EUROPEAN FOOD SAFETY AUTHORITY

MRL APPLICATIONS MANUAL
IUCLID 6.8

European Food Safety Authority (EFSA)

CONTENTS


efsa
EUROPEAN FOOD SAFETY AUTHORITY

Changes to this document

Version	Changes
5	July 2024 Update to: - reflect the new functionalities of IUCLID 6.8 (including newly created documents and updated documents as reported in the IUCLID release note) - remove sections included the EFSA Administrative guidance - include recommendation on setting up IUCLID Drive
4	October 2023 Update to reflect the new functionalities of IUCLID 6.7 Newly created documents: FLEXIBLE_RECORD.ChangeLog FIXED_RECORD.AddTranspRegInfo Updated documents: EU PPP Maximum residue levels (MRL) application (DOSSIER HEADER) ENDPOINT_STUDY_RECORD.BasicToxicokinetics ENDPOINT_STUDY_RECORD.EpidemiologicalData ENDPOINT_STUDY_RECORD.GeneticToxicityInVitro ENDPOINT_STUDY_RECORD.GeneticToxicityInVivo ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral ENDPOINT_STUDY_RECORD.EyeIrritation ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion ENDPOINT_STUDY_RECORD.ToxicityToReproduction ENDPOINT_STUDY_RECORD.MetabolismInCrops ENDPOINT_STUDY_RECORD.MetabolismInLivestock ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod ENDPOINT_STUDY_RECORD.ResiduesInLivestock ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod ENDPOINT_STUDY_RECORD.AdsorptionDesorption ENDPOINT_STUDY_RECORD.AgedSorption ENDPOINT_STUDY_RECORD.BiodegradationInSoil ENDPOINT_STUDY_RECORD.FieldStudies ENDPOINT_STUDY_RECORD.OtherDistributionData

	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil ENDPOINT_STUDY_RECORD.AdsortpionDesorption ENDPOINT_SUMMARY.MagnitudeResiduesPlants ENDPOINT_SUMMARY.MetabolismLiveStock ENDPOINT_SUMMARY.MetabolismPlants ENDPOINT_SUMMARY.NatureMagnitudeResiduesProcessedCommodities ENDPOINT_SUMMARY.ResidueFood ENDPOINT_SUMMARY.StabilityResiduesCommodities ENDPOINT_SUMMARY.SupplementaryStudies FLEXIBLE_SUMMARY.MRLProposal FLEXIBLE_SUMMARY.ResiduesInLiveStock ENDPOINT_SUMMARY.AcuteToxicity ENDPOINT_SUMMARY.Carcinogenicity ENDPOINT_SUMMARY.GeneticToxicity ENDPOINT_SUMMARY.ToxicityToReproduction FLEXIBLE_SUMMARY.ToxRefValue ENDPOINT_SUMMARY.Phototoxicity ENDPOINT_SUMMARY.RepeatedDoseToxicity ENDPOINT_SUMMARY.Neurotoxicity ENDPOINT_SUMMARY.AdditionalToxicologicalInformation ENDPOINT_SUMMARY.Immunotoxicity ENDPOINT_SUMMARY.BiodegradationInSoil ENDPOINT_SUMMARY.EnvironmentalFateAndPathways ENDPOINT_SUMMARY.FieldStudies ENDPOINT_SUMMARY.OtherDistributionData ENDPOINT_SUMMARY.PhotoTransformationInSoil ENDPOINT_SUMMARY.RouteDegSoil FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest FLEXIBLE_SUMMARY.Metabolites FLEXIBLE_SUMMARY.RelevantMetabolitesGroundWater FLEXIBLE_RECORD.IntermediateEffects FLEXIBLE_RECORD.AssessmentOtherAuthorities FLEXIBLE_RECORD.GAP FLEXIBLE_RECORD.Manufacturer_EU_PPP FLEXIBLE_RECORD.SubstanceComposition FLEXIBLE_RECORD.MixtureComposition Chapter:Referenced entities and common blocks

3	February 2022 Update to fix editorial issues
2	February 2022 Update to reflect the new functionalities of IUCLID 6.6
	First version - March 2021

Introduction

Introductory note

This manual is intended to support applicants in compiling MRL applications in line with the relevant changes released with IUCLID 6.8.

Regulations and data requirements 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 1107/2009[2] 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 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)

The **data requirements** for an MRL application dossier are indicated in **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) 2019/1381[5]), 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.

How to build an IUCLID dossier

Before starting to compile a dossier, it is recommended to check EFSA's Applicants Toolkit for the latest resources available in support of its preparation (https://www.efsa.europa.eu/en/applications/toolkit).

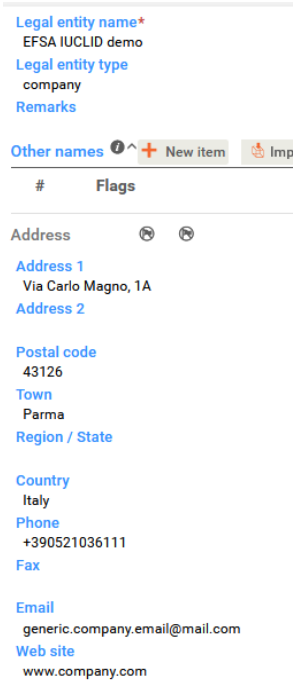
For specifics on the IUCLID tool, it is recommended to consult the IUCLID 6 user manual describing the features of IUCLID 6, accessible via its web interface.

For further details on how to use IUCLID check the "IUCLID for Applicants" training available in EU Academy[8] (https://academy.europa.eu/courses/iuclid-for-applicants).

For further details on confidentiality, please refer to the User guide on confidentiality https://www.efsa.europa.eu/en/applications/toolkit .

The **first step** is to create a Legal Entity for the organization which is submitting the application and to create **user accounts** for the people authoring the dossier. See the Overview of ECHA Cloud Services section of 'IUCLID Training for applicants, Video 8 and the image below. More details on user management can also be found in ECHA accounts manual.

Important! A functional mailbox address and the number of a switchboard must be provided in the 'Legal entity' since this is always published. Personal contact details should be included in the 'Contact' entity.



The **second step** to build a valid **IUCLID dossier** for MRL application is to create a new "Mixture" dataset and select the **'EU_PPP MRL application**' Working context.

The **third step** is to compile the IUCLID dossier with relevant information.

[6] https://www.efsa.europa.eu/en/corporate/pub/tr-practical-arrangements
[7] https://www.efsa.europa.eu/en/applications/pesticides/regulationsandguidance
[8] Please note that EU Login is required for accessing the training platform

The **dossier header** must be completed. It should identify the type of submission and provide administrative information to support the processing of the dossier.

Two main datasets must be completed:

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.

If appropriate, **one/several METABOLITE dataset(s)** with data on the relevant metabolite(s) can be created under section "Information on metabolites". All **metabolites** should be listed in the FLEXIBLE SUMMARY.Metabolites document and link the relevant metabolite datasets.

Information on **other substances** relevant for the assessment (e.g. relevant impurities and co-formulants) can be reported creating an additional row under the Product composition / active substance information document (Section 1.2) and compiling the relevant newly created dataset.

Safeners, synergists and co-formulants can be entered in the Product composition / active substance information document (Section 1.2) 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.

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 the "Active substance (other, not to be assessed)".

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 within same dataset to avoid duplicate data entry.

Since it is currently not possible to cross-reference between different datasets, when data provided for the product dataset are needed also for the active substance dataset (or vice-versa), a waiver should be included to indicate where the scientific data can be found. In such cases, reference to the UUID of a IUCLID document can be made in the Reason field of the cross-reference section.

In case of studies conducted on parent substance 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 a **metabolite**, the studies should be reported under the **metabolite dataset**;
- If the test material is a **mixture of parent substance and metabolite,** the 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.

As a general principle, IUCLID documents should be fully completed. The required data **must be reported in the relevant IUCLID documents** (Dossier Header, Endpoint summaries, Endpoint study records, Flexible records, Flexible summaries, etc).

Duplication of information should be avoided and attachments should be provided only as indicated in the instructions provided in this manual.

Where the IUCLID document does **not contain a structured section and templates** have been recommended by evaluators, the data should be entered as specified in the published templates and attached to the IUCLID dossier following the instructions provided in this manual.

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.

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 those sections except 6.9, applicants are requested to complete at least one endpoint study record and one endpoint summary. For sections 6 and 6.7. 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.

Instructions provided in this manual are also applicable to MRL applications for minor crops.

Dossier and study naming – best practices

Dossier naming

- A dossier name must always be provided
- For an MRL this should be the ISO name of the active substance + crop(s)/various crops
- AVOID details on (re)submissions, versioning, dates, etc

Study naming

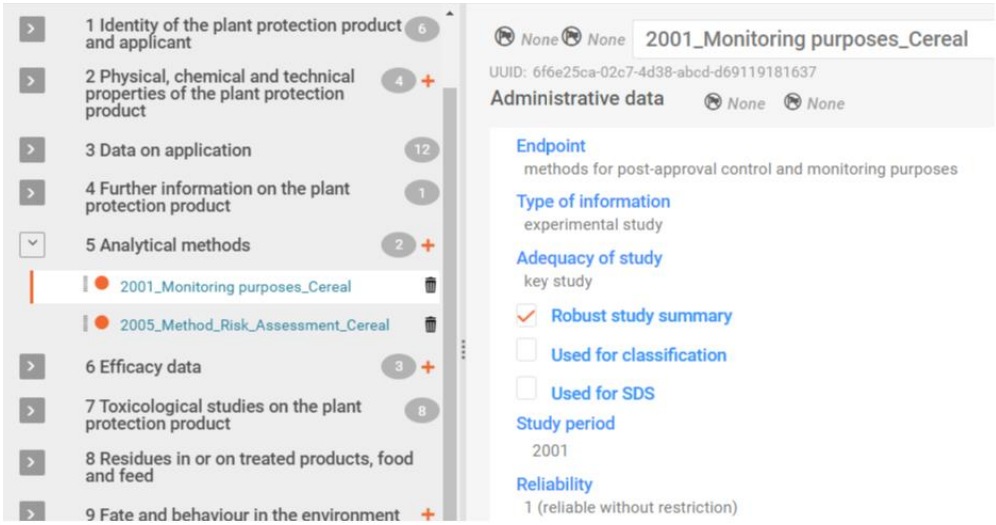
Personal data must be avoided e.g. endpoint study records should not include author names.

It is recommended to name the study with the shortest name possible.

It is recommended to use the Year of the study, the endpoint and additional relevant context where 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*



Components of a IUCLID dossier

Data entry in IUCLID is done in **entities** and **documents**.

Entities are data elements that can be re-used and are usually managed in inventories, for example Reference Substance entity, Legal Entity, Literature Reference entity.

Documents gather all relevant data fields for a specific type of information, for example endpoint study record on acute oral toxicity or Flexible summary on Proposed residue definition.

Endpoint study records

An endpoint study record is a document (template) with predefined fields in which data is entered to describe a study carried out within the subject area defined by the section's title.

For data requirements where experimental data can be provided, the relevant endpoint study record should be completed for each study which has been notified and is used as evidence of safety in the submitted dossier.

IUCLID captures information complying with the reporting requirements of the OECD Test Guidelines, as well as other national/international methods used for chemical studies. The OECD Harmonised Templates for Reporting Chemical Test Summaries (OHTs) are standard data formats designed to be used in a wide range of regulatory contexts. More information on OHTs can be found on the OECD website[9]. ECHA has recently published a Guidance and Standard Procedure for Drafting Robust Study Summaries which can be consulted for generic guidance on the completion of OHTs.

Endpoint study records usually consist of the following data entry blocks: 'Administrative data', 'Data source', 'Materials and methods', 'Test material', and 'Results and discussion'. There are also sections for any 'Overall remarks, attachments' and the 'Applicant's summary and conclusion'.

Important note: The main information requested in the data entry boxes of the endpoint study record document (e.g. materials and methods, results and discussion) must always be filled-in, also in the case of an endpoint that is considered supportive by the applicant and it is based on literature data.

9 https://www.oecd.org/ehs/templates/

Endpoint summaries

Endpoint summaries are found in the same Section as the endpoint study records and are used to provide a conclusion from the available studies.

The link/s for the endpoint studies considered to be relevant and reliable should be added in the Endpoint summary. When linking endpoint study records with multiple results make sure to check the relevant checkboxes to identify the **KEY RESULTS**. Provide the scientific conclusion for the endpoint/s reported in the endpoint study records. Information provided in this document will be used to generate **lists of endpoints** with Report Generator.

The final values for assessment must be provided under the section "Key value for chemical safety assessment" in all summaries.

Note: None of the fields in ENDPOINT SUMMARIES are subject to the UNLESS_CONF flags, as they are not expected to contain confidential business information ('CBI'). These documents should be completed in a clear and transparent manner as they will be published without redaction as part of the Public Consultation Process foreseen in the Transparency Regulation.

Flexible/fixed records

Similarly to the endpoint study records or to the endpoint summary, this type of entry is used for documents in IUCLID in which the information stored in the record is usually not a study and it is not based on an OHT.

A fixed record is created in a section in which there can be only one record.

A flexible record is created in a section in which there can be more than one record.

Attachments

Applicants should provide the following as attachments:

- full study reports (in line with the provisions of the Transparency Regulation)

  or

- other supporting material (e.g label of packaging) in case they cannot be entered in a specific IUCLID document.

Full study reports (including publications and (Q)SAR, QMRF or QPRF reporting forms) must be uploaded as attachments ONLY to the relevant literature reference entities. The "Attachments" field of the endpoint study records (when present) should be not used to attach the full study reports and duplication of attachments should be avoided. The public version of any attachment should not be in word/rtf format, but rather in pdf format.

In case a study report is revised during the dossier life-cycle, do not provide additional attachments – this not only contributes to unnecessarily increasing the size of the dossier but might also create confusion on versioning of the files. Remove the obsolete files and replace them with a newer version in which, ideally, the changes are highlighted in order to facilitate the assessors' work.

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 material** (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.

For attachments other than the full study report, indications are provided below.

Table of Content (Active	**Attachment**

substance DATASET)	
Proposed maximum residue levels and justification	Sanitised version of OECD calculator (attached to the Flexible summary-mandatory)
1.8 Method of manufacture (synthesis pathway) of the active substance	Document J Note: work is on-going to ensure that all information can be reported in the IUCLID documents and as from April 2025, the PDF Document J will no longer be accepted in EU PPP dossiers. Please note that the information contained in Document J must also be provided in the correct sections of the IUCLID documents. To the extent information typically provided via Document J can already be provided in and flagged confidential via relevant IUCLID records/summaries, applicants should abstain from including the same information in Document J with a view to avoiding duplication of information.
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- mandatory if the study is not already in the MetaPath database)
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 to endpoint summary-optional)
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-optional)
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 (attached to the endpoint summary-optional) -MSS composer xml file (attached to the literature entity of the endpoint study record- mandatory if the study is not already in the MetaPath database)
6.2.2 Metabolism of residues in livestock (incl. fish)	-Template 6.2 Template for reporting metabolism studies https://zenodo.org/record/4621090#.YZt9DtDMJPY (attached to the endpoint summary-optional) -MSS composer xml file (attached to the literature entity of the endpoint study record- mandatory if the study is not already in the MetaPath database)
6.3 Magnitude of residues in plants	Template 6.3 Template for reporting trials on magnitude of residues in primary crops and rotational crops https://zenodo.org/record/4621117 (attached to the endpoint study record-optional)
6.4 Feeding studies	Template 6.4 Excel animal burden calculator https://zenodo.org/record/827275#.YYqcuGDMJPY (attached to the

	endpoint summary- mandatory depending on the uses under assessment)
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 study record-optional)
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-mandatory)
9.1 Literature data	Bibliographic results of the literature searches
11.1 Assessment from other authorities	Relevant only for import tolerance: 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	Administrative documents such as cover letters (attached to the "Reports and administrative information" field). *Important note*: 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-mandatory)

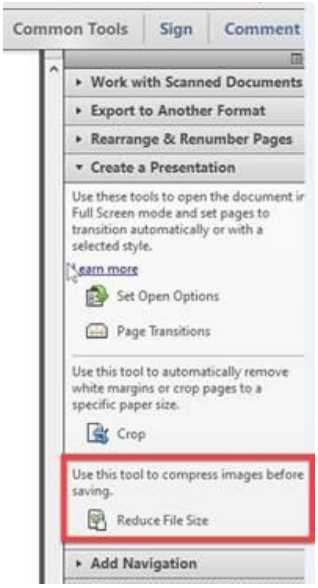
Attachments greater than 100MB will cause issues upon dossier submission. In case of large attachments please follow the instructions below. Reducing the size of attachments in IUCLID documents will result in better performance for dossier processing steps and it is therefore always recommended as best 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.

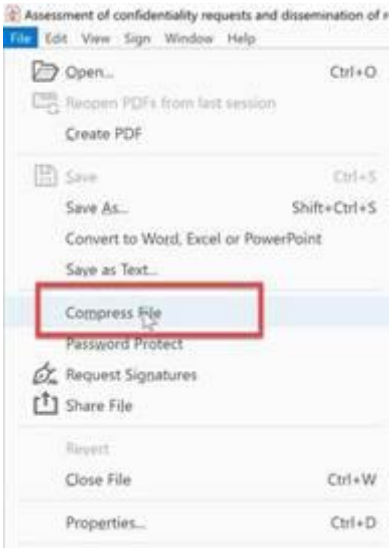
These attachment reports that generate a .csv file (that can be opened in Excel) and lists all attachments with their size and type is available.

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).

Submission of MRL dossiers

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 'standalone' MRL dossier. Such a dossier follows the standard rules defined above. Therefore, at least one GAP document should be provided 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 whether data or information are 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 endpoint 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. In this case, 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). and it is not necessary 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.

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

For those endpoints that are addressed by studies already assessed in a previous active substance approval/renewal (or also in a previous MRL assessment)and not available in IUCLID, it is not requested to provide full summaries and study report(s). Nevertheless, applicants 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 endpoint study records, applicants 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 endpoint summaries, applicants 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).

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

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 standalone MRL dossier described in case 1 also apply. In addition to the mandatory endpoints of Section 4 and Section 6, it is relevant that other sections (e.g. Section 5: Toxicological and metabolism studies on the active substance) are addressed by the applicant by means of new studies. Although not mandatory, the other sections of the table of content should also be carefully checked and applicants should assess whether 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, endpoint study records should be fully completed, including full and sanitized versions of any reports used to support the application.

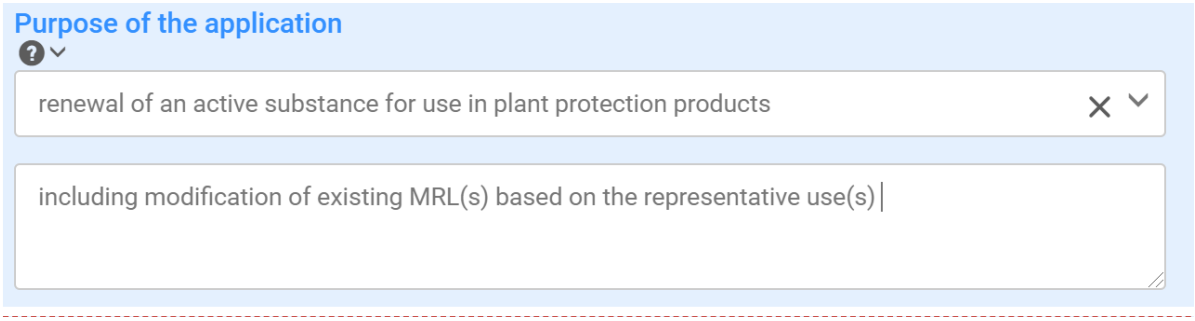
For import tolerances (IT) requests, it is highlighted that all background information linked to the assessment in the third country (evidence of registration in the exporting country, residue definition in the exporting country, existing MRL in exporting country, legislation in the third country, etc), 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.

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:



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 GAPS(s) for representative use(s)** of the approval/renewal dossier, **a separate MRL dossier is required.** GAP document(s) relevant for the MRL application (e.g. GAP for non-representative uses) must be created only in the MRL dossier. GAP document(s) relevant for the representative uses (within the approval/renewal application) must be created only in the approval/renewal dossier.

As for any standalone 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 provide the European Reference Number (ERN) of the other dossier (please also refer to the dedicated Chapter on MRL Dossier header). This can be done only when dossiers are submitted within a reasonable delay from each other (e.g. within the same week).

During the assessment of an active substance application, the need to set/modify MRL values for non-representative uses might arise. In such cases the applicant should submit a separate MRL application and select the relevant checkbox in the MRL dossier header including the ERN of the approval/renewal application under the section "Other submission related information". The link to the new MRL application and its ERN should subsequently be added to the dossier header of the active substance application at the next requested update.

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 and they 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 proposed MRLs, 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), 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"[10].

If the confirmatory data for art 12 (e.g. residue trials) are provided to support the representative uses, these data should be addressed in the approval/renewal dossier and there is no need to repeat them in the MRL dossier.

