short description of the content of the attached document if the file name is not self-explanatory.	Text	FLEXIBLE_SUMMARY.RelevantMetabolitesGroundWater.Discussion.AttachedBackgroundMaterial.Remarks
Attached background material			

Links to support material:

Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council Directive 91/414/EEC (Guidance Sanco/221/2000 –rev.10- final)

11.4 Endocrine disrupting properties – Flexible summary

Purpose:

To report the assessment of the endocrine disrupting (ED) properties (for both human health and the environment) according to the ECHA/EFSA Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009.

Endpoint Study Records of individual mammalian toxicology ED studies should be included under 5.8.3 and 5.8.4 whereas Endpoint Study Records of individual ecotoxicology ED studies are presented under 8.2.3. Please add under this section cross references to the respective Endpoint Study Records are presented.

Besides presenting the conclusions of the weight of evidence assessment, it is also requested to make a proposal for a further testing strategy where this is necessary to conclude the ED assessment (e.g. in case the data package is insufficient) and timeline for the execution of the additional study/ies proposed in the strategy. The conclusions of the weight of evidence assessment should be complemented by the inclusion of the substantiating line of evidence and of the mode of action (MoA) analysis.

In the ECHA/EFSA Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009, particular instructions on how to present the assessment are provided. The applicant is kindly requested to present the assessment in line with the Guidance

document. Furthermore, the Excel file, completed in line with the template for reporting the available information relevant for ED assessment (Appendix E.1 to the Guidance) should be submitted as attachment.

This document replaces Appendix I.

FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest – v.2.1 (Final)			
Name	Instructions	Type	Field Path
Administrative data	The general rules on confidentiality requests apply in setting the flags (Administrative data summary – common block). See section on Confidentiality of dossiers	Header 1	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.AdministrativeDataSummary
		Confidentiality	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.AdministrativeDataSummary.DataProtection
ED assessment		Header 1	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment
Assessment of ED for humans (T-modality)		Header 2	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForHumansTmodality
Assessment of the lines of evidence		Header 3	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForHumansTmodality.AssessmentLinesOfEvidence
Have T-mediated parameters been sufficiently investigated?	Provide an assessment for the following information by specifying if the <u>T-mediated adversity in humans</u> has been sufficiently investigated (or not) and the rationale	Closed list with remarks	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForHumansTmodality.AssessmentLinesOfEvidence.SufficientInvestigationT

Lines of evidence for adverse effects	<p>List the relevant lines of evidence for adversity (also using a tabular representation).</p> <p>Example: WoE for T-mediated adversity</p> <ul style="list-style-type: none"> Thyroid histological changes (follicular dilatation, FC hyperplasia and FC adenoma) observed in two species (mouse and rat) in the carcinogenesis studies (study ID x and y) and considered adverse (intermediate and high doses). The two carcinogenesis studies were conducted at the MTD. Based on survival, body weight, food consumption, clinical chemistry and clinical signs The proliferative effect was confirmed by an increase in cell proliferation observed in a short study (up to 28 days) and lower dose (time & dose concordance). Additional target organ toxicity was observed in the adrenal, kidney (only mouse) and liver at the same doses (relevant for consideration on potential non-endocrine MOA) For the liver, changes were mainly characterized by panlobular hypertrophy, hepatocellular necrosis, fatty change and hepatocellular neoplasm. Considered adverse and observed in multiple studies also of shorter duration (likely lead toxic effect) 	Ri ch te xt ar ea	FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessmen tPest.EdAssessment. EdForHumansTmodal ity.AssessmentLinesO fEvidence.EvidenceA dverseEffects
Lines of evidence for endocrine activity	<p>List the relevant lines of evidence for endocrine activity (also using a tabular representation).</p> <p>Example: WoE for T-mediated endocrine activity</p> <ul style="list-style-type: none"> TPO in vitro investigation negative Decrease in THs in the mouse was observed in studies of shorter duration (14 and 28 days) and at lower doses (35 and 350 mg/kg/day). Decrease in THs in the rat was observed is a study of shorter duration (14 days) and dose tested of 700 mg/kg bw per day. 	Ri ch te xt ar ea	FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessmen tPest.EdAssessment. EdForHumansTmodal ity.AssessmentLinesO fEvidence.EvidenceEn docrineActivity

	<ul style="list-style-type: none"> Increase at week 16 only in TSH (measured in rat and mouse) were observed in mouse. 										
WoE for adversity and endocrine activity	Based on the lines of evidence presented above, the overall WoE for adversity and endocrine activity should be reported. This is needed to then select the relevant scenario and to decide if it is possible to conclude without performing a MoA analysis.	Text area	FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessment tPest.EdAssessment. EdForHumansTmodality. AssessmentLinesOfEvidence.WoeAdversityEndocrineActivity								
Has endocrine activity been sufficiently investigated?	Provide an assessment for the following information by specifying if the <u>T-mediated endocrine activity in humans</u> has been sufficiently investigated (or not) and the rationale.	Comments with remarks	FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessment tPest.EdAssessment. EdForHumansTmodality. AssessmentLinesOfEvidence.HasEndocrineActivityBeenSufficientlyInvestigated								
Selection of relevant scenario	<p>In case of pesticides, for applications submitted for the renewal of approval of active substances after 10 November 2018, the regulatory dossier should already contain the ED assessment in line with the new scientific criteria, and therefore there is no possibility to apply a clock stop to request additional data in accordance with the provisions of Regulation (EU) 2018/1659.</p> <p>For new active substances an additional clock stop in accordance with the provisions Regulation (EU) 2018/1659 cannot be applied.</p> <p>Under the conditions as specified above, the selection of scenario 2(iii) is not applicable.</p> <p>Selection of relevant scenario</p> <table border="1"> <thead> <tr> <th>Adversity based on T-mediated parameters</th><th>Positive mechanistic OECD CF level 2/3 Test</th><th>Scenario</th><th>Next step of the assessment</th></tr> </thead> <tbody> <tr> <td>No (sufficiently investigated)</td><td>Yes/No</td><td>1a</td><td>Conclude: ED criteria not met because there is not</td></tr> </tbody> </table>	Adversity based on T-mediated parameters	Positive mechanistic OECD CF level 2/3 Test	Scenario	Next step of the assessment	No (sufficiently investigated)	Yes/No	1a	Conclude: ED criteria not met because there is not	Comments with remarks	FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessment tPest.EdAssessment. EdForHumansTmodality. AssessmentLinesOfEvidence.SelectionOfRelevantScenario
Adversity based on T-mediated parameters	Positive mechanistic OECD CF level 2/3 Test	Scenario	Next step of the assessment								
No (sufficiently investigated)	Yes/No	1a	Conclude: ED criteria not met because there is not								

				"T-mediated" adversity		
	Yes (sufficiently investigated)	Yes/No	1b	Perform MoA analysis		
	No (not sufficiently investigated)	Yes	2a (i)	Perform MoA analysis (additional information may be needed for the analysis)		
	No (not sufficiently investigated)	No (sufficiently investigated)	2a (ii)	Conclude: ED criteria not met because no T-mediated endocrine activity observed		
	No (not sufficiently investigated)	No (not sufficiently investigated)	2a (iii)	Generate missing level 2 and 3 information. Alternatively, generate missing "EATS-mediated" parameters. Depending on the outcome move to corresponding scenario		
	Yes (not sufficiently investigated)	Yes/No	2b	Perform MoA analysis		
MoA analysis	The fields in the MoA analysis fields should be completed only for scenarios 1b, 2a(i) and 2b.				Header	FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessmen

	<p>In some cases, a detailed MoA analysis is not needed as explained in Section 3.5.2 of the ECHA-EFSA Guidance to identify EDs: "In the case of adversity based on "EATS-mediated" parameters, the underlying knowledge (i.e. by coherence analysis (Susser, 1991)) of the likely endocrine nature of the effects may be such that judgement can be reached on the biological plausibility of a link without recourse to a detailed MoA analysis."</p> <p>Where the information available is sufficient to establish a biological plausible link between endocrine activity and T-mediated adversity. Therefore, in such case, the assessment can be finalised and the conclusion described in the field 'Conclusion on MoA Analysis'.</p>	3	tPest.EdAssessment. EdForHumansTmodality.MoaAnalysis
Postulated MoA	Based on the assessed lines of evidence described above, postulate the MoA. In case it is concluded that the available information is not sufficient to postulate the MoA, this conclusion should be in the field 'Conclusion on MoA Analysis'.		FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessment tPest.EdAssessment. EdForHumansTmodality.MoaAnalysis.PostulatedMoa
Name of postulated MoA	Name of the postulated mode of action, this element must be completed if more than one mode of action is postulated. Group the events and supporting evidence for each mode of action postulated.	Multiple	FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessment tPest.EdAssessment. EdForHumansTmodality.MoaAnalysis.PostulatedMoa.PostulatedMoa
Event type	Indicate the event type e.g. MIE, KE1, KE2, KEn, ..., AO.	Multiple	FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessment tPest.EdAssessment. EdForHumansTmodality.MoaAnalysis.PostulatedMoa.EventType
Event description	Description of the event e.g. TSH; increased or Nuclear receptor activation (liver).	Multiple	FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessment tPest.EdAssessment. EdForHumansTmodality.MoaAnalysis.PostulatedMoa.EventDescription
Supporting evidence	Supporting evidence at the Lowest Observable Adverse Effect Level e.g. One-generation study (64.6 mg/kg/day in dam).	Multiple	FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessment tPest.EdAssessment. EdForHumansTmodality.MoaAnalysis.PostulatedMoa

		text	latedMoa.Supporting Evidence																												
Link to relevant study records	Link to the reference entity for the supporting evidence.	Literature reference record list	FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessmentPest.EdAssessment. EdForHumansTmodality.MoaAnalysis.PostulatedMoa.RelevantRecords																												
Postulated MoA																															
Empirical support	<p>When relevant, empirical support should be reported in a tabular format. Reproduce table from guidance document. Example Dose: and temporal-concordance between key events of the postulated MoA</p> <table><tr><th></th><th>MIE CAR-PXR activation</th><th>KE1 Phase I /Phase II catalytic activation</th><th>KE2 ↓serum concentration of T4</th><th>KE3 ↑ in TSH</th><th>KE4 ↑ in follicular cells proliferation</th><th>AO Thyroid hyperplasia/adenoma</th></tr><tr><td>In vitro 3-10 μM</td><td>96 hours +++</td><td></td><td></td><td></td><td></td><td></td></tr><tr><td>35 mg/kg bw per day mouse</td><td>7-28 days +++</td><td>7-28 days +++</td><td>7-28 days ++</td><td>7-28 days ++</td><td>7-28 days ++</td><td></td></tr><tr><td>460 (mouse) / 318 (rat) mg/kg bw per day</td><td></td><td></td><td></td><td></td><td></td><td>104 weeks +</td></tr></table>		MIE CAR-PXR activation	KE1 Phase I /Phase II catalytic activation	KE2 ↓serum concentration of T4	KE3 ↑ in TSH	KE4 ↑ in follicular cells proliferation	AO Thyroid hyperplasia/adenoma	In vitro 3-10 μM	96 hours +++						35 mg/kg bw per day mouse	7-28 days +++	7-28 days +++	7-28 days ++	7-28 days ++	7-28 days ++		460 (mouse) / 318 (rat) mg/kg bw per day						104 weeks +	Rich text area	FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessmentPest.EdAssessment. EdForHumansTmodality.MoaAnalysis.EmpiricalSupport
	MIE CAR-PXR activation	KE1 Phase I /Phase II catalytic activation	KE2 ↓serum concentration of T4	KE3 ↑ in TSH	KE4 ↑ in follicular cells proliferation	AO Thyroid hyperplasia/adenoma																									
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460 (mouse) / 318 (rat) mg/kg bw per day						104 weeks +																									

Conclusion on MoA analysis	The conclusion of the MoA analysis should be presented in a tabular form.						Rich text area	FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessment tPest.EdAssessment. EdForHumansTmodal ity.MoaAnalysis.Concl usionOnMoa
	In this section, when relevant, comparative MoA analysis can be reported as well.							
	When more than one MoA is postulated, include a conclusion for each MoA postulated.							
	Example: Summary of the MoA analysis							
	MIE to KE1	KE1 to KE2	KE2 to KE3	KE3 to KE4	KE4 to KE5	KE5 to AO		
Biological plausibility for the KER	Strong, well documented	Strong, well documented	Strong, well documented	Strong well documented	Strong, well documented	Strong well documented		
Empirical support for the KER	Moderate, /strong, some evidence is indirect	Moderate, evidence is indirect, THs clearance was not measured	Moderate, only in one species and occasionally controversial	Strong, dose and time related	Strong dose and time related	Strong, dose and time related		
Essentiality of the KE	Strong	Na	Na	Na	Na	Na		
Consistency	Some KEs are consistently observed in different studies and species The pattern of effect is consistent across studies and species and in line with the postulated MOA							
Analogy	The same MOA has been seen in the same species with multiple substances and this is well documented							

	Specificity	This MOA is not very specific and can occur as a consequence of activation of different MIE. However, the upstream KEs are specific of a liver mediated MIE. As such, this MOA is specific.		
Uncertainty analysis			Header 3	FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessmentPest.EdAssessment.EdForHumansTmodality.UncertaintyAnalyses
Uncertainty analysis	List all points of uncertainty, consider uncertainty associated with assessment inputs e.g. missing studies and uncertainty associated with methodology e.g. excluded factors			FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessmentPest.EdAssessment.EdForHumansTmodality.UncertaintyAnalyses.UncertaintyAnalysis
Identified uncertainties	Describe each uncertainty related to the both MoA analysis and assessment of the lines of evidence.		Text area	FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessmentPest.EdAssessment.EdForHumansTmodality.UncertaintyAnalyses.UncertaintyAnalysis .IdentifiedUncertainties
Justification	Characterize the overall impact of the source of uncertainty on the assessment conclusion		Text area	FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessmentPest.EdAssessment.EdForHumansTmodality.UncertaintyAnalyses.UncertaintyAnalysis .Justification
Uncertainty analysis				
Assessment of ED for humans (EAS-modality)			Header 2	FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessmentPest.EdAssessment.EdForHumansEasmodality
Assessment of the lines of evidence			Header 3	FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessmentPest.EdAssessment.EdForHumansEasmodality.AssessmentLinesOfEvidence

Have EAS-mediated parameters been sufficiently investigated?	Provide an assessment for the following information by specifying if the <u>EAS-mediated adversity in humans</u> has been sufficiently investigated (or not) and the rationale	Classified with remarks	FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessment tPest.EdAssessment. EdForHumansEasmo dality.AssessmentLin esOfEvidence.Sufficie ntInvestigationEas
Lines of evidence for adverse effects	<p>List the relevant lines of evidence for adversity (also using a tabular representation).</p> <p>Example: WoE for EAS-mediated adversity</p> <ul style="list-style-type: none"> The most relevant studies for adversity are 2 two-years rat studies Leydig cells adenoma observed in 2 two-year rat studies. Dose-dependent increase observed below MTD. Dose-dependent decrease of testis weight observed in 1 two-year rat study. Effect observed below MTD. The two carcinogenesis studies were conducted at the MTD. (Based on survival, body weight, food consumption, clinical chemistry and clinical signs). Additional target organ toxicity was observed in the liver. 	Rich text area	FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessment tPest.EdAssessment. EdForHumansEasmo dality.AssessmentLin esOfEvidence.Eviden ceAdverseEffects
Lines of evidence for endocrine activity	<p>List the relevant lines of evidence for endocrine activity (also using a tabular representation).</p> <p>Example: WoE for EAS-mediated endocrine activity</p> <ul style="list-style-type: none"> Several <i>in vitro</i> assays providing evidence indicative of anti-androgenic activity. 	Rich text area	FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessment tPest.EdAssessment. EdForHumansEasmo dality.AssessmentLin esOfEvidence.Eviden ceEndocrineActivity

	<ul style="list-style-type: none"> Decreased serum testosterone and increased testicular testosterone in 90-days rat study in male. Increased LH levels (rat 2-weeks) in males. Decreased weight of several male reproductive organs from 3 Hershberger studies. 		
WoE for adversity and endocrine activity	Based on the lines of evidence presented above, the overall WoE for adversity and endocrine activity should be reported. This is needed to then select the relevant scenario and to decide if it is possible to conclude without performing a MoA analysis.	Text area	FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessmentPest.EdAssessment. EdForHumansEasmodality.AssessmentLinesOfEvidence.WoeAdversityEndocrineActivity
Has endocrine activity been sufficiently investigated?	Provide an assessment for the following information by specifying if the <u>EAS-mediated endocrine activity in humans</u> has been sufficiently investigated (or not) and the rationale.	Closed list with remarks	FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessmentPest.EdAssessment. EdForHumansEasmodality.AssessmentLinesOfEvidence.HasEndocrineActivityBeenSufficientlyInvestigated
Selection of relevant scenario	<p>In case of pesticides, for applications submitted for the renewal of approval of active substances after 10 November 2018, the regulatory dossier should already contain the ED assessment in line with the new scientific criteria, and therefore there is no possibility to apply a clock stop to request additional data in accordance with the provisions of Regulation (EU) 2018/1659.</p> <p>For new active substances an additional clock stop in accordance with the provisions Regulation (EU) 2018/1659 cannot be applied.</p> <p>Under the conditions as specified above, the selection of scenario 2(iii) is not applicable.</p> <p>Selection of relevant scenario</p> <p>Example: Selection of relevant scenario</p>	Closed list with remarks	FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessmentPest.EdAssessment. EdForHumansEasmodality.AssessmentLinesOfEvidence.SelectionOfRelevantScenario

Adversity based on EAS-mediated parameters	Positive mechanistic OECD CF level 2/3 Test	Scenario	Next step of the assessment
No (sufficiently investigated)	Yes/No	1a	Conclude: ED criteria not met because there is not " EAS-mediated " adversity
Yes (sufficiently investigated)	Yes/No	1b	Perform MoA analysis
No (not sufficiently investigated)	Yes	2a (i)	Perform MoA analysis (additional information may be needed for the analysis)
No (not sufficiently investigated)	No (sufficiently investigated)	2a (ii)	Conclude: ED criteria not met because no EAS-mediated endocrine activity observed
No (not sufficiently investigated)	No (not sufficiently investigated)	2a (iii)	Generate missing level 2 and 3 information. Alternatively, generate missing "EATS-mediated" parameters. Depending on the outcome move to corresponding scenario
Yes (not sufficiently investigated)	Yes/No	2b	Perform MoA analysis
<p>In some cases, a detailed MoA analysis is not needed as explained in Section 3.5.2 of the ECHA-EFSA Guidance to identify EDs: "In the case of adversity based on "EATS-mediated" parameters, the underlying knowledge (i.e. by</p>			

	<p>coherence analysis (Susser, 1991)) of the likely endocrine nature of the effects may be such that judgement can be reached on the biological plausibility of a link without recourse to a detailed MoA analysis.”</p> <p>Where the information available is sufficient to establish a biological plausible link between endocrine activity and T-mediated adversity. Therefore, in such case, the assessment can be finalised and the conclusion described in the field ‘Conclusion on MoA Analysis’.</p>		
MoA analysis	<p>The following fields should be completed only for scenarios 1b, 2a(i) and 2b.</p> <p>In some cases, a detailed MoA analysis is not needed as explained in Section 3.5.2 of the ECHA-EFSA Guidance to identify EDs: “In the case of adversity based on “EATS-mediated” parameters, the underlying knowledge (i.e. by coherence analysis (Susser, 1991)) of the likely endocrine nature of the effects may be such that judgement can be reached on the biological plausibility of a link without recourse to a detailed MoA analysis.”</p> <p>Where the information available is sufficient to establish a biological plausible link between endocrine activity and T-mediated adversity. Therefore, in such case, the assessment can be finalised and the conclusion described in the field ‘Conclusion on MoA Analysis’.</p>	Header 3	FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessment. tPest.EdAssessment. EdForHumansEasmo dality.MoaAnalysis
Postulated MoA	Based on the assessed lines of evidence described above, postulate the MoA. In case it is concluded that the available information is not sufficient to postulate the MoA, this conclusion should be reflected here.		FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessment. tPest.EdAssessment. EdForHumansEasmo dality.MoaAnalysis.Po stulatedMoa
Name of postulated MoA	Name of the postulated mode of action, this element must be completed if more than one mode of action is postulated. Group the events and supporting evidence for each mode of action postulated.	Multi-line text	FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessment. tPest.EdAssessment. EdForHumansEasmo dality.MoaAnalysis.Po stulatedMoa.Postulat edMoa
Event type	Indicate the event type e.g. MIE, KE1, KE2, KEn, ..., AO.	Multi-line text	FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessment. tPest.EdAssessment. EdForHumansEasmo dality.MoaAnalysis.Po stulatedMoa.EventTy pe