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

Similarly, 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 them in the MRL dossier.

However, in both cases, 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. The 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 is 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 cases 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 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.

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

An application for the deletion of the existing MRL may be submitted if, for instance, consumer intake concerns are identified. The need to set lower MRLs should be justified by the applicant and/or the Evaluating Member State (EMS) to avoid that resources are spent to assess applications which do not lead to a change to the MRLs, which are already set in the EU.

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.

Summary table

MRL application submitted after the approval or renewal	Submit always a separate standalone MRL dossier Note: - when the approval/renewal dossier is submitted in IUCLID, provide all data using the copy and paste function for data already submitted in IUCLID format - when the approval/renewal dossier is NOT submitted in IUCLID, provide all data for new information and justifications for data waiving for study already evaluated in the previous assessments
MRL application submitted as part of the approval/renewal when GAP(s) when GAP(s) are NOT identical to representative uses	Submit a separate standalone MRL dossier. Make reference to the renewal dossier in the dossier header.
MRL application submitted as part of the active substance approval/renewal when GAP(s) are identical to representative uses	Do not submit a separate standalone MRL dossier. Indicate in the Dossier Header that an application for modification of existing MRL(s) based on representative uses is included in the approval/renewal dossier
MRL application for inclusion in Annex IV submitted as part of the approval/renewal	Do not submit a separate standalone dossier. Indicate in the Dossier Header that an application for inclusion in Annex IV is included in the approval/renewal dossier

Notification of studies (NoS)

In accordance with Art. 32b of Regulation (EU) 2019/1381, "*business operators must, without delay, notify the Authority of the title and the scope of any study commissioned or carried out by them to support an application or a notification, as well as the laboratory or testing facility carrying out that study, and its starting and planned completion dates.*

Laboratories and other testing facilities located in the Union shall also, without delay, notify the Authority of the title and the scope of any study commissioned by business operators and carried out by such laboratories or other testing facilities to support an application or a notification, its starting and planned completion dates, as well as the name of the business operator who commissioned such a study".

Pursuant to the EFSA Practical Arrangements on pre-submission phase and public consultation a justification must always be provided in the dossier header of each application in IUCLID for:

- studies notified but not submitted in the application;
- studies notified with delay, i.e. after the study starting date;
- studies notified and later withdrawn;
- studies commissioned or carried out after 27 March 2021, not notified but submitted in the application.

IUCLID Report Generator enables applicants to generate a NoS extraction report listing all the studies submitted in the application that were notified, justified and without notification.

Further information on Notification of Studies are available in the User Guide on Notification of studies at the following link: https://www.efsa.europa.eu/sites/default/files/2021-07/user-guide-notification-of-studies.pdf

Validation assistant

Before submitting a dossier, it is important to run the validation assistant to check the dossier is technically complete. As the rules applied are dependent on the information included in the Dossier Header, make sure this is completed correctly. 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 may encounter problems during the admissibility check.

It is important to resolve all validation assistant warnings since this will support the admissibility check of the EMS. If Applicants cannot resolve all the warnings they should download the "Validation assistant Report" in excel format (this excel file replaces document O) and include in this file the justification for not resolving the warning(s) and provide this directly to the EMS. Note that missing studies for a specific data requirement/endpoint should be justified using the data waiver section in the relevant endpoint study record.

In addition to the automated checks, it is important to make sure all the IUCLID documents are well completed and that all the relevant scientific data is provided.

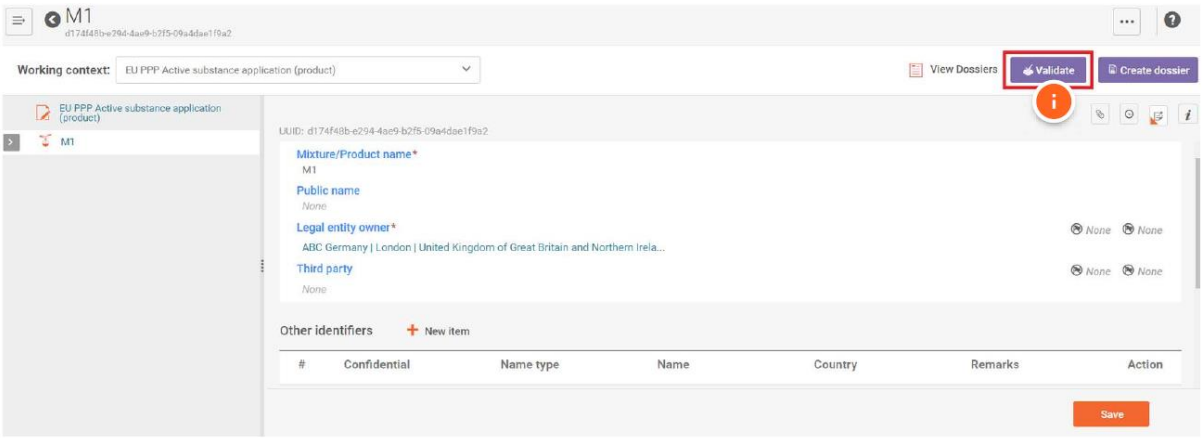
Information on the applicable validation rules is available here:

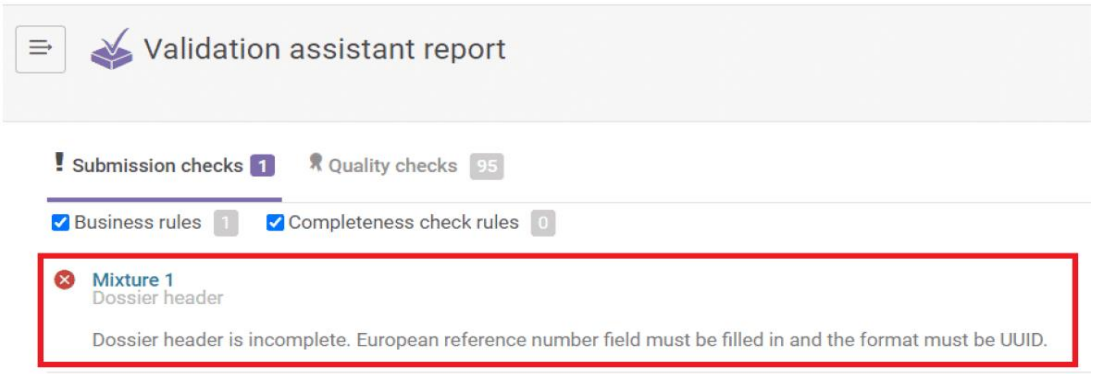
https://doi.org/10.5281/zenodo.5141356

Watch the video on validation assistant: https://zenodo.org/record/6603483#.YpoTY6hBxD9

Common mistakes training on Validation rules

https://zenodo.org/record/6603483#.Y1_cZHbMKUm)



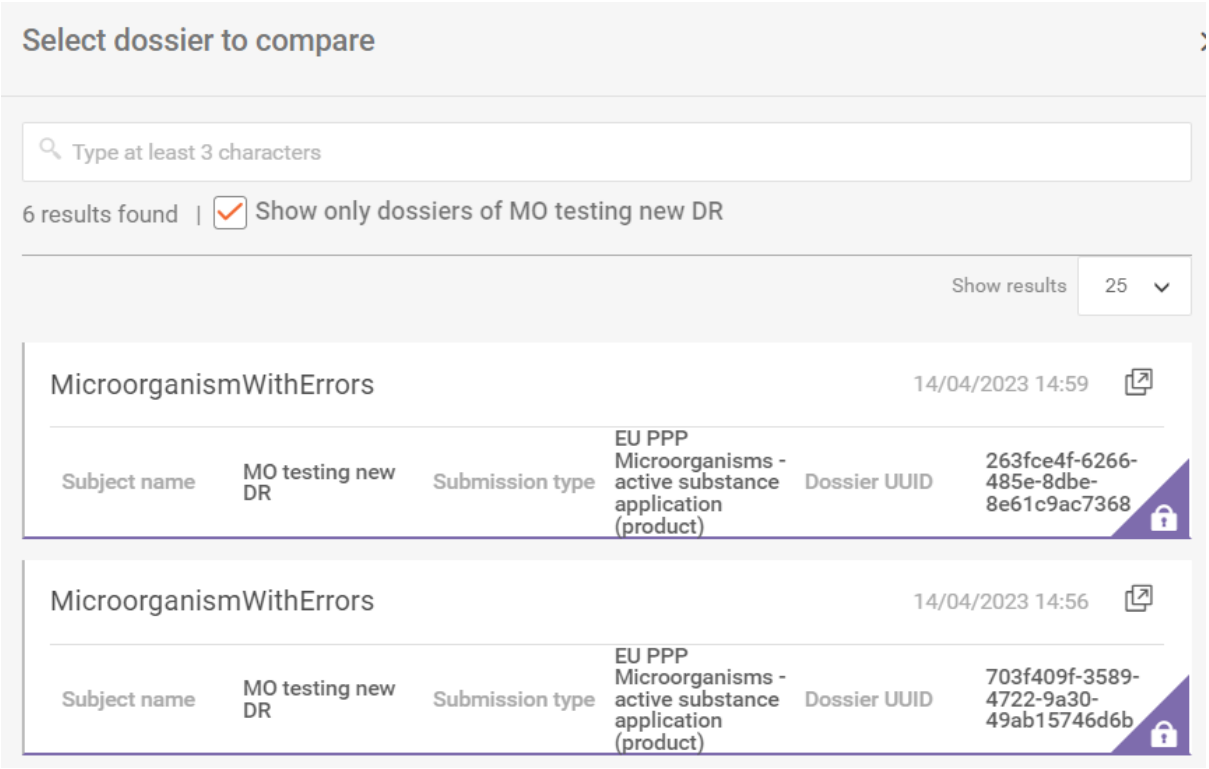

Validation assistant report
Submission checks 1
Quality checks 95
Business rules 1
Completeness check rules 0
Mixture 1
Dossier header
Dossier header is incomplete. European reference number field must be filled in and the format must be UUID.

Compare tool

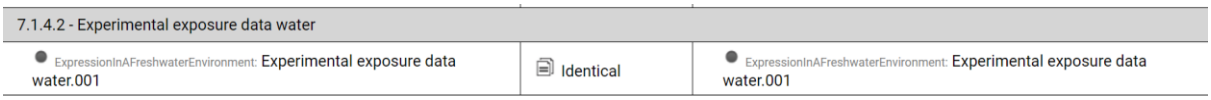
The Compare tool can be used for comparing different versions of a dossier and highlights the differences between the latest submission and any previous versions. It can be used by Applicants before re-submitting a dossier to check which changes were made.

The compare tool can be accessed from the Dossier actions menu (three dots next to the Validation button).

A window will open showing all related dossiers. Select the version of the dossier you want to compare with the current version. An .HTML file is downloaded, open this in a browser application.



If nothing has changed for a specific section/document in a dosser the report indicates 'identical'



If there is a difference in a section/document in the dossier the report indicates 'different'

Clicking on the 'different' link will provide more information on the nature of the changes in the dossier when compared with the selected comparator.

Field	Source	Target
Estimation of concentrations from other routes of exposure > Description of key information	*default* Predicted concentrations in the environment	
PEC other routes Estimation of concentrations from other routes of exposure > PEC from other routes of exposure > PEC other routes	**PEC other routes** Use description • GAP: Data on application (GAP).001 Parent / metabolite parent Substance Microorganism a.s. Genus species Route of exposure *default* Freshwater Method of calculation *default* OECD Calculation method	

In this case a Predicted concentrations document has been completed in the newer dossier. Using compare, deletions can also be checked, in this case the target column would be completed and the source would not.

Watch these Videos on how to use the compare tool

- Comparison of **Dossiers**: SPC Comparison tool demonstration - YouTube
- Comparison of **Documents**: https://www.youtube.com/watch?v=cUy6ahta3dE

Report generator

IUCLID provides a feature called the "Report Generator" which allows to extract data from single IUCLID dossiers or datasets and generate a readable, user-friendly, customised report of IUCLID information in different output formats, for example, RTF, PDF, CSV and HTML.

Where available, Report generator should be used to compile the reported information into the format required for evaluation.

Many reports are ready to use and made available by default inside IUCLID 6. Templates to create PPP-specific reports are published in Zenodo Knowledge Junction and new versions, including changes and bug fixes, are published regularly and included in the list of "Default IUCLID reports" at each IUCLID release. These templates can also be uploaded in Report Manager as indicated in the IUCLID user manual https://iuclid6.echa.europa.eu/documents/1387205/1809908/iuclid_user_manual_en.pdf/9d01cb53-902d-dbb6-fb00-fa141688c395?t=1684669746962. After downloading they will appear under the section *"Uploaded IUCLID reports"* of Report Generator.

The list of available reports for PPP can be found on the Applicants toolkit page: Toolkit | EFSA (europa.eu)

Note: report generator and other tasks are now run as 'Background tasks' which can also be accessed from the IUCLID dashboard.

Submission and sharing of studies

If more than one applicant wishes to submit a joint MRL application for the same substance, they should reach an agreement on sharing studies and data within a Joint Submission.

In this case a third-party representative, who could be e.g. a consultant, is needed. The third party representative will manage the "joint submission" on behalf of the "lead applicant" who will provide most of the data and the "members".

To identify the studies provided by the different parties in the joint submission it is possible to use **Inherited templates**. Each template has a legal entity, the studies linked to a specific legal entity can be included in a single template and it can also be useful when Letter of Access (LoA) to studies not owned by the applicant are to be included in a dossier. Data segregation among applicants is guaranteed provided that a third party is involved and manages the submission as a whole. To include a template, use the inherited templates link at the end of the dataset. More information can be found in the IUCLID User Manual.

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 MRL application 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:

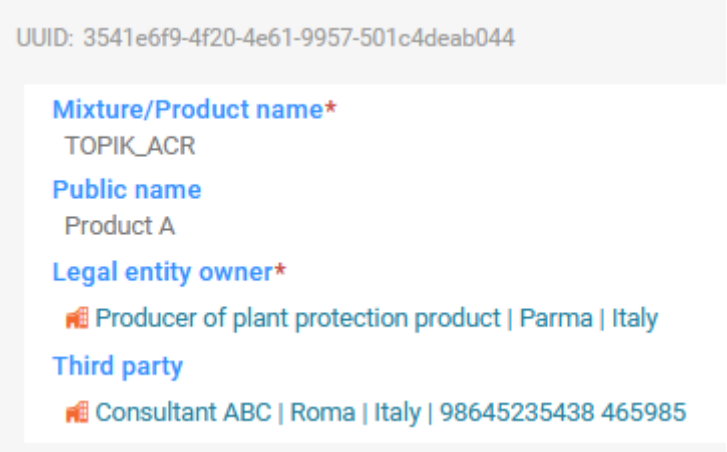
- In the data access field: indicate that data submitter has a letter of access
- In the data protection claimed field: indicate data protection was claimed by the data owner
- In the Attached document field: upload the letter of access in the literature reference entity and set type to 'Letter of access' (if you wish to provide the LoA)

N.B. Pursuant to Article 7(d) of the MRL Regulation 396/2005 providing a Letter of Access to the data is not sufficient to fulfil the data requirements since all studies supporting the MRL application must be provided. Applicants must ensure that the the full text of each test/study report, together with the sanitised version if the full text version contains confidential material is either included in their dossier or provided by the data owner in a linked submission (or in the applicant's submission by means of inherited templates).

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 legal entity 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).



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.

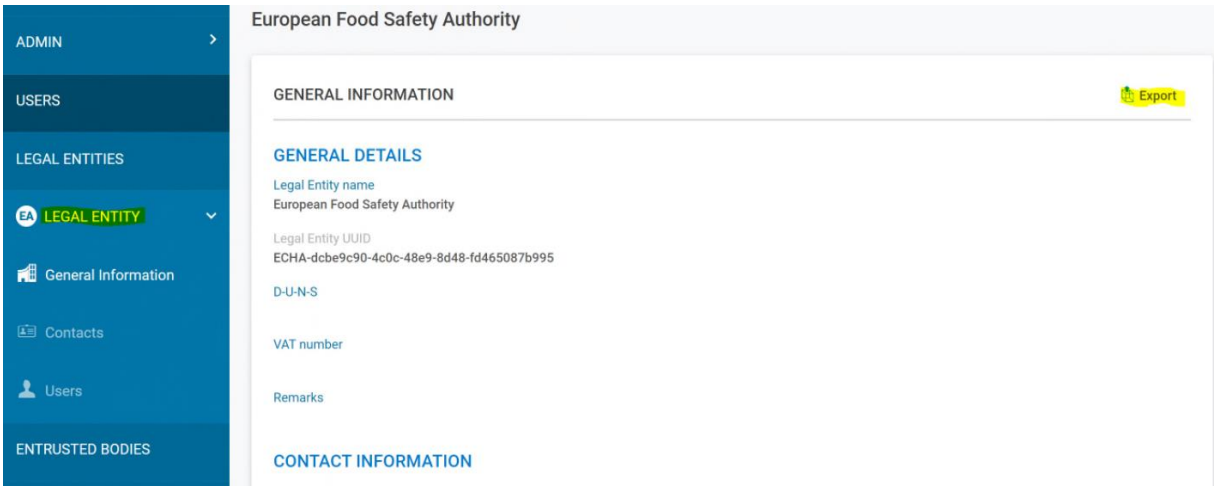
Please see this short explanatory video for more information on foreign users:

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

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.

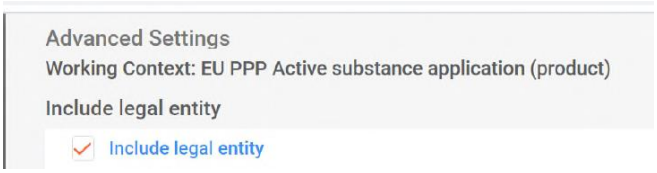
Exporting the Legal Entity: To view the details, please visit: https://ulem.echa.europa.eu/ui/dashboard. Log in with a user account that has the Legal Entity Manager role assigned. Navigate to the Legal Entities tab (on the left) and from the updated central page select the legal entity of the dossier.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



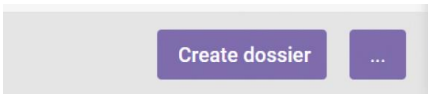
The Legal Entity information will be exported as a IUCLID i6z file which you can then import in IUCLID.

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 directly[11], 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.

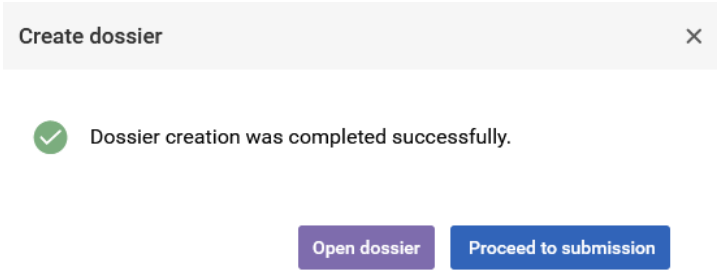


The advanced settings can be accessed from the 'three dots' button

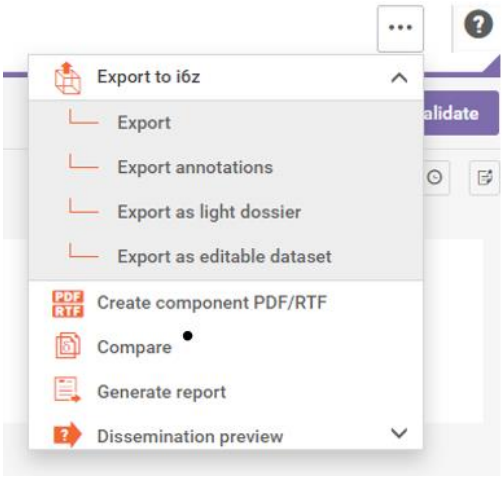


Proceed to submission: If you are using the IUCLID 6 ECHA Cloud services to author the dossier, simply use 'Create Dossier' and 'Proceed to submission' function. Then follow the submission portal steps listed below. This is the recommended approach for MRL dossiers.

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



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.

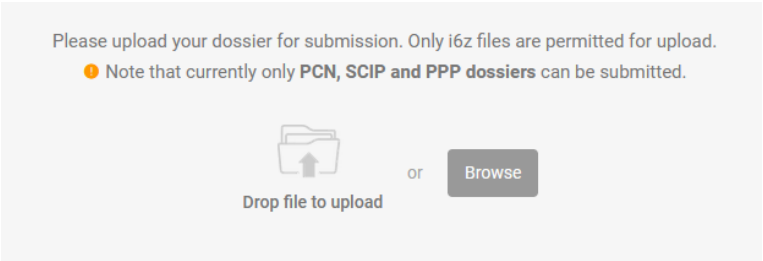


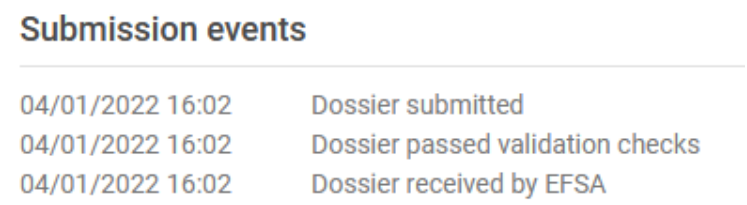
3

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

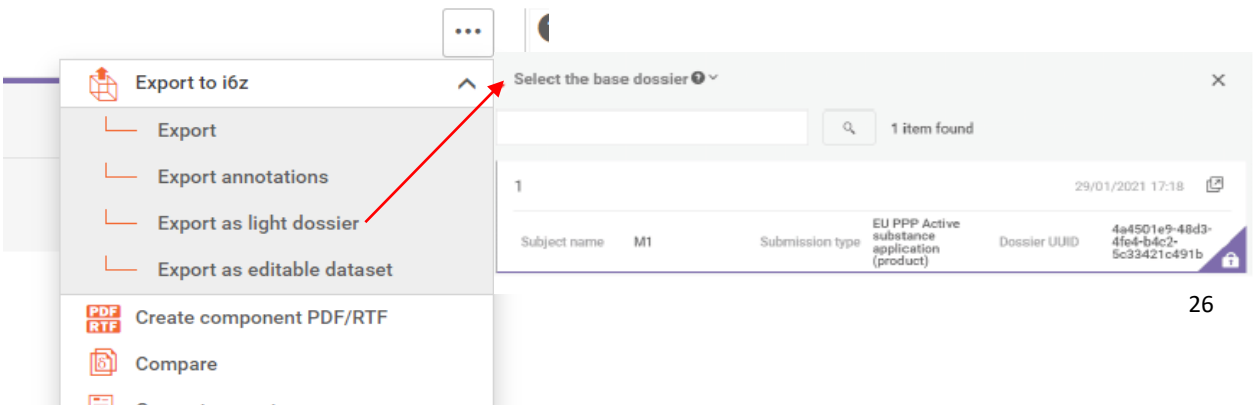
N.B. Exporting and importing large dossiers e.g. larger than 3GB, can result in errors during the dossier download and upload processes. We advise companies to consider requesting their IT team to set up the 'IUCLID Drive' feature in their IUCLID instance as this feature improves the reliability of file transfers therefore eliminating potential sources of issues. See IUCLID server manual for further details (https://iuclid6.echa.europa.eu/documents/1387205/1506740/installation_manual_server_en.pdf).

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 depend 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.**





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.

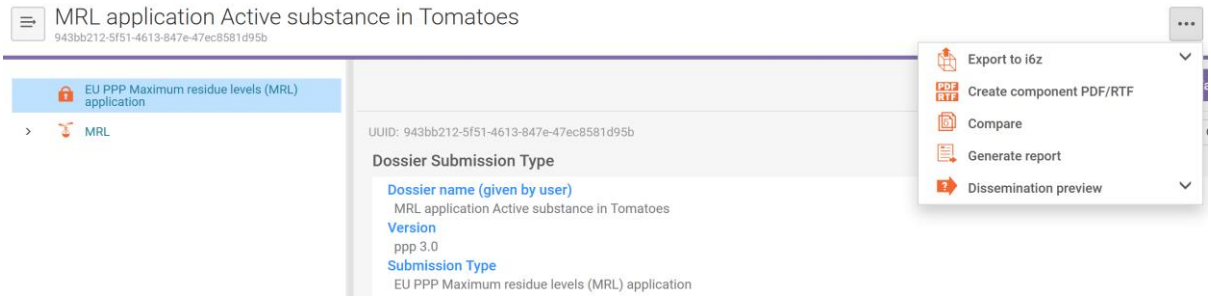


This option can also be used to sequentially load a large dossier if issues importing a dossier into the submission portal are encountered. The first submission should include as a minimum the Mixture dataset, a completed mixture composition dataset including the active substance component with a completed 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.

Dossier publication

Information not meant to be published is removed from the dossier in accordance with the published version of the filtering rules (https://zenodo.org/doi/10.5281/zenodo.4627147). 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-42dk		DOSSIER/EU_PPP_BASIC_SUBSTANCE.NA
3	Dossier		Efsa basic	EU PPP Basic substance	Not published	de84bbd8-7acf-42db-b09a-c3735c1f94b5/de84bbd8-7acf-42dk		DOSSIER/EU_PPP_BASIC_SUBSTANCE.LE(
4	Dossier		Efsa basic	EU PPP Basic substance	Not published	de84bbd8-7acf-42db-b09a-c3735c1f94b5/de84bbd8-7acf-42dk		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-42dk		DOSSIER/EU_PPP_BASIC_SUBSTANCE.Ba
6	Dossier		Efsa basic	EU PPP Basic substance / Basic substance a	Published	de84bbd8-7acf-42db-b09a-c3735c1f94b5/de84bbd8-7acf-42dk		DOSSIER/EU_PPP_BASIC_SUBSTANCE.Ba
7	Mixture/Product	1 identity and applicant	efsa test basic 1	Mixture / Mixture/Product name	Published	69295a37-e087-4416-aa8e-8f840b506c95/de84bbd8-7acf-42d		MIXTURE.MixtureName
8	Mixture/Product	1 identity and applicant	efsa test basic 1	Mixture / Legal entity owner	Published	69295a37-e087-4416-aa8(	ECHA-fc3c9382-ed4a-4990-bdf2-70(	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-42d		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-42d		MIXTURE.ContactPersons[1]
11	Mixture/Product	1 identity and applicant	efsa test basic 1	Mixture / Role in the supply chain / Manufa	Published	69295a37-e087-4416-aa8e-8f840b506c95/de84bbd8-7acf-42d		MIXTURE.RoleInSupplyChain.Manufact
12	Flexible Record	2 Preparation of the substance for use	Mixture composition.001	Composition (mixture) / Components / 1 / Na	Published	3fe10c84-2eb8-4c8c-961c-	8340efb6-efea-4086-9cb6-4667854(	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-dabd08febd14/de84bbd8-7acf-42db		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-dabd08febd14/de84bbd8-7acf-42db		FLEXIBLE_RECORD/MixtureComposition
15	Flexible Record	2 Preparation of the substance for use	Mixture composition.001	Composition (mixture) / Components / 2 / Na	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-dabd08febd14/de84bbd8-7acf-42db		FLEXIBLE_RECORD/MixtureComposition
17	Flexible Summary	4 Application template, studies, bibliograp	Application template, studies, bibliography and confidentiality requests.001		Not published	523fb0ff-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/de84bbd8-7ac		LEGAL_ENTITY.GeneralInfo.LegalEntityNa
19	Legal entity		Breaking Bad	Legal entity / General information / Address	Published	ECHA-fc3c9382-ed4a-4990-bdf2-70041a08dd23/de84bbd8-7ac		LEGAL_ENTITY.GeneralInfo.ContactAddr
20	Legal entity		Breaking Bad	Legal entity / General information / Address	Published	ECHA-fc3c9382-ed4a-4990-bdf2-70041a08dd23/de84bbd8-7ac		LEGAL_ENTITY.GeneralInfo.ContactAddr
21	Legal entity		Breaking Bad	Legal entity / General information / Address	Published	ECHA-fc3c9382-ed4a-4990-bdf2-70041a08dd23/de84bbd8-7ac		LEGAL_ENTITY.GeneralInfo.ContactAddr
22	Legal entity		Breaking Bad	Legal entity / General information / Address	Published	ECHA-fc3c9382-ed4a-4990-bdf2-70041a08dd23/de84bbd8-7ac		LEGAL_ENTITY.GeneralInfo.ContactAddr
23	Legal entity		Breaking Bad	Legal entity / General information / Address	Published	ECHA-fc3c9382-ed4a-4990-bdf2-70041a08dd23/de84bbd8-7ac		LEGAL_ENTITY.GeneralInfo.ContactAddr
24	Legal entity		Breaking Bad	Legal entity / General information / Address	Published	ECHA-fc3c9382-ed4a-4990-bdf2-70041a08dd23/de84bbd8-7ac		LEGAL_ENTITY.GeneralInfo.ContactAddr
25	Reference substance		Water	Reference substance / Reference substance r	Published	8340efb6-efea-4086-9cb6-4667854d269b/de84bbd8-7acf-42dk		REFERENCE_SUBSTANCE.ReferenceSubst
26	Reference substance		Water	Reference substance / IUPAC name	Published	8340efb6-efea-4086-9cb6-4667854d269b/de84bbd8-7acf-42dk		REFERENCE_SUBSTANCE.IupacName
27	Reference substance		Water	Reference substance / Inventory / CAS numbe	Published	8340efb6-efea-4086-9cb6-4667854d269b/de84bbd8-7acf-42dk		REFERENCE_SUBSTANCE.Inventory.CASN
28	Reference substance		Bis(2-(2-methoxyethoxy)ethyl) eth	Reference substance / Reference substance r	Published	4094f25d-7eb4-412d-af25-767d92b5cee0/de84bbd8-7acf-42dk		REFERENCE_SUBSTANCE.ReferenceSubst
29	Reference substance		Bis(2-(2-methoxyethoxy)ethyl) eth	Reference substance / IUPAC name	Published	4094f25d-7eb4-412d-af25-767d92b5cee0/de84bbd8-7acf-42dk		REFERENCE_SUBSTANCE.IupacName
30	Reference substance		Bis(2-(2-methoxyethoxy)ethyl) eth	Reference substance / Inventory / Inventory (	Published	4094f25d-7eb4-412d-af25-767d92b5cee0/de84bbd8-7acf-42dk		REFERENCE_SUBSTANCE.Inventory.Inven
31	Reference substance		Bis(2-(2-methoxyethoxy)ethyl) eth	Reference substance / Inventory / CAS numbe	Published	4094f25d-7eb4-412d-af25-767d92b5cee0/de84bbd8-7acf-42dk		REFERENCE_SUBSTANCE.Inventory.CASN
32	Contact		kon; Breaking Bad		Not published	d4e869be-babf-45dd-bba7-4b2a074a6eb2/de84bbd8-7acf-42d		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.

Confidentiality of dossiers submitted via IUCLID

For guidelines on requesting confidentiality in IUCLID dossiers, please refer to the "User Guide: submission of confidentiality requests" available on the EFSA toolkit page: https://www.efsa.europa.eu/en/applications/toolkit

Validation rules

IUCLID submission rules for PPP dossiers currently applicable in the Submission portal are available in a separate document at the following link: IUCLID Validation Assistant rules for PPP dossiers

Filtering rules

IUCLID filtering rules for PPP dossiers currently applicable are available in a separate document at the following link: IUCLID for PPP Filter rules | Zenodo

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 on 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 is published by default. Confidential data should be provided elsewhere in the dossier as appropriate.

EU PPP Maximum residue levels (MRL) application		
Name	**Instructions**	**Data type**
Dossier name (given by user)	Report short name for the dossier (this should be maintained in all versions). Refer to the active substance name and the commodity/ies in the text (e.g. "MRL application for *active substance* in *commodity(ies)*" or "Import tolerance for *active substance* in *commodity(ies)*). Avoid additional information such as Company codes, Company name and dossier versioning.	Text
Dossier subject		Block
Submitting legal entity	Select submitting legal entity	Link to entity
Dossier submission remark		Text area
MRL application		Block
Dossier specific information		Header 2
European reference number	The European Reference Number (ERN) is the unique identifier used for linking all versions of a dossier submitted under a regulatory action. It can be generated within the IUCLID application and must NEVER be changed with subsequent submissions unless specifically requested to do so by EFSA.	Text
Purpose of the application	Select at least one purpose of the application and add (optional) remarks. Remarks can be used to specify the following:	Multi-Picklist

	- 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 explain the context of the application (optional)	
Evaluating Member State (EMS)	Indicate the member state assessing the dossier 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. 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)	Picklist
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-Picklist
Data requirements used to assess the dossier	Select the data requirements applied to assess the dossier	Picklist
Remark	Add remarks if needed	Free text
Additional information on data requirements	Clarify the rationale for choosing the data requirements	Text
Specific submissions		Block
EFSA Question number	If the dossier is a re-submission, provide the the assigned EFSA question number in EFSA-Q-YYYY-NNNNN format	Text
The submission is an update	Indicate whether the submission is an update by selecting Yes or No	Picklist
Official request		Repeatable list

Requester	Indicate which organisation has requested the resubmission	Picklist
Request type	Indicate in which context the update was requested	Multi-Picklist
Remarks	Add remarks if needed	Text
Spontaneous update		Repeatable List
Reason for resubmission	Indicate reason for resubmission	Multi-Picklist
Remarks	Add remarks if needed	Text
Notification of studies		Block
Pre-application identification	Enter any pre submission identifiers issued whilst notifying studies for inclusion in regulated product dossiers relevant for this dossier subject	Repeatable list
Studies requiring NoS justification		Repeatable list
NoS ID	List all Notification of Studies identifiers which require a justification	Text
Justification	- Report justifications for any deviations from notification obligations e.g-(i)justifications explaining the non-notification in the database of studies that have been included in the application; - (ii) justifications explaining the non-inclusion in the application of studies notified in the database; - (iii) justifications for the withdrawal of a study notification submitted in the database in support of the application; - (iv) justifications for the delayed submission of a study notification in support of the application in question after the starting date of the study; - (v) justifications explaining any other deviation from the process	Text
Other submission related information		Block

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
European Reference Number of the active substance application dossier	If the box above is checked, provide the European Reference Number (ERN) of the related active substance approval/renewal of approval dossier	Text

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

PRODUCT DATASET

1. Identity of the product / active substance information

1.1 Identity of the product

Mixture		
Name	**Instructions**	**Type**
Mixture/Product name	This must be completed; this information is also included in the dossier header as 'Dossier subject'	Multi-line text
Public name	Public name of the mixture	Multi-line text
Legal entity flags	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	Confidentiality
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, 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
Third party flags	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	Confidentiality
Third party	Option to link to the legal entity of a third party	Entity reference field
Other identifiers		Header 1
	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	
Confidential	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	Confidentiality
Name type	Select name type	Open list
Name	Provide name	Multi-line text
Country	Provide the country where the identifier is relevant.	Multi select open list

Remarks	Include remarks if relevant	Text area
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. This information is not published by default.	
Person flags	This flag is not needed since the details on the Contact persons are not published by default.	Confidentiality
Person	See Legal Entity (including contact person)	Entity reference field
Role in the supply chain		Header 1
	Check 'Manufacturer' to indicate the applicant is the Producer of the plant protection product	
Role flags	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	Confidentiality

Links to support material:

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/mixture
Product formulation type and function of the components
This document is used to link the active substance dataset (and if relevant the other substance datasets) to the Mixture/product.

FLEXIBLE_RECORD.MixtureComposition		
Name	**Instructions**	**Type**
Administrative data		Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	Confidentiality
General information		Header 1
Mixture/product name	Report name of the main formulation/mixture. In case of additional mixtures, more than one document can be completed in Section 1.4.5 Other Representative products. The reference substance with the function	Text

	'active substance' must be the same for all mixture composition documents included in the dossier	
Trade names		
Country	Provide the country in which the trade name is relevant.	Multi select open list
Trade name	Report trade name of formulation/mixture	Multi-line text
Brief description	Additional information on the formulation/mixture can be added here	Text
Formulation type	Select the formulation type in accordance with the international coding system for pesticides from the scroll down list	Picklist
Components		Header 1
Component flag	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	Confidentiality
Name	Link to a 'reference substance' or 'substance'. Select 'substance' for the Active substance/micro-organism and Relevant impurities, Active substance (other, not to be assessed), Safeners and Synergists or any other component which has linked studies or summaries This creates a dataset for each component of this type. Link to 'reference substance' for other components e.g. co-formulants, by-products, culture medium where no information other than the amount in the formulation is required. 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.	Entity reference field
Function	Indicate the function of the component in the formulation. For all mixture formulations in the dossier only one component with the function 'active substance' can be reported. This must be linked to a substance dataset. If an additional active substance is included in the formulation but is not the substance under assessment the function should be 'active substance (other, not to be assessed)'. For impurities select "Other" from the picklist and specify "Impurity" in the 'Remark' field. **Important:** Active substance, Active substance (other, not to be assessed), Safener and Synergist datasets are always published and should not be claimed confidential.	Open list
Typical concentration	Complete the Typical concentration reporting % (w/w) – never to be used for micro-organisms. For micro-organsims, the nominal content of viable material is required. For reporting the typical concentration it is recommended to select the most	Half-bounded with open list (Decimal)

	appropriate units of measurement depending on the type of micro-organism (e.g. CFU/kg). For relevant impurities the range including the maximum content is required. For micro-organisms the range - maximum and minimum viable material is required Where relevant, the corresponding content of the variant (such as salts and esters) of the active substances should be included as components.	
Concentration range	Scientific notation can be used, e.g. 1e-3 = 0.001 or 1e6 = 1000000	Range with open list (Decimal)
Remarks	Additional information on the quantity of each component in the formulation/preparation which cannot be provided in the other fields	Text area
Substance of concern	The additional check boxes in this table are not relevant for European Plant Protection Products	Check box
Generic component identifier (GCI)	Not relevant for EU PPP	Check box
Interchangeable component group (ICG)	Not relevant for EU PPP	Check box
Standard formula (SF) component	Not relevant for EU PPP	Check box
Substance generated in situ (from one or more precursors, at the place of use)		Check box
Authorised co-formulant	The check box should be checked if the co-formulant is NOT included in Annex III to Regulation (EC) No 1107/2009	Check box

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 to human and animal health, the environment or to groundwater must 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		
Name	**Instructions**	**Type**
Metabolites information		Header 1
Metabolites information overview	Description of the metabolites included in the dossier.	Rich text area
Parent of metabolites	Link to the parent of the metabolites in the 'List of metabolites'. If more than one active substance is included in the dossier mixture composition, then parent of the metabolites must be reported If the metabolite is secondary or tertiary, then the parent of the metabolites must be reported The link should be made to the reference substance of the parent	Entity reference field
List of metabolites		Header 1
Metabolites		Repeatable block of fields
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	Confidentiality
Link to metabolite dataset	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	Entity reference field

	studies. The Table of Contents for a metabolite is the 'Other substance' dataset Where a metabolite is detected and reported in an endpoint study record and the test material is the active substance only a link to a reference substance is required. 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. 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	
Remarks	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'	Multi-line text
Toxicological assessment	Indicate the genotoxic potential of the metabolite where any indication of toxicity or antimicrobial activity was identified in the initial assessment based on literature and experimental data. Further assessment is necessary to determine if a metabolite of potential concern is of actual concern.	Picklist
The metabolite is claimed active metabolite	Check this box if the metabolite is claimed active metabolite.	Check box
Metabolite WGS-evidence	Check this box if there is any WGS-evidence demonstrating the production of the metabolite	Check box

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 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

When creating a new GAP, a name will be assigned automatically to the document, containing as default name 'Good agricultural practices (GAP)'
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	
Name	**Instructions**
Administrative data	
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.
Product	This field is mandatory. Click on the red plus sign to select the appropriate mixture composition document. If notavailable in the inventory, create first a new one . 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. 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.
Description of key information	The free text field can be used to give a short explanation/description of the GAP. This information is not mandatory. 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).
Purpose of the GAP	
Active substance / microorganism	Select the term that describes the purpose of the GAP. Not relevant for EU PPP MRL applications.

/ basic substance applications	
MRL applications	Select the term that describes the purpose of the GAP. Only relevant for EU PPP MRL applications.
Crop information	
Crop/treated object	Information on the crop/treated object is mandatory. A picklist is implemented to describe the crop or object to be treated with the product. 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: • 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); • 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).

<table>
<tr><td></td><td>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.
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  .
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:
<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></td></tr>
<tr><td>Genetical modification of crop</td><td>If relevant, describe variety of genetically modified crops on which the use of the product is intended to be used or authorised.</td></tr>
<tr><td>Crop destination(s)</td><td>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</td></tr>
<tr><td>Authorisation zone</td><td>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.</td></tr>
<tr><td>MRL zone</td><td>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).</td></tr>
<tr><td>Country or territory</td><td>Select the country or the territory related to the GAP.
The selection of more than one country is possible if the same GAP applies.</td></tr>
<tr><td>Crop location (F/G/I)</td><td>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.</td></tr>
</table>

	The available picklist contains EPPO codes with detailed descriptions of the cases. 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. 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. F: Fields and other structures which do not prevent release of products into the environment. 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.
Pest/disease to be treated	
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.
Scientific name	Select the appropriate code and scientific name from picklist. The picklist is based on the EPPO list (https://gd.eppo.int/taxon/). 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. If the target organism is not listed, select 'other' and specify. If a scientific name is not relevant or not known, select 'no data'. 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)'. Please make sure that the scientific name entered in this field matches with the organism described in the field 'Common name'.
Common name	Please add the common name of the target organism in this field that matches with the Scientific name.
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 diseases caused by fungi). If no appropriate description is available in the list, select 'other:' and specify the development stage in the remarks. If the development stage is not known or not further specified, select 'not specified'. If the development stage is not relevant/applicable, leave field empty. Multiple selection of terms is allowed.
Development stage of target plant	For herbicide uses, indicate the developmental stage of the target plant. 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. 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.
Major/minor use	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'.