Event description	Description of the event e.g. LH; increased or Leydig cells hyperplasia	Multiline text	FLEXIBLE_SUMMARY .EndocrineDisruptingPropertiesAssessmentPest.EdAssessment. EdForHumansEasmodality.MoaAnalysis.PostulatedMoa.EventDescription														
Supporting evidence	Supporting evidence at the Lowest Observable Adverse Effect Level e.g. One-generation study (64.6 mg/kg/day in dam).	Multiline text	FLEXIBLE_SUMMARY .EndocrineDisruptingPropertiesAssessmentPest.EdAssessment. EdForHumansEasmodality.MoaAnalysis.PostulatedMoa.SupportingEvidence														
Link to relevant study records	Link to the reference entity for the supporting evidence.	Literature reference ncelists	FLEXIBLE_SUMMARY .EndocrineDisruptingPropertiesAssessmentPest.EdAssessment. EdForHumansEasmodality.MoaAnalysis.PostulatedMoa.RelevantRecords														
Postulated MoA																	
Empirical support	<p>When relevant, empirical support should be reported in a tabular format. Reproduce table from guidance document.</p> <p>Example: Dose- and temporal-concordance between key events of the postulated MoA</p> <table><tr><th></th><th>MI E</th><th>KE1 ↓ serum testosterone</th><th>KE2 ↑ LH levels</th><th>KE3 ↑ testicular testosterone</th><th>KE4 Leydig cells hyperplasia</th><th>AO Leydig cells tumors</th></tr><tr><td>6.25 mg/kg bw per day (rat)</td><td></td><td></td><td></td><td></td><td>104 weeks ++</td><td>104 weeks ++</td></tr></table>		MI E	KE1 ↓ serum testosterone	KE2 ↑ LH levels	KE3 ↑ testicular testosterone	KE4 Leydig cells hyperplasia	AO Leydig cells tumors	6.25 mg/kg bw per day (rat)					104 weeks ++	104 weeks ++	Rich text area	FLEXIBLE_SUMMARY .EndocrineDisruptingPropertiesAssessmentPest.EdAssessment. EdForHumansEasmodality.MoaAnalysis.EmpiricalSupport
	MI E	KE1 ↓ serum testosterone	KE2 ↑ LH levels	KE3 ↑ testicular testosterone	KE4 Leydig cells hyperplasia	AO Leydig cells tumors											
6.25 mg/kg bw per day (rat)					104 weeks ++	104 weeks ++											

	10 mg/k g bw per day (rat)					117 weeks ++	117 week s ++		
	23 mg/k g bw per day (rat)					24-52 weeks +			
	31.2 6 mg/k g bw per day (rat)					26 weeks +	26 week s +		
	100 mg/k g bw per day (rat)		13 weeks ++		13 weeks ++				
	200 mg/k g bw per day (rat)			2 week s ++					
Conclusion on MoA analysis	<p>The conclusion of the MoA analysis should be presented in a tabular form.</p> <p>In this section, when relevant, comparative MoA analysis can be reported as well.</p> <p>When more than one MoA is postulated, include a conclusion for each MoA postulated.</p> <p>Example: Summary of the MoA analysis</p>						Rich text area	FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessment tPest.EdAssessment. EdForHumansEasmo dality.MoaAnalysis.Co nclusionOnMoa	

		MIE to KE1 Androgen receptor to decreased testosterone	KE1 to KE2 Decreased testosterone to increased LH	KE2 to KE3/4 Increased LH to Leydig cell hyperplasia	KE4 to AO Leydig tumors		
	Biological plausibility	STRONG: well documented that anti-androgenic activity leads to ↓ testosterone	STRONG: ↓ testosterone induces negative feedback to hypothalamus to ↑ LH production	STRONG: LH induces Leydig cells to produce Testosterone. This over time can lead to hyperplasia	STRONG: It is known that a continuum exists between epithelial cell hyperplasia and tumors		
	Empirical support	WEAK: Dose and time concordance were compromised by the dose selection and study design (selected parameters, hormones, and length of the study)			STRONG: dose and temporal concordance observed in several rat studies		
	Essentiality	No data					
	Consistency	Particularly Leydig cells hyperplasia and tumors have been observed in several studies. Also AR anti-androgenic activity supported by several <i>in vitro</i> assays					
	Analogy	Similar effects are known to occur with multiple chemicals acting on the same MIE, including therapeutic drugs.					
	Specificity	Although a clear experimental understanding of early KEs is lacking, the sequence of KEs from the MIE to the AO is considered specific					
Uncertainty analysis						Header 3	FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessmentPest.EdAssessment. EdForHumansEasmodality.UncertaintyAnalysis

Uncertainty analysis	List all points of uncertainty, consider uncertainty associated with assessment inputs e.g. missing studies and those associated with methodology e.g. excluded factors		FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessmentPest.EdAssessment. EdForHumansEasmodality.UncertaintyAnalysis.UncertaintyAnalysis
Identified uncertainties	Describe each uncertainty related to both MoA analysis and assessment of the lines of evidence.	Text area	FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessmentPest.EdAssessment. EdForHumansEasmodality.UncertaintyAnalysis.UncertaintyAnalysis.IdentifiedUncertainties
Justification	Characterize the overall impact of the source of uncertainty on the assessment conclusion	Text area	FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessmentPest.EdAssessment. EdForHumansEasmodality.UncertaintyAnalysis.UncertaintyAnalysis.Justification
Uncertainty analysis			
Assessment of ED for non-target organisms (T-modality)		Header 2	FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessmentPest.EdAssessment. EdForNonTargetOrganismsTmodality
Assessment of the lines of evidence		Header 3	FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessmentPest.EdAssessment. EdForNonTargetOrganismsTmodality.AssessmentLinesOfEvidence
Have T-mediated parameters been sufficiently investigated?	Provide an assessment for the following information by specifying if the <u>T-mediated adversity in non-target organisms</u> has been sufficiently investigated (or not) and the rationale.	Comments with remarks	FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessmentPest.EdAssessment. EdForNonTargetOrganismsTmodality.AssessmentLinesOfEvidence.SufficientInvestigationT

Lines of evidence for adverse effects	List the relevant lines of evidence for adversity (also using a tabular representation).	Rich text area	FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessmentPest.EdAssessment. EdForNonTargetOrganismsTmodality.AssessmentLinesOfEvidence.EvidenceAdverseEffects
Lines of evidence for endocrine activity	List the relevant lines of evidence for endocrine activity (also using a tabular representation).	Rich text area	FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessmentPest.EdAssessment. EdForNonTargetOrganismsTmodality.AssessmentLinesOfEvidence.EvidenceEndocrineActivity
WoE for adversity and endocrine activity	Based on the lines of evidence presented above, the overall WoE for adversity and endocrine activity should be reported. This is needed to select the relevant scenario and to decide if it is possible to conclude without performing a MoA analysis.	Text area	FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessmentPest.EdAssessment. EdForNonTargetOrganismsTmodality.AssessmentLinesOfEvidence.WoeAdversityEndocrineActivity
Has endocrine activity been sufficiently investigated?	Provide an assessment for the following information by specifying if the <u>T-mediated endocrine activity in non-target organisms</u> has been sufficiently investigated (or not) and the rationale.	Comments	FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessmentPest.EdAssessment. EdForNonTargetOrganismsTmodality.AssessmentLinesOfEvidence.HasEndocrineActivityBeenSufficientlyInvestigated
Selection of relevant scenario	<p>In case of pesticides, for applications submitted for the renewal of approval of active substances after 10 November 2018, the regulatory dossier should already contain the ED assessment in line with the new scientific criteria, and therefore there is no possibility to apply a clock stop to request additional data in accordance with the provisions of Regulation (EU) 2018/1659.</p> <p>For new active substances an additional clock stop in accordance with the provisions Regulation (EU) 2018/1659 cannot be applied.</p> <p>Under the conditions as specified above, the selection of scenario 2(iii) is not applicable.</p>	Comments	FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessmentPest.EdAssessment. EdForNonTargetOrganismsTmodality.AssessmentLinesOfEvidence.SelectionOfRelevantScenario

	Example: Selection of relevant scenario				
	Adversity based on T-mediated parameters	Positive mechanistic OECD CF level 2/3 Test	Scenario	Next step of the assessment	
	No (sufficiently investigated)	Yes/No	1a	Conclude: ED criteria not met because there is not " T-mediated " adversity	
	Yes (sufficiently investigated)	Yes/No	1b	Perform MoA analysis	
	No (not sufficiently investigated)	Yes	2a (i)	Perform MoA analysis (additional information may be needed for the analysis)	
	No (not sufficiently investigated)	No (sufficiently investigated)	2a (ii)	Conclude: ED criteria not met because no T-mediated endocrine activity observed	
	No (not sufficiently investigated)	No (not sufficiently investigated)	2a (iii)	Generate missing level 2 and 3 information. Alternatively, generate missing "EATS-mediated" parameters. Depending on the outcome move to corresponding scenario	
	Yes (not sufficiently investigated)	Yes/No	2b	Perform MoA analysis	
MoA analysis	The following fields should be completed only for scenarios 1b, 2a(i) and 2b.			H ea de	FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessmen tPest.EdAssessment.

	<p>In some cases, a detailed MoA analysis is not needed as explained in Section 3.5.2 of the ECHA-EFSA Guidance to identify EDs: "In the case of adversity based on "EATS-mediated" parameters, the underlying knowledge (i.e. by coherence analysis (Susser, 1991)) of the likely endocrine nature of the effects may be such that judgement can be reached on the biological plausibility of a link without recourse to a detailed MoA analysis."</p> <p>Where the information available is sufficient to establish a biological plausible link between endocrine activity and T-mediated adversity. Therefore, in such case, the assessment can be finalised, and the conclusion described in the field 'Conclusion on MoA Analysis'.</p>	r 3	EdForNonTargetOrganismsTmodality.MoaAnalysis
Postulated MoA	Based on the assessed lines of evidence described above, postulate the MoA. In case it is concluded that the available information is not sufficient to postulate the MoA, this conclusion should be reflected here.		FLEXIBLE_SUMMARY .EndocrineDisruptingPropertiesAssessmentPest.EdAssessment. EdForNonTargetOrganismsTmodality.MoaAnalysis.PostulatedMoa
Name of postulated MoA	Name of the postulated mode of action, this element must be completed if more than one mode of action is postulated. Group the events and supporting evidence for each mode of action postulated. .	M ult i- lin e te xt	FLEXIBLE_SUMMARY .EndocrineDisruptingPropertiesAssessmentPest.EdAssessment. EdForNonTargetOrganismsTmodality.MoaAnalysis.PostulatedMoa.PostulatedMoa
Event type	Indicate the event type e.g. MIE, KE1, KE2, KEn, ..., AO.	M ult i- lin e te xt	FLEXIBLE_SUMMARY .EndocrineDisruptingPropertiesAssessmentPest.EdAssessment. EdForNonTargetOrganismsTmodality.MoaAnalysis.PostulatedMoa.EventType
Event description	Description of the event e.g. Change in Thyroid histopathology	M ult i- lin e te xt	FLEXIBLE_SUMMARY .EndocrineDisruptingPropertiesAssessmentPest.EdAssessment. EdForNonTargetOrganismsTmodality.MoaAnalysis.PostulatedMoa.EventDescription
Supporting evidence	Supporting evidence at the Lowest Observable Adverse Effect Level e.g. Amphibian metamorphosis assay (AMA), 5 mg/l	M ult i- lin e	FLEXIBLE_SUMMARY .EndocrineDisruptingPropertiesAssessmentPest.EdAssessment. EdForNonTargetOrganismsTmodality.MoaAnalysis.PostulatedMoa.EventDescription

		text	nismsTmodality.Moa Analysis.PostulatedMoa.SupportingEvidence																														
Link to relevant study records	Link to the reference entity for the supporting evidence.	Literature reference nclist	FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessment. tPest.EdAssessment. EdForNonTargetOrganismsTmodality.Moa Analysis.PostulatedMoa.RelevantRecords																														
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Empirical support	<p>When relevant, empirical support should be reported in a tabular format. Reproduce table from guidance document.</p> <p>Example: Dose- and temporal-concordance between key events of the postulated MoA</p> <table><tr><th></th><th>MIE</th><th>KE1</th><th></th><th></th><th>AO</th></tr><tr><td></td><td>TPO inhibition</td><td>change in thyroid histopathology</td><td></td><td></td><td>Delayed development /time to metamorphosis</td></tr><tr><td><i>In vitro</i></td><td>+++</td><td></td><td></td><td></td><td></td></tr><tr><td>AMA</td><td></td><td>7-21 days ++</td><td>21 days +</td><td></td><td></td></tr><tr><td>LAGDA</td><td></td><td>16 weeks +++ (interim sacrifice)</td><td></td><td></td><td>16 weeks+++ (interim sacrifice)</td></tr></table>		MIE	KE1			AO		TPO inhibition	change in thyroid histopathology			Delayed development /time to metamorphosis	<i>In vitro</i>	+++					AMA		7-21 days ++	21 days +			LAGDA		16 weeks +++ (interim sacrifice)			16 weeks+++ (interim sacrifice)	Rich text area	FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessment. tPest.EdAssessment. EdForNonTargetOrganismsTmodality.Moa Analysis.EmpiricalSupport
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Conclusion on MoA analysis	The conclusion of the MoA analysis should be presented in a tabular form.	Rich text	FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessment																														

	<p>In this section, when relevant, comparative MoA analysis can be reported as well.</p> <p>When more than one MoA is postulated, include a conclusion for each MoA postulated.</p> <p>Example: Summary of the MoA analysis</p> <table><tr><th></th><th>MIE to KE1</th><th>KE1 to A0</th><th></th><th></th><th></th><th></th></tr><tr><td>Biological plausibility for the KER</td><td>Strong, well documented</td><td>Strong, well documented</td><td></td><td></td><td></td><td></td></tr><tr><td>Empirical support for the KER</td><td>Moderate, /strong, some evidence is indirect</td><td>Moderate, evidence is indirect, THs clearance was not measured</td><td></td><td></td><td></td><td></td></tr><tr><td>Essentiality of the KE</td><td>Strong</td><td>Na</td><td></td><td></td><td></td><td></td></tr><tr><td>Consistency</td><td colspan="6">Some KEs are consistently observed in different studies and species</td></tr><tr><td></td><td colspan="6">The pattern of effect is consistent across studies and species and in line with the postulated MOA</td></tr><tr><td>Analogy</td><td colspan="6">The same MOA has been seen in the same species with multiple substances and this is well documented</td></tr><tr><td>Specificity</td><td colspan="6">This MOA is not very specific and can occur as a consequence of activation of different MIE. However, the upstream KEs are specific of a liver mediated MIE. As such, this MOA is specific.</td></tr></table>		MIE to KE1	KE1 to A0					Biological plausibility for the KER	Strong, well documented	Strong, well documented					Empirical support for the KER	Moderate, /strong, some evidence is indirect	Moderate, evidence is indirect, THs clearance was not measured					Essentiality of the KE	Strong	Na					Consistency	Some KEs are consistently observed in different studies and species							The pattern of effect is consistent across studies and species and in line with the postulated MOA						Analogy	The same MOA has been seen in the same species with multiple substances and this is well documented						Specificity	This MOA is not very specific and can occur as a consequence of activation of different MIE. However, the upstream KEs are specific of a liver mediated MIE. As such, this MOA is specific.						xt ar ea	tPest.EdAssessment. EdForNonTargetOrga nismsTmodality.Moa Analysis.ConclusionO nMoa
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Uncertainty analysis	List all points of uncertainty, consider uncertainty associated with assessment inputs e.g. missing studies and uncertainty associated with methodology e.g. excluded factors.		FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessmentPest.EdAssessment. EdForNonTargetOrganismsTmodality.UncertaintyAnalysis.UncertaintyAnalysis
Identified uncertainties	Describe each uncertainty related to both MoA analysis and assessment of the lines of evidence.	Text area	FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessmentPest.EdAssessment. EdForNonTargetOrganismsTmodality.UncertaintyAnalysis.UncertaintyAnalysis.IdentifiedUncertainties
Justification	Characterize the overall impact of the source of uncertainty on the assessment conclusion	Text area	FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessmentPest.EdAssessment. EdForNonTargetOrganismsTmodality.UncertaintyAnalysis.UncertaintyAnalysis.Justification
Uncertainty analysis			
Assessment of ED for non-target organisms (EAS-modality)		Header 2	FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessmentPest.EdAssessment. EdForNonTargetOrganismsEasModality
Assessment of the lines of evidence		Header 3	FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessmentPest.EdAssessment. EdForNonTargetOrganismsEasModality.AssessmentLinesOfEvidence
Have EAS-mediated parameters been sufficiently investigated?	Provide an assessment for the following information by specifying if the <u>EAS-mediated adversity in non-target organisms</u> has been sufficiently investigated (or not) and the rationale	Content list with remark	FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessmentPest.EdAssessment. EdForNonTargetOrganismsEasModality.AssessmentLinesOfEvidence.SufficientInvestigationEas

		arks	
Lines of evidence for adverse effects	List the relevant lines of evidence for adversity (also using a tabular representation).	Richtext area	FLEXIBLE_SUMMARY .EndocrineDisruptingPropertiesAssessmentPest.EdAssessment. EdForNonTargetOrganismsEasModality.AssessmentLinesOfEvidence.EvidenceAdverseEffects
Lines of evidence for endocrine activity	List the relevant lines of evidence for endocrine activity (also using a tabular representation).	Richtext area	FLEXIBLE_SUMMARY .EndocrineDisruptingPropertiesAssessmentPest.EdAssessment. EdForNonTargetOrganismsEasModality.AssessmentLinesOfEvidence.EvidenceEndocrineActivity
WoE for adversity and endocrine activity	Based on the lines of evidence presented above, the overall WoE for adversity and endocrine activity should be reported. This is needed to select the relevant scenario and to decide if it is possible to conclude without performing a MoA analysis.	Text area	FLEXIBLE_SUMMARY .EndocrineDisruptingPropertiesAssessmentPest.EdAssessment. EdForNonTargetOrganismsEasModality.AssessmentLinesOfEvidence.WoeAdversityEndocrineActivity
Has endocrine activity been sufficiently investigated?	Provide an assessment for the following information by specifying if the <u>EAS-mediated endocrine activity in non-target organisms</u> has been sufficiently investigated (or not) and the rationale.	Comment with remarks	FLEXIBLE_SUMMARY .EndocrineDisruptingPropertiesAssessmentPest.EdAssessment. EdForNonTargetOrganismsEasModality.AssessmentLinesOfEvidence.HasEndocrineActivityBeenSufficientlyInvestigated
Selection of relevant scenario	In case of pesticides, for applications submitted for the renewal of approval of active substances after 10 November 2018, the regulatory dossier should already contain the ED assessment in line with the new scientific criteria, and therefore there is no possibility to apply a clock stop to request additional data in accordance with the provisions of Regulation (EU) 2018/1659. For new active substances an additional clock stop in accordance with the provisions Regulation (EU) 2018/1659 cannot be applied.	Comment with remarks	FLEXIBLE_SUMMARY .EndocrineDisruptingPropertiesAssessmentPest.EdAssessment. EdForNonTargetOrganismsEasModality.AssessmentLinesOfEvidence.SelectionOfRelevantScenario

	<p>Under the conditions as specified above, the selection of scenario 2(iii) is not applicable.</p> <p>Example: Selection of relevant scenario</p> <table> <tr> <th>Adversity based on T-mediated parameters</th><th>Positive mechanistic OECD CF level 2/3 Test</th><th>Scenario</th><th>Next step of the assessment</th></tr> <tr> <td>No (sufficiently investigated)</td><td>Yes/No</td><td>1a</td><td>Conclude: ED criteria not met because there is not "T-mediated" adversity</td></tr> <tr> <td>Yes (sufficiently investigated)</td><td>Yes/No</td><td>1b</td><td>Perform MoA analysis</td></tr> <tr> <td>No (not sufficiently investigated)</td><td>Yes</td><td>2a (i)</td><td>Perform MoA analysis (additional information may be needed for the analysis)</td></tr> <tr> <td>No (not sufficiently investigated)</td><td>No (sufficiently investigated)</td><td>2a (ii)</td><td>Conclude: ED criteria not met because no T-mediated endocrine activity observed</td></tr> <tr> <td>No (not sufficiently investigated)</td><td>No (not sufficiently investigated)</td><td>2a (iii)</td><td>Generate missing level 2 and 3 information. Alternatively, generate missing "EATS-mediated" parameters. Depending on the outcome move to corresponding scenario</td></tr> <tr> <td>Yes (not sufficiently investigated)</td><td>Yes/No</td><td>2b</td><td>Perform MoA analysis</td></tr> </table>	Adversity based on T-mediated parameters	Positive mechanistic OECD CF level 2/3 Test	Scenario	Next step of the assessment	No (sufficiently investigated)	Yes/No	1a	Conclude: ED criteria not met because there is not " T-mediated " adversity	Yes (sufficiently investigated)	Yes/No	1b	Perform MoA analysis	No (not sufficiently investigated)	Yes	2a (i)	Perform MoA analysis (additional information may be needed for the analysis)	No (not sufficiently investigated)	No (sufficiently investigated)	2a (ii)	Conclude: ED criteria not met because no T-mediated endocrine activity observed	No (not sufficiently investigated)	No (not sufficiently investigated)	2a (iii)	Generate missing level 2 and 3 information. Alternatively, generate missing "EATS-mediated" parameters. Depending on the outcome move to corresponding scenario	Yes (not sufficiently investigated)	Yes/No	2b	Perform MoA analysis		
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Name of postulated MoA	Name of the postulated mode of action, this element must be completed if more than one mode of action is postulated. Group the events and supporting evidence for each mode of action postulated.	Multiple line text	FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessmentPest.EdAssessment.EdForNonTargetOrganismsEasModality.MoaAnalysis.Postulated Moa.PostulatedMoa
Event type	Indicate the event type e.g. MIE, KE1, KE2, KEn, ..., AO.	Multiple line text	FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessmentPest.EdAssessment.EdForNonTargetOrganismsEasModality.MoaAnalysis.Postulated Moa.EventType
Event description	Description of the event e.g. decrease in VTG level	Multiple line text	FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessmentPest.EdAssessment.EdForNonTargetOrganismsEasModality.MoaAnalysis.Postulated Moa.EventDescription
Supporting evidence	Supporting evidence at the Lowest Observable Adverse Effect Level e.g. FSTRA (Fish Short-term reproduction Assay) (0.5 mg/l)	Multiple line text	FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessmentPest.EdAssessment.EdForNonTargetOrganismsEasModality.MoaAnalysis.Postulated Moa.SupportingEvidence
Link to relevant	Link to the reference entity for the supporting evidence.	Liter	FLEXIBLE_SUMMARY .EndocrineDisrupting

study records		at ur e re fe re nc e lis t	PropertiesAssessmentPest.EdAssessment. EdForNonTargetOrganismsEasModality.MoaAnalysis.PostulatedMoa.RelevantRecords																																																	
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	<p>When more than one MoA is postulated, include a conclusion for each MoA postulated.</p> <p>Example Summary of the MoA analysis</p> <table><tr><th></th><th>MIE to KE1</th><th>KE1 to KE2</th><th>KE2 to KE3 Increased LH to</th><th>KE to AO</th></tr><tr><td>Biological plausibility</td><td>STRONG: The link between aromatase inhibition and decrease in estradiol level (E2) is supported by the available knowledge (AOP 25, Villeneuve 2016)</td><td>MODERATE – The role of E2 as major regulator of VTG production is well known. Therefore, it can be assumed that a decrease in estradiol level will also lead to a decrease in VTG in plasma.</td><td>MODERATE – Based on the available knowledge it is not clear whether a decrease in VTG can lead to the observed histopathology changes in ovary. However, specific gonad histopathology is categorised as 'EAS-mediated' by the OECD GD 150. In addition, the link between VTG level and yolk formation is also supported by the biological knowledge.</td><td>STRONG - the link between changes in female gonad histopathology and decreased fecundity is supported by the biological knowledge.</td></tr><tr><td>Empirical support</td><td>MODERATE – There is little direct support</td><td>STRONG – Although the decrease in estradiol</td><td>MODERATE – histopathology changes</td><td>STRONG – fecundity was observed at the</td></tr></table>		MIE to KE1	KE1 to KE2	KE2 to KE3 Increased LH to	KE to AO	Biological plausibility	STRONG: The link between aromatase inhibition and decrease in estradiol level (E2) is supported by the available knowledge (AOP 25, Villeneuve 2016)	MODERATE – The role of E2 as major regulator of VTG production is well known. Therefore, it can be assumed that a decrease in estradiol level will also lead to a decrease in VTG in plasma.	MODERATE – Based on the available knowledge it is not clear whether a decrease in VTG can lead to the observed histopathology changes in ovary. However, specific gonad histopathology is categorised as 'EAS-mediated' by the OECD GD 150. In addition, the link between VTG level and yolk formation is also supported by the biological knowledge.	STRONG - the link between changes in female gonad histopathology and decreased fecundity is supported by the biological knowledge.	Empirical support	MODERATE – There is little direct support	STRONG – Although the decrease in estradiol	MODERATE – histopathology changes	STRONG – fecundity was observed at the	area	EdForNonTargetOrganismsEasModality.MoaAnalysis.ConclusionOnMoa
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Empirical support	MODERATE – There is little direct support	STRONG – Although the decrease in estradiol	MODERATE – histopathology changes	STRONG – fecundity was observed at the														

		for dose-response concordance of these key events in vivo. However, using in vitro systems concentrations that reduce aromatase activity tend to elicit reductions in estradiol production.	and VTG levels were observed at the same concentrations, this can be scientifically explained by a number of factors (e.g. dose spacing in the test system; higher variation in VTG concentration in plasma than in circulating steroids)	were measured only in longer term study and only observed at the highest tested concentration. The VTG decrease was observed at the same concentration. However, this can be due to the dose spacing and tested concentrations	same concentration as histopathology changes and above.		
	Essentiality	MODERATE- No data are available to support the assessment of essentiality. However, the available knowledge and validated AOP (25) supports the essentiality of key events.					
	Consistency	The KEs have been observed consistently in three different studies with different duration. The pattern of effects is consistent between the studies; there are no conflicting observations. Consistency across species cannot be assessed because there are only studies on one species.					
	Analogy	Aromatase inhibition is well established for compounds belonging to the same chemical class.					
	Specificity	Liver histopathology changes observed in one study at the highest tested concentration where other effects were also observed. However, the positive indication of endocrine activity from various studies and cell lines allowed to exclude a non-ED MOA.					
Uncertainty analysis						Header 3	FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessment tPest.EdAssessment. EdForNonTargetOrga nismsEasModality.Un certaintyAnalysis

Uncertainty analysis	List all points of uncertainty, consider uncertainty associated with assessment inputs e.g. missing studies and those associated with methodology e.g. excluded factors		FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessmentPest.EdAssessment. EdForNonTargetOrganismsEasModality.UncertaintyAnalysis.UncertaintyAnalysis
Identified uncertainties	Describe each uncertainty related to both MoA analysis and assessment of the lines of evidence.	Text area	FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessmentPest.EdAssessment. EdForNonTargetOrganismsEasModality.UncertaintyAnalysis.UncertaintyAnalysis. IdentifiedUncertainties
Justification	Characterize the overall impact of the source of uncertainty on the assessment conclusion	Text area	FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessmentPest.EdAssessment. EdForNonTargetOrganismsEasModality.UncertaintyAnalysis.UncertaintyAnalysis. Justification
Uncertainty analysis			
Overall conclusion ED assessment	Report under this section whether the ED criteria are met according to Regulation EU 2018/605.	Header 1	FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessmentPest.OverallConclusionEdAssessment
Overall conclusion ED assessment for humans		Header 2	FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessmentPest.OverallConclusionEdAssessment. OverallConclusionEdAssessmentHumans
Does the substance meet the ED criteria for humans?	Is there a biologically plausible link between endocrine activity and observed adverse effect(s) that are relevant for humans? Provide the reasoning behind the conclusion.	Conclusion with remarks	FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessmentPest.OverallConclusionEdAssessment. OverallConclusionEdAssessmentHumans. CriteriaForHumansMet

Overall conclusion ED assessment for non-target organisms		Header 2	FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessmentPest.OverallConclusionEdAssessment.OverallConclusionEdAssessmentNonTargetOrganisms
If ED criteria are met for humans, is the adverse effect identified relevant for wild mammals' population ?	<p>When replying this question, explain the relevance at population level of the adverse effect(s) observed in the dataset for concluding on the ED criteria for humans.</p> <p>Provide the reasoning behind the conclusion.</p>	Closed list with remarks	FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessmentPest.OverallConclusionEdAssessment.OverallConclusionEdAssessmentNonTargetOrganisms.AdverseEffectRelevantForMammals
Does the substance meet the ED criteria for wild mammals?	<p>Is there a biologically plausible link between endocrine activity and observed adverse effect(s) that are relevant for wild animals?</p> <p>Provide the reasoning behind the conclusion.</p>	Closed list with remarks	FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessmentPest.OverallConclusionEdAssessment.OverallConclusionEdAssessmentNonTargetOrganisms.EdCriteriaMammalsMet
Does the substance meet the ED criteria for non-target organisms other than wild mammals?	<p>Is there a biologically plausible link between endocrine activity and observed adverse effect(s) that are relevant for non-target organisms other than wild mammals?</p> <p>Provide the reasoning behind the conclusion.</p>	Closed list with remarks	FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessmentPest.OverallConclusionEdAssessment.OverallConclusionEdAssessmentNonTargetOrganisms.ImpactOnOtherOrganisms
Additional information	<p>Discussion(Header 1) – common block</p> <p>Provide any additional information to support this assessment of endocrine disrupting properties</p> <p>Upload the Excel file, in the format for reporting the available information specified in the guidance (this excel</p>	Header 1	FLEXIBLE_SUMMARY .EndocrineDisrupting PropertiesAssessmentPest.Discussion

	file with be published). Appendix E.1 to the Guidance (https://doi.org/10.2903/j.efsa.2018.5311)		
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Link to support material:

ECHA (European Chemicals Agency) and EFSA (European Food Safety Authority) with the technical support of the Joint Research Centre (JRC), Andersson N, Arena M, Auteri D, Barmaz S, Grignard E, Kienzler A, Lepper P, Lostia AM, Munn S, Parra Morte JM, Pellizzato F, Tarazona J, Terron A and Van der Linden S, 2018.

Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009. EFSA Journal 2018;16(6):5311, 135 pp.

<https://doi.org/10.2903/j.efsa.2018.5311>. ECHA-18-G-01-EN

EFSA Scientific Committee (2017) Scientific Opinion on the guidance on the use of the weight of evidence approach in scientific assessments. EFSA Journal 2017;15(8):4971

OECD Series on Testing and Assessment: No 150: Guidance document on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption. ENV/JM/MONO(2012)22, 524 pp

EFSA Scientific Committee; Scientific Opinion on the hazard assessment of endocrine disruptors: scientific criteria for identification of endocrine disruptors and appropriateness of existing test methods for assessing effects mediated by these substances on human health and the environment. EFSA Journal 2013;11(3):3132

Workshop report on OECD countries activities regarding testing, assessment and management of endocrine disruptors. Series on testing and assessment No 118. 18 January 2010.

OECD Series on Testing and Assessment: No 148: Guidance document on the androgenized female stickleback screen

Guidance on Uncertainty Analysis in Scientific Assessments, 10.2903/j.efsa.2018.5123

Referenced entities

Reference substance

Purpose

Chemicals: Identity of the active substance – ISO common name and synonyms, Chemical name in accordance with IUPAC and CA nomenclature, CAS Reg number EC number, molecular and structural formula, molar mass

Microorganisms: Identity of the microorganism – Name, taxonomy, species description and strain characterisation

The Reference substance inventory gives the possibility to use the same information for the same chemical/microorganism identity avoiding duplicate data entry and to ensure that the data is centrally managed and updated. Each reference substance can be linked to an unlimited number of substance or mixture datasets.

Reference substance/s can be exported and shared from the Reference substance entity manager

Name	Instructions	Type	Field Path
	<p>Set confidentiality and regulatory program flags.</p> <p>See Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants</p> <p>Important: Setting this flag ensures that substance identity is not published in any IUCLID document where a link to the reference substance is used. This should be used for confidential substances included mixture or substance composition documents</p>	Confidentiality	REFERENCE_SUBSTANCE.DataProtection
Reference substance name	Name of substance, microorganism, metabolite, residue, impurity or other	Multi-line text	REFERENCE_SUBSTANCE.ReferenceSubstance Name

	<p>substance included in the dossier</p> <p>For the active substances the ISO common name or proposed ISO name should be reported</p>		
IUPAC name	<p>IUPAC name (Note that, if a name following the IUPAC nomenclature cannot be derived, you should still provide a name defining the chemical nature of the substance).</p> <p>For microorganisms the scientific name (species and strain) should be reported in this field.</p>	Multi-line text	REFERENCE_SUBSTANCE.IupacName
Description	<p>Specify any additional information relevant for the description of the reference substance in this field</p> <p>For microorganisms the taxonomic information family, genus, species, strain, serotype, pathovar or any other denomination relevant to the micro-organism should be reported.</p> <p>In addition it should be indicated whether the microorganism</p> <ul style="list-style-type: none"> - is indigenous or non-indigenous at the species level to the intended area of application - is a wild type 	Text template	REFERENCE_SUBSTANCE.Description

	<ul style="list-style-type: none"> - is a spontaneous or induced mutant - has been modified using techniques described in Part 2 of Annex IA and in Annex IB to Directive 2001/18/EC (*) of the European Parliament and of the Council 		
Inventory	Can be used to select existing substances with pre-assigned EC numbers.	Header 1	REFERENCE_SUBSTANCE.Inventory
Inventory number	Can be used to select existing substances with pre-assigned EC numbers.	Entity reference list	REFERENCE_SUBSTANCE.Inventory.InventoryEntry
No inventory information available - Justification	Not relevant for EU PPP	Open list with remarks	REFERENCE_SUBSTANCE.Inventory.InventoryEntryJustification
CAS number	CAS Registry Number	Text	REFERENCE_SUBSTANCE.Inventory.CASNumber
CAS name	CAS name	Multi-line text	REFERENCE_SUBSTANCE.Inventory.CASName
CIPAC number	CIPAC number		
Synonyms		Header 1	REFERENCE_SUBSTANCE.Synonyms
Synonyms	<p>List any synonyms for the substance</p> <p>For microorganisms alternative names should be added in the table and the accession number/s from internationally recognised culture collections</p> <p>EFSA paramCode should be added in the table</p>		REFERENCE_SUBSTANCE.Synonyms.Synonyms
	Set confidentiality and regulatory program flags	Confidentiality	REFERENCE_SUBSTANCE.Synonyms.Synonyms.DataProtection

Identifier	Select the type of identifier you wish to provide using the picklist. If none of pre-defined items apply, select 'other:'. A text field is then activated next to the list field in which you can specify the type of identifier you wish to provide.	Open list	REFERENCE_SUBSTANCE.Synonyms.Synonyms.Identifier
Identity	Enter here the identity (name, number, code) corresponding to the identifier type selected.	Text area	REFERENCE_SUBSTANCE.Synonyms.Synonyms.Name
Remarks		Text	REFERENCE_SUBSTANCE.Synonyms.Synonyms.Remarks
Synonyms			
Molecular and structural information		Header 1	REFERENCE_SUBSTANCE.MolecularStructuralInfo
		Confidentiality	REFERENCE_SUBSTANCE.MolecularStructuralInfo.DataProtection
Molecular formula	Molecular formula (if a molecular formula cannot be derived from the reference substance, a justification should be indicated in the Remarks field at the bottom of the section)	Multi-line text	REFERENCE_SUBSTANCE.MolecularStructuralInfo.MolecularFormula
Molecular weight	Molecular weight should be reported as a single numeric value	Range (Decimal)	REFERENCE_SUBSTANCE.MolecularStructuralInfo.MolecularWeightRange
SMILES notation	The SMILES notation should be in the canonical form https://cactus.nci.nih.gov or generated by ChemSketch or ChemDraw	Multi-line text	REFERENCE_SUBSTANCE.MolecularStructuralInfo.SmilesNotation
InChI	The IUPAC international chemical identifier	Multi-line text	REFERENCE_SUBSTANCE.MolecularStructuralInfo.InChI

	https://cactus.nci.nih.gov or generated by ChemSketch or ChemDraw		
Structural formula	The structural formula for the active substance https://chem.nlm.nih.gov/chemidplus/structure3D/viewer/ ChemSketch, ChemDraw	Image	REFERENCE_SUBSTANCE.MolecularStructuralInfo.StructuralFormula
Remarks	See molecular formula	Text area	REFERENCE_SUBSTANCE.MolecularStructuralInfo.Remarks
Chemical structure files	Upload chemical structures files (both machine readable and an image file) For machine readable files the format should be .sk2 or .cdx or .mol For image files the format should be jpg or png		REFERENCE_SUBSTANCE.MolecularStructuralInfo.ChemicalStructureFiles
Structure file		Single file attachment	REFERENCE_SUBSTANCE.MolecularStructuralInfo.ChemicalStructureFiles.StructureFile
Remarks on structure file		Text	REFERENCE_SUBSTANCE.MolecularStructuralInfo.ChemicalStructureFiles.RemarksChemStruct
Chemical structure files			
Related substances	Not relevant for EU PPP	Header 1	REFERENCE_SUBSTANCE.RelatedSubstances
			REFERENCE_SUBSTANCE.RelatedSubstances.RelatedSubstances
Identifier		Open list	REFERENCE_SUBSTANCE.RelatedSubstances.RelatedSubstances.Identifier
Identity		Text area	REFERENCE_SUBSTANCE.RelatedSubstances.

			RelatedSubstances.Identity
Remarks		Text	REFERENCE_SUBSTANCE.RelatedSubstances. RelatedSubstances.Remarks
Relation		Open list	REFERENCE_SUBSTANCE.RelatedSubstances. RelatedSubstances.Relation
Group / category information		Multi-line text	REFERENCE_SUBSTANCE.RelatedSubstances. GroupCategoryInfo

Links to support materials

CIPAC number: <https://cipac.org/index.php/code-numbers/navigate-code-numbers>

<https://www.cas.org/support/documentation/chemical-substances>

<http://doi.org/10.5281/zenodo.3243215> - European Food Safety Authority. (2020). Harmonized terminology for scientific research [Data set]. Zenodo.