<table>
<tr><td></td><td>Other EU uses are to be considered as major use (combination of crop/target organism).
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 flags (e.g. not all crops are major crops).
The field is not relevant for uses in third countries (e.g. import tolerances).</td></tr>
<tr><td>Application details</td><td></td></tr>
<tr><td>Application target</td><td>The target to be treated can be selected from a picklist. The following terms are implemented:
<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>
<tr><td>Agricultural Commodity</td><td>Post-harvest application to an agricultural product that can be bought and sold (e.g., treatment to grain, fibre, cut flowers, packaged animal feed, etc).</td></tr>
<tr><td>Soil (surface)</td><td>Application to the ground in which plants can grow.</td></tr>
<tr><td>Soil (subsurface)</td><td>Application below the ground, or immediately incorporated.</td></tr>
<tr><td>Water</td><td>Application to water in systems, pools, pipes, tanks or other containers, or bodies of water, such as lakes, ponds, bays, estuaries, oceans, reservoirs.</td></tr>
<tr><td>Air</td><td>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.</td></tr>
<tr><td>Surface</td><td>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.</td></tr>
<tr><td>Non-porous Surface</td><td>Surfaces where liquids will not absorb such as ceramic, porcelain, glass, metal, plastic/vinyl, rubber, stainless steel.</td></tr>
</table></td></tr>
</table>

	<table><tr><td>Porous Surface</td><td>Surfaces where a liquid is likely to absorb such as fabric, drywall, composition board surfaces, paint films and surfaces, plaster surfaces, and wood.</td></tr><tr><td>other</td><td></td></tr></table> Please select the most appropriate treatment target.
Method of application	Information on the application method is mandatory. Select the treatment/application method relevant for the GAP. The picklist is based on the EPPO list (https://gd.eppo.int/taxon/). 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: - bait treatment - basal bark treatment - dabbing/rubbing - [local treatment] - incorporation into compost - material incorporation or impregnation - [no class] - paint - [local treatment] - paste guns for volatile substances - pressure treatment - prune/wound treatment - [local treatment] - soil bed solarization The remarks field can be also used to provide further details on the EPPO code selected to describe the method of application. Examples for further specification of some EPPO codes are listed below: Circulating water application (3CWATM) - hydroponic/aquaponic water treatment Fogging (3FOGGM) - mechanical fogging - thermal fogging Fumigating (3FUMIM) - fumigation: enclosed spaces - fumigation: vacuum chamber - gassing Injecting (3INJEM) - stem injection Placing (3PLACM) - doseable matrix dispensors for volatile substances - retrievable active dispensors for volatile substances - retrievable passive dispensors for volatile substances - non retrievable active dispensors for volatile substances - non retrievable passive dispensors for volatile substances Spraying (3SPRYM): - air assisted broadcast spraying - high volume spraying - low volume spraying - ultra low volume spraying - application in overhead irrigation water - banded spraying - spot treatment (spraying)

	Spreading (3SPRDM) - granules application in row - granules application overall 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.
Application equipment	Select the types of application equipment used. This information is used in the operator and worker exposure scenarios
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. 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. 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. 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.
Growth stage of crop (first application)	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). 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)). For a range, also select the relevant BBCH code in the field 'Growth stage of crop (last application)'. 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.). 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). Please note that BBCH codes 71 to 79 is not used, if the main fruit growth happens in principal growth stage 8.
Growth stage of crop (last application)	Please select from the picklist the growth stage of crop at last application. See above (Growth stage of crop (first application)) for further details.

Treatment season	For autumn/winter sown crops, report whether the treatment is foreseen in autumn/winter or in spring/summer. Multiple selection is allowed. If necessary, any other restrictions for the treatment season can be reported in the remarks field, selecting the option 'other:'
Number of applications (range)	Information on the number of applications is mandatory. Report the number of applications (e.g. 1 – 3) per crop cycle. If only one treatment is foreseen, report '1' in the lower numeric field.
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.
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).
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.
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.
Concentration of target a.s. in dilution	For products applied after dilution with water, report the concentration of the active substance in the diluted solution.
Concentration of formulation in dilution	For products applied after dilution with water, report the concentration of the formulation in the solution.
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. 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)	It is mandatory to report the application rate for the target a.s. 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). 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 per treatment. Use the second numeric field to report the upper application rate per treatment. 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!). 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).
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).
Non-target a.s.	
Non-target a.s.	Select non-target active substance
Application rate per treatment for other a.s. (range)	This field is intended to specify the application rate for other active substance. For reporting the application rate, follow the recommendations on dose expression for products (EPPO General Standard PPI/239(3)).
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).
Concentration of other a.s. in dilution	For products applied after dilution with water, report the concentration of other active substance/s in the diluted solution.
Treatment window (for dispensers)	For dispensers or similar application forms, the duration of treatment window needs to be reported.
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.
Planting density	The field is not mandatory. Describe the planting density (number of plants per ha or m^2).
Pre-harvest interval not applicable	The checkbox should be ticked if the PHI is 'Not Applicable' e.g. cases where the pesticide is applied to empty storage rooms, or for treatment of fields after harvest. In case 'not applicable' is selected, further clarifications should be provided in the 'Remark' field.
Remarks	Provide any further clarifications as needed
Minimum pre-harvest	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

interval (in days)	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.
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.
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.
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'.
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).
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.
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.
Restrictions	The field is not mandatory. If relevant, please report any relevant restrictions that would have an impact on the risk assessment e.g.: - 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.
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.
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.

3. Additional transparency regulation information

Name	Instructions	Type
EFSA identifiers		Header
EFSA IT system and regulatory identifiers	Provide here identifiers required for integration with EFSA IT systems	Block of fields (repeatable)
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.	List sup. (picklist with remarks) Display: Basic
Identity	Enter here the identity (name, number, code) corresponding to the identifier type selected.	Text (2,000 char.) Display: Basic
Remarks		Text (32,768 char.) Display: Basic
Confidentiality assessment		Header
Contact for confidentiality assessment	Report the contact person or persons who will receive communications and decisions on the EFSA confidentiality assessment from the EFSA confidentiality team	Block of fields (repeatable)
Person		Link to entity (multiple) Display: Basic
Studies requiring confidential NoS justification		Header
Confidential NoS justification	Justification explaining any procedural deviations from the NoS obligations	Block of fields (repeatable)
Component flag		
NoS ID	List all Notification of Studies identifiers which require a justification.	
Link to study		

Confidential justification	Confidential Justification for (i) the absence of notification of a study (ii) the delayed notification of a study (iii) the withdrawal of a notification (iv) the non-inclusion in the dossier of a notified study	

ACTIVE SUBSTANCE DATASET

Proposed maximum residue levels and justification – Flexible summary

Purpose

This document should be compiled to 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		
Name	**Instructions**	**Type**
Administrative data		Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	Confidentiality
Description of key information		Header 1
	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
Maximum residue level	Use the repeatable block to create as many 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.	Block of fields (repeatable)
Rationale for MRL proposal	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	Open list with remarks (2000)

	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 wheat leads to a significant increase of the dietary burden, please select "increase of the livestock dietary burden". -If the purpose of the MRL application is to delete an MRL (see case 4), please select "other" and explain the rational for lowering MRL at the LOQ in the remark field, e.g. "a risk for consumer is identified with the existing MRL, therefore it is propose to lower the MRL at the LOQ"	
Critical GAP	This entry refers to the critical GAP(s), on which the MRL proposal is based. 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. 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 correponding GAP is/are the critical GAP(s), on which the MRL proposal is based. 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 here the GAP leading to highest residue in soil.	MultiLineText2000
Commodity	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. 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).	Multi select open list
MRL proposal	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	Unit measure with Closed List (Decimal)

	in this table. Therefore, provisional MRLs are not expected to be reported in this table.	
Residue definition monitoring	Enter the monitoring residue definition relevant for the selected commodities of plant or animal origin. This is the residue definition on which the MRL is derived.	Multi-line text
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
Remarks	Any additional remarks linked to the MRL derived.	Multi-line text
Maximum residue level		
Additional information	Follow instructions reported in "Additional information – common block"	Header 1
	Provide any additional information related to the MRL proposal(s), e.g., cases were MRL proposal are based on results from other crops. 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. Upload this information into the Attached (sanitised) documents for publication field	Rich text area

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-a195-2e1c158951e1	✓ 0110050 - Mandarins (0100000 - Fruits, fresh or frozen; tree nuts > 0110000 - Citrus fruits > 0110050 - Mandarins)	2 mg/kg	parent	☐

1. Identity of the active substance and applicant

1.1 Identity of the active substance and applicant

SUBSTANCE		
Name	**Instructions**	**Type**
Substance name	The International Organization for Standardization (ISO) common name, or proposed ISO common name. If an ISO name is not available, other proposed or accepted common names or the chemical name of the active substance can be used	Multi-line text
Public name	Public name of the active substance	Multi-line text
Legal entity flags	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	Confidentiality
Legal entity	Include here the name of the legal entity i.e. Company name for the applicant.	Entity reference field
Third party flags	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	Confidentiality
Third party	If appropriate, include link to the legal entity of a third party. This option is to be filled in by consultants if the are working on a dossier.	Entity reference field
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	
Flags	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	Confidentiality
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
Identity	Enter here the identity (name, number, code) corresponding to the identifier type selected.	Multi-line text

Country	Provide the country where the identifier is relevant. The field is a multi-select field; several countries can be selected for the same identifier. If none of pre-defined items apply, select 'other:'. A text field is then activated next to the list field in which you can enter information on the country.	Multi select open list
Relation	If relevant, indicate the reason for providing an identifier other than the reference substance identifiers used to identify the Substance.	Open list
Remarks	Include remarks if relevant.	Text area
Contact persons	Contact entity	Header 1
Person flags	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	Confidentiality
Person	Select contact person or create new contact.	Entity reference field
Identification of substance		Header 1
Reference substance flags	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	Confidentiality
Reference substance	Link to the reference substance	Entity reference field
Type of substance		Header 1
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
Origin	Picklist to indicate class of active substance e.g organic or inorganic	Open list
Role in the supply chain	Check 'Manufacturer' to indicate the applicant is the Producer of the active substance	Header 1
Role flags	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	Confidentiality

Links to support material:

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 manufacturing plant, describe the purity of the starting materials, chemical pathways and identity of impurities present in the final product as well as the identity of impurities present in the final product.

FLEXIBLE_RECORD.Manufacturer_EU_PPP		
Name	**Instructions**	**Type**
Administrative data		Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	Confidentiality
Related compositions	Link to one or more compositions of the substance can be made which will then dis-play 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
Description of key information		Header 1
	Describe the manufacturing process e.g. chemical pathways involved. 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. For basic substances simply provide a description of the method/s of manufacture (as indicated in the application procedure document). Description of the manufacturing process, Flowcharts can be uploaded as images in the Attached background material section.	Rich text area
Quality Control	Describe the quality control criteria and steps in the production process. Indicate techniques to ensure a uniform product. Quantitative Information on impurities should be reported the Substance Composition document.	Rich text area
Additional information		Header 1
	State the manufacturing plant if separate documents are provided for each manufacturing plant	Rich text area

Document J	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. The completed "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) must be included in Document J however, all relevant IUCLID documents including this information should also be completed. For MRL applications this document should be provided only upon request. For this reason, analytical methods for impurities which are not toxicologically relevant should be reported in Doc J. N.B. Note that **Document J will be dismissed as from April** 2025 so we strongly recommend that applicants familiarise with the filtering rules and start to provide the data in the appropriate IUCLID fields	Single file attachment
Sanitised Document J	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 to 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. N.B. Note that the **sanitised Document J will be dismissed as from April** 2025 so we strongly recommend that applicants familiarise with the filtering rules and start to provide the data in the appropriate IUCLID fields	Single file attachment
Attached background material	Additional background material can be uploaded here, use remarks to indicate the contents of the uploaded files 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.	
Attached confidential document	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. 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
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 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 non-confidential version removing the redactions relating to confidentiality requests that were rejected in part or in full must be uploaded here.	Attachments list
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

Links to support material:

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 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.
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		
Name	**Instructions**	**Type**
General Information		Header 1
Name	Indicate a name representative of the composition.	Text
Type of composition	Select the type of composition as appropriate. For pesticide dossier the type of compostition should be 'legal entity composition of the substance', that refers to a composition specific to the party carrying out the application/notification/registration. When reporting the batch composition, select 'other:' and indicate "batch composition"	Open list
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
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
Justification for deviations	Provide in this field, if relevant, the justification for deviating from agreed conventions when reporting the composition.	Text area
Attached description / justification	Attach 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.	
Attached document	Upload a file by clicking the upload icon. Documents with confidential material should not be uploaded in this field.	Single file attachment
Remarks	Provide information about the contents of the attached document.	Text
Related composition(s)		Header 2
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.	Endpoint

	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)'.	referenc e list
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
Degree of purity		Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	Confide ntiality
	For specification documents: Report the proposed minimun purity of the active substance as manufactured. For batch documents: Report the content of the pure active substance measured in the batch analysed. 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 (Decima l)
Constituents	This part is a repeatable block subsection enabling to provide detail on all constituents the active substance as manufactured. Click the Plus button to open the repeatable block. If the active substance is a mixture (e.g. of different isomers or a plant exctract etc.) then all components of this mixture should be reported here with their proposed level of specification (or measured level in case of batch analysis results) using the repeatable block i.e. one raw per component.	Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	Confide ntiality
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	Entity referenc e field

	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. Where relevant detailed information on all components such as condensates, culture medium, etc. must be provided	
Typical concentration	Use this field when you want to report the minimun OR the maximun content. For active substances manufactured as technical materials and **specification** documents: Report the proposed minimun purity of the active substance as manufactured. For active substances manufactured as technical materials or technical concentrates and for **batch** documents: Report the content of the pure active substance measured in the batch analysed. Note: scientific notation can be used, 5e7= 50000000	Half-bounded with open list (Decimal)
Concentration range	Use this field when you want to report a concentration range (e.g. for technical concentrates, plants extracts etc.). For active substances manufactured as technical concentrates and **specification** documents: Report the proposed concentration range of the pure active substance.	Range with open list (Decimal)
Remarks	Provide additional information about the constituent, as relevant.	Text area
Impurities		Header 1
	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.	
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	Confidentiality
Reference substance	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 information on reference substances, see chapter 10 of 'Functionalities of IUCLID', in the left pane of the Help system window.	Entity reference field
Typical concentration	Use this field when you want to report the minimun OR the maximun content. Indicate the typical concentration of the impurity in the active substance as manufactured. Ensure to follow regulatory guidance on what constitutes an impurity. For active substances manufactured as technical materials and specification documents: Report the proposed maximun specification of the impurity.	Half-bounded with open list (Decimal)

	For active substances manufactured as technical materials or technical concentrates and for batch documents: Report the measured content of the imputity in the batch analysed.	
Concentration range	Use this field when you want to report a concentration range (e.g. for technical concentrates, plants extracts etc.). Indicate the concentration range of the impurity the active substance as manufactured. 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 '<='. For active substances manufactured as technical concentrates and specification documents: Report the proposed concentration range of the impurity.	Range with open list (Decimal)
Remarks	Provide additional information about the impurity, as relevant.	Text area
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.	Check box
Additives		Header 1
	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 <image> to open the repeatable block. If the composition contains more than one additive, add a new block to describe each additive.	
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	Confidentiality
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 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.	Entity reference field
Typical concentration	Use this field when you want to report the minimun OR the maximun content. Indicate the measured concentration of the additive in the specific batch analysed.	Half-bounded with open list (Decimal)
Concentration range	Use this field when you want to report a concentration range (e.g. for technical concentrates, plants extracts etc.). Indicate the minimum and maximum content in g/kg of each additive in the technical active substance.	Range with open list (Decimal)

	This information should be completed for each specification document.	
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
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
Remarks	Provide additional information about the additive, as relevant.	Text area
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.	Check box
Characterisation of polymers	This section is not relevant for pesticides	Header 1

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

Purpose

Report summary information of the most relevant study(ies) from which the key value for chemical safety assessment is extrapolated.
In the context of MRL application, provide only the most relevant details for:
- Solubility in water
- Partition coefficient

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

ENDPOINT_SUMMARY.PhysicalChemicalProperties		
Name	**Instructions**	**Type**
Administrative data		Header 1
Legal entity flags	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	Confidentiality
Description of key information		Header 1
	Provide a brief description of the phys- chem properties	Rich text area
Additional information	Provide additional information related to the assessment of the endpoints that are relevant to this section	Header 1
Attached background material	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).	

2.5 Solubility in water

Solubility in water Endpoint summary

Purpose

This document should be compiled to provide summary information on the most relevant study(ies) from which the key value for 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.

ENDPOINT_SUMMARY.WaterSolubility		
Name	**Instructions**	**Type**
Administrative data		Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see:	Confidentiality

	"User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	
Link to relevant study record(s)		Header 1
Link to relevant study record(s)	Provide here the link(s) to the study record(s) supporting the choice of the key value for assessment.	Link to endpoint (multiple)
Description of key information		Header 1
	Report Information to support solubility in water for example: - the structural formula - vapour pressure - dissociation constant - temperature - purity and pH	Rich text area
Key value for chemical safety assessment		Header 1
Water solubility	Report solubility in water in mg or g/L	Unit measure with Closed List (Decimal)
at the temperature of	Report temperature and unit measure	Unit measure with Closed List (Decimal)
Additional information	Follow instructions reported in "Additional information– common block"	Header 1

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.

ENDPOINT_STUDY_RECORD.WaterSolubility		
Name	**Instructions**	**Type**
Administrative data	Follow instructions reported in "Administrative data – common block"	Header 1
Data source	Follow instructions reported in "Data source (Literature Reference) – common block"	Header 1

Materials and methods	Follow instructions reported in "Material and methods – common block" Guideline: OECD 105.	Header 1
Test material	Follow instructions reported in "Test Material – common block"	Header 2
Study design		Header 2
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
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
Model and software	Follow instructions reported in "Model and software – common block". Note: This block of fields is displayed only when "Type of information" is set to (Q)SAR.	Header 2
Any other information on materials and methods incl. tables	Follow instructions reported in "Any other information on materials and methods incl. tables – common block"	Header 2
Results and discussion		Header 1
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 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
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)
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	Open list with remarks

	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.	
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)
Incubation duration	Specify the time until equilibrium was reached in the test.	Range with closed list (Decimal)
Temp.	Enter numeric value and unit.	Unit measure with Closed List (Decimal)
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)
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)
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.	
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box
Type of test	Select from drop-down list.	Open list with remarks
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)

Element analysed	Specify the element analysed.	Multi-line text
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)
Incubation duration	Specify the duration of incubation for the loading applied. Select from drop-down list.	Unit measure with Closed List (Decimal)
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
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)
Details on results		Text area
Additional information about applicability domain and reliability of (Q)SAR predictions	Follow instructions reported in "Additional information about applicability domain and reliability of (Q)SAR predictions – common block"	Header 2
Any other information on results incl. tables	Follow instructions reported in "Any other information on results incl. tables – common block"	Header 2
Overall remarks, attachments	Follow instructions reported in "Overall remarks, attachments – common block"	Header 1
Applicant's summary and conclusion	Follow instructions reported in "Applicant's summary and conclusion – common block"	Header 1

2.7 Partition coefficient n-octanol/water

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 .

ENDPOINT_SUMMARY.PartitionCoefficient		
Name	**Instructions**	**Type**
Administrative data		Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	Confidentiality
Link to relevant study records		Header 1
	Provide here the link(s) to the study record(s) supporting the choice of the key value for assessment.	Link to endpoint (multiple)
Description of key information		Header 1
	Report Information to support the partition coefficient, for example state: temperature, pH and purity	Reach text area
Key value for chemical safety assessment		Header 1
Log Kow (Log Pow)	Provide a unique numeric value to be used in the chemical safety assessment. A justification for why this specific value was selected should be provided in the field "Additional information". You may provide a numeric range in the field "Description of key information".	Decimal
at the temperature of	Provide temperature value and unit measure	Unit measure with Closed List (Decimal)
Additional information	Follow instructions reported in "Additional information– common block"	Header 1

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.PartitionCoefficient		
Name	**Instructions**	**Type**
Administrative data	Follow instructions reported in "Administrative data – common block"	Header 1
Data source	Follow instructions reported in "Data source (Literature Reference) – common block"	Header 1
Materials and methods	Follow instructions reported in "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
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 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'.	Open list
Test material	Follow instructions reported in "Test Material – common block"	Header 2
Study design		Header 2
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
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
Model and software	Follow instructions reported in "Model and software – common block". Note: This block of fields is displayed only when "Type of information" is set to (Q)SAR.	Header 2

Any other information on materials and methods incl. tables	Follow instructions reported in "Any other information on materials and methods incl. tables - common block"	Header 2
Results and discussion		Header 1
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.	
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box
Type	Indicate if Pow or log Pow is given.	Closed list
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)
Temp.	Enter numeric value and unit.	Unit measure with Closed List (Decimal)
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)
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)
Partition coefficient		
Details on results	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'). If requested by the regulatory programme, also attach a chart of relation and fitted regression equation (which includes a correlation	Text area

	coefficient) in field 'Attached background material'.	
Additional information about applicability domain and reliability of (Q)SAR predictions	Follow instructions reported in "Additional information about applicability domain and reliability of (Q)SAR predictions – common block"	Header 2
Any other information on results incl. tables	Follow instructions reported in "Any other information on results incl. tables – common block"	Header 2
Overall remarks, attachments	Follow instructions reported in "Overall remarks, attachments – common block"	Header 1
Applicant's summary and conclusion	Follow instructions reported in "Applicant's summary and conclusion – common block"	Header 1

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

  Only one endpoint summary should be created under this section.