<https://iupac.org/who-we-are/divisions/division-details/inchi/>

<https://www.iso.org/committee/50160/x/catalogue/>

http://www.alanwood.net/pesticides/index_cn_frame.html

<https://cactus.nci.nih.gov/chemical/structure/>

<https://iuclid6.echa.europa.eu/inventories-iuclid>

UUID: 4f1c5970-dede-40e3-a833-15800a404834

Reference substance name*

DIFLUBENZURON

Inventory

Inventory number

EC / 252-529-3 / N-[[[(4-chlorophenyl)amino]carbonyl]-2,6-difluorobenzamide / 35367-38-5 / C14H9ClF2N2O2

No inventory information available

Justification

None

Reference substance information

 None  None

IUPAC name

1-(4-chlorophenyl)-3-(2,6-difluorobenzoyl)urea

Description

1-(4-chlorophenyl)-3-(2,6-difluorobenzoyl)urea

Synonyms

 New item

#...	Identifier	Identity	Remarks	Action
1	other: CIPAC number	339	None	
2	other: ISO common name	Diflubenzuron	E-ISO, (m) F-ISO, ANSI, ESA	

CAS information

CAS number

35367-38-5

CAS name

None

Legal entity (including contact entity)

Purpose:

Submissions require a Legal entity which has to be defined including contact details prior to submission. A Legal Entity (LE) may represent anything between a complex business structure and a simple organised business, for example, a corporation, a company, or a single person. LEs are identified by their name, universally unique identifier (UUID), address, country, and general contact information. You can create a LEO via ECHA accounts

A legal entity should identify in an unambiguous manner a company or organisation with a role in the submission of dossiers. The submissions attributed to a specific company/applicant should all have the same legal entity. The same applies to third party consultants, they should also maintain a unique legal entity that can be included in the 'Third Party' field.

The information provided in the Legal entity should be similar to that provided in a publicly accessible company register. It should contain the address and contact details, including fax and phone number as well as e-mail address, of the legal person. The information provided in the Legal Entity is published. Hence, no personal information relating to natural persons should be provided under these fields... **!Do not include personal e-mail addresses and telephone numbers!**

Note that the information regarding the Contact person is to be managed in the Contact entity manager. The information provided in the Contact entity is by default not published.

If you are installing a local version of IUCLID, a LEO will have been created during the installation of the client version of IUCLID. You can then export it from IUCLID and import it to you ECHA account. If you have an ECHA account and define a LEO there, you can export the LEO and import it to your own local IUCLID installation.

You can add more legal entities within the IUCLID application via the inventory.

Field name	Instructions	Path
General information		LEGAL_ENTITY.GeneralInfo
Legal Entity name	Name of the legal entity i.e. Company name	LEGAL_ENTITY.GeneralInfo.LegalEntityName
Legal entity type	Select one legal entity type from the dropdown menu. If other, please include an explanation in the free text field below.	LEGAL_ENTITY.GeneralInfo.LegalEntityType
Remarks	Any additional information on the legal entity, if relevant	LEGAL_ENTITY.GeneralInfo.Remarks
Other names	Other names can be specified and if needed these names can be marked as confidential	LEGAL_ENTITY.GeneralInfo.OtherNames
Address	See Confidentiality Requests	LEGAL_ENTITY.GeneralInfo.ContactAddress.DataProtection
Address 1	Street address of the legal entity	LEGAL_ENTITY.GeneralInfo.ContactAddress.Address1
Address 2	Secondary address, if relevant	LEGAL_ENTITY.GeneralInfo.ContactAddress.Address2
Postal Code	Postal code of the legal entity	LEGAL_ENTITY.GeneralInfo.ContactAddress.Postal
Town	Town of the legal entity	LEGAL_ENTITY.GeneralInfo.ContactAddress.Town
Region/State	Region/State of the legal entity	LEGAL_ENTITY.GeneralInfo.ContactAddress.Region
Country	Select the country in which the legal entity is located from the dropdown menu. If other, enter the appropriate country information in the free text field below.	LEGAL_ENTITY.GeneralInfo.ContactAddress.Country
Phone	Phone number of the legal entity (this field must not	LEGAL_ENTITY.GeneralInfo.ContactAddress.Phone

	contain personal data, therefore e.g. the number of a switchboard should be provided)	
Fax	Fax number of the legal entity (this field must not contain personal data)	LEGAL_ENTITY.GeneralInfo.ContactAddress.Fax
Email	Email address of the legal entity (this field must not contain personal data, therefore e.g. the email address of a functional mailbox should be provided)	LEGAL_ENTITY.GeneralInfo.ContactAddress.Email
Website	Legal entity website	LEGAL_ENTITY.GeneralInfo.ContactAddress.WebSite
Identifiers	Optional: Other identifiers can be reported. Legal entity identifiers, Regulatory programme identifiers, and Other IT system identifiers. Each type contains a menu from which relevant sub-types of identifier can be selected. For example, Legal entity has an option for DUNS (Data Universal Numbering System for identification of a Legal Entity. Click on New Item and set values. See Confidentiality Requests.	LEGAL_ENTITY.Identifiers
Contact information	An address can be defined for a contact person of the Legal entity and links can be made to one or more Contact entities	LEGAL_ENTITY.ContactInfo
Contact Person	This can be managed in the Contact entity manager	
General information		CONTACT.GeneralInfo
Contact type	Select one contact type from the dropdown menu. If other, enter the appropriate contact type in the free text field below.	CONTACT.GeneralInfo.ContactType
Last name	Last name of the contact person. Note that this field is mandatory	CONTACT.GeneralInfo.LastName
First name	First name of the contact person.	CONTACT.GeneralInfo.FirstName
Organisation	Name of the Organisation. Note that this field is mandatory	CONTACT.GeneralInfo.Organisation
Department	e.g. Scientific Department	CONTACT.GeneralInfo.Department
Title	Title of the contact person (e.g. Mr.).	CONTACT.GeneralInfo.Title

Phone	Phone number of the contact person	CONTACT.GeneralInfo.Phone
Mobile	Mobile phone number of the contact person	CONTACT.GeneralInfo.Mobile
Fax	Fax number of the contact person	CONTACT.GeneralInfo.Fax
Email	Email address of the contact person	CONTACT.GeneralInfo.Email
Address 1	Street address of the contact person	CONTACT.GeneralInfo.Address1
Address 2	Secondary address, if relevant	CONTACT.GeneralInfo.Address2
Postal Code	Postal code of the street address of the contact person	CONTACT.GeneralInfo.Postal
Town	Town of the contact person	CONTACT.GeneralInfo.Town
Region/State	Region/State of the contact person	CONTACT.GeneralInfo.Region
Country	Select the country in which the contact person is located from the dropdown menu. If other, enter the appropriate country information in the free text field below.	CONTACT.GeneralInfo.Country
Remarks	Any additional information, if relevant	CONTACT.GeneralInfo.Remarks

Links to support material:

<https://echa.europa.eu/support-echa-accounts-and-eu-login>

https://iuclid6.echa.europa.eu/documents/21812392/22308501/iuclid_functionalities_html_en.pdf/9d01cb53-902d-dbb6-fb00-fa141688c395

https://echa.europa.eu/documents/10162/21721613/echa_accounts_en.pdf

<https://www.youtube.com/watch?v=4JGsQUBGYqw>

Contact entity

Name	Instructions	Type	Field path
General information		Header 1	CONTACT.GeneralInfo
Contact type	Select one contact type from the dropdown menu. If other, enter the appropriate contact type in the free text field below.	Open list	CONTACT.GeneralInfo. ContactType
Last name	Last name of the contact person. Note that this field is mandatory	Text	CONTACT.GeneralInfo. LastName
First name	First name of the contact person.	Text	CONTACT.GeneralInfo. FirstName
Organisation	Name of the Organisation. Note that this field is mandatory	Text	CONTACT.GeneralInfo. Organisation
Department	e.g. scientific department.	Text	CONTACT.GeneralInfo. Department
Title	Title of the contact person (e.g. Mr.).	Text	CONTACT.GeneralInfo. Title
Phone	Phone number of the contact person.	Text	CONTACT.GeneralInfo. Phone
Mobile	Mobile phone number of the contact person.	Text	CONTACT.GeneralInfo. Mobile
Fax	Fax number of the contact person.	Text	CONTACT.GeneralInfo. Fax
Email	Email address of the contact person.	Text	CONTACT.GeneralInfo. Email
Address 1	Street address of the contact person.	Text	CONTACT.GeneralInfo. Address1
Address 2	Secondary address, if relevant	Text	CONTACT.GeneralInfo. Address2
Postal code	Postal code of the street address of the contact person.	Text	CONTACT.GeneralInfo. Postal
Town	Town of the contact person.	Text	CONTACT.GeneralInfo. Town
Region / state	Region/State of the contact person.	Text	CONTACT.GeneralInfo. Region
Country	Select the country in which the contact person is located from the dropdown menu. If other, enter the appropriate country information in the free text field below.	Open list	CONTACT.GeneralInfo. Country

Remarks	Any additional information, if relevant.	Text area	CONTACT.GeneralInfo. Remarks
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Literature reference

Purpose

Storage of bibliographic metadata with attached documents including full study reports and published scientific papers

Linking studies to the Notification of Studies Database

Used as the data source in OECD harmonised templates and DOMAIN Endpoint Study Records.

It is important to create a Literature reference for all studies used as evidence in the dossier. This would also include all relevant studies selected for full-text assessment identified from a literature search (when required).

Additional considerations

The applicant must ensure that terms and conditions asserted by any rightsholder of studies, information or data submitted to EFSA are fully satisfied. The applicant may consult with copyright licensing authorities (i.e. at national level) for guidance on purchasing the appropriate licenses to provide studies, information or data to EFSA, taking into account the proactive disclosure requirements as detailed in the relevant section of this manual. For publications already available to the public upon payment of fees (e.g. studies published in scientific journals) for which the applicant does not have or cannot obtain IPRs for the purposes of the proactive public disclosure requirements, the applicant must provide (a) a copy of the relevant publications along with the relevant bibliographic references/ citations for scientific assessment purposes only, in the confidential version of its application and (b) these relevant bibliographic references/citations where these publications are available to the public in the non-confidential version of its application for public dissemination on the OpenEFSA portal.

Name	Instructions	Type	Field Path
General information		Header 1	LITERATURE.GeneralInfo
Reference Type	<p>Select 'study report' for a full study report used as a data source for an endpoint study record.</p> <p>Select 'published' for relevant studies identified from a literature search to address data requirements</p> <p>Only in case of a publication already available to the public (studies published in scientific journals or similar publications) but subject to access restrictions (e.g. upon payment of a fee) for</p>	Open list	LITERATURE.GeneralInfo. LiteratureType

	<p>which the applicant does not have or cannot obtain IPRs for the purposes of the proactive public disclosure requirements, select 'publication (copyright not owned for reproduction)'</p> <p>The other reference types can also be used</p>		
Title	Title of the study report, publication or other report type	Text	LITERATURE.GeneralInfo. Name
Author	Author names for the study. These will be redacted from the published dossier for unpublished toxicology studies.	Multi-line text	LITERATURE.GeneralInfo. Author
Year	The year the report must be reported (this is used for sorting and filtering)	Integer	LITERATURE.GeneralInfo. ReferenceYear
Bibliographic source	For published studies information on the journal and edition should be completed. This should include the DOI (Digital Object Identifier)	Text	LITERATURE.GeneralInfo. Source
Testing facility	For study reports information on the testing facility should be completed. This information will not be published for studies involving tests on vertebrate animals.	Text	LITERATURE.GeneralInfo. TestLab
Report date	Report date or publication date in full. For study reports this must be after the date the study was notified in the notification of studies database	Date	LITERATURE.GeneralInfo. ReportDate
Report number	Specify the report number allocated by the testing laboratory. This information will not be published for studies involving tests on vertebrate animals.	Text	LITERATURE.GeneralInfo. ReportNo
Study sponsor	Information on the source of funding of the study can be provided	Text	LITERATURE.GeneralInfo. CompanyOwner

Study number	Report the company identifier, if it differs from the laboratory report number	Text	LITERATURE.GeneralInfo. CompanyOwnerStudyNo
Other study identifier(s)	<p>Applies to study reports. When other study identifiers are available e.g. NOS number or MAP number, click on 'New item' and compile relevant fields accordingly.</p> <p>For rat/plant/livestock metabolism studies: If a MSS/DER composer file is not available in the existing collections of maps (and is therefore created and attached in the dossier), no need to create a new item.</p> <p>-</p>		LITERATURE.GeneralInfo. StudyIdentifiers
Study ID type	<p>Select 'Notification of studies (NoS) ID when reporting an NoS ID or studies started after March 2021</p> <p>For rat/plant/livestock metabolism studies:</p> <ul style="list-style-type: none"> - if a MSS/DER composer file is already available in the existing collections of maps (and is therefore not attached in the dossier), select 'other' and specify "Unique Individual MetaPath File Number (MAP-number/card number)" in the free text field. Optionally, if a Master Record Identification (MRID) is available 	Open list	LITERATURE.GeneralInfo. StudyIdentifiers.StudyIDT ype

	for the existing MSS/DER composer file, create an additional item and select "Master Record Identification (MRID)".		
Study ID	Report the relevant identification number	Text	LITERATURE.GeneralInfo.StudyIdentifiers.StudyID
Remarks	<p>If the study was not notified provide a justification to explain why the study is included in the dossier to meet the data requirements but was not included in the Notification of Studies database. Example 'Study commissioned before 27 March 2021'.</p> <p>This section should also be used to include justifications in cases where a study was notified and the NoS ID is reported but the notification date is after the starting date of the study (delayed notification)..</p>	Text area	LITERATURE.GeneralInfo.Remarks
Other study identifier(s)			
Attachments			LITERATURE.GeneralInfo.Attachments
Attachment type	<p>Select 'full study report' to identify the original study report. Only one set of attachments (original and sanitised) can be set to 'full study report'. Use 'other' to indicate the type of content of the other sets of attachments e.g. addendum</p> <p>For rat/plant/livestock metabolism studies:</p>	Open list	LITERATURE.GeneralInfo.Attachments.AttachmentType

	<ul style="list-style-type: none"> - if a MSS/DER composer file is newly created for this dossier (because it was not available in the existing collections of maps), the newly created MSS/DER composer file should be attached here. Select "other" and specify "MSS composer file" or "DER composer file". - if a MSS/DER composer file is already available in the existing collections of maps, it is required not to attach it in the dossier. Only the reference to the Individual MetaPath File Number (MAP-number) is required (cf. above instructions in "Other study identifier(s)"). 		
Attached confidential document	<p>The applicant has selected the option "publication (copyright not owned for reproduction)" from the drop-down list pertaining to the field "GeneralInfo.ReferenceType":</p> <p>a copy of the relevant publication in PDF format along with the relevant bibliographic references/ citations needs to be provided for scientific assessment purposes only.</p>	Single file attachment	LITERATURE.GeneralInfo. Attachments.AttachedDocuments


	<p>The uploaded attachment will not be included in published dossier but the citation will be published.</p> <p>The applicant has not selected the option "publication (copyright not owned for reproduction)" from the drop-down list pertaining to the field "GeneralInfo.ReferenceType":</p> <p>The original file only needs to be attached here if the non-confidential file uploaded under "Attached (sanitised) documents for publication" contains redactions. If a file is uploaded under this field, (a) confidentiality claim(s) must be submitted for each part of the file considered confidential via the related endpoint record and the information claimed confidential must be clearly boxed or earmarked consistently with the redactions applied in the corresponding non-confidential file. This file will not be published.</p>		
Attached (sanitised) document for publication	<p>The applicant has selected the option "publication (copyright not owned for reproduction)" from the drop-down list pertaining to the field "GeneralInfo.ReferenceType":</p> <p>Only a citation including the abstract of the relevant publication should be uploaded in this field. The uploaded attachment will be included in the published dossier.</p>	Single file attachment	LITERATURE.GeneralInfo.Attachments.AttachedSanitisedDocsForPublication

	<p>The applicant has not selected the option "publication (copyright not owned for reproduction)" from the drop-down list pertaining to the field "GeneralInfo.ReferenceType":</p> <p>any document uploaded here must be uploaded in their public (non-confidential) version. The public version will be published once the dossier has been considered valid/admissible. All elements therein claimed confidential should be sanitised. Save for the elements blackened, if applicable, content and layout-wise the public version must be fully identical with the confidential version. Upon conclusion of the confidentiality assessment, if applicable, a revised public version removing the redactions relating to confidentiality requests that were rejected in part or in full must be uploaded here.</p> <p>Other supporting documentation e.g. addendum can be uploaded.</p>		
Attachments			
Remarks	Additional remarks on the uploaded literature reference content can be added here	Text	LITERATURE.GeneralInfo.StudyIdentifiers.Remarks

Links to support material

Links to support materials

Practical arrangement for Notification of studies



UUID: b7a08e40-7dbd-4591-9d54-fec23c7bda03

General information

Reference Type
study report

Title*
An avian oral pathogenicity and toxicity study in the bobwhite

Author
An author

Year
1993

Bibliographic source
None

Testing facility
Laboratory A, Country B

Report date
1993-06-23

Report number
None

Study sponsor
Study sponsor

Study number
xxxxx123456

Other study identifier(s) + New item 📄 Import file ▼

#	Study ID type	Study ID	Remarks
1	Notification of Studies (NoS) ID	EFSA_2021_793478584756987	NOS_ID

Attachments + New item 📄 Import file ▼

#	Attachment type	Attached confidential document	Attached (sanitised) document
1	other: Raw data	None	BirdMeasuredEndpoints.csv
2	full study report	Full original study report.pdf	Sanitised Study Report.pdf

Remarks
None

Test material

Purpose

For the product: A detailed description of the composition used shall be provided.

Chemicals: The test material used should be essentially the same, for the purposes of toxicological, ecotoxicological, environmental and residue testing and assessment. In the case of studies in which dosing extends over a period (for example repeated dose studies), dosing shall be done using a single batch of active substance if stability permits. When tests shall be conducted using purified active substance the purity must be (≥ 980 g/kg) of stated specification otherwise a justification shall be provided in cases where the degree of purity achieved is less than 980 g/kg.

In case of renewals, if the new (proposed) representative formulation for the renewal is different to the former (reference) formulation, it should be demonstrated by the applicant that differences are minor for the different sections (ecotox, tox...) in case that data from the former (reference) formulation should also be used for the assessment of the new (proposed) formulation.

Test material must clearly identify the batches used as test material in the different studies included in the dossier. To facilitate the assessment of the compliance of the batches used in the (eco)toxicological studies with the technical specification (Template 1.1)

Microorganisms: Where studies are conducted using micro-organisms produced in the laboratory or in a pilot plant production system, the studies must be repeated using micro-organisms as manufactured, unless it can be demonstrated that the test material used is essentially the same for the purposes of the testing and assessment

Name	Instructions	Type	Field Path
Name	Number of the batch	Multi-line text	TEST_MATERIAL_INFORMATION.Name
Composition		Header 1	TEST_MATERIAL_INFORMATION.Composition
Composition			TEST_MATERIAL_INFORMATION.Composition.CompositionList
Type	Indicate for each component if it is a constituent, impurity or additive	Closed list	TEST_MATERIAL_INFORMATION.Composition.CompositionList.Type
Reference substance	Link to the reference substance for the component	Entity reference field	TEST_MATERIAL_INFORMATION.Composition.CompositionList.ReferenceSubstance
Concentration	Concentration of the component. For the chemical active substance and impurities this should be in g/kg.	Range with open list (Decimal)	TEST_MATERIAL_INFORMATION.Composition.CompositionList.Concentration
Remarks	Specific remarks related to the concentration of the component reported	Multi-line text	TEST_MATERIAL_INFORMATION.Composition.CompositionList.Remarks
Composition			

Composition / purity: other information	'analytical grade' or 'technical grade' can be used to provide a qualitative indication of the purity for active substances where quantification is not technically possible	Open list with remarks	TEST_MATERIAL_INFORMATION.Composition.CompositionPurityOtherInformation
Other characteristics		Header 2	TEST_MATERIAL_INFORMATION.Composition.OtherCharacteristics
Test material form	Select the form of the test material	Open list with remarks (2000)	TEST_MATERIAL_INFORMATION.Composition.OtherCharacteristics.TestMaterialForm
Details on test material	Provide the expiry date. Differences between non-radio labelled and radio labelled can be indicated in this field.	Text template	TEST_MATERIAL_INFORMATION.Composition.OtherCharacteristics.DetailsOnTestMaterial
Confidential details on test material	The percent difference in concentration from the reference specification can be indicated for the active substance and impurities	Text template	TEST_MATERIAL_INFORMATION.Composition.OtherCharacteristics.ConfidentialDetailsOnTestMaterial

Links to support materials

https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_guidance_equivalence-chemical-substances_en.pdf

Template 1.1– Template for presentation the assessment for the equivalence of batches
(<https://doi.org/10.5281/zenodo.4557366>)

Endpoint Summaries – Common blocks

Links to support material:

Template to be used for the List of Endpoints SANCO/12483/2014– rev. 3

https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_doss_temp-list-endpoints_rev-3.pdf

Administrative data summary – common block

Name	Instructions	Type	Field Path
Administrative data		Header 1	AdministrativeDataSummary
	Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants Use the Confidentiality flag and/or the Regulatory purpose flag to filter out data in subsequent operations such as exporting, printing or dossier creation. A justification is required when the confidentiality flag is set.	Confidentiality	AdministrativeDataSummary.DataProtection
Link to relevant study record(s)	Provide here the link to the most relevant study(ies) from which the key value for safety assessment is extrapolated.	Header 1	LinkToRelevantStudyRecord
Study name / type		Endpoint reference list	LinkToRelevantStudyRecord.Link
Results		Read-only	LinkToRelevantStudyRecord.Results
Description of key information	Report Information to support the most relevant endpoint. Ensure that information presented includes the information specified in the Template to be	Header 1	KeyInformation

Study name / type	The study giving rise to the highest concern should be chosen. The following factors, among others, should be taken into account when the robust study summary is selected: quality of the study (e.g. Klimisch score), duration of the study, whether or not the study is GLP. Available epidemiological data are preferred provided that they are reliable and relevant.	LinkToRelevantStudyRecords.StudyNameType
Results		LinkToRelevantStudyRecords.Results

Administrative data None None

Description of key information

None

Key value for chemical safety assessment

Skin irritation / corrosion

Link to relevant study records

Study name / type

Select

press Esc to close

Endpoint conclusion



Endpoint conclusion

None

Endpoint conclusion block (quality of database)

Name	Instructions	Type	Field Path
Endpoint conclusion		Header 3	EndpointConclusion
Endpoint conclusion	Adverse effect observed" should be chosen if mortality or severe effects were observed in any of the studies. "No adverse effect observed" should be chosen if no animals died or no severe	Closed list	EndpointConclusion.EndpointConclusion

	effects were observed at limit dose level. If "No study available" is chosen, a justification needs to be provided.		
Dose descriptor	Type of reference value reported e.g. LD50. Reference value derived from the reported endpoint study records	Closed list	EndpointConclusion.EffectLevelUnit
Value		Range with closed list (Decimal)	EndpointConclusion.EffectLevelValue
Quality of whole database	The following factors should be considered: - To what extent the whole available information meets the data requirements under EU Pesticide legislation. - Reliability and consistency across different studies (i.e. quality of testing methods, size and statistical power of study design, biological plausibility, dose-response relationships and statistical testing)	Multi-line text	EndpointConclusion.DataBaseQuality

Administrative data  None  None

Description of key information

None

Key value for chemical safety assessment

Acute toxicity: via oral route

Link to relevant study records

Study name / type

None

Endpoint conclusion

Endpoint conclusion

None

Dose descriptor

None

Value

None

Quality of whole database

None

Endpoint conclusion block (Species version)

Name	Instructions	Type	Field Path
Endpoint conclusion		Header 3	EndpointConclusion
Endpoint conclusion	Add the relevant endpoint conclusions by picking from provided list. In case where no picklist is provided, please add the relevant species / organ / system which was investigated in the study.	Closed list	EndpointConclusion.EndpointConclusion
Dose descriptor	If it is a corrected value, please indicate why.	Closed list	EndpointConclusion.EffectLevelUnit
		Unit measure with Closed List (Decimal)	EndpointConclusion.EffectLevelValue
Study duration		Closed list	EndpointConclusion.TestType
Experimental exposure time per week (hours/week)	In this field, you should add the experimental exposure conditions in hours per week. This can be done considering the hours per day and the days per week the animals were exposed.	Decimal	EndpointConclusion.ExperimentalExposureTimePerWeek

Species		Open list	EndpointConclusion.Species
Quality of whole database	The following factors should be considered: - To what extent the whole available information meets the data requirements under EU Pesticide legislation. - Reliability and consistency across different studies (i.e. quality of testing methods, size and statistical power of study design, biological plausibility, dose-response relationships and statistical testing)	Multi-line text	EndpointConclusion.DataBaseQuality
System		Open list	EndpointConclusion.System
Organ		Multi select open list	EndpointConclusion.Organ

Endpoint conclusion

Endpoint conclusion

adverse effect observed

Dose descriptor

NOAEL

3.3 mg/kg bw/day

Study duration

chronic

Experimental exposure time per week (hours/week)

1

Species

dog

Quality of whole database

ok

System

other: general appearance

Organ

✓ other: Body weight loss, clinical symptoms

Discussion (Header 1) – common block

Name	Instructions	Type	Field Path
Additional information	<p>Provide additional information related to the endpoint, for example:</p> <ul style="list-style-type: none"> - information on the potential data gaps - relevance of the results for the risk assessment - the rationale for the choice of the key study(ies) and the choice for the key value that characterizes the endpoint - the rationale for any user-derived values for the sake of transparency -the possible reasons for differentiating results when several studies were identified to be relevant for the assessment. <p>If there is no additional information to be reported this field may be left empty.</p>	Header 1	Discussion
	Provide any additional information related to the endpoint.	Rich text area	Discussion.Discussion
Attached background material	Provide the original version of any document that contains confidential material		Discussion.AttachedBackgroundMaterial
Attached confidential document	<p>Provide any additional documents relevant for the submission, not already provided under the methods or results section or in the full study report.</p> <p>Examples are:</p>	Single file attachment	Discussion.AttachedBackgroundMaterial.AttachedDocument

	<ul style="list-style-type: none"> - Scientific publication - GLP documentation - (Q)SAR: supporting information - Data analysis file (calculation of parameters) - Data supporting the reliability and sensitivity of the method - Specific information on the test material or test system - Justification - Other <p>For test guidelines that provide a reporting template (data analysis file), the file must be completed and can be uploaded here if not yet done in the results section.</p> <p>The original file only needs to be attached here if the non-confidential file uploaded under "Attached (sanitised) documents for publication" contains redactions. If a file is uploaded under this field (a) confidentiality claim(s) must be submitted for each part of the file considered confidential and the information claimed confidential must be clearly boxed or earmarked consistently with the redactions applied in the corresponding non-confidential file. This file will not be published.</p>		
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Attached (sanitised) documents for publication	A non-confidential version of any submitted background material must be uploaded here. These will be published once the dossier has been considered valid/admissible. All elements therein claimed confidential should be sanitised. Save for the blackened elements, if applicable, content and layout-wise the public version must be fully identical with the confidential version. Upon conclusion of the confidentiality assessment, if applicable, a revised non-confidential version removing the redactions relating to confidentiality requests that were rejected in part or in full must be uploaded here.	Single File Attachment	Discussion.AttachedBackgroundMaterial.AttachedSanitisedDocsForPublicationDiscussion.AttachedSanitisedDocsForPublication
Remarks	As appropriate, include remarks, e.g., a short description of the content of the attached document if the file name is not self-explanatory.	Text	Discussion.AttachedBackgroundMaterial.Remarks
Attached background material			

Additional information

None

[Attached background material](#)

 New item

 Import file 

#	Attached confidential docu...	Attached (sanitised) docum...	Remarks
1	None	Animal model 2017 (2).xls	OECD Animal burden calculator

Study naming – best practices

- 'Endpoint study records should not include author names'
- 'It is recommended to use the Year of the study, the endpoint and additional relevant context where a multiple studies exist for an endpoint.'

Examples:

- Analytical methods: 2007_Post-approval control and monitoring purposes_cereal
- Metabolism in plants: 2009_primary_crop_metabolism_wheat
- Feeding studies: 2010_residues in livestock_lactating_cows
- Biodegradation in soil: 2011_biodegradation in soil simulation_anaerobic
- Toxicity aquatic invertebrates: 2012_short term toxicity_daphnia magna
- Good agricultural practices (GAP).001: Crop_zone.001, ex. Apples_NEU.001

The screenshot displays the IUCLID software interface. On the left is a navigation pane with a tree structure of sections: 1 Identity of the plant protection product and applicant (6), 2 Physical, chemical and technical properties of the plant protection product (4), 3 Data on application (12), 4 Further information on the plant protection product (1), 5 Analytical methods (2), 6 Efficacy data (3), 7 Toxicological studies on the plant protection product (8), 8 Residues in or on treated products, food and feed, and 9 Fate and behaviour in the environment. Under section 5, two sub-items are listed: '2001_Monitoring purposes_Cereal' and '2005_Method_Risk_Assessment_Cereal'. The main panel on the right is titled '2001_Monitoring purposes_Cereal' and shows the 'Administrative data' section. It includes fields for 'Endpoint' (methods for post-approval control and monitoring purposes), 'Type of information' (experimental study), 'Adequacy of study' (key study), 'Robust study summary' (checked), 'Used for classification' (unchecked), 'Used for SDS' (unchecked), 'Study period' (2001), and 'Reliability' (1 (reliable without restriction)).

Endpoint studies – Common blocks

Administrative data – common block

Purpose

Describes how to fill in all the administrative data available on a particular endpoint study, entered into the relevant fields. This information includes the type of information, adequacy of study, study period, reliability, data waiving.

Name	Instructions	Type	Field Path
Administrative data		Header 1	AdministrativeData
	Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	See Confidentiality of dossiers	AdministrativeData.DataProtection
Endpoint	Select from the picklist the relevant endpoint. An endpoint must always be selected when entering data into an Endpoint Study Record. This also applies to 'data waiving'	Closed list with remarks	AdministrativeData.Endpoint
Type of information	Indicate 'experimental study' or 'read-across from similar mixture/product' or 'read-across from supporting substance'	Open list with remarks	AdministrativeData.StudyResultType

	(structural analogue or surrogate)' or 'read-across based on grouping of substances (category approach)' unless the information is retrieved from a literature search in this case indicate 'other': 'Study from literature search'		
Adequacy of study	<p>Indicate the purpose of the record selecting the adequacy in terms of usefulness for fulfilling the information requirements for the hazard/risk assessment.</p> <ul style="list-style-type: none"> • A key study is a study that has been identified as most suitable to describe an endpoint from the perspective of quality, completeness and representativeness of data. • A supporting study provides some additional information to support the conclusions from the key study/ies or the weight of evidence approach. • A weight of evidence is selected to indicate that an endpoint study record contributes to a weight of evidence approach. • Disregarded due to major methodological deficiencies is a study that is 	Closed list	AdministrativeData.PurposeFlag

	<p>available to the applicant but is not taken into account because of lack of reliability or because the study is obsolete.</p> <ul style="list-style-type: none"> • Other information is other available information which does not directly contribute to the conclusions for the setting the endpoint <p>For each data requirement at least one 'key study' or two records identified as 'weight of evidence' is expected unless data waiving has been indicated.</p> <p>Where 'key study' or 'weight of evidence' is selected, the Validation assistant checks for document completeness.</p>		
Robust study summary	<p>Set this flag if relevant for the respective regulatory programme. It is used as filter for printing or exporting records flagged as 'Robust Study Summary' or in combination with 'Adequacy of study'. If not relevant, disregard this field.</p>	Check box	AdministrativeData.RobustStudy
Used for classification	<p>Set this flag if relevant for the respective regulatory programme or if otherwise useful as filter for printing or exporting records flagged as 'Used for classification'.</p>	Check box	AdministrativeData.UsedForClassification

	<p>If not relevant, disregard this field.</p> <p>Not relevant for micro-organisms since they do not fall under the CLP Regulation.</p>		
Used for SDS	Not relevant for EU-PPP	Check box	AdministrativeData.Use dForMSDS
Study period	<p>Indicate the period during which the study was conducted, i.e. start and end date.</p> <p>For 'Notified' studies this should be after the date of notification</p>	Text	AdministrativeData.Stu dyPeriod
Reliability	<p>The term reliability defines the inherent quality of a test report or publication.</p> <p>In field Reliability, enter a reliability score as judged at your discretion, i.e. 1 (reliable without restriction), 2 (reliable with restrictions), 3 (not reliable) or 4 (not assignable).</p> <p>The "other:" option may be selected if this scoring system is not used.</p> <p>Studies indicated as key study must have a reliability score of 1 or 2.</p> <p>The validation check will verify consistency between 'Adequacy of study' field and 'Reliability' field (EU_PPP_007, EU_PPP_003).</p> <p>Further explanations on the reliability assessment can be provided in the 'Rationale for reliability incl. deficiencies' field.</p> <p>In terms of 'Acceptability / Reliability'</p>	Open list	AdministrativeData.Reli ability

	<p>Key studies and weight of evidence studies are considered to have 'Acceptability / Reliability' = Yes.</p> <p>A supporting study is considered to be 'Supportive only'</p> <p>The others are considered to have 'Acceptability / Reliability' = No.</p>		
Rationale for reliability incl. deficiencies	<p>Describe the rationale for the reliability score chosen considering the possible impact of deficiencies and/or implications on test results.</p> <p>The deviations from the guideline should be described in 'Test guideline' section but the impact of these deviations should be considered in the rationale for reliability.</p> <p>When assessing an older study against the current guideline, the current guideline can be specified in this field</p> <p>Standard justifications from picklist may be sufficient in some cases. Otherwise select 'Other' and provide for additional explanation in the 'Remarks' field.</p>	Open list with remarks (32000)	AdministrativeData.RationalReliability
Data waiving	<p>If no 'key study' or 'weight of evidence' study is provided for a data requirement then data waiving must be completed. The validation check will flag when this field</p>	Closed list	AdministrativeData.DataWaiving



	<p>must be completed (EU_PPP_013).</p> <p>Select the reason for data waiving or other and provide a justification in 'Justification for data waiving' field.</p>		
Justification for data waiving	<p>In addition to the more generic justification selected in the preceding field 'Data waiving', it is possible to provide here a more detailed justification.</p> <p>To this end one of the specific standard phrase(s) can be selected if it/they give an appropriate rationale of the description given in the preceding field 'Data waiving'.</p> <p>If you select the option 'Other' you need to indicate the type of data waiving you are submitting. Validation check will flag uncomplete compiling (EU_PPP_002).</p>	Multi select open list with remarks (32000)	AdministrativeData.DataWaivingJustification
Justification for type of information	<p>This field can be used for entering free text. Please complete field only when submitting a waiving justification</p>	Text template	AdministrativeData.JustificationForTypeOfInformation
Attached justification	<p>A document can be uploaded to support data waiving, but it is recommended to complete in full the data waiving fields</p>		AdministrativeData.AttachedJustification

Attached justification		Single file attachment	AdministrativeData.AttachedJustification.AttachedJustification
Reason / purpose		Closed list with remarks	AdministrativeData.AttachedJustification.ReasonPurpose
Attached justification			
Cross-reference	<p>In case the study has been reported for another data requirement use cross reference to link to the study to this section.</p> <p>The creation of duplicate versions of endpoint studies should be avoided.</p> <p>Cross reference should be used to link to an 'Analytical Methods' document when a specific method is used in a study. This allows an overview of methods used in different studies e.g. toxicology and ecotoxicology</p>		AdministrativeData.CrossReference
Reason / purpose for cross-reference	If the cross reference is used to link to an 'Analytical Methods' document, please use "reference to other study" and specify in the remark "Validation data for the analytical method(s) used in the present study"	Open list with remarks	AdministrativeData.CrossReference.ReasonPurpose
Related information		Endpoint reference field	AdministrativeData.CrossReference.RelatedInformation
Remarks		Text area	AdministrativeData.CrossReference.Remarks
Cross-reference			

Links to support materials:

Appendix to: EFSA (European Food Safety Authority), 2011. Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009. EFSA Journal 2011;9(2):2092. 49 pp. doi:10.2903/j.efsa.2011.2092

<https://efsa.onlinelibrary.wiley.com/action/downloadSupplement?doi=10.2903%2Fj.efsa.2011.2092&file=efs22092-sup-0001-Appendix.pdf>

Administrative data	 None  EU: PPP
Endpoint stability of residues in stored commodities	
Type of information experimental study	
Adequacy of study key study	
<input checked="" type="checkbox"/> Robust study summary	
<input type="checkbox"/> Used for classification	
<input type="checkbox"/> Used for SDS	
Study period 6. April 1993 - 27. April 1995	
Reliability 1 (reliable without restriction)	
Rationale for reliability incl. deficiencies guideline study	
Data waiving None	
Justification for data waiving None	
Justification for type of information None	

Reason / purpose for cross-reference

reference to other study

Validation data for the analytical method(s) used in the present study

Related information

 AnalyticalMethods (Endpoint Study Record) | 4.1.1 NEW_Adolph S. (2013)

Remarks

None

Data waiving

other justification

Justification for data waiving

✓ other: Study not needed due to the use described in the GAP document

Data source (Literature Reference) – common block

Name	Instructions	Type	Field Path
Data source		Header 1	DataSource
Reference	Link to Literature reference	Literature reference list	DataSource.Reference
Data access	Select appropriate indication for data access. Enter 'Not applicable' if the summary consists of information that is commonly accessible such as guidance on safe use. Select 'data submitter has permission to refer' if the information requirement can be covered based on a permission to refer to old data as issued by the relevant regulatory agency. In addition, provide, in the adjacent free-text field, the statement according to instructions you received from the relevant regulatory authority together with the permission to refer.	Open list with remarks	DataSource.DataAccess
Data protection claimed	Indicate as appropriate. Note: 'yes' should be selected only if 'Data submitter is data owner' or 'Data submitter has Letter of Access'. Options 'yes, but willing to share' or 'yes, but not willing to share' may be relevant for specific regulatory	Closed list with remarks	DataSource.DataProtectionClaimed

	<p>programmes where the submitter is requested to indicate whether he is willing to share studies conducted (e.g. with vertebrates).</p> <p>In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. 'for justification see attached document X')</p>		
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Additional considerations:

The applicant must ensure that terms and conditions asserted by any rightsholder of studies, information or data submitted to EFSA are fully satisfied. The applicant may consult with copyright licensing authorities (i.e. at national level) for guidance on purchasing the appropriate licenses to provide studies, information or data to EFSA, taking into account the proactive disclosure requirements as detailed above. For publications already available to the public upon payment of fees (e.g. studies published in scientific journals) for which the applicant does not have or cannot obtain IPRs for the purposes of the proactive public disclosure requirements, the applicant must provide (a) a copy of the relevant publications along with the relevant bibliographic references/ citations for scientific assessment purposes only, in the confidential version of its application and (b) these relevant bibliographic references/citations where these publications are available to the public in the non-confidential version of its application for public dissemination on the OpenEFSA portal.