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

ENDPOINT_SUMMARY. Effects on harmful organisms, function, mode of action and possible resistance		
Name	**Instructions**	**Type**
Administrative data		Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	Confidentiality
Description of Key information	Provide a summary of the key information related to the studies here. The summary could include, for example: - the test type - the test guideline used (and any deviations from it) - the test organism - the exposure duration - other contextual information on the origin of the key value	
Additional information	Follow instructions reported in "Additional information – common block"	Header 1

ENDPOINT_STUDY_RECORD. Effects on harmful organisms, function, mode of action and possible resistance		
Name	**Instructions**	**Type**
Administrative data	Follow instructions reported in "Administrative data – common block"	Header 1
General information		Header 1

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 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 u purpose additional pieces of information may have to be Consult the programme-specific guidance on the details t	Multi-line text
Pest / target organisms to be controlled		Header 2
Target organisms	Specify the target organism(s) to be controlled. Repeat this block of fields as 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.	
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
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 entered in the supplementary remarks field. EPPO codes for common name relevant	Open list with remarks

	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
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
Target organisms		
Products, organisms or objects to be protected / under study		Header 2
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, plants, plant products, seeds, storage goods, drinking water, hard surface material, porous surface.	Multi-line text
Information on intended use and application		Header 2
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
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
Field of use envisaged / User	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. If this is provided additional information on the use of the product already described in the GAP document does not need to be provided	Text area

Information on application of product		Header 2
Method of application	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. 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 guidance. If so, indicate the type of coding system in parentheses, e.g. 'VII.1 (EU BPD)'. Reference to use description document is sufficient. Alternatively, see **Field of use envisaged / User**	Multi select open list with remarks (2000)
Details on application	See **Field of use envisaged / User**	Text template
General information on effectiveness		Header 2
Effects on target organisms	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 standards). 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'.	Text area
Mode of action	Indicate the principles of the mode of action for the function indicated in above field, e.g. 'acute toxin: contact poison'. If not listed, select 'other' and specify. 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)'. For plant protection products mode of action, FRAC, HRAC and IRAC codes can be reported.	Open list with remarks
Details on mode of action	For the function indicated in above field, indicate the principles of the mode of action; e.g. 'contact poison' or 'stomach poison'. Briefly describe the biochemical and	Text template

	physiological mechanisms, e.g. 'cholinesterase inhibition' and the biochemical pathway and specify any time delay between application and effect. Use the freetext template as appropriate (delete/add elements). For further instructions refer to the relevant guidance documents	
(Possible) Occurrence of resistance	Indicate whether resistance can possibly develop including cross-resistance. As appropriate include an appraisal of the information gained from the efficacy studies.	Text area
Management strategies to avoid resistance	Describe any appropriate management strategies towards the minimization of the development of resistance.	Text area
Any other known limitations and management strategies	As applicable describe any other known limitations and relevant management strategies towards them.	Text area
Model and software	Follow instructions reported in "Model and software – common block". Note: This block of fields is displayed only when "Type of information" is set to (Q)SAR.	Header 2
Results and discussion		Header 1
Details on results		Text area
Additional information about applicability domain and reliability of (Q)SAR predictions	Follow instructions reported in "Additional information about applicability domain and reliability of (Q)SAR predictions – common block"	Header 2
Any other information on results incl. tables	Follow instructions reported in "Any other information on results incl. tables – common block"	Header 2
Overall remarks, attachments	Follow instructions reported in "Overall remarks, attachments – common block"	Header 1
Applicant's summary and conclusion	Follow instructions reported in "Applicant's summary and conclusion – common block"	Header 1

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

Analytical methods- Endpoint summary

Purpose

Summary information of the most relevant study(ies) from which the key value for assessment is supported. Provide all relevant validation data, including matrix effects, description of calibration procedure, calibration data, limit of detection (LOD), limit of quantification (LOQ), recovery (individual data and mean) and repeatability, data providing the selectivity and specificity of the method, confirmatory data (if required), independent laboratory validation data (if required), extraction efficiency of solvents used in methods for food and feed.

ENDPOINT_SUMMARY.AnalyticalMethods		
Name	**Instructions**	**Type**
Administrative data		Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	Confidentiality
Link to relevant study record(s)		Header 1
Link to relevant study record(s)	Provide here the link(s) to the study record(s) supporting the choice of the key value for assessment.	Cross-reference: ENDPOINT_STUDY_RECORD.AnalyticalMethods
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	
Additional information	Follow instructions reported in "Additional information – 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

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		
Name	**Instructions**	**Type**
Administrative data	Follow instructions reported in "Administrative data – common block"	Header 1
Data source	Follow instructions reported in "Data source – common block"	Header 1
Background		Header 1
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'. PURPOSE OF THIS TEMPLATE: 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 feeding stuffs, formulated product, other.	Multi-line text
Method class	Indicate the method classes reported in this document.	Picklist
Materials and methods	Follow instructions reported in "Material and methods – common block" 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) Residues: EU guidance document on pesticide analytical methods for risk assessment and post-approval control and monitoring purposes (SANTE/2020/12830, Rev.2) 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.	Header 1

Matrix / medium	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. Note: The picklist is not descriptive as to whether analytical methods have to be submitted for each of 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.	Multi select open list with remarks
Test material	Follow instructions reported in "Test material – common block"	Header 2
Analytical (primary) method		Header 2
Instrument / detector	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'. 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.	Multi select open list
Residue method	Indicate if the method detects multiple analytes. Further details can be provided in the remarks.	Picklist
Extraction and clean-up	Indicate the method used for extraction and clean-up. For major deviations or different methods, select other and provide remarks.	
Flow diagram	Provide an image of the analytical method steps	image
Further details on analytical 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 free text 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
Enforcement method	This section should be completed if Enforcement has been selected in the Method Class field. Provide information only	Header 2

(if applicable)	where it differs from the information provided in the 'Principles of the analytical methods section'.	
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
Residue method	Indicate if the method detects multiple analytes. Further details can be provided in the remarks.	picklist
Extraction and clean-up	Indicate the method used for extraction and clean-up. For major deviations or different methods, select other and provide remarks.	picklist
Flow diagram	Provide an image of the analytical method steps	image
Further 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 free text 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
Confirmatory method (if applicable)	This section should be completed if Confirmatory has been selected in the Method Class field. Provide information only where it differs from the information provided in the 'Principles of the analytical methods section'.	Header 2
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
Residue method	Indicate if the method detects multiple analytes. Further details can be provided in the remarks.	picklist
Extraction and clean-up	Indicate the method used for extraction and clean-up. For major deviations or different methods, select other and provide remarks.	picklist
Suitability of the method	Indicate the method type used to confirm correct analyte identity and quantification.	picklist

for confirmation		
Further 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. Consult the programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) thereof.	Multi-line text
Independent Laboratory Validation – ILV (if applicable)	This section should be completed for primary monitoring methods for food of plant and animal origin.	Header 2
Instrument/detector	Indicate the instrument / detector used for the quantitative analysis of the parent compound / transformation products 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'. 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.	Multiselect open list
Residue method	Indicate if the method detects multiple analytes. Further details can be provided in the remarks.	picklist
Extraction and clean-up	Indicate the method used for extraction and clean-up. For major deviations or different methods, select other and provide remarks.	picklist
Flow diagram	Provide an image of the analytical method steps	image
Details on ILV	Briefly describe further details on the principles of the ILV 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
Any other information on materials and methods incl. tables	Follow instructions reported in "Any other information on materials and methods incl. tables – common block"	Header 2
Results and discussion	Report the results for the method described in the 'Principles of the analytical methods section'.	Header 1

Results using analytical (primary) method		Header 2
Recovery	Complete the template for the evaluated recovery with the following information	Text template
Analyte	Link the reference substance of the analyte	
Matrix	Indicate the matrix the analyte was extracted from	text
MRM/ m/z	Report the mass transition monitored	Numeric range
Fortification level	Report the fortification levels at which repeatability was evaluated	Numeric
Number replicates	Number of determinations (n) per concentration level	Numeric
Range recovery (%)	Report lowest and highest values of the recovery	Numeric range
Mean recovery (%)	Report mean value of recovery	Numeric range
RSD (%)	Report recovery relative standard deviation	numeric
Remarks	Report relevant remarks if any.	text
Additional details on recovery results	Report any additional detail not covered by the other fields, if any.	text
Repeatability	Complete the template for the evaluated repeatability with the following information	Template
Analyte	Link the reference substance of the analyte	
Matrix	Indicate the matrix the analyte was extracted from	text
Number replicates	Report number of replicates	Numeric
Mean content	Report mean concentration of the analyte	Numeric
RSD_R (%)	Report reproducibility relative standard deviation	Numeric
RSDr (%)	Report repeatability relative standard deviation	Numeric
Horrat value	Report Horrat value	Numeric
Remarks	Report relevant remarks if any.	text
LOQ/LOD	Complete the template for the determined LOQ/LOD with the following information	template
Analyte	Link the reference substance of the analyte	
Matrix	Short description of the matrix tested	text
Limit of quantification	Enter the limit of quantification (LOQ)	numeric
Limit of detection	Enter the limit of detection (LOD), if relevant and validated	numeric
Remarks	Report relevant remarks if any.	test
Calibration	Complete the template for the calibration with the following information	template

Analyte	Link the reference substance of the analyte	
Standards	Describe the standards used in the calibration	Picklist
Matrix	Short description of the matrix tested	text
MRM m/z	Report the mass transition monitored	Numeric range
Calibration range	Report lowest and highest value of calibration values	Numeric range
Calibration equation	Report the calibration equation	text
Correlation coefficient (r)	Report the value of the correlation coefficient	numeric
Correlation coefficient (r2)	Report the value of the correlation coefficient	numeric
Number replicates	Indicate the number of replicates	numeric
Remarks	Report relevant remarks if any.	text
Matrix effects (%)	Report the matrix effect (100 * peak area or slope (matrix)/ peak area or slope (solvent) – 100)	Numeric
Matrix effects remarks	Provide additional information on the Matrix effects, further information should be provided if matrix effects exceed 20%	text
Additional details on analytical (primary) method	Provide additional information on the results of the primary method. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	text
Results using enforcement method (if applicable)		Header 2
Recovery	Complete the template for the evaluated recovery with the following information.	Text template
Analyte	Link the reference substance of the analyte	
Matrix	Indicate the matrix the analyte was extracted from	text
MRM/ m/z	Report the mass transition monitored	Numeric range
Fortification level	Report the fortification levels at which repeatability was evaluated	Numeric
Number replicates	Number of determinations (n) per concentration level	Numeric
Range recovery (%)	Report lowest and highest value of the range recovery	Numeric range
Mean recovery (%)	Report mean value of the recovery	Numeric range
RSD(%)	Report recovery relative standard deviation	numeric

Remarks	Report relevant remarks if any.	text
Additional details on recovery results	Report any additional detail not covered by the other fields, if any.	text
Repeatability	Complete the template for the evaluated repeatability with the following information	Template
Analyte	Link the reference substance of the analyte	
Matrix	Indicate the matrix the analyte was extracted from	text
Number replicates	Report number of replicates	Numeric
Mean content	Report mean concentration of the analyte	Numeric
RSD_R (%)	Report reproducibility relative standard deviation	Numeric
RSDr (%)	Report repeatability relative standard deviation	Numeric
Horrat value	Report Horrat value	Numeric
Remarks	Report relevant remarks if any.	text
LOQ/LOD	Complete the template for the determined LOQ/LOD with the following information	template
Analyte	Link the reference substance of the analyte	
Matrix	Short description of the matrix tested	text
Limit of quantification	Enter the limit of quantification (LOQ)	numeric
Limit of detection	Enter the limit of detection (LOD), if relevant and validated	numeric
Remarks	Report and relevant remarks if any.	test
Calibration	Complete the template for the calibration with the following information	template
Analyte	Link the reference substance of the analyte	
Standards	Describe the standards used in the calibration	Picklist
Matrix	Short description of the matrix tested	text
MRM m/z	Report the mass transition monitored	Numeric range
Calibration range	Report lowest and highest calibration values	Numeric range
Calibration equation	Report calibration equation	text
Correlation coefficient (r)	Report the value of the correlation coefficient	numeric
Correlation coefficient (r2)	Report the value of the correlation coefficient	numeric
Number replicates	Report number of replicates	numeric
Remarks	Report relevant remarks if any.	text

Matrix effects (%)	Report the matrix effect (100 * peak area or slope (matrix)/ peak area or slope (solvent) – 100)	Numeric
Matrix effects remarks	Provide additional information on the Matrix effects, further information should be provided if matrix effects exceed 20%	text
Additional details on enforcement method	Provide additional information on the results of the enforcement method. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	text
Results using confirmatory method (if applicable)	If not applicable, ignore this field. If applicable (as for enforcement methods), present the results of the confirmation (whether it is simultaneous to the primary detection or by an independent analytical technique) in terms of whether or not it was conducted according to guideline specifications.	Header 2
Recovery	Complete the template for the evaluated recovery with the following information.	template
Analyte	Link the reference substance of the analyte	
Matrix	Indicate the matrix the analyte was extracted from	text
MRM/ m/z	Report the mass transition monitored. For confirmation simultaneous to primary detection, discuss whether enough number of qualifier ions/mass transitions were monitored according to guideline specifications.	Numeric range
Fortification level	Report the fortification levels at which repeatability was evaluated. Repeatability should be evaluated at least at the level of the respective LOQ of the primary method.	Numeric
Number replicates	Number of determinations (n) per concentration level	Numeric
Range recovery (%)	Report lower and highest values of recovery	Numeric range
Mean recovery (%)	Report mean value of recovery	Numeric range
RSD (%)	Report recovery relative standard deviation	numeric
Remarks	Report relevant remarks if any.	text
Repeatability	Complete the template for the evaluated repeatability with the following information	Template
Analyte	Link the reference substance of the analyte	
Matrix	Indicate the matrix the analyte was extracted from	text
Number replicates	Report number of replicates	Numeric
Mean content	Report mean concentration of the analyte	Numeric
RSD_R (%)	Report reproducibility relative standard deviation	Numeric
RSDr (%)	Report repeatability relative standard deviation	Numeric
Horrat value	Report Horrat value	Numeric
Remarks	Report relevant remarks if any.	text

LOQ/LOD	For confirmation method this template (table) is not relevant.	template
Analyte	Link the reference substance of the analyte	
Matrix	Indicate the matrix the analyte was extracted from	text
Limit of quantification	Enter the limit of quantification (LOQ)	numeric
Limit of detection	Enter the limit of detection (LOD), if relevant and validated	numeric
Remarks	Report relevant remarks if any.	test
Calibration	Complete the template for the calibration with the following information	template
Analyte	Link the reference substance of the analyte	
Standards	Describe the standards used in the calibration	Picklist
Matrix	Short description of the matrix tested	text
MRM m/z	Report the mass transition monitored	Numeric range
Calibration range	Report lowest and highest values of calibration values	Numeric range
Calibration equation	Report calibration equation	text
Correlation coefficient (r)	Report the value of the correlation coefficient	numeric
Correlation coefficient (r2)	Report the value of the correlation coefficient	numeric
Number replicates	Indicate the number of replicates	numeric
Remarks	Report relevant remarks if any.	text
Matrix effects (%)	Report the matrix effect (100 * peak area or slope (matrix)/ peak area or slope (solvent) – 100)	Numeric
Matrix effects remarks	Provide additional information on the Matrix effects, further information should be provided if matrix effects exceed 20%	text
Additional details on confirmatory method	Provide additional information on the results of the confirmatory method. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	text
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.	Header 2
Recovery	Complete the template for the evaluated recovery with the following information.	text template
Analyte	Link the reference substance of the analyte	
Matrix	Indicate the matrix the analyte was extracted from	text

MRM/ m/z	Report the mass transition monitored.	Numeric range
Fortification level	Report the fortification levels at which repeatability was evaluated.	Numeric
Number replicates	Number of determinations (n) per concentration level	Numeric
Range recovery (%)	Report lowest and highest values of the recovery	Numeric range
Mean recovery (%)	Report mean value of recovery	Numeric range
RSD (%)	Report recovery relative standard deviation	numeric
Remarks	Report relevant remarks if any.	text
Repeatability	Complete the template for the evaluated repeatability with the following information	Template
Analyte	Link the reference substance of the analyte	
Matrix	Indicate the matrix the analyte was extracted from	text
Number replicates	Report number of replicates	Numeric
Mean content	Report mean concentration of the analyte	Numeric
RSD_R (%)	Report reproducibility relative standard deviation	Numeric
RSDr (%)	Report repeatability relative standard deviation	Numeric
Horrat value	Report Horrat value	Numeric
Remarks	Report relevant remarks if any.	text
LOQ/LOD	Complete the template for the determined LOQ/LOD with the following information	template
Analyte	Link the reference substance of the analyte	
Matrix	Short description of the matrix tested	text
Limit of quantification	Enter the limit of quantification (LOQ). It should confirm the LOQ of the primary method.	numeric
Limit of detection	Enter the limit of detection (LOD), if relevant and validated	numeric
Remarks	Report and relevant remarks if any.	test
Calibration	Complete the template for the calibration with the following information	template
Analyte	Link the reference substance of the analyte	
Standards	Describe the standards used in the calibration	Picklist
Matrix	Short description of the matrix tested	text
MRM m/z	Report the mass transition monitored	Numeric range
Calibration range	Report lowest and highest value of calibration values	Numeric range
Calibration equation	Report the calibration equation	text
Correlation	Report the value of the correlation coefficient	numeric

coefficient (r)		
Correlation coefficient (r2)	Report the value of the correlation coefficient	numeric
Number replicates	Indicate the number of replicates	numeric
Remarks	Report relevant remarks if any.	text
Matrix effects (%)	Report the matrix effect (100* peak area or slope (matrix)/peak area or slope (solvent) – 100)	numeric
Matrix effects remarks	Provide additional information on the Matrix effects, further information should be provided if matrix effects exceed 20%.	text
Additional details on independent laboratory validation	Use this field to detail any differences between the primary method and the ILV method. If this is reported in a separate study, the ILV study should be cross-referenced to this study.	picklist
Remarks	Provide additional information on the results of the ILV not covered in the previous fields.	text
Any other information on results incl. tables	Follow instructions reported in "Any other information on results incl. tables – common block" Provide here the results of the evaluation of extraction efficiency according to SANTE/2017/10632. Rev. 5. Extraction efficiency should be evaluated for all plant matrix groups or animal commodities for which residue analytical methods are required (pre- and post-registration). As a first step, the evaluation of extraction efficiency should be done with radiolabelled material. If not available for the matrix group where the crop(s) of interest belong(s), cross-validation studies should be performed and detailed results provided as indicated in the extraction efficiency technical guideline SANTE/2017/10632. Enter any details (including tables) that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. If this is reported in a separate study, the evaluation of extraction efficiency should be cross-referenced to this study and ideally, the main conclusions with a conclusive justification reported here.	Header 2
Overall remarks, attachments	Follow instructions reported in "Overall remarks, attachments – common block"	Header 1
Applicant's summary and conclusion	Follow instructions reported in "Applicants summary and conclusion – common block"	Header 1

Links to support material:

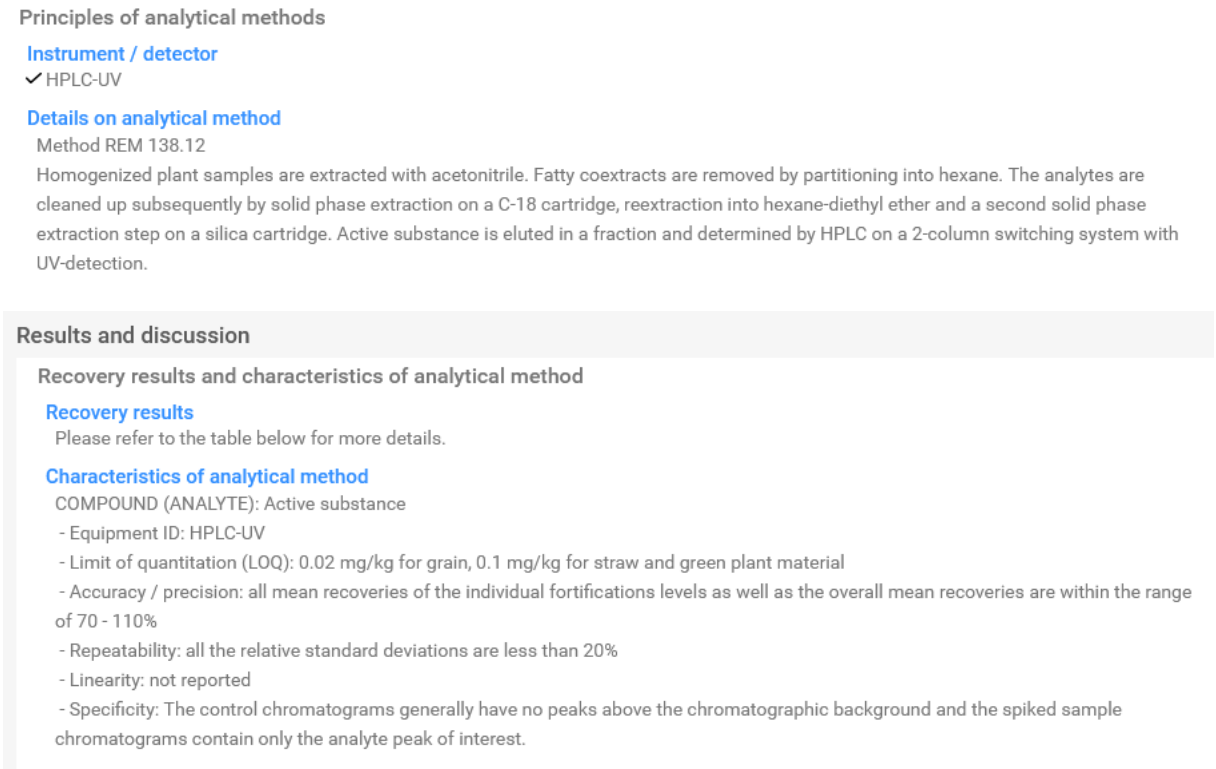
OECD GUIDANCE DOCUMENT ON PESTICIDE RESIDUE ANALYTICAL METHODS http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2007)17&doclanguage=en

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/11312/2021 – 1 January 2022

Technical Guideline on the Evaluation of Extraction Efficiency of Residue Analytical Methods – SANTE 2017/10632 rev.5, 11 May 2023

Residue analytical methods for risk assessment and post-approval control and monitoring purposes – SANTE/2020/12830. Rev 2 – 14 February 2023.