Data source

Reference

 study report | Flammability of solids | An Author | 2000

Data access

data no longer protected

Data protection claimed

yes

Test material – common block

Name	Instructions	Field path
Test material	All TM batches should be entered in the TM entity manager and then the appropriate TM selected	TestMaterials
Test material information	Select the appropriate Test material	TestMaterials.TestMaterialInformation
Additional test material information	Select additional Test material i entities if relevant. For example, in longer term studies where more than one batch of test material has been applied or there may be differences between the labelled and unlabeled test materials.	TestMaterials.AdditionalTestMaterialInformation
Specific details on test material used for the study	<p>Use this field for reporting specific details on the test material as used for the study if they differ from the starting material specified under 'Test material information'. This can include information on the pre-defined items, but not all or additional ones may be relevant. The determination shall also include quantities of unknown materials, if any, to account for 100% of the sample</p> <p>Use free text template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g., OECD Programme, EU pesticides, Pesticides NAFTA or EU REACH) thereof.</p> <p>If applicable, relevant available information on the following items should be given:</p> <p>RADIOLABELLING INFORMATION</p> <ul style="list-style-type: none"> - Radiochemical purity - Specific activity - Locations of the label 	TestMaterials.SpecificDetailsOnTestMaterialUsedForTheStudy

	<p>- Expiration date of radiochemical substance</p> <p>STABILITY AND STORAGE</p> <p>CONDITIONS OF TEST MATERIAL</p> <p>- Storage condition of test material</p> <p>- Stability under test conditions</p> <p>- Solubility and stability of the test substance in the solvent/vehicle</p> <p>- Reactivity of the test substance with the solvent/vehicle or the cell culture medium</p> <p>TREATMENT OF TEST MATERIAL PRIOR TO TESTING</p> <p>- Treatment of test material prior to testing (e.g., warming, grinding)</p> <p>- Preliminary purification step</p> <p>- Final dilution of a soluble solid, stock liquid, or gel (e.g., neat liquid, stock diluted liquid, or dissolved solid) to final concentration and the solvent(s) used</p> <p>- Final preparation of a solid (e.g., stock crystals ground to fine powder using a mortar and pestle)</p> <p>FORM AS APPLIED IN THE TEST (if different from that of starting material)</p> <p>Specify the relevant form characteristics if different from those in the starting material, such as state of aggregation, shape of particles or particle size distribution.</p> <p>FORMULATED PRODUCT (for biocides/pesticides)</p> <p>Description of the formulation, e.g., formulated product for foliar application; formulated product soil application; solution in organic solvent for soil application; formulated product seed treatment; solution in organic solvent seed treatment.</p> <p>OTHER SPECIFICS</p>	
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	Provide any other relevant information needed for characterizing the tested material.	
Specific details on test material used for the study (confidential)	<p>Use this field for reporting specific details on the test material as used for the study if they differ from the starting material specified under 'Test material information'. This can include information on the pre-defined items, but not all or additional ones may be relevant. Use free text template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g., OECD Programme, EU pesticides, Pesticides NAFTA or EU REACH) thereof. If applicable, relevant available information on the following items should be given:</p> <p>RADIOLABELLING INFORMATION</p> <ul style="list-style-type: none"> - Radiochemical purity - Specific activity - Locations of the label - Expiration date of radiochemical substance <p>STABILITY AND STORAGE CONDITIONS OF TEST MATERIAL</p> <ul style="list-style-type: none"> - Storage condition of test material - Stability under test conditions - Solubility and stability of the test substance in the solvent/vehicle - Reactivity of the test substance with the solvent/vehicle or the cell culture medium <p>TREATMENT OF TEST MATERIAL PRIOR TO TESTING</p>	TestMaterials.SpecificDetailsOnTestMaterialUsedForTheStudyConfidential

	<ul style="list-style-type: none"> - Treatment of test material prior to testing (e.g., warming, grinding) - Preliminary purification step - Final dilution of a soluble solid, stock liquid, or gel (e.g., neat liquid, stock diluted liquid, or dissolved solid) to final concentration and the solvent(s) used - Final preparation of a solid (e.g., stock crystals ground to fine powder using a mortar and pestle) <p>FORM AS APPLIED IN THE TEST (if different from that of starting material)</p> <p>Specify the relevant form characteristics if different from those in the starting material, such as state of aggregation, shape of particles or particle size distribution.</p> <p>FORMULATED PRODUCT (for biocides/pesticides)</p> <p>Description of the formulation, e.g., formulated product for foliar application; formulated product soil application; solution in organic solvent for soil application; formulated product seed treatment; solution in organic solvent seed treatment.</p> <p>OTHER SPECIFICS</p> <p>Provide any other relevant information needed for characterizing the tested material.</p>	
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Material and methods – common block

Name	Instructions	Type	Field Path
Test guideline	Indicate according to which test guideline the study was conducted. If no test guideline was explicitly followed, but the methodology used		Guideline

	<p>is equivalent or similar to a specific guideline, you can indicate so in the 'Qualifier' subfield preceding the field 'Guideline'.</p> <p>Copy this block of fields for specifying more than one guideline (e.g. US EPA in addition to OECD guideline).</p>		
Qualifier	<p>Select appropriate qualifier, i.e.</p> <ul style="list-style-type: none"> - 'according to guideline' (if a given test guideline was followed); - 'equivalent or similar to guideline' (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - 'no guideline followed' (if none of above qualifiers apply. If so, fill in field 'Principles of method if other than guideline'); - 'no guideline available' (if so, fill in field 'Principles of method if other than guideline'); - 'no guideline required' (if so, fill in field 'Principles of method if other than guideline'); 	Closed list	Guideline.Qualifier
Guideline	<p>Select the applicable test guideline, e.g. 'OECD Guideline xxx'. If the test guideline used is not listed, choose 'other:' and specify the test guideline in the related text field.</p> <p>Information on the version and date of the guideline used and/or any other specifics can be entered in the next</p>	Open list	Guideline.Guideline

	<p>field 'Version / remarks'.</p> <p>If no test guideline can be specified, this should be indicated in the preceding field 'Qualifier'. The method used should then be shortly described in the field 'Principles of method if other than guideline', while details can be given in other distinct fields.</p> <p>Please note: Test guidelines used for the validation of (Q)SAR models should be reported in the description of the relevant model in field 'Justification for type of information' or 'Attached justification'.</p>		
Version / remarks	<p>In this text field, you can enter any remarks as applicable, particularly:</p> <ul style="list-style-type: none"> - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline); - To indicate if the study was performed prior to the adoption of the test guideline specified; - To indicate if the methodology used was based on an extension of the test guideline specified; - To indicate what protocol was followed for methods that allow 	Multi-line text	Guideline.VersionRemarks

	the optional determination of more than one parameter if this cannot be indicated in a distinct field of the Materials and methods section.		
Deviations	In case a test guideline or other standardised method was used, indicate if there are any deviations. Briefly state relevant deviations in the supplementary remarks field (e.g. 'other test system used', 'different exposure duration'); details should be described in the respective fields of the section MATERIALS AND METHODS.	Closed list with remarks	Guideline.Deviation
Test guideline			
Principles of method if other than guideline	If no guideline was followed, include a description of the principles of the test protocol or estimated method used in the study. As appropriate use either of the pre-defined freetext template options for 'Method of non-guideline study' or '(Q)SAR'. Delete / add elements and edit text set in square brackets [...] as appropriate. For a non-guideline experimental study a high-level freetext template can be used for summarising the principle of test, test conditions and parameters analysed / observed. Details should be entered in appropriate distinct fields of section	Text template	MethodNoGuideline

	MATERIALS AND METHODS if available. Also provide a justification for using this method if appropriate.		
GLP compliance	Indicate whether the study was conducted following Good Laboratory Practice or not. In case 'yes' is selected, a Quality Assurance (QA) statement must be provided with the report. You can give an explanation in the supplementary remarks field, e.g. for explaining why GLP was not complied with or for specifying which (national) GLP was followed.	Closed list with remarks	GLPComplianceStatement
Other quality assurance	Indicate any non-GLP quality assurance system adhered to, if any.	Open list with remarks	OtherQualityAssurance
Type of method	Indicate which type of method was used according to the options provided in the test guideline or, if no guideline was applied, according to the methodology used.	Closed list with remarks	MethodType

Links to support material:

[GEP https://www.eppo.int/ACTIVITIES/plant_protection_products/gep](https://www.eppo.int/ACTIVITIES/plant_protection_products/gep)

Materials and methods

Test guideline

 New item  Import file 

#	Qualifier	Guideline	Version / remarks	Deviations
1	according to guideline	OECD Guideline 407 (Repeated Dose 28-Day Oral Toxicity Study in Rodents)	1981	None

Principles of method if other than guideline

None

GLP compliance

yes

This study was carried according to GLP principles but not subjected to periodic quality assurance evaluation.

Test animals (OHT: Repeated dose toxicity)

Name	Instructions	Field path
Test animals		TestAnimals
Species	Select species as appropriate. If not available from picklist, select 'other' and specify.	TestAnimals.Species
Strain	Select strain as appropriate. If not available from picklist, select 'other' and specify.	TestAnimals.Strain
Details on species / strain selection	For robust study summaries or as requested by the regulatory programme, provide details explaining the choice of species and strain.	TestAnimals.DetailsOnSpeciesStrain Selection
Sex	Select as appropriate. If females were used, indicate in field "Details on test animals and environmental conditions" whether nulliparous and non-pregnant.	TestAnimals.Sex
Details on test animals or test system and environmental conditions	Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD Programme, EU pesticides, Pesticides NAFTA or EU REACH) thereof. Explanations: - Diet: Describe type of diet (e.g. conventional laboratory diet / caloric restriction) and whether it was provided ad	TestAnimals.OrganismDetails

	libitum. - Water: Describe type (e.g. drinking water) and whether it was provided ad libitum. - Food quality and water quality: provide analytical information on the nutrient and dietary contaminant levels. Similarly provide analytical information on the drinking water used in the study. - IN-LIFE DATES: If required, specify the in-life dates (i.e. the phase of a study following treatment in which the test system is alive/growing).	
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Test animals

Species

rat

Strain

other: Tif RAIf

Sex

male/female

Details on test animals or test system and environmental conditions

Weight at study initiation: 166-227 g

Source: xxx

Initial age: 7-8 weeks

Husbandry: Caging in Macrolon cages type 4 (5 animals per cage) with standardized soft wood bedding. The animal room was air conditioned:

Temperature: 22+/-3°C

Relative humidity: 55+/-15%

12 hours light/day, approximately 15 air changes/h

Acclimatization period: at least 5 days

Any other information on materials and methods incl. tables - (H2) – common block

Name	Instructions	Field Path
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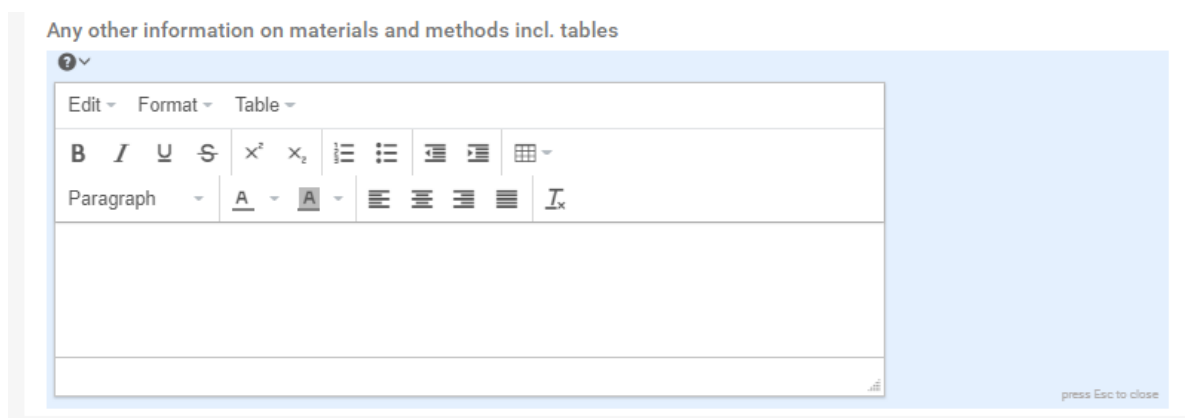
Any other information on materials and methods incl. tables		AnyOtherInformationOnMaterialsAndMethodsInclTables
	<p>In this field, you can enter any information on materials and methods, for which no distinct field is available, or transfer free text from other databases. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. You can also upload any htm or html document.</p> <p>Note: One rich text editor field each is provided for the MATERIALS AND METHODS and RESULTS section. In addition the fields 'Overall remarks' and 'Executive summary' allow rich text entry.</p>	AnyOtherInformationOnMaterialsAndMethodsInclTables.OtherInformation

Any other information on materials and methods incl. tables

Any other information on results incl. tables Block

Name	Instructions	Field path
Any other information on results incl. tables		AnyOtherInformationOnResultsInclTables
	<p>In this field, you can enter any other remarks on results. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet</p>	AnyOtherInformationOnResultsInclTables.OtherInformation

	document, provided it was converted to the HTML format. Note: One rich text editor field each is provided for the MATERIALS AND METHODS and RESULTS section. In addition the fields 'Overall remarks' and 'Executive summary' allow rich text entry.	
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Results of examinations BLOCK (OHT: Repeated dose toxicity: oral)

Name	Instructions	Data type	IUCLID6 Path
Clinical signs	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ObservClinSigns
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data,	Text area	DescriptionIncidenceAndSeverityObservClinSigns

	include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Dermal irritation (if dermal study)	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ObservDermalIrritationIfDermalStudy
Description (incidence and severity)		Text area	DescriptionIncidenceAndSeverityObservDermalIrritationIfDermalStudy
Dermal irritation		Closed list	ObservDermalIrritation
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the	Text area	DescriptionIncidenceAndSeverityObservDermalIrritation

	<p>toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Mortality	Indicate whether mortality was observed and whether it was treatment-related or not.	Closed list	ObservMortality
Description (incidence)	Describe the incidence of mortality by sex and dose group. An explanation should be provided when there was a need to humanely sacrifice animals in pain or showing signs of severe and enduring distress.	Text area	DescriptionIncidenceMortality
Body weight and weight changes	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ObservBodyweight
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results	Text area	DescriptionIncidenceAndSeverityObservBodyweight

	incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Food consumption and compound intake (if feeding study)	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ObservFoodConsum
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory	Text area	DescriptionIncidenceAndSeverityObservFoodConsum

	programme some form of a table(s) (predefined table) may be mandatory.		
Food efficiency	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ObservFoodEfficiency
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	DescriptionIncidenceAndSeverityObservFoodEfficiency
Water consumption and compound intake (if drinking water study)	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ObservWaterConsum

Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	DescriptionIncidenceAndSeverityObservWaterConsumum
Ophthalmological findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ObservOphthalm
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows,	Text area	DescriptionIncidenceAndSeverityObservOphthalm

	<p>whether the effects are reversible or irreversible.</p> <p>Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p> <p>NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Haematological findings	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	ObservHaematol
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.</p> <p>Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should</p>	Text area	DescriptionIncidenceAndSeverityObservHaematol

	<p>mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Clinical biochemistry findings	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	ObservClinChem
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s)</p>	Text area	DescriptionIncidenceAndSeverityObservClinChem

	(predefined table) may be mandatory.		
Endocrine findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	EndocrineFindings
Description (incidence and severity)	<p>Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen.</p> <p>Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p> <p>NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>	Text area	DescriptionIncidenceAndSeverityEndocrine
Urinalysis findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ObservUrin
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect	Text area	DescriptionIncidenceAndSeverityObservUrin

	<p>related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.</p> <p>Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p> <p>NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Behaviour (functional findings)	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ObservNeurobehaviour
Description (incidence and severity)	<p>Where relevant describe functional investigations in relation to motor activity, sensory function, grip strength or bizarre behaviour (e.g. walking backwards).</p> <p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the</p>	Text area	DescriptionIncidenceAndSeverityObservNeurobehaviour

	<p>effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.</p> <p>Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p> <p>NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Immunological findings	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	ImmunologicalFindings
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.</p> <p>Particularly with comprehensive data, include a table in the rich text field 'Any other information on results</p>	Text area	DescriptionIncidenceAndSeverityImmunologicalFindings

	incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Organ weight findings including organ / body weight ratios	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ObservOrganWeights
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory	Text area	DescriptionIncidenceAndSeverityObservOrganWeights

	programme some form of a table(s) (predefined table) may be mandatory.		
Gross pathological findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ObservGrpathol
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	DescriptionIncidenceAndSeverityObservGrpathol
Neuropathological findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ObservNeuropathol

Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	DescriptionIncidenceAndSeverityObservNeuropathol
Histopathological findings: non-neoplastic	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ObservHistopathol
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows,	Text area	DescriptionIncidenceAndSeverityObservHistopathol

	<p>whether the effects are reversible or irreversible.</p> <p>Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p> <p>NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Histopathological findings: neoplastic	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	ObservHistopatholNeoplastic
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.</p> <p>Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should</p>	Text area	DescriptionIncidenceAndSeverityObservHistopatholNeoplastic

	<p>mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p> <p>NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.</p>		
Other effects	<p>Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.</p>	Closed list	OtherEffects
Description (incidence and severity)	<p>Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).</p> <p>NOTE: Depending on the regulatory programme some form of a table(s)</p>	Text area	DescriptionIncidenceAndSeverityOtherEffects

	(predefined table) may be mandatory.		
Details on results	Provide any other relevant details if not entered in the specific "Description" fields for the examined parameters.	Text area	DetailsOnResults

Results and discussion

Results of examinations

Clinical signs

effects observed, treatment-related

Description (incidence and severity)

Beginning with day 5 of treatment all male animals of group 4 (200 mg/kg) showed symptoms like apathia, ruffled fur, hunched posture, altered locomotion, ptosis, muscular weakness and in some cases salivation, ventral body position and bluish discoloration of the tail. No clinical symptoms were noted in all other treated male groups. Only one female (group 4, 200 mg/kg) showed similar symptoms like apathia, ruffled fur and hunched body position prior to death. Female number 60 (group 2, 5 mg/kg) died following misapplication by gavage.

Mortality

mortality observed, treatment-related

Description (incidence)

All treated males of group 4 (200 mg/kg bw.) died between day 7 and 10 of the treatment, while only one treatment-related death occurred in female group 4 (200 mg/kg). Female number 60 (group 2, 5 mg/kg bw.) died from causes unrelated to the treatment (misapplication) and female number 47 (control) died following blood withdrawal at scheduled sacrifice. No other deaths were registered during the course of the study.

Body weight and weight changes

effects observed, treatment-related

Description (incidence and severity)

The mean body weight of treated male group 4 (200 mg/kg) was depressed at week 1 prior to death of the animals. Further, the mean body weight of treated male group 3 (40 mg/kg) was slightly and that of female group 4 (200 mg/kg) was significantly depressed. The mean body weight of all other treated male and female groups was comparable to that of the respective controls (see Table 1)

Food consumption and compound intake (if feeding study)

effects observed, treatment-related

Description (incidence and severity)

The mean food consumption of male group 4 (200 mg/kg) was markedly reduced during the first week. Further, the mean food consumption in male group 3 (40 mg/kg) and in female group 4 (200 mg/kg) was depressed. The mean feed consumption in all other treated male and female groups was similar to that of the respective control groups during the whole experiment. No statistical analysis was performed.

Effect levels BLOCK (OHT 67-69, 72-74)

Name	Instructions	Data type	Field path
			Efflevel
Key result	Set this flag for identifying the key information which is of potential relevance for	Check box	Efflevel.KeyResult

	hazard/risk assessment or classification purpose. Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field.		
Dose descriptor	As appropriate, include remarks, e.g. a short description of the content of the attached document if the file name is not self-explanatory.	Closed list with remarks	Efflevel.Endpoint
Generation		Closed list	Efflevel.Generation
Effect level	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with closed list (Decimal)	Efflevel.EffectLevel
Based on	Indicate whether the concentration is based on the test material (test mat.), active ingredient (act. ingr.) or element. As appropriate the measured / addressed fraction can be specified for either of these entities by selecting the relevant item, e.g. 'element (dissolved fraction)' or 'test mat. (total fraction)'. Further information can be given in the supplementary remarks field, e.g. for specifying the type of fraction if it is not clear per se from	Open list with remarks	Efflevel.BasedOn

	the test material specification. Select 'not specified' if the effect concentration type is not known.		
Sex	Select from drop-down list.	Closed list	Efflevel.Sex
Basis for effect level	Indicate the parameter(s) used to establish the given effect level. Multi-selection of different pre-defined values is possible. If none is available, you can select 'other:'. Any explanations can always be entered in the related supplementary text field.	Multi select closed list with remarks (32000)	Efflevel.Basis
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:'	Open list with remarks (2000)	Efflevel.RemarksOnResults

#	Key result	Dose descriptor	Effect level	Based on	Sex	Basis for effect le...	Remarks on result
1	<input type="checkbox"/>	NOAEL	6 ppm	test mat.	male/female	✓ histopathology: non-neoplastic liver toxicity	other: 6 ppm, equivalent to a mean daily intake of 0.88 mg/kg in males and 1.05 mg/kg in females

Target system BLOCK (OHT RepDoseTox etc.)

Name	Instructions	Data type	Field path
	Record the target system(s) where toxicity was observed that is considered of biological relevance and the specific target organ(s). Copy this block of fields for referring to different target systems, lowest effective dose(s) / concentration(s) and/or treatment relationship, dose response relationship and relevance for humans.		TargetSystemOrganToxicity
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose. Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field.	Check box	TargetSystemOrganToxicity.KeyResult
Critical effects observed	Flag to indicate if critical effects were observed in the study within specific organs or systems.	Closed list	TargetSystemOrganToxicity.CriticalEffectsObserved

Lowest effective dose / conc.	Enter a numeric value and select the unit in the next field for indicating the lowest dose / concentration with significant and/or severe toxic effects on the target organ(s) affected.	Unit measure with Closed List (Decimal)	TargetSystemOrganToxicity.LowestEffectiveDoseConc
System	Select any specific system where toxicity was observed that is considered of biological relevance.	Open list	TargetSystemOrganToxicity.System
Organ	Select from the multiple drop-down list the target organ(s) where toxicity was observed. This field provides context-related picklist values depending on the selection made in the preceding field 'System'.	Multi select open list	TargetSystemOrganToxicity.Organ
Treatment related	Flag to indicate if the effects in systems and/or organs are treatment related.	Closed list	TargetSystemOrganToxicity.TreatmentRelated
Dose response relationship	Flag to indicate if the effects observed and reported in systems and/or organs are in a dose-response manner.	Closed list	TargetSystemOrganToxicity.DoseResponseRelationship
Relevant for humans	Flag to indicate if the effects observed and reported in systems and/or organs on the basis of animal experiments are also relevant for humans. Choose "no" from the picklist if the effects in target system/organ are species specific and not relevant for humans.	Closed list	TargetSystemOrganToxicity.RelevantForHumans

#	Key result	Critical effects observ...	Lowest effective dose...	System	Organ	Treatment related	Dose response relatio...	Relevant for humans
1	<input checked="" type="checkbox"/>	yes	None	hepatobiliary	✓ liver	yes	yes	not specified

Overall remarks, attachments – common block

Name	Instructions	Type	Field Path
Overall remarks, attachments		Header 1	OverallRemarksAttachments
Overall remarks	<p>In this field, you can enter any overall remarks or transfer free text from other databases. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing document. Use this field <u>only if strictly necessary</u> i.e. when no other specific fields such as repeatable blocks exist in the document to enter the data of interest.</p> <p>Note: One rich text editor field each is provided for the MATERIALS AND METHODS and RESULTS section. In addition, the fields 'Overall remarks' and 'Executive summary' allow rich text entry.</p>	Rich text area	OverallRemarksAttachments.RemarksOnResults
Attachments	<p>Attach any background document that cannot be inserted in any rich text editor field, particularly image files (e.g., an image of a structural formula). Copy this block of fields</p>		OverallRemarksAttachments.AttachedBackgroundMaterial

	for attaching more than one file.		
Type	Classify the type of attachment uploaded e.g 'Appendix F mammalian toxicology result' Full study reports should be uploaded in the Literature reference entity	Open list	OverallRemarksAttachments.AttachedBackgroundMaterial.Type
Attached (confidential) document	The original file only needs to be attached here if the non-confidential file uploaded under "Attached (sanitised) documents for publication" contains redactions. If a file is uploaded under this field (a) confidentiality claim(s) must be submitted for each part of the file considered confidential and the information claimed confidential must be clearly boxed or earmarked consistently with the redactions applied in the corresponding non-confidential file. This file will not be published.	Single file attachment	OverallRemarksAttachments.AttachedBackgroundMaterial.AttachedDocument
Attached (sanitised) documents for publication	Provide any additional documents relevant for the submission, not already provided under the literature reference entity. For test guidelines that provide a reporting	Single File Attachment	OverallRemarksAttachments.AttachedBackgroundMaterial.AttachedSanitisedDocsForPublication

	<p>template (data analysis file), that file must be completed and can be uploaded here if not yet done in the results section.</p> <p>See IUCLID templates for PPP Risk Assessment Templates on EFSA Knowledge Junction (zenodo).</p> <p>Any additional background documents uploaded here must be uploaded in their public (non-confidential) version . The public version will be published once the dossier has been considered valid/admissible. All elements therein claimed confidential should be sanitised. Save for the elements blackened, if applicable, content and layout-wise the public version must be fully identical with the confidential version. Upon conclusion of the confidentiality assessment, if applicable, a revised public version removing the redactions relating to confidentiality requests that were rejected in part or in full must be uploaded here.</p>		
Remarks	As appropriate, include remarks, e.g., a short description of the content of the attached document if the file name is not self-explanatory.	Text	OverallRemarksAttachments.AttachedBackgroundMaterial.Remarks

Illustration (picture/graph)	Upload file by clicking the upload icon. As appropriate, enter any additional information, e.g., language. The file name is displayed after uploading the document. If the image contains confidential material it should be uploaded in the confidential field above.	Image	OverallRemarksAttachments.IllustrationPicGraph
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Overall remarks, attachments

Overall remarks

None

Attachments

New item
 Import file

#	Type	Attached (confidential) do...	Attached (sanitised) docu...	Remarks
1	other: Mammalian toxicology results	None	Template 5.1 - Template for presentation of results in tabular format for mamtox studies.docx	None

Illustration (picture/graph)

None

Applicants summary and conclusion – common block

Name	Instructions	Type	Field Path
Applicant's summary and conclusion		Header 1	ApplicantSummaryAndConclusion
Validity criteria fulfilled	State whether validity criteria in the test guideline have been fulfilled or not. Use supplementary remarks field to state the criteria and supporting information.	Closed list with remarks	ApplicantSummaryAndConclusion.ValidityCriteriaFulfilled

	Clearly indicate if the criteria used are not consistent with those given by the test guideline. If so, give justification in field 'Rationale for reliability incl. deficiencies' as to why this study summary is considered reliable.		
Interpretation of results	<p>Conclude if the study results fall under relevant classification criteria of the Globally Harmonised System of Classification and Labelling of Chemicals (UN GHS). Further explanations can be entered in the supplementary remarks field.</p> <p>Note that a classification in the strict sense cannot always be based on an individual study but includes a weight of evidence evaluation of all relevant data. To this end wording such as 'is classified in Category 1' should be used only in the conclusions provided in the relevant classification section.</p>	Closed list with remarks (2000)	ApplicantSummaryAndConclusion.InterpretationOfResults
Conclusions	This field should be used to summarize the conclusions by the applicant and will be used in study summaries produced using report generator.	Text area	ApplicantSummaryAndConclusion.Conclusions
Executive summary	If relevant for the respective regulatory programme, briefly summarize the relevant aspects of the study including the conclusions reached. If	Rich text area	ApplicantSummaryAndConclusion.ExecutiveSummary

	a specific format is prescribed, copy it from the corresponding document or upload it if provided as htm or html document.		
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Applicant's summary and conclusion

Interpretation of results

GHS criteria not met

Conclusions

As a conclusion, on the basis of the composition, the classification for the co-formulants and the resistance to attrition/dust, it is assumed that ARY-0711a-01 has no explosive properties.

Executive summary

None

Validation rules

Summary	Issue Type	Message	Target documents	Checked field reference
QLT_PPP_001: Endpoint must be indicated	Quality rules/Warning	'Administrative data' is not complete. The 'Endpoint' addressed by the study record must be indicated.	All endpoint study records	Administrative data – common block
QLT_PPP_002: Data waiving must be justified	Quality rules/Warning	'Administrative data' is not complete. If you want to submit a data waiving then the rationale for waiving the information requirement must be indicated in the field 'Data waiving' and an appropriate justification must be selected in the field 'Justification for data waiving'. If none of the	All endpoint study records	Administrative data – common block

		<p>available justifications in the picklist apply, select 'other:' and provide the justification in the below field.</p> <p>If you wish to provide further information in support of the data waiving, use the field 'Justification for type of information' and/or attach a document under 'Attached justification' heading. A reference to a record with relevant information for the data waiving can be made under 'Cross-reference' heading.</p>		
QLT_PPP_003: Reliability must be provided for KS and WoE	Quality rules/Warning	<p>'Administrative data' is not complete. For each endpoint study record marked as 'key study' or 'weight of evidence', the field 'Reliability' must be provided. Note: If you select 'other:' then the below field must be filled in.</p>	All endpoint study records	Administrative data – common block

<p>QLT_PPP_004: Reference must be provided for KS and WoE</p>	<p>Quality rules/Warning</p>	<p>'Data source' is not complete. For each endpoint study record marked as 'key study' or 'weight of evidence' the 'Reference' entry must be completed. For each reference, the 'Year' or the 'Report date' must always be indicated. In addition, as a minimum, the following must be provided:</p> <p>#study report# - If the data is from a study report, the field 'Testing facility' (with the full address of the testing laboratory, including city and country), an entry for Study ID type="notification of Studies (NoS) ID" under 'Other study identifier(s)', either 'Report number' or 'Study number' and 'Title' must be provided</p> <p>#other company data# - If the data is from a company, either the field</p>	<p>All endpoint study records</p>	<p>Data source (Literature Reference) – common block</p>
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		<p>'Report no.' or the field 'Study no.' must be provided. In addition, information must be given under 'Author', 'Study sponsor' and/or 'Title'.</p> <p># publication, If the data is from a literature source, the field 'Bibliographic source' must be provided. Sufficient information should be given to be able to identify the literature source.</p>		
QLT_PPP_005: Guideline must be given for KS, WoE and testing proposal	Quality rules/Warning	<p>'Materials and methods' is not complete. For each endpoint study record marked as 'key study' or 'weight of evidence', or indicated as a testing proposal, the test guideline (to be) used in the study must be indicated in the 'Guideline' under the 'Test guideline' heading. If you add several entries, then the 'Guideline' must be specified for each of them. If</p>	<p>All endpoint study records</p> <p>except of ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms</p>	<p>Material and methods – common block</p>

		<p>the test guideline applied is not found in the picklist, select 'other:' and provide information on the guideline in the below field.</p> <p>If no test guideline can be specified (e.g. because the study is a non-guideline study, or (Q)SAR was applied), a description of the principles of the test protocol or the method must be provided in the field 'Principles of method if other than guideline'.</p>		
QLT_PPP_006: Test material must be given for KS, WoE and testing proposal	Quality rules/Warning	<p>'Materials and methods' is not complete. For each endpoint study record marked as 'key study' or 'weight of evidence', or indicated as a testing proposal, the test material (to be) used in the study must be identified by linking a test material information (TMI) record in the 'Test material information' entry.</p> <p>The TMI record should contain</p>	<p>All endpoint study records</p> <p>except of ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms</p>	Test material – common block

		<p>sufficient information to allow the understanding of the identity of the tested substance. As a minimum, under 'Composition' at least one 'Constituent' must be reported. Each created component must contain at least one of the following identifiers in the designated fields: EC number, CAS number, IUPAC name.</p> <p>For a read-across target record, the test material information should identify the target substance of the read-across.</p>		
QLT_PPP_007: Key studies should have reliability 1 or 2	Quality rules/Warning	Administrative data is inconsistent. This endpoint study record has been indicated with the adequacy 'key study' but the assigned 'Reliability' score indicates that the study is not reliable. A key study is expected to correspond to a robust study summary of sufficient quality	All endpoint study records	Administrative data – common block

		and reliability (score 1 or 2) to independently fulfil the information requirements for an endpoint. You are advised to reconsider whether this study is of sufficient quality to be used as key study to fulfil the information requirements for this endpoint.		
QLT_PPP_008: Deviations in the guideline must be explained	Quality rules/Warning	Materials and methods is inconsistent. In the entry 'Test guideline' the field 'Deviations' has been set to 'yes'. In this case, you are expected to provide a brief explanation summarising the deviations from the guideline in the below 'Remarks' field. More detailed information should be described in the respective fields of the 'Materials and methods' part. Moreover, all possible effects that such a deviation may have on the obtained test results should be analysed and	All endpoint study records except of ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms	Material and methods – common block

		reported in the 'Overall remarks, attachments' part of the endpoint study record.		
QLT_PPP_009: Attached (sanitised) documents for publication must be provided for KS/WoE (all ESR)	Quality rules/Warning	'Data source' is not complete. For each endpoint study record marked as 'key study' or 'weight of evidence' the entry 'Reference' must be completed. For each reference a version of the full study report must be provided under the 'Attached (sanitised) documents for publication' field. - If the information is confidential, a sanitised version should be provided under the 'Attached (sanitised) documents for publication' and the confidential report should be added under the 'Attached documents' field in the Literature reference.	All endpoint study records	Literature reference
QLT_PPP_010: Study ID and/or Justification (remarks) must be provided	Technical completeness check	Data source': is not complete. For each endpoint study record marked as 'key study' or 'weight of evidence',	All endpoint study records	Literature reference

		<p>report the notification of studies status of the submitted study in the Literature reference entity.</p> <p>If the study has been notified in the Notification of Studies Database then report the number in the 'Other study identifier(s)' - 'Study ID' and indicate Study ID type="notification of Studies (NoS ID)"</p> <p>If the study has not been notified provide a justification in 'Other study identifier(s)' - 'Remarks' field</p> <p>The 'notification of Studies (NoS) ID' must follow the format: EFSA-YYYY-NNNNNNNN (where YYYY-year with minimum value set to 2021 and numeric and N-8digit number).</p> <p>Study ID type of "notification of Studies (NoS) ID"</p>		
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		entry must be provided must be completed providing a justification.		
QLT_PPP_011: KS/WoE must be provided for all required sections (Microorganisms Substance dataset)	Quality/Warning	Section : At least one endpoint study record indicated as either a key study, weight of evidence, or data waiving must be provided for this section. Supporting studies should be provided as appropriate, as additional endpoint study records, but they cannot be used to fulfil the information requirement.	Required endpoint study records	Administrative data – common block
QLT_PPP_012: Summaries must be provided for all required sections (Microorganisms Substance Dataset)	Quality rules/Warning	Section : At least one endpoint study summary must be provided for this section.	Required endpoint summaries	N/A
QLT_PPP_013 KS/WoE must be provided for all required sections (Chemical Mixture Dataset)	Quality/Warning	Section : At least one endpoint study record indicated as either a key study, weight of evidence, or data waiving must be provided for this section.	Required endpoint study records	Administrative data – common block

		<p>Supporting studies should be provided as appropriate, as additional endpoint study records, but they cannot be used to fulfil the information requirement.</p> <p>- To indicate an endpoint study record as a key study or as part of a weight of evidence approach, select 'key study' or 'weight of evidence' in the 'Adequacy of study' picklist and fill in all relevant fields under 'Administrative data', 'Data source', 'Materials and methods', and 'Results and discussion' for this endpoint.</p> <p>Other types of study summaries (e.g. supporting studies) should be filled in as much as possible.</p> <p>- To indicate an endpoint study record as data waiving, make a selection in the field 'Data waiving' and provide a justification in the</p>		
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		field 'Justification for data waiving'.		
QLT_PPP_014 Summaries must be provided for all required sections (Chemical Mixture Dataset)	Quality/Warning	Section: At least one endpoint study summary must be provided for this section.	Required I endpoint summaries	N/A
QLT_PPP_015: KS/WoE must be provided for all required sections (Microorganisms Mixture dataset)	Quality/Warning	Section : At least one endpoint study record indicated as either a key study, weight of evidence, or data waiving must be provided for this section. Supporting studies should be provided as appropriate, as additional endpoint study records, but they cannot be used to fulfil the information requirement.	Required endpoint study records	Administrative data – common block
QLT_PPP_016: Summaries must be provided for all required sections (Microorganisms Mixture Dataset)	Quality rules/Warning	Section : At least one endpoint study summary must be provided for this section.	Required endpoint summaries	N/A

<p>QLT_PPP_017</p> <p>KS/WoE must be provided for all required sections (Chemical Substance Dataset)</p>	<p>Quality/Warning</p>	<p>Section: At least one endpoint study record indicated as either a key study, weight of evidence, or data waiving must be provided for this section.</p> <p>Supporting studies should be provided as appropriate, as additional endpoint study records, but they cannot be used to fulfil the information requirement.</p> <p>- To indicate an endpoint study record as a key study or as part of a weight of evidence approach, select 'key study' or 'weight of evidence' in the 'Adequacy of study' picklist and fill in all relevant fields under 'Administrative data', 'Data source', 'Materials and methods', and 'Results and discussion' for this endpoint.</p> <p>Other types of study summaries (e.g. supporting studies) should be</p>	<p>Required endpoint study records</p>	<p>N/A</p>
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		<p>filled in as much as possible.</p> <p>- To indicate an endpoint study record as data waiving, make a selection in the field 'Data waiving' and provide a justification in the field 'Justification for data waiving'.</p>		
<p>QLT_PPP_018</p> <p>Summaries must be provided for all required sections (Chemical Substance Dataset)</p>	Quality/Warning	<p>Section: At least one endpoint study summary must be provided for this section.</p>	Required I endpoint summaries	N/A
<p>QLT_PPP_019</p> <p>KS/WoE must be provided for all required sections (MRL Substance Dataset)</p>	Quality/Warning	<p>Section At least one endpoint study record indicated as either a key study, weight of evidence, or data waiving must be provided for this section.</p> <p>Supporting studies should be provided as appropriate, as additional endpoint study records, but they cannot be used to fulfil the information requirement.</p> <p>- To indicate an endpoint study</p>	Required endpoint study records	N/A

		<p>record as a key study or as part of a weight of evidence approach, select 'key study' or 'weight of evidence' in the 'Adequacy of study' picklist and fill in all relevant fields under 'Administrative data', 'Data source', 'Materials and methods', and 'Results and discussion' for this endpoint.</p> <p>Other types of study summaries (e.g. supporting studies) should be filled in as much as possible.</p> <p>- To indicate an endpoint study record as data waiving, make a selection in the field 'Data waiving' and provide a justification in the field 'Justification for data waiving'.</p>		
QLT_PPP_020: Summaries must be provided for all required sections (Substance_MRL)	Quality rules/Warning	Section: At least one endpoint study summary must be provided for this section.	Required endpoint summaries	N/A

QLT_PPP_021: At least one Mixture must exist with linked Active (Substance)_PPP_All_Submissions	Quality rules/Warning	Mixture composition is incomplete. At least one Mixture composition must be present in the dossier function. This must include a linked substance which has the the Function = 'active substance'.	FLEXIBLE_RECORD.MixtureComposition	
QLT_PPP_022: At least one valid constituent must exist (for each Active substance) All_EU_PPP	Quality rules/Warning	For each Active substance composition, at least one constituent must be defined. All constituents must be identified by linking a reference substance.	FLEXIBLE_RECORD.MixtureComposition FLEXIBLE_RECORD.SubstanceComposition	N/A
QLT_PPP_023: At least one LE composition must exists in Active subsatance dataset_Only Active sub.	Quality rules/Warning	Each substance must be identified by at least one specification of purity. Specify the following information: - Degree of purity of the active substance - Constituents - Impurities, if applicable - Additives, if applicable Each constituent, impurity and additive must be identified by linking a reference	FLEXIBLE_RECORD.MixtureComposition, FLEXIBLE_RECORD.SubstanceComposition	N/A

		substance, complete with available identifiers and molecular and structural information, and by providing the concentration range.		
QLT_PPP_024: each (active) substance must have a reference substance in section 1.1 All_EU_PPP	Quality rules/Warning	A reference substance must be linked in IUCLID section 1.1.	1.1_Identification FLEXIBLE_RECORD.MixtureComposition SUBSTANCE	N/A
QLT_PPP_025: All Active substances must be the same (same UUID)_ All_PPP	Quality rules/Warning	Mixture compositions is incomplete. Where more than one mixture (product formulation/preparation) is reported, the components with the Function = 'active substance' must be the same. This is confirmed by checking that the substance UUID for each active substance is identical.	1.1_Identification FLEXIBLE_RECORD.MixtureComposition SUBSTANCE	N/A
QLT_PPP_026: at least one GAP must be created in All_PPP	Quality rules	Section 2, Good Agricultural Practices (GAP) is incomplete. At least one Good Agricultural Practices (GAP) must be created.	FLEXIBLE_RECORD.GAP	N/A