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) [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]. For presenting the results in tabular format for repeated dose toxicity studies by the oral route the applicant should use the common block detailed toxicological results implemented in OHT 67.

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.

(Q)SAR(Q)SAR(Q)SARIn case (Q)SARs are submitted, please refer to specific instructions in the relevant fields of each endpoint study record.

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 5.3 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) documeendpointnts 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.

Toxicological and metabolism studies on the active substance – Flexible record

Purpose

To report Health-based guidance values that 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		
Name	**Instructions**	**Type**
Administrative data		Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	Confidentiality
Description of key information		Header 1
	If all key information is provided in the linked study records, this field can be left empty. In case there is no linked study record, or in case you want to point to specific information in the linked study record, provide a summary of the key information related to the studies here. The summary could include, for example: - the test type - the test guideline used (and any deviations from it) - the test organism - the exposure duration - other contextual information on the origin of the key value	Rich text area
Human health hazard characteristics		Header 1
AOEL (Acceptable operator exposure level)		Header 2
Not allocated	Check the box if an AOEL is not necessary for the application	Check box
Justification	Justification for the non-derivation of an AOEL	Text
AOEL	Report the AOEL value and select the relevant units	Unit measure with Closed List (Decimal)
Population	Select the relevant population	Multi-picklist
Assessment body	Select the relevant assessment body	Picklist
Study retained	Type of study used to derive the AOEL (species and duration)	Multi select open list with remarks
Route of original study	Route of exposure in the study used to derive the AOEL	Closed list

Oral absorption value (%)	Oral absorption value derived from the toxicokinetic studies expressed as a percentage	Decimal
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
Justification of the overall UF	Justification for the uncertainty factor applied considering intra/inter species extrapolation. Please detail if additional UF are applied e.g.: - 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 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. e.g. In case some studies are missing, additional UF can be added. - UF for remaining uncertainties. In that case, the assessment factor should where relevant be applied and justified on a case-by-case basis.	Multi-line text
Dose descriptor starting point	Critical endpoint value, type (e.g. NOAEL, BMDL05), value and units	Open list
Value	Report the numerical value.	Unit measure with Closed List (Decimal)
Critical endpoint	Link to the critical endpoint study record	Reference
Justification and comments	Provide additional information related to the derivation of this specific toxicological reference value.	Rich text area
ADI (Acceptable daily intake)		Header 2
Not allocated	Check the box if an ADI is not necessary for the application	Check box
Justification	Justification for the non-derivation of an ADI	Text

ADI	Report the ADI value and select the relevant units 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.	Numeric range (decimal with picklist)
Population	Select the relevant population	Multi-Picklist
Assessment body	Select the relevant assessment body	Picklist
Study retained	Type of study used to derive the ADI (species and duration)	Multi select open list with remarks
Route of original study	Route of exposure in the study used to derive the ADI. It should be by default: oral.	Closed list
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). Please detail if additional UF are applied e.g.: - 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. - 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. - 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. e.g. In case some studies are missing, additional UF can be added. - UF for remaining uncertainties. In that case, the assessment factor should where relevant be applied and justified on a case-by-case basis.	Text
Justification of the overall UF	Justification for the uncertainty factor applied considering intra/inter species extrapolation	Multi-line text
Dose descriptor starting point	Critical endpoint value, type (e.g. NOAEL, BMDL05), value and units	Open list
Value	Report the numerical value	Unit measure with Closed List (Decimal)

Critical endpoint	Link to the critical endpoint study record	Reference
Justification and comments	Provide additional information related to the derivation of this specific toxicological reference value.	Rich text area
ARfD (Acute reference dose)		Header 2
Not allocated	Check the box if an ARfD is not necessary for the application	Check box
Justification	Justification for the non-derivation of an ARFD	Text
ARfD	Report the ARfD value and select the relevant units 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.	Numeric range (decimal with picklist)
Population	Select the relevant population	Multi-picklist
Assessment body	Select the relevant assessment body.	Picklist
Study retained	Type of study used to derive the ARfD (species and duration)	Multi select open list with remarks
Route of original study	Route of exposure in the study used to derive the ARfD. It should be by default: oral.	Closed list
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
Justification of the overall UF	Please detail if additional UF are applied e.g.: - 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 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. e.g. In case some studies are missing, additional UF can be added.	Multi-line text

	- UF for remaining uncertainties. In that case, the assessment factor should where relevant be applied and justified on a case-by-case basis. Justification for the uncertainty factor applied considering intra/inter species extrapolation	
Dose descriptor starting point	Critical endpoint value, type (e.g. NOAEL, BMDL05), value and units	Open list
Value	Report the numerical value	Unit measure with Closed List (Decimal)
Critical endpoint	Link to the critical endpoint study record	Reference
Justification and comments	Provide additional information related to the derivation of this specific toxicological reference value.	Rich text area
AAOEL (Acute acceptable operator exposure level)		Header 2
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
Justification	Justification for the non-derivation of an AAOEL	Text
AAOEL	Report the AOEL and if they are available select the relevant units.	Unit measure with Closed List (Decimal)
Population	Select the relevant population.	Multi-picklist
Assessment body	Select the relevant assessment body.	Picklist
Study retained	Type of study used to derive the AAOEL (species and duration)	Multi select open list with remarks
Route of original study	Route of exposure in the study used to derive the AAOEL	Closed list
Oral absorption value (%)	Oral absorption value derived from the toxicokinetic studies expressed as a percentage	Decimal
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
Justification of the overall UF	Justification for the uncertainty factor applied considering intra/inter species extrapolation. Please detail if additional UF are applied e.g.: - 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 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	Multi-line text

	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 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. e.g. In case some studies are missing, additional UF can be added. - UF for remaining uncertainties. In that case, the assessment factor should where relevant be applied and justified on a case-by-case basis.	
Dose descriptor starting point	Critical endpoint value, type (e.g. NOAEL, BMDL05), value and units	Open list
Value	Report the numerical value	Unit measure with Closed List (Decimal)
Critical endpoint	Link to the critical endpoint study record	Reference
Justification and comments	Provide additional information related to the derivation of this specific toxicological reference value.	Rich text area
Other reference values		Header 2
Not allocated	Select if the derivation of the reference dose is not necessary.	Checkbox
Justification	Justify the non-derivation of the reference dose.	Text
Reference value descriptor	Select the relevant reference value. Refer to EFSA Glossary for further information (https://www.efsa.europa.eu/en/glossary-taxonomy-terms).	Picklist
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.	Quantity
Population	Select the relevant population.	Multi-picklist
Assessment body	Select the relevant assessment body.	Picklist
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). Please detail if additional UF are applied e.g.: - UF for dose response relationship i.e. consideration should be	Text

	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. - 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. - 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. e.g. In case some studies are missing, additional UF can be added. - UF for remaining uncertainties. In that case, the assessment factor should where relevant be applied and justified on a case-by-case basis. Refer to the Scientific Opinion (EFSA, 2012) 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.	
Justification of the overall UF		text
Critical endpoint	Link to the critical endpoint study record	Reference
Justification and comments	Explain the choice of the study(ies) retained for the reference value setting; of the starting point chosen, etc.	Rich text
Reference to EFSA Opinion	Link to the relevant EFSA Output/Opinion in case the critical endpoint is not available (e.g., TTC, MOE)	Link to lit. reference (multiple)
Additional information	Follow instructions reported in "Additional information– common block"	Header 1

Links to support material:

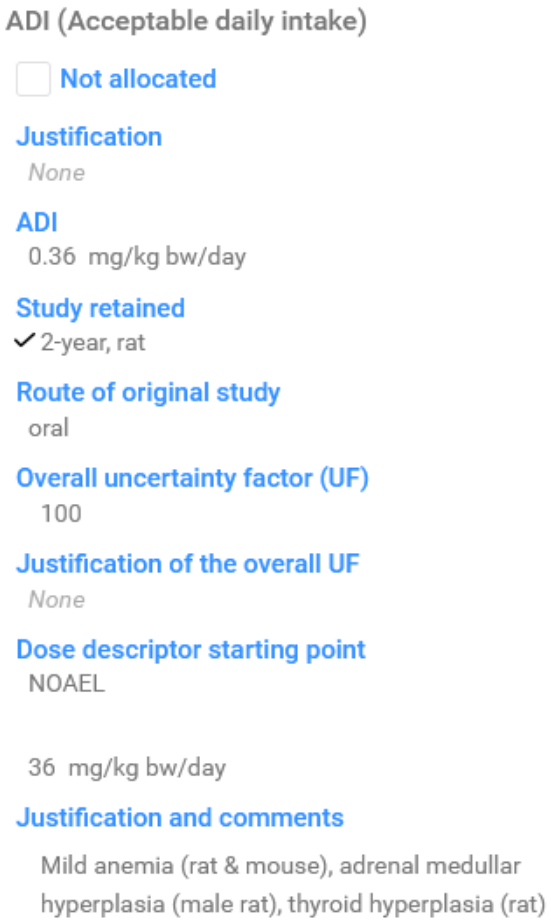
OECD (2010) "Guidance for the Derivation of an Acute Reference Dose" OECD Series on testing and assessment, No. 124, 08-Jun-2010
http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2010)15&doclanguage=en

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://doi.org/10.2903/j.efsa.2022.7584


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

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 (Cmax, Tmax, Plasma T1/2
- Distribution (indicate which organs have the highest levels
- Rate an 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		
Name	**Instructions**	**Type**
Administrative data	Follow instructions reported in "Administrative data summary – common block" Study name / type: 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.AdditionalToxicological Information - v.6.3). Description of key information: Provide a brief description of toxicity studies and effects. The information provided for absorption, distribution, metabolism and excretion, or observations based on physicochemical properties should be described. The interpretation of the result should be done considering: - a discussion on potential data gaps, - the relevant of the results for the risk assessment (e.g. the extent to which the results from an animal study are relevant for human health).	Header 1
Key value for chemical safety assessment		Header 1
Bioaccumulation potential	This information is usually based on physicochemical properties (e.g. log Kow, molecular structure and molecular weight) and on metabolism. The rationale for the indicated value should be	Closed list

	explained in the "Description of key information" field.	
Absorption rate - oral (%)	This information can be obtained experimentally or generated considering physicochemical properties (e.g. water solubility, log Kow, molecular structure, molecular weight)	Decimal
Absorption rate - dermal (%)		Decimal
Absorption rate - inhalation (%)	This information can be obtained experimentally or generated considering physicochemical properties (e.g. water solubility, log Kow, molecular structure, molecular weight)	Decimal
Additional information	Follow instructions reported in "Additional information – 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

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		
Name	**Instructions**	**Type**
Administrative data	Follow instructions reported in "Administrative data – common block"	Header 1
Data source	Follow instructions reported in "Data source– common block"	Header 1
Reference	Follow instructions reported in "Literature reference" common block	Literature reference list

Materials and methods	Follow instructions reported in "Material and methods – common block" 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) Guideline: Guideline: Method B.36 Toxicokinetics (Annex to Regulation (EC) No 440/2008). OECD Test Guideline 417: Toxicokinetics	Header 1
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
Test material	Follow instructions reported in "Test Material – common block"	Header 2
Radiolabelling	Indicate if labelled or non-labelled test material was used. Details on labelled material to be described in the repeatable block of fields 'Radiolabelled 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
Radiolabelled test material	This block of field not mandatory in the study record. This information shall be reported via the DER composer (please make sure that this information is available in the XML-file attached to this record).	Header
Test animals	Follow instructions reported in "Test animals – common block" .	Header 2
Administration / exposure		
Route of administration	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list
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
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

Duration and frequency of treatment / exposure	Indicate duration and frequency of application, e.g. 'single application' or 'multiple application: 14 days, 2 doses per day, 5 days per week'.	Multi-line text
Doses / concentrations	This repeated block of field not mandatory in the study record. This information shall be reported via the DER composer (please make sure that this information is available in the XML-file attached to this record).	Header.
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
Positive control reference chemical	Indicate if a positive control was used and if appropriate indicate purity, Lot/batch No.	Multi-line text
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 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
Details on dosing and sampling	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.	Text template
Statistics	List parameters that were analysed by which statistical methods, computer programme used.	Multi-line text
Model and software	Follow instructions reported in "Model and software – common block". Note: This block of fields is displayed only when "Type of information" is set to (Q)SAR.	Header 2
Any other information on materials and methods incl. tables	Follow instructions reported in "Any other information on materials and methods incl. tables – common block"	Header 2
Results and discussion		Header 1
Preliminary studies	Briefly describe the results of preliminary / pilot study or studies if any.	Text area
Main ADME results	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'. If required, copy block of fields to include several parameters. 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. Distribution: For each treatment group / study design or combined groups, describe levels of radioactivity measured at given time points in tissues/organs. 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. Material balance: Indicate mass balance of study. Metabolism including clearance: describe any decrease of the test chemical concentration from the incubation vial measured to determine the clearance in vitro.	
Type	Select either 'absorption', 'distribution', 'metabolism', 'excretion' or 'other:' from drop-down list.	Open list
Results	Briefly describe the most relevant results.	Text
Main ADME results		
Toxicokinetic / pharmacokinetic studies		Header 2
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
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
Transfer into organs	Indicate the transfer of the radiolabelled test substance into organs. Copy this block of fields for each transfer type and/or different test runs if applicable.	
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box

Test no.	Select a consecutive test number from drop-down list if more than one test runs are reported.	Closed list
Transfer type	Select type of transfer (e.g. 'blood/brain transfer') from picklist.	Open list with remarks
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
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
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.'.	
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box
Test no.	Select a consecutive test number from drop-down list if more than one test runs are reported.	Closed list
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
Toxicokinetic parameters		
Metabolite characterisation studies		Header 2
Metabolites identified	Indicate whether metabolites were identified.	Closed list with remarks
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	Text area

	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 figure. Note: Specific tables may be required.	
Distribution of metabolites in matrices	This block of field not mandatory in the study record. This information shall be reported via the DER composer (please make sure that this information is available in the XML-file attached to this record).	Header 2
Appendix: Metabolites and their parents in treatment groups	This block of field not mandatory in the study record. This information shall be reported via the DER composer (please make sure that this information is available in the XML-file attached to this record).	Header 2
Enzymatic activity		Header 2
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
Bioaccessibility (or Bioavailability)		Header 2
Bioaccessibility (or Bioavailability) testing results	Indicate the results of the bio-accessibility (or bio-availability) tests, if applicable.	Text area
Additional information about applicability domain and reliability of (Q)SAR predictions	Follow instructions reported in "Additional information about applicability domain and reliability of (Q)SAR predictions – common block"	Header 2
Any other information on results incl. tables	Follow instructions reported in "Any other information on results incl. tables – common block"	Header 2

Overall remarks, attachments	Follow instructions reported in "Overall remarks, attachments – common block"	Header 1
Applicant's summary and conclusion	Follow instructions reported in "Applicant's summary and conclusion – common block"	Header 1

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 using the MetaPath DER composer under the following link:

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

5.2 Acute toxicity – Endpoint Summary

Purpose

Provide summary information of the most relevant study(-ies) from which the key values for 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

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).

Only ONE endpoint summary should be created for acute toxicity.

ENDPOINT_SUMMARY.AcuteToxicity		
Name	**Instructions**	**Type**
Administrative data		Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	Confidentiality
Description of key information		Header 1
	Provide a brief description of toxicity studies and effects.	Rich text area
Key value for chemical safety assessment		Header 1
Acute toxicity: via oral route		Header 2
Link to relevant study records	Follow instructions reported in "Administrative data" Common block for endpoint summaries. 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 conclusion	Note: In case of acute studies with micro-organisms, less severe but still adverse effects are also considered during the assessment.	Header 3
Dose descriptor	LD50 should usually be chosen. However, if the acute toxicity was established by determining the discriminating dose, that should be chosen.	

Effect level	Select the qualifier according to the key value: - if none specifically apply, leave the field empty. - if the effect level is based on "no effect seen" at the highest tested concentration, the qualifier ">" should be used and the highest tested concentration should be reported. When there is no effect observed at the highest tested concentration, and when such concentration is above the test limit dose, then it can be assumed in the further assessment process that no hazard has been identified. - if effects have been observed at the lowest tested concentration and you are not able to extrapolate an adequate dose descriptor, use the qualifier "<". Nevertheless, note that the reporting of such an effect concentration may be difficult to use appropriately in further processing of the value. As a consequence, if you can justify the extrapolation of the value to one of the proposed dose descriptors, you may do so in your assessment and explain your method in the field "Additional information". The following units should only be used in the case of microbial active substances: - cells - CFU (colony-forming unit) - ITU (International Toxic Unit) - IU (International Unit) - OB (occlusion bodies) - spores	
Acute toxicity: via dermal route		Header 2
Link to relevant study records	Follow instructions reported in "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 conclusion	Note: In case of acute studies with micro-organisms, less severe but still adverse effects are also considered during the assessment.	Header 3
Dose descriptor	LD50 should usually be chosen. However, if the acute toxicity was established by determining the discriminating dose, that should be chosen.	
Effect level	Select the qualifier according to the key value: - if none specifically apply, leave the field empty. - if the effect level is based on "no effect seen" at the highest tested concentration, the qualifier ">" should be used and the highest tested concentration should be reported. When there is no effect observed at the highest tested concentration, and when such concentration is above the test limit dose, then it can be assumed in the further assessment process that no hazard has been identified. - if effects have been observed at the lowest tested concentration and you are not able to extrapolate an adequate dose descriptor, use the qualifier "<". Nevertheless, note that the reporting of such an effect	

	concentration may be difficult to use appropriately in further processing of the value. As a consequence, if you can justify the extrapolation of the value to one of the proposed dose descriptors, you may do so in your assessment and explain your method in the field "Additional information". The following units should only be used in the case of microbial active substances: - cells - CFU (colony-forming unit) - ITU (International Toxic Unit) - IU (International Unit) - OB (occlusion bodies) - spores	
Acute toxicity: via inhalation route		Header 2
Link to relevant study records	Follow instructions reported in "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 conclusion	Note: In case of acute studies with micro-organisms, less severe but still adverse effects are also considered during the assessment.	Header 3
Dose descriptor	LC50 should usually be chosen. However, if the acute toxicity was established by determining the discriminating concentration, that should be chosen.	
Effect level	Select the qualifier according to the key value: - if none specifically apply, leave the field empty. - if the effect level is based on "no effect seen" at the highest tested concentration, the qualifier ">" should be used and the highest tested concentration should be reported. When there is no effect observed at the highest tested concentration, and when such concentration is above the test limit dose, then it can be assumed in the further assessment process that no hazard has been identified. - if effects have been observed at the lowest tested concentration and you are not able to extrapolate an adequate dose descriptor, use the qualifier "<". Nevertheless, note that the reporting of such an effect concentration may be difficult to use appropriately in further processing of the value. As a consequence, if you can justify the extrapolation of the value to one of the proposed dose descriptors, you may do so in your assessment and explain your method in the field "Additional information". The following units should only be used in the case of microbial active substances: - cells - CFU (colony-forming unit) - ITU (International Toxic Unit) - IU (International Unit) - OB (occlusion bodies) - spores	

Physical form	Indicate in what physical form the test material was administered.	Open list
Justification for classification or non-classification	Not relevant for micro-organisms.	Header 1
Additional information	Follow instructions reported in "Additional information– common block" Provide additional information related to the endpoint, for example: Rat LD50 oral Rat LC50 inhalation Rat LD50 intraperitoneal/subcutaneous	Header 1

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.