		<p>The following fields must be complete:</p> <ul style="list-style-type: none"> - Crop / treated object, - Target organisms: at least one row must be created with at least 'Scientific name' or 'Common name' fields being filled in) - Method of application - Growth stage is mandatory if GAP refers to a crop; if GAP refers to treatment of non-crop objects (children of 3NOCFO) or to children codes of 3CRPAO (treatment of crop parts) it is not required; if GAP refers to treatment of harvested crops (children codes of 3HARVO), BBCH 99 should be provided. If number of applications is greater than 1, the information on the growth stage needs to be reported for the first and the last application. Treatment season is not mandatory. - Number of 		
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		<p>applications (range)</p> <ul style="list-style-type: none"> - Application rate per treatment (product) – range - Application rate per treatment for target a.s. (range) - Pre-harvest interval (either the days of PHI or 'not applicable'). 		
<p>QLT_PPP_027: Exactly one literature reference must be provided in KS, WoE ESRs_All_EU_P PP</p>	Quality rules	<p>Data source' is not complete. The primary literature reference entity must be either a Study report (full) or a Publication or a Publication (copyright not owned for reproduction). Additional literature reference entities with other Reference types can provide supporting information. Note more than one file can be included in a literature reference entity 'Attachments' block if they have the same authors.</p>	All endpoint study records	Literature reference
<p>QLT_PPP_028: All reference substances in sections 1.1 and 1.2 of Active substance must contain an</p>	Quality rules/Warning	<p>Reference substance information is not complete. Each reference substance must contain at least one of the</p>	<p>1.1_Identification, 1.2_Composition, FLEXIBLE_RECORD.MixtureComposition, FLEXIBLE_RECORD.SubstanceComp</p>	Reference substance v.6.4 (Final)

identifier_Active Sub & MRL		following identifiers in the designated fields: EC number, CAS number, IUPAC name. If you use a reference substance to report (a group of) unknown constituents/impurities, you need to enter in the IUPAC name field: "Unknown constituents/impurities". In addition you should specify, as far as possible, the number and nature of these unknown constituents/impurities in the 'Remarks' field of the constituent/impurity block.	osition, SUBSTANCE	
QLT_PPP_029: All constituents in the first composition record in Active substance must represent distinct substance identities_All_PPP	Quality rules/Warning	Multiple constituents in the active substance composition/purity specification are identified with the same reference substance. Remove the duplicate entries.	FLEXIBLE_RECORD.MixtureComposition, FLEXIBLE_RECORD.SubstanceComposition	N/A
QLT_PPP_030: Constituents should have a typical concentration_Active Sub & MRL	Quality rules/Warning	The 'Typical concentration' for each Active substance composition constituent should be specified (value	FLEXIBLE_RECORD.MixtureComposition, FLEXIBLE_RECORD.SubstanceComposition	N/A

		<p>and unit). The value should be representative for the substance as manufactured/imported.</p> <p>Active substance composition results shall include quantitative data, in terms of g/kg content, for all components present in quantities of 1 g/kg or more.</p>		
QLT_PPP_037: each CFD must be justified, in case justification is provided it must have CFD	Quality rules/Warning	Data protection: If the Confidentiality flag is checked the Justification must be completed.	DATA_PROTECTION	All documents
QLT_PPP_040: Summaries: A sanitised version must be provided if Attached document is provided	Quality rules/Warning	'Additional information' is incomplete. A public (sanitised) version of attachments must be provided. A file has been attached in the Endpoint study summary document under the 'Attached background material' header > Attached confidential document, but there is no file in the field 'Attached (sanitised) documents for publication'. Upload the	All summaries	Discussion (Header 1) – common block

		<p>sanitised version for publication in the 'Attached (sanitised) documents for publication' field. Note: if there is no difference between the two files provide a single copy in the 'Attached (sanitised) documents for publication' field.</p>		
<p>QLT_PPP_041: Studies : If Attached document or Attached full study report is provided, a sanitised version must be provided as well (MO, MRL, AS)</p>	<p>Quality rules/Warning</p>	<p>Overall remarks, attachments is incomplete. A sanitised version of attachments must be provided. A file has been attached in the Endpoint study record under the 'Overall remarks, attachments' 'Attached (confidential) document' field, but there is no file in the field 'Attached (sanitised) documents for publication'.</p> <p>Upload the sanitised version for publication in the 'Attached (sanitised) documents for publication' field. Note: if there is no difference between the two files provide a</p>	<p>All endpoint study records</p>	<p>Overall remarks, attachments – common block</p>

		<p>single copy in the 'Attached (sanitised) documents for publication' field.</p> <p>Note: full study reports and related files should be uploaded in the Literature reference entity of the Data Source.</p>		
<p>QLT_PPP_042: If attachment is provided a sanitised version must be provided as well in SummaryEvaluation_EU_PPP</p>	<p>Quality rules/Warning</p>	<p>'Reports and administrative information' is incomplete. A sanitised version of attachments must be provided. A file has been attached in the document under the 'Reports and administrative information' header > 'Attached document' field, but there is no file in the field 'Attached (sanitised) documents for publication'. Upload the sanitised version for publication in the 'Attached (sanitised) documents for publication' field. Note: if there is no difference</p>	<p>FLEXIBLE_SUMMARY.Summary Evaluation_EU_PPP</p>	

		between the two files provide a single copy in the 'Attached (sanitised) documents for publication' field.		
QLT_PPP_043: If Document J is provided a sanitised version must be provided as well in Manufacturer_EU_PPP	Quality rules/Warning	'Additional information' is incomplete. A sanitised version of attachments must be provided. A file has been attached in the document under the 'Additional information' header > 'Document J' field, but there is no file in the field 'Sanitised Document J'. Upload the sanitised version for publication in the 'Sanitised Document J' field. Note: if there is no difference between the two files provide a single copy in the 'Sanitised Document J' field.	FLEXIBLE_REC ORD.Manufacturer_EU_PPP	
QLT_PPP_044: If attached document is provided a sanitised	Quality rules/Warning	A sanitised version of attachments must be provided. A file has been attached in the	FLEXIBLE_SUMM ARY.EcotoxRiskAssessmentPesticides	

version must be provided as well in EcotoxRiskAssessmentPesticides		document under the 'Attached background material' 'Attached confidential document' field, but there is no file in the field 'Attached (sanitised) documents for publication'. Upload the sanitised version for publication in the 'Attached (sanitised) documents for publication' field. Note: if there is no difference between the two files provide a single copy in the 'Attached (sanitised) documents for publication' field.		
QLT_PPP_045: If attached document is provided a sanitised version must be provided as well in Flexible summaries	Quality rules/Warning	A sanitised version of attachments must be provided. A file has been attached in the document under the 'Additional information' header > 'Attached confidential document' field, but there is no file in the field 'Attached (sanitised) documents for publication'. Upload the sanitised version	FLEXIBLE_SUMMARY.AquaticToxicity RacReporting FLEXIBLE_SUMMARY.DefinitionResidueFate FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest FLEXIBLE_SUMMARY.EstConcGroundwater FLEXIBLE_SUMMARY.EstConcOtherRoutes FLEXIBLE_SUMMARY.EstConcSoil FLEXIBLE_SUMMARY.EstConcWaterSed	

		for publication in the 'Attached (sanitised) documents for publication' field. Note: if there is no difference between the two files provide a single copy in the 'Attached (sanitised) documents for publication' field.	FLEXIBLE_SUMMARY.ExpectedExposure FLEXIBLE_SUMMARY.Metabolites FLEXIBLE_SUMMARY.MRLProposal FLEXIBLE_SUMMARY.NonDietaryExposure FLEXIBLE_SUMMARY.RelevantMetabolitesGroundWater FLEXIBLE_SUMMARY.ToxRefValues	
QLT_PPP_046: If attached document is provided a sanitised version must be provided as well in IntermediateEffects	Quality rules/Warning	A sanitised version of attachments must be provided. A file has been attached in the 'Attached (confidential) document' field of the Intermediate Effects document (Intermediate effects-mechanistic information) . Upload a sanitised version for publication in the 'Attached (sanitised) documents for publication' field. Note: if there is no difference between the two files provide a single copy in the 'Attached (sanitised) documents for publication' field. Full study reports should be included	FLEXIBLE_RECORD.IntermediateEffects	

		in the literature reference entity.		
QLT_PPP_047: Attachments block in Literature reference must be complete	Quality rules/Warning	<p>'Data source' is not complete. For each endpoint study record marked as 'key study' or 'weight of evidence' the 'Attachments' block in the Literature Reference entity must be completed. For each 'Attachments' block a version of the attachment must be provided under the 'Attached (sanitised) documents for publication' field, in addition, a selection under the field 'Attachment type' must be filled in.</p> <p>If the information is confidential, the original version should be added under the under the 'Attached confidential document' field in the Literature reference.</p>	All endpoint study records	Literature reference
QLT_PPP_048: For the study report reference type a type of attachment	Quality rules/Warning	'Data source' is not complete. For each endpoint study record marked as 'key	LITERATURE.GeneralInfo.Attachments.AttachmentType	Literature reference

must be 'full study report'		study' or 'weight of evidence' the Reference type specified as study report must have a report provided under the 'Attachments' block and 'Attachment type' must be 'full study report'.		
QLT_PPP_049: If attached document is provided a sanitised version must be provided as well in	Quality rules/Warning	A sanitised version of attachments must be provided. A file has been attached in the document under the 'Attached background material' header > 'Attached confidential document' field, but there is no file in the field 'Attached (sanitised) documents for publication'. Upload the sanitised version for publication in the 'Attached (sanitised) documents for publication' field. Note: if there is no difference between the two files provide a single copy in the 'Attached (sanitised) documents for publication' field.	FLEXIBLE_SUMMARY.EcotoxRiskAssessmentPesticides	

QLT_PPP_050: In case Mixture is provided under the 'Other representative products', it must have the same Active substance as in the main mixture	Quality rules/Warning	Other representative product is incomplete. The Mixture composition must include one linked substance which has the Function = 'active substance'. This substance must be the same in the Main product mixture and in the Other Representative products.	FIXED_RECORD.OtherRepresentativeProducts FLEXIBLE_RECORD_MixtureComposition	
BR_PPP_033 European reference number in UUID format	Business rule/Failure	Dossier header is incomplete. European reference number field must be filled in and the format must be UUID.	DOSSIER.EU_PPP_ACTIVE_SUBSTANCE_FOR_MIXTURES	N/A
BR_PPP_034 European reference number in UUID format	Business rule/Failure	Dossier header is incomplete. European reference number field must be filled in and the format must be UUID.	DOSSIER.EU_PPP_MICROORGANISMS_FOR_MIXTURES	N/A
BR_PPP_035 European reference number in UUID format	Business rule/Failure	Dossier header is incomplete. European reference number field must be filled in and the format must be UUID.	DOSSIER.EU_PPP_MAXIMUM_RESIDUE_LEVELS	N/A
BR_PPP_036 European reference	Business rule/Failure	Dossier header is incomplete. European reference number field must be filled	DOSSIER.EU_PPP_BASIC_SUBSTANCE	N/A

number in UUID format		in and the format must be UUID.		
BR_PPP_038 European joint submission number must be provided in UUID format	Business rule/Failure	Dossier header is incomplete. You have indicated under the 'Purpose of the application' field that the application is a renewal of an active substance for use in plant protection products. In this case you must provide an entry under the 'European joint submission number' field in UUID format.	DOSSIER.EU_PPP_ACTIVE_SUBSTANCE_FOR_MIXTURES DOSSIER.EU_PPP_MICROORGANISMS_FOR_MIXTURES	N/A
BR_PPP_039: If the 'Application purpose' is renewal then it must be indicated whether the submitter is the lead applicant	Business rule/Failure	Dossier header is incomplete. You have indicated under the 'Purpose of the application' field that the application is a renewal of an active substance for use in plant protection products. If the submitter is the lead applicant and the dossier is the main dossier select 'yes'. If the dossier is submitted by a third party consultant and it is the main	DOSSIER.EU_PPP_ACTIVE_SUBSTANCE_FOR_MIXTURES DOSSIER.EU_PPP_MICROORGANISMS_FOR_MIXTURES	N/A

		dossier select 'yes'. 'No' should only be selected if the submitted dossier is a supplementary confidential dossier. If 'no' is selected a justification in the 'Remarks' field must be provided.		
BR_PPP_062 Active substance identifiers must be provided All_EU_PPP	Business rule/Failure	Components of the mixture composition. Reference substance information is not complete. The reference substance must contain at least one of the following identifiers in the designated fields: EC number, CAS number, IUPAC name. For microorganisms the species and strain should be reported in the IUPAC name. In the case of extracts or other cases where an IUPAC name cannot be defined this field should be completed e.g. 'Extract of ginger' or 'Unknown mixture'.	FLEXIBLE_RECORDER.MixtureComposition	
BR_PPP_085 Section 1: Identity of the plant protection product	Business rule/Failure	A mixture composition document must be completed. Provide details on the formulation.	FLEXIBLE_RECORDER.MixtureComposition	

All_EU_PPP except BASIC substance				
BR_PPP_086 Section 2: Preparation of the substance for use BASIC substance	Business rule/Failure	A mixture composition document must be completed. Provide details on the preparation.	FLEXIBLE_RECOR D.MixtureComposi tion	
BR_PPP_087 A mixture composition document must be completed All_EU_PPP	Business rule/Failure	The components of the mixture, preparation or formulation must be listed and associated with a reference substance entity, substance dataset or mixture dataset. For each component the 'Name' field must be completed.	FLEXIBLE_RECOR D.MixtureComposi tion	
BR_PPP_088 Mixture composition is incomplete All_EU_PPP	Business rule/Failure	The component with the Function = 'active substance' must be linked in the 'Name' field to a reference substance or substance dataset.	FLEXIBLE_RECOR D.MixtureComposi tion	
BR_PPP_089 Mixture composition is incomplete All_EU_PPP	Business rule/Failure	There must be one component with the Function = 'active substance'. The function 'active substance (other, not to be assessed)' can be used for active substances which are included in the application but not for approval	FLEXIBLE_RECOR D.MixtureComposi tion	

Submission portal rules:

General rules (checked for all the files sent to Portal):

[BR565] Currently only the following submission types are accepted in 'ECHA Submission Portal':

- 'Poison centre notifications'
- 'SCIP notifications'
- 'EU PPP Active substance application (product)'
- 'EU PPP Basic substance application'
- 'EU PPP Microorganisms - active substance application (product)'
- 'EU PPP MRL application'

[QLT732] The maximum number (500) of IUCLID Validation Assistant rules that can be reported for the submitted dossier has been exceeded.

PPP rules:

[BR900] Same dossier should not be submitted twice (compares dossier UUID's)

[BR903] Legal entity in 'EU PPP Active substance application (product)': Submitting Legal entity in Portal must be same as Legal entity owner in IUCLID (compares legal entity UUID's)

[BR904] Legal entity in 'EU PPP Basic substance application': Submitting Legal entity in Portal must be same as Legal entity owner in IUCLID (compares legal entity UUID's)

[BR905] Legal entity in 'EU PPP Microorganisms – active substance application (product)': Submitting Legal entity in Portal must be same as Legal entity owner in IUCLID (compares legal entity UUID's)

[BR906] Legal entity in 'EU PPP MRL application': Submitting Legal entity in Portal must be same as Legal entity owner in IUCLID (compares legal entity UUID's)

[BR907] Indicated 'European reference number' should not be associated with different substances in ECHA Submission Portal. (compares EC number/CAS number/IUPAC names of 'Substance' and 'Reference substance' datasets that are marked to be 'Active substances')¹

[BR909] Indicated 'European reference number' should not be associated with other PPP dossier types in ECHA Submission Portal

[QLT908] Indicated 'European reference number' should not be associated with other legal entities in ECHA Submission Portal. (compares legal entity UUID's)

[BR910] Dossier could not be imported in EFSA Agency IUCLID (When a PPP dossier passes IUCLID VA and Submission Portal rules but doesn't get stored in EFSA Agency IUCLID then a relevant BR is logged on the validation report of the dossier's submission)

Updated sections and documents

The following sections and documents have been updated in the latest version of IUCLID MRL application Manual.

Section	Subsection	Document
Introduction		
Confidentiality of dossiers submitted via IUCLID		
Dossier Header: EU PPP MRL Application		DOSSIER.EU_PPP_MAXIMUM_RESIDUE_LEVELS
	1.2 Product composition / active substance information	FLEXIBLE_RECORD.MixtureComposition
	1.2.1 Information on metabolites	FLEXIBLE_SUMMARY.Metabolites
	2.Good agricultural practices (GAP)	FLEXIBLE_RECORD.GAP
EU PPP Active substance information	1.8 Method of manufacture (synthesis pathway) of the active substance	FLEXIBLE_RECORD.Manufacturer_EU_PPP
	3.2 Effects on harmful organisms, function, mode of action and possible resistance – Endpoint study record	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms
	4 Analytical Methods - Endpoint study record	ENDPOINT_STUDY_RECORD.AnalyticalMethods
	5. Toxicological and metabolism studies on the active substance – Flexible summary	FLEXIBLE_SUMMARY.ToxRefValues
	5.2.1 Oral (includes acute oral toxicity to mammals)– Endpoint study record	ENDPOINT_STUDY_RECORD.AcuteToxicityOral
	6.1 Storage stability of residues – Endpoint summary	ENDPOINT_SUMMARY.StabilityResiduesCommodities

	6.1 Storage stability of residues – Endpoint study record	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod
	6.3 Magnitude of residues in plants – Endpoint summary	ENDPOINT_SUMMARY.MagnitudeResiduesPlants
	6.3 Magnitude of residues in plants - Endpoint study record	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops
	6.4 Feeding studies – Flexible summary	FLEXIBLE_SUMMARY.ResiduesInLivestock
	6.4 Feeding studies – Endpoint study record	ENDPOINT_STUDY_RECORD.ResiduesInLivestock
	6.5 Effects of processing – Endpoint summary	ENDPOINT_SUMMARY.NatureMagnitudeResiduesProcessedCommodities
	6.5.1 Nature of the residue – Endpoint study record	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod
	6.7.1 Proposed residue definitions – Endpoint summary	ENDPOINT_SUMMARY.ResidueFood
	6.7.2 Proposed maximum residue levels – Flexible summary record	FLEXIBLE_SUMMARY.MRLProposal
	6.9 Estimation of the potential and actual exposure through diet and other sources – Flexible summary	FLEXIBLE_SUMMARY.ExpectedExposure
	6.10.1 Effect on the residue level in pollen and bee products – Endpoint summary	ENDPOINT_SUMMARY.SupplementaryStudies
	6.10.1 Effect on the residue level in pollen and bee products – Endpoint study record	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities
	7.1.1 Route and rate of degradation in soil, aerobic and anaerobic (laboratory studies)- Endpoint study record	ENDPOINT_STUDY_RECORD.BiodegradationInSoil
	7.1.1 Route and rate of degradation in soil, aerobic and anaerobic (laboratory studies) - Endpoint Summary	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP
Referenced entities	Literature reference	
Endpoint summaries – common blocks	Discussion (Header 1) – common block	

Endpoint study records – common blocks	Administrative data — common block	
	Applicants summary and conclusion — common block	
	Overall remarks, attachments — common block	
	Test material — common block	
Validation rules		