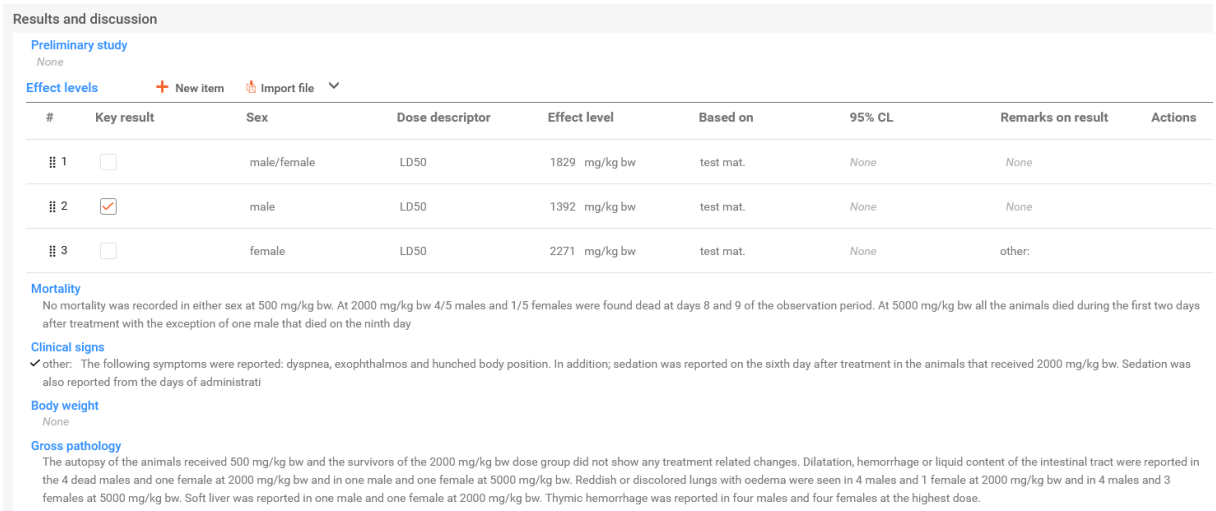
ENDPOINT_STUDY_RECORD.AcuteToxicityOral		
Name	**Instructions**	**Type**
Administrative data	Follow instructions reported in "Administrative data – common block"	Header 1
Data source	Follow instructions reported in "Data source– common block"	Header 1
Materials and methods	Follow instructions reported in "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). OECD Test Guideline 420: Acute oral toxicity: fixed dose procedure OECD Test Guideline 423: Acute oral toxicity: acute toxic class method OECD Test Guideline 425: Acute oral toxicity: up-and-down procedure Microbial Pesticide Test Guidelines: OPPTS 885.3050 Acute Oral Toxicity/Pathogenicity 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'.	Header 1
Test type	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	Open list

	used any more. However, it may apply to existing studies. 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.	
Limit test	Indicate if the experiment was a limit test.	Closed list
Test material	Follow instructions reported in "Test material – common block"	Header 2
Test animals	Follow instructions reported in "Test animals – common block" Species 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.	Header 2
Administration / exposure		Header 2
Route of administration	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list
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
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
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
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
Control animals	Indicate whether concurrent control group was used.	Open list with remarks
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

Statistics	Indicate the method of calculating the LD50 or other.	Multi-line text
High dose level used	Where a test method offers flexibility in the study design, for example in relation to the choice of dose levels, the chosen study design shall ensure that the data generated are adequate for hazard identification and risk assessment. To this end, testing shall be performed at appropriately high dose levels. If dose (concentration) selection is limited by the physicochemical properties or biological effects of the test substance, justification shall be provided.	
Model and software	Follow instructions reported in "Model and software – common block". Note: This block of fields is displayed only when "Type of information" is set to (Q)SAR.	Header 2
Any other information on materials and methods incl. tables	Follow instructions reported in "Any other information on materials and methods incl. tables – 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
Results and discussion		Header 1
Preliminary study	Summarise evidence of toxicity and mortality of any preliminary sighting study.	Multi-line text
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'.	
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box
Sex	Select from drop-down list.	Closed list
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 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'.	Open list with remarks

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)
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
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)
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)
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
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. 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.	Multi-line text
Body weight	Briefly describe whether animals gained or lost weight. Indicate if body weight loss was greater than 10%.	PickListWithRemarks2000
Gross pathology	Briefly describe whether there were any treatment related effects. Do not stress effects due to agonal death.	Multi-line text

Additional information about applicability domain and reliability of (Q)SAR predictions	Follow instructions reported in "Additional information about applicability domain and reliability of (Q)SAR predictions – common block"	Header 2
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
Any other information on results incl. tables)	Follow instructions reported in "Any other information on results incl. tables – common block"	Header 2
Overall remarks, attachments	Follow instructions reported in "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
Applicant's summary and conclusion	Follow instructions reported in "Applicant's summary and conclusion – common block"	Header 1



5.2.2 Dermal – Endpoint study record

Purpose

: 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.

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		
Name	**Instructions**	**Type**
Administrative data	Follow instructions reported in "Administrative data – common block"	Header 1
Data source	Follow instructions reported in "Data source– common block"	Header 1
Materials and methods	Follow instructions reported in "Material and methods – common block" Applicable test guideline: - Method B.3 Acute toxicity (dermal) (Annex to Regulation (EC) No 440/2008). - OECD Test Guideline 402: Acute Dermal Toxicity	Header 1
Test type	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. 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
Limit test	Indicate if the experiment was a limit test.	Closed list
Test material	Follow instructions reported in "Test material – common block"	Header 2
Test animals	Follow instructions reported in "Test animals – 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. 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'.	Header 2

Administration / exposure		Header 2
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
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
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
Duration of exposure	Indicate total duration of exposure in hours, e.g. '4 hrs'.	Multi-line text
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
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
Control animals	Indicate whether and what type of concurrent control groups were used or select 'not required' if applicable.	Open list with remarks
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
Statistics	Indicate the method of calculating the LD50 or other, if applicable.	Multi-line text
High dose level used	Where a test method offers flexibility in the study design, for example in relation to the choice of dose levels, the chosen study design shall ensure that the data generated are adequate for hazard identification and risk assessment. To this end, testing shall be performed at appropriately high dose levels. If dose (concentration) selection is limited by the physicochemical properties or biological effects of the test substance, justification shall be provided.	
Justification for deviation from the high dose level	Provide a justification for deviating from the high dose level.	Text template

Model and software	Follow instructions reported in "Model and software – common block". Note: This block of fields is displayed only when "Type of information" is set to (Q)SAR.	Header 2
Any other information on materials and methods incl. tables	Follow instructions reported in "Any other information on materials and methods incl. tables– common block"	Header 2
Results and discussion		Header 1
Preliminary study	Summarise evidence of toxicity and mortality of any preliminary sighting study.	Multi-line text
Effect levels		
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box
Sex	Select from drop-down list.	Closed list
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 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
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)
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
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)
Remarks on result	This field can be used for: - giving a qualitative description of results where required and	Open list with

	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:'	remarks (2000)
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'). 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.	Multi-line text
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. 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.	Multi-line text
Body weight	Briefly describe whether animals gained or lost weight.	Multi-line text
Gross pathology	Briefly describe whether there were any treatment related effects. Do not stress effects due to agonal death.	Multi-line text
Other findings	Report results related to pathogenicity, infectiveness or clearance in studies with micro-organisms	Text template
Additional information about applicability domain and reliability of (Q)SAR predictions	Follow instructions reported in "Additional information about applicability domain and reliability of (Q)SAR predictions – common block"	Header 2
Any other information on results incl. tables)	Follow instructions reported in "Any other information on results incl. tables – common block"	Header 2
Overall remarks, attachments	Follow instructions reported in "Overall remarks, attachments – common block"	Header 1

Applicant's summary and conclusion	Follow instructions reported in "Applicant's summary and conclusion – common block"	Header 1

5.2.3 Inhalation – Endpoint study record

Purpose

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 × 10–2 Pa at 20 °C;
- the active substance is a powder containing a significant proportion of particles of a diameter < 50 µm (> 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.

ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation		
Name	**Instructions**	**Type**
Administrative data	Follow instructions reported in "Administrative data – common block"	Header 1
Data source	Follow instructions reported in "Data source – common block"	Header 1
Materials and methods	Follow instructions reported in "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
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
Limit test	Indicate if the experiment was a limit test.	Closed list
Test material	Follow instructions reported in "Test material – common block"	Header 2
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

Administration / exposure		Header 2
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
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
Vehicle	Select the vehicle used. If not available from picklist, select 'other'.	Open list with remarks
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)
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)
Remark on MMAD/GSD	Enter any remarks related to the mass median aerodynamic diameter.	Multi-line text
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
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 of the study, discuss this in field 'Rationale for reliability incl. deficiencies'.	Closed list with remarks
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)
Remarks on duration	Enter any remarks related to the recorded value as appropriate.	Text

Concentrations	Provide rationale for the selection of the starting concentration. 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)'. For micro-organisms (CFU/L air or some other units should be used) As appropriate include notes in parentheses, e.g. '(male)'. For robust study summaries, also provide the analytical concentrations in the results table (see field 'Mortality').	Multi-line text
No. of animals per sex per dose	Enter number or state numbers for different groups if varying, e.g. '10 (controls), 5 (in test 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 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'). Note: Specific tables may be required.	Multi-line text
Control animals	Indicate whether concurrent control group was used.	Open list with remarks
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
Statistics	Indicate the method of calculating the category. LC50 or other, if applicable.	Multi-line text
High dose level used	Where a test method offers flexibility in the study design, for example in relation to the choice of dose levels, the chosen study design shall ensure that the data generated are adequate for hazard identification and risk assessment. To this end, testing shall be performed at appropriately high dose levels. If dose (concentration) selection is limited by the physicochemical properties or biological effects of the test substance, justification shall be provided.	
Justification for deviation from the high dose level	Provide a justification for deviating from the high dose level.	Text template
Model and software	Follow instructions reported in "Model and software – common block". Note: This block of fields is displayed only when "Type of information" is set to (Q)SAR.	Header 2
Any other information on materials and methods incl. tables	Follow instructions reported in "Any other information on materials and methods incl. tables– 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

Results and discussion		Header 1
Preliminary study	Summarise evidence of toxicity and mortality of any preliminary sighting study (if performed).	Multi-line text
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'.	
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment.	Check box
Sex	Select from drop-down list.	Closed list
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 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. For micro-organisms (CFU/L air or some other units should be used) 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
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)
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
95% CL	For robust study summaries or as requested by the regulatory programme, provide the 95% confidence limits if relevant 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	Range (Decimal)

	both numeric fields together 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)
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)
Effect levels		
Mortality	Summarise evidence of toxicity and mortality of any preliminary sighting study.	Multi-line text
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 and 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
Body weight	Briefly describe whether animals gained or lost weight. Indicate if body weight loss was greater than 10%.	Text template
Gross pathology	Briefly describe whether there were any treatment related effects. Do not stress effects due to agonal death.	Multi-line text
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
Any other information on results incl. tables)	Follow instructions reported in "Any other information on results incl. tables – common block"	Header 2
Overall remarks, attachments	Follow instructions reported in "Overall remarks, attachments – common block"	Header 1

Applicant's summary and conclusion	Follow instructions reported in "Applicant's summary and conclusion – common block"	Header 1
Executive summary		Rich text area

5.2.4 Irritation – Endpoint summary

Purpose

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		
Name	**Instructions**	**Type**
Administrative data		Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	Confidentiality
Description of key information	Provide a brief description of irritation studies and effects	
Key value for chemical safety assessment		Header 1
Skin irritation / corrosion		Header 2
Link to relevant study records	Follow instructions reported in "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 conclusion		Header 3
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 observed (not irritating)" should be chosen if the substance does not meet the criteria for classification.	Closed list

	If "No study available" is chosen, a justification needs to be provided.	
Eye irritation		Header 2
Link to relevant study records	Follow instructions reported in "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 conclusion		Header 3
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 does not meet the criteria for classification. If "No study available" is chosen, a justification needs to be provided.	Closed list
Respiratory irritation		Header 2
Endpoint conclusion		Header 3
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
Justification for classification or non-classification		Header 1
	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
Additional information	Provide additional information related to the endpoint, for example: skin/eye irritant or non-irritant Follow instructions reported in "Additional information– common block"	Header 1

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.

ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion		
Name	**Instructions**	**Type**
Administrative data	Follow instructions reported in "Administrative data – common block"	Header 1
Data source	Follow instructions reported in "Data source – common block"	Header 1
Materials and methods	Follow instructions reported in "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). OECD TG 431 / Method B.40 bis In vitro skin corrosion: human skin model test (Annex to Regulation (EC) No 440/2008). OECD Test Guideline 404: Acute Dermal Irritation/Corrosion OECD Test Guideline 431: In vitro Skin Corrosion: Human Skin Model Test OECD Test Guideline 430: In vitro Skin Corrosion: Transcutaneous Electrical Resistance Test OECD Test Guideline 435: In vitro Membrane Barrier Test Method for Skin Corrosion OECD Test Guideline 439: In vitro Skin Irritation: Reconstructed Human Epidermis Test Method	Header 1

	OECD TG 439 / Method B.46 In vitro skin irritation: reconstructed human epidermis model test (Annex III of Regulation (EC) No 761/2009 (7).	
Test material	Follow instructions reported in "Test material – common block"	Header 2
In vitro test system		Header 2
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
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
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
Cell source	For in vitro tests, e.g. according to OECD Guidelines 431 and 439, indicate the source of the cells used to construct the in vitro test system. If not available from picklist, select 'other:' and specify.	Open list
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
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
Justification for test system used	Provide a justification for the test system used	Multi-line text
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
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	Text template

	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 ³ 10 kΩ) - 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. - 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. - 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. - 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) - PREDICTION MODEL / DECISION CRITERIA: Describe and justify the prediction model / decision criteria used to derive the corrosion/irritation classification	
Control samples	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, a concurrent	Multi select open list with remarks

	negative control, non-specific colour controls and non-specific MTT reduction 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
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
Duration of post-treatment incubation (if applicable)	Indicate length of post-treatment incubation period as applicable.	Multi-line text
Number of replicates	Indicate the number of replicate tissues/skin discs used in each treatment / exposure and control groups.	Multi-line text
Test animals	Follow instructions reported in "Test animals – common block" 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
Test system		Header 2
Type of coverage	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list
Preparation of test site	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list with remarks
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
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	Multi select open list with

	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.	remarks
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
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
Observation period	Indicate length of observation period.	Multi-line text
Number of animals	Indicate number of animals used.	Multi-line text
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
High dose level used	Where a test method offers flexibility in the study design, for example in relation to the choice of dose levels, the chosen study design shall ensure that the data generated are adequate for hazard identification and risk assessment. To this end, testing shall be performed at appropriately high dose levels. If dose (concentration) selection is limited by the physicochemical properties or biological effects of the test substance, justification shall be provided. Select as appropiate.	Open list with justification.
Justification for deviation from the high dose level	Provide a justification for deviating from the high dose level.	Text template
Model and software	Follow instructions reported in "Model and software – common block". Note: This block of fields is displayed only when "Type of information" is set to (Q)SAR.	Header 2
Any other information on materials and methods incl. tables	Follow instructions reported in "Any other information on materials and methods incl. tables – common block"	Header 2
Results and discussion		Header 1
In vitro		Header 2
Results	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. 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". (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.	
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.	
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
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: 2 hours); Run 1, replicate 1 (duration of exposure: 2 hours), Mean of three runs with two replicates each.	Text
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)
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
Negative controls validity	Indicate whether test with negative control(s) is valid, i.e. substance(s) with known lack of iritation/corrosion in the test conducted. Relevant remarks can be given in the supplementary remarks field.	Open list with remarks
Positive controls validity	Indicate whether test with positive control(s) is valid, i.e. substance(s) with known iritation/corrosion in the test conducted. Relevant remarks can be given in the supplementary remarks field.	Open list with remarks

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)
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 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
In vivo		Header 2
Results	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. 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". 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. Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field.	
Irritation parameter	Select type of parameter from picklist. Further details can be given in the supplementary remarks field.	Open list with remarks
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
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
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)
Max. score	Provide the numeric value of the total possible score depending on the scale used.	Decimal
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
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)
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	Text area

	method of calculation used. Note: Specific tables may be required.	
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
Any other information on results incl. tables	Follow instructions reported in "Any other information on results incl. tables – common block"	Header 2
Applicant's summary and conclusion	Follow instructions reported in "Applicant's summary and conclusion – common block"	Header 1

5.2.4.2 Eye Irritation – Endpoint study record

Purpose

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.

ENDPOINT_STUDY_RECORD.EyeIrritation		
Name	**Instructions**	**Type**
Administrative data	Follow instructions reported in "Administrative data – common block"	Header 1
Data source	Follow instructions reported in "Data source– common block"	Header 1
Materials and methods	Follow instructions reported in "Material and methods – common block" Applicable test guideline: Method B.5 Acute toxicity: eye irritation/corrosion OECD 405 OECD 437	Header 1

	OECD 438 Method B.47 Bovine corneal opacity and permeability test method for identifying ocular corrosives and severe irritants (Method B.48 Isolated chicken eye test method for identifying ocular corrosives and severe irritants	
Test material	Follow instructions reported in "Test material – common block"	Header 2
Test material physicochemical properties	Use this field for highlighting the physicochemical properties of the test material that are relevant for evaluating this study summary, if not already provided elsewhere in the dataset. Use freetext template and delete/add elements as appropriate.	Text Template
Test animals / tissue source		Header 2
Species	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. 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 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.	Open list
Strain	Select strain as appropriate. If not available from picklist, select 'other' and specify.	Open list with remarks
Details on test animals or tissues 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. - 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).	Text template
Test system		Header 2
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
Controls	Indicate whether and what type of concurrent control groups were used or select 'not required' if applicable.	Multi select

	In the supplementary remarks field, specify the name of the control substance and other identifiers (e.g. CAS number, the physical state, lo/batch No. including expirations 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.	open list with remarks
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
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
Observation period (in vivo)	Indicate length of observation period.	Multi-line text
Duration of post-treatment incubation (in vitro)	Indicate length of post-treatment incubation period as appropriate.	Multi-line text
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
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
High dose level used	Where a test method offers flexibility in the study design, for example in relation to the choice of dose levels, the chosen study design shall ensure that the data generated are adequate for hazard identification and risk assessment. To this end, testing shall be performed at appropriately high dose levels. If dose (concentration) selection is limited by the physicochemical properties or biological effects of the test substance, justification shall be provided.	
Justification for deviation from the high dose level	Provide a justification for deviating from the high dose level.	Text template
Model and software	Follow instructions reported in "Model and software – common block". Note: This block of fields is displayed only when "Type of information" is set to (Q)SAR.	Header 2
Any other information on materials and methods incl. tables	Follow instructions reported in "Any other information on materials and methods incl. tables – common block"	Header 2

Results and discussion		Header 1
In vitro		Header 2
Results	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. 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". (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.	
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.	
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
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
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)
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
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	Open list with remarks

	within the acceptance criteria range as described in the TG. Relevant remarks can be given in the supplementary remarks field.	
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
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)
Results		
Other effects / acceptance of results	Select 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 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
In vivo		Header 2
Results	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. 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". (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.	
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.	
Irritation parameter	Select type of parameter from picklist. Further details can be given in the supplementary remarks field.	Open list with remarks
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
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
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)
Max. score	Provide the numeric value of the total possible score depending on the scale used.	Decimal
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
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)
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 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.	Text area
Other effects	Select freetext template and delete/add elements as appropriate. Describe any other relevant results including lesions and clinical observations, ophthalmoscopic and	Text template

	histopathological findings, effects of rinsing or washing if applicable.	
Any other information on results incl. tables	Follow instructions reported in "Any other information on results incl. tables – common block"	Header 2
Overall remarks, attachments	Follow instructions reported in "Overall remarks, attachments – common block"	Header 1
Applicant's summary and conclusion	Follow instructions reported in "Applicant's summary and conclusion – common block"	Header 1

5.2.5 Skin sensitisation

Skin sensitisation – Endpoint Summary

Purpose

Chemical (Active) - 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.

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		
Name	**Instructions**	**Type**
Administrative data		Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	Confidentiality
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
Skin sensitisation		Header 2
Link to relevant study records	Follow instructions reported in "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 conclusion		Header 3
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
Additional information	Provide additional information related to the endpoint, for example: - relevance of the results for the risk assessment	Rich text area

	- 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.	
Respiratory sensitisation		Header 2
Link to relevant study records	Follow instructions reported in "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 conclusion		Header 3
Endpoint conclusion	"Adverse effect observed (sensitising)" should be chosen if the micro-organism shows effects of respiratory 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.	Closed list
Justification for classification or non-classification		Header 1
	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
Additional information	Provide additional information related to the endpoint, for example: sensitising (state source of evidence, e.g. type of study, clinical data, etc) Follow instructions reported in "Additional information– common block"	Rich text area

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.

ENDPOINT_STUDY_RECORD.SkinSensitisation		
Name	**Instructions**	**Type**
Administrative data	Follow instructions reported in "Administrative data – common block"	Header 1
Data source	Follow instructions reported in "Data source– common block"	Header 1
Materials and methods	Follow instructions reported in "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
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
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	Multi-line text

	welfare. Refer to the relevant legislation-specific guidance document.	
Test material	Follow instructions reported in "Test material – common block"	Header 2
In vitro test system		Header 2
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
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. 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. 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. APPLICATION OF THE TEST CHEMICAL AND CONTROL SUBSTANCES: describe the application of test chemical and control substance exposure conditions in detail. SEEDING AND INCUBATION: describe the seeding and incubation conditions and whether precipitation was noted. 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 LUCIFERASE ACTIVITY MEASUREMENTS: describe the steps taken to ensure the suitability of the luciferase activity measurements for the test chemical, including solvents used DATA EVALUATION: report the cytotoxicity measurements taken and the prediction model to be used.	Text template
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
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
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
In chemico test system		Header 2
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
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	Text template

	(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.	
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
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
In silico test system		Header 2
Details of test system	Select the test system as appropriate. If not available from the picklist, select 'other:' and provide detailed justification for not using a standard test system.	Multi select open list with remarks
Details on the study design	TEST PROTOCOL - Derek Nexus: Skin sensitisation predictions according to OECD TG 497 (Annex 2): - OECD (Q)SAR Toolbox: Skin sensitisation predictions according to OECD TG 497 (Annex 2): other:to be specified	Text template
In vivo test system		Header 2
Test animals		Header 3
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
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
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
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.	Text template

	- Water: Describe type (e.g. drinking water) and whether it was provided ad libitum. - 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
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.	
Route	Indicate the route of induction exposure.	Open list
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
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
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
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
Induction		
Challenge	Record the vehicle, test substance concentrations used for challenge 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.	
No.	For indicating multiple challenges or rechallenge select a consecutive number from drop-down list.	Closed list
Route	Indicate the route of challenge exposure.	Open list
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
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
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
Adequacy of challenge	Indicate if the test concentration used for the challenge exposure was the highest non-irritation dose.	Open list

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
Details on study design	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. Example for Freund's Complete Adjuvant (FCA) test (partly adopted from OECD 406): - 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
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
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
Study design: in vivo (LLNA)		Header 3
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
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
No. of animals per dose	Provide number of animals per dose or range if different numbers were used.	Multi-line text
Details on study design	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	Text template

	study summary or that are requested by the respective regulatory programme. - 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). MAIN STUDY - 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 inter-peritoneally 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 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
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
High dose level used	Where a test method offers flexibility in the study design, for example in relation to the choice of dose levels, the chosen study design shall ensure that the data generated are adequate for hazard identification and risk assessment. To this end, testing shall be performed at appropriately high dose levels. If dose (concentration) selection is limited by the physicochemical properties or biological effects of the test substance, justification shall be provided.	
Justification for deviation from the high dose level	Provide a justification for deviating from the high dose level.	Text template
Model and software	Follow instructions reported in "Model and software – common block". Note: This block of fields is displayed only when "Type of information" is set to (Q)SAR.	Header 2
Any other information on materials and	Follow instructions reported in "Any other information on materials and methods incl. tables– common block"	Header 2

methods incl. tables		
Results and discussion		Header 1
Positive control results	Discuss the positive control results and demonstrate that the laboratory has the capability to identify positive dermal sensitizers.	Multi-line text
In vitro / in chemico		Header 2
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 "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
Group		Open list
Run / experiment	Indicate the run / experiment the measurement relates to.	Open list
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
Value	Indicate also the unit of measurement e.g. µM, mM, µg/ml, mg/ml etc.	Unit measure with Closed List (Decimal)
At concentration		Unit measure with Open List (Decimal)
Cell viability		Text area

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
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
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
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)
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
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
In silico		Block
Results		Repatable table
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Checkbox
Group		Picklist
Parameter		Picklist
Value	For the in silico prediction, a positive outcome is assigned a score of 1 and a negative outcome is assigned a score of 0.	Picklist

Remarks on results	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:'	Picklist
Outcome of the prediction model		Picklist
In vivo (non-LLNA)		Header 2
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.	
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box
Reading	Select from drop-down list.	Open list
Hours after challenge	Enter numeric value.	Decimal
Group	Select from drop-down list.	Open list
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
No. with + reactions	Enter numeric value.	Integer
Total no. in group	Enter numeric value.	Integer
Clinical observations	Briefly describe relevant clinical observations.	Text
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)
Results		
In vivo (LLNA)		Header 2
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 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
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
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)
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
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
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)
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.	Text template

	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.	
Additional information about applicability domain and reliability of (Q)SAR predictions	Follow instructions reported in "Additional information about applicability domain and reliability of (Q)SAR predictions – common block"	Header 2
Any other information on results incl. tables	Follow instructions reported in "Any other information on results incl. tables – common block"	Header 2
Overall remarks, attachments	Follow instructions reported in "Overall remarks, attachments – common block"	Header 1
Applicant's summary and conclusion	Follow instructions reported in "Applicant's summary and conclusion – common block"	Header 1

5.2.6 Phototoxicity

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		
Name	**Instructions**	**Type**
Administrative data		Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	Confidentiality
Link to relevant study records	Follow instructions reported in "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
Description of key information	Provide a brief description of the phototoxicity studies and effects	
Key value for chemical safety assessment		Header 1
Phototoxicity	Select from the picklist "No photoreactivity" or "no phototoxicity" should be chosen, if no such adverse effects were observed. "Photoreactivity" or "phototoxicity" should be chosen if the substance was found to be photoreactive or phototoxic. "No information available" should be chosen if there is not enough or no data to conclude on phototoxicity.	Picklist
Additional information	Follow instructions reported in "Additional information – common block" Provide additional information related to the endpoint, for example: state 'not required' or 'not phototoxic/probably phototoxic/phototoxic'	Header 1

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 L × mol−1 × cm−1, no toxicity testing is required.

ENDPOINT_STUDY_RECORD.PhototoxicityVitro		
Name	**Instructions**	**Type**
Administrative data	Follow instructions reported in "Administrative data – common block"	Header 1
Data source	Follow instructions reported in "Data source – common block"	Header 1
Materials and methods	Follow instructions reported in "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
Test material	Follow instructions reported in "Test Material – common block"	Header 2
Test system		Header 2
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.	
Species / strain / cell type	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list with remarks
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
Species / strain		
Controls	Indicate whether vehicle, true negative and/or positive controls were tested.	
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	Open list with remarks

	can be given in the supplementary remarks field. In particular, indicate the concentration (and/or volume) of vehicle added.	
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
Positive control substance	If applicable, indicate which substance(s) was/were used as positive control(s). Multiple items can be selected. 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.	Open list with remarks
Remarks	Enter any remarks related to the recorded controls as appropriate.	Text
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
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
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) 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.	Text template
Evaluation criteria	Describe the evaluation criteria used in the study to judge if a substance is positive, negative or equivocal.	Multi-line text
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

Model and software	Follow instructions reported in "Model and software – common block". Note: This block of fields is displayed only when "Type of information" is set to (Q)SAR.	Header 2
Any other information on materials and methods incl. tables	Follow instructions reported in "Any other information on materials and methods incl. tables – common block"	Header 2
Results and discussion		Header 1
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box
Results	Include the main test results.	Text template
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
Results with reference substance (positive control)	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. Use freetext template and delete/add elements as appropriate.	Text template
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
Additional information about applicability domain and reliability of (Q)SAR predictions	Follow instructions reported in "Additional information about applicability domain and reliability of (Q)SAR predictions – common block"	Header 2
Any other information on results incl. tables	Follow instructions reported in "Any other information on results incl. tables – common block"	Header 2
Overall remarks, attachments	Follow instructions reported in "Overall remarks, attachments – common block"	Header 1
Applicant's summary and conclusion	Follow instructions reported in "Applicant's summary and conclusion – common block"	Header 1

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		
Name	**Instructions**	**Type**
Administrative data	Follow instructions reported in "Administrative data – common block"	Header 1
Data source	Follow instructions reported in "Data source (Literature Reference) – common block"	Header 1
Materials and methods	Follow instructions reported in "Material and methods – common block"	Header 1
Limit test	Indicate if the experiment was a limit test.	Closed list
Test material	Follow instructions reported in "Test Material – common block"	Header 2
Test animals	Follow instructions reported in "Test animals – 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
Administration / exposure		Header 2
Route of administration	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list
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
Details on exposure	Briefly describe details of exposure.	Multi-line text

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
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
Control animals	Indicate whether concurrent control group was used.	Open list with remarks
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
Statistics	Indicate the method of calculating the LD50 or other.	Multi-line text
High dose level used	Where a test method offers flexibility in the study design, for example in relation to the choice of dose levels, the chosen study design shall ensure that the data generated are adequate for hazard identification and risk assessment. To this end, testing shall be performed at appropriately high dose levels. If dose (concentration) selection is limited by the physicochemical properties or biological effects of the test substance, justification shall be provided.	
Justification for deviation from the high dose level	Provide a justification for deviating from the high dose level.	Text Template
Model and software	Follow instructions reported in "Model and software – common block". Note: This block of fields is displayed only when "Type of information" is set to (Q)SAR.	Header 2
Any other information on materials and methods incl. tables	Follow instructions reported in "Any other information on materials and methods incl. tables – common block"	Header 2
Results and discussion		Header 1
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'.	

Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box
Sex	Select from drop-down list.	Closed list
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
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)
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
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)
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)
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	Multi-line text

	1'). Note: Specific tables may be required.	
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
Body weight	Briefly describe whether animals gained or lost weight.	Multi-line text
Gross pathology	Briefly describe whether there were any treatment related effects. Do not stress effects due to agonal death.	Multi-line text
Other findings	Report results related to pathogenicity, infectiveness or clearance in studies with micro-organisms	Text template
Any other information on results incl. tables	Follow instructions reported in "Any other information on results incl. tables – common block"	Header 2
Overall remarks, attachments	Follow instructions reported in "Overall remarks, attachments – common block"	Header 1
Applicant's summary and conclusion	Follow instructions reported in "Applicant's summary and conclusion – common block"	Header 1

5.3 Repeated dose toxicity– Endpoint Summary

Purpose

Provide consolidated information across the four routes (oral/inhalation/dermal/other) in both rodent (after sub-chronic and chronic exposure) and non-rodent species (after sub-chronic exposure). The studies, data and information to be provided and evaluated, shall be sufficient to permit the identification of effects following repeated exposure after short-term (e.g. 28-days), sub-chronic (e.g. 90-days) and chronic (e.g. 2-years) to the active substance, and in particular to further establish, or indicate:

- Target organ / critical effect after short-term, sub-chronic and chronic exposure.
- Relevant oral reference point (e.g. NOAELs) after short-term, sub-chronic and chronic exposure..
- Relevant dermal reference point (e.g. NOAELs) after short-term, sub-chronic and chronic exposure; if available.
- Relevant inhalation reference point (e.g. NOAELs) after short-term, sub-chronic and chronic exposure, if available.

It is noted that repeated dose toxicity after chronic exposure was previously summarised within the carcinogenicity summary (5.5) since the same study may address both carcinogenicity and long-term toxicity. Currently the summary on repeated dose toxicity after chronic (long-term) exposure should be reported here.

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).

Create a summary for each species tested after repeated dose toxicity (dog, rat, mice), since at least two species are required for short-term toxicity (e.g. rat and dogs) and two species for long-term toxicity (i.e. rat and mice).

ENDPOINT_SUMMARY.RepeatedDoseToxicity		
Name	**Instructions**	**Type**
Administrative data		Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	Confidentiality
Description of key information	Provide brief description of the toxicity studies and effects.	Header 1
Key value for chemical safety assessment		Header 1
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 conclusion – systemic effects, oral route	"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. "No information available" should be chosen if there is no data to conclude on repeated dose toxicity.	List (picklist)
Endpoint conclusion – systemic effects, dermal	"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. "No information available" should be chosen if there is no data to conclude on repeated dose toxicity.	List (picklist)
Endpoint conclusion – systemic effects, inhalation	"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. "No information available" should be chosen if there is no data to conclude on repeated dose toxicity.	List (picklist)
Short term repeated dose toxicity - systemic effects		Header 2
Oral route		Header 3
Link to relevant study record(s)	Follow instructions reported in "Endpoint summary block for relevant study record"	Link to endpoint (multiple)
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.	List (picklist)
Effect level	Select the qualifier according to the key value: - if none specifically apply, leave the field empty. - if the effect level is based on "no effect seen" at the highest tested concentration, the qualifier ">" should be used and the highest tested concentration should be reported. When there is no effect observed at the highest tested concentration, and when such concentration is above the test limit dose, then it can be assumed in the further assessment process that no hazard has been identified. - if effects have been observed at the lowest tested concentration and you are not able to extrapolate an adequate dose descriptor, use the qualifier "<". Nevertheless, note that the reporting of such an effect concentration may be difficult to use appropriately in further processing of the value. As a consequence, if you can justify the	Numeric range (half bounded)

	extrapolation of the value to one of the proposed dose descriptors, you may do so in your assessment and explain your method in the field "Additional information".	
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.	Numeric (decimal)
Species	The species reported in the selected endpoint study record should be chosen here.	List (picklist)
System	The system in which adverse effects were observed should be specified here. If adverse effects were observed in several systems, the target system(s) in which the adverse effects gives rise to highest concern should be selected, i.e. the system(s) associated with the dose descriptor.	List multi. (multi-select list)
Organ	The organ in which adverse effects were observed should be specified here. If adverse effects were observed in several organs, the target organ(s) in which the adverse effects gives rise to highest concern should be selected, i.e. the organ(s) associated with the dose descriptor.	List multi. (multi-select list)
Dermal		Header 3
Link to relevant study record(s)	Follow instructions reported in "Endpoint summary block for relevant study record"	Link to endpoint (multiple)
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.	List (picklist)
Effect level	Select the qualifier according to the key value: - if none specifically apply, leave the field empty. - if the effect level is based on "no effect seen" at the highest tested concentration, the qualifier ">" should be used and the highest tested concentration should be reported. When there is no effect observed at the highest tested concentration, and when such concentration is above the test limit dose, then it can be assumed in the further assessment process that no hazard has been identified. - if effects have been observed at the lowest tested concentration and you are not able to extrapolate an adequate dose descriptor, use the qualifier "<". Nevertheless, note that the reporting of such an effect concentration may be difficult to use appropriately in further processing of the value. As a consequence, if you can justify the extrapolation of the value to one of the proposed dose descriptors, you may do so in your assessment and explain your method in the field "Additional information".	Numeric range (half bounded)
Experimental exposure time per	In this field, you should add the experimental exposure conditions in hours per week. This can	Numeric (decimal)

week (hours/week)	be done considering the hours per day and the days per week the animals were exposed.	
Species	The species reported in the selected endpoint study record should be chosen here.	List (picklist)
System	The system in which adverse effects were observed should be specified here. If adverse effects were observed in several systems, the target system(s) in which the adverse effects gives rise to highest concern should be selected, i.e. the system(s) associated with the dose descriptor.	List multi. (multi-select list)
Organ	The organ in which adverse effects were observed should be specified here. If adverse effects were observed in several organs, the target organ(s) in which the adverse effects gives rise to highest concern should be selected, i.e. the organ(s) associated with the dose descriptor.	List multi. (multi-select list)
Inhalation		Header 3
Link to relevant study record(s)	Follow instructions reported in "Endpoint summary block for relevant study record"	Link to endpoint (multiple)
Dose descriptor	The primary dose descriptor in this endpoint is the NOAEC. In some studies also the BMCL (benchmark concentration level). The LOAEC should be used only if NOAEC is not available.	List (picklist)
Effect level	Select the qualifier according to the key value: - if none specifically apply, leave the field empty. - if the effect level is based on "no effect seen" at the highest tested concentration, the qualifier ">" should be used and the highest tested concentration should be reported. When there is no effect observed at the highest tested concentration, and when such concentration is above the test limit dose, then it can be assumed in the further assessment process that no hazard has been identified. - if effects have been observed at the lowest tested concentration and you are not able to extrapolate an adequate dose descriptor, use the qualifier "<". Nevertheless, note that the reporting of such an effect concentration may be difficult to use appropriately in further processing of the value. As a consequence, if you can justify the extrapolation of the value to one of the proposed dose descriptors, you may do so in your assessment and explain your method in the field "Additional information".	Numeric range (half bounded)
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.	Numeric (decimal)
Species	The species reported in the selected endpoint study record should be chosen here.	List (picklist)

System	The system in which adverse effects were observed should be specified here. If adverse effects were observed in several systems, the target system(s) in which the adverse effects gives rise to highest concern should be selected, i.e. the system(s) associated with the dose descriptor.	List multi. (multi-select list)
Organ	The organ in which adverse effects were observed should be specified here. If adverse effects were observed in several organs, the target organ(s) in which the adverse effects gives rise to highest concern should be selected, i.e. the organ(s) associated with the dose descriptor.	List multi. (multi-select list)
Sub-chronic toxicity -systemic effects		Header 2
Oral route		Header 3
Link to relevant study record(s)	Follow instructions reported in "Endpoint summary block for relevant study record"	Link to endpoint (multiple)
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.	List (picklist)
Effect level	Select the qualifier according to the key value: - if none specifically apply, leave the field empty. - if the effect level is based on "no effect seen" at the highest tested concentration, the qualifier ">" should be used and the highest tested concentration should be reported. When there is no effect observed at the highest tested concentration, and when such concentration is above the test limit dose, then it can be assumed in the further assessment process that no hazard has been identified. - if effects have been observed at the lowest tested concentration and you are not able to extrapolate an adequate dose descriptor, use the qualifier "<". Nevertheless, note that the reporting of such an effect concentration may be difficult to use appropriately in further processing of the value. As a consequence, if you can justify the extrapolation of the value to one of the proposed dose descriptors, you may do so in your assessment and explain your method in the field "Additional information".	Numeric range (half bounded)
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.	Numeric (decimal)
Species	The species reported in the selected endpoint study record should be chosen here.	List (picklist)
System	The system in which adverse effects were observed should be specified here. If adverse effects were observed in several systems, the target system(s) in which the adverse effects	List multi. (multi-select list)

	gives rise to highest concern should be selected, i.e. the system(s) associated with the dose descriptor.	
Organ	The organ in which adverse effects were observed should be specified here. If adverse effects were observed in several organs, the target organ(s) in which the adverse effects gives rise to highest concern should be selected, i.e. the organ(s) associated with the dose descriptor.	List multi. (multi-select list)
Dermal		Header 3
Link to relevant study record(s)	Follow instructions reported in "Endpoint summary block for relevant study record"	Link to endpoint (multiple)
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.	List (picklist)
Effect level	Select the qualifier according to the key value: - if none specifically apply, leave the field empty. - if the effect level is based on "no effect seen" at the highest tested concentration, the qualifier ">" should be used and the highest tested concentration should be reported. When there is no effect observed at the highest tested concentration, and when such concentration is above the test limit dose, then it can be assumed in the further assessment process that no hazard has been identified. - if effects have been observed at the lowest tested concentration and you are not able to extrapolate an adequate dose descriptor, use the qualifier "<". Nevertheless, note that the reporting of such an effect concentration may be difficult to use appropriately in further processing of the value. As a consequence, if you can justify the extrapolation of the value to one of the proposed dose descriptors, you may do so in your assessment and explain your method in the field "Additional information".	Numeric range (half bounded)
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.	Numeric (decimal)
Species	The species reported in the selected endpoint study record should be chosen here.	List (picklist)
System	The system in which adverse effects were observed should be specified here. If adverse effects were observed in several systems, the target system(s) in which the adverse effects gives rise to highest concern should be selected, i.e. the system(s) associated with the dose descriptor.	List multi. (multi-select list)
Organ	The organ in which adverse effects were observed should be specified here. If adverse effects were observed in several organs, the target organ(s) in which the adverse effects gives rise to highest	List multi. (multi-select list)

	concern should be selected, i.e. the organ(s) associated with the dose descriptor.	
Inhalation		Header 3
Link to relevant study record(s)	Follow instructions reported in "Endpoint summary block for relevant study record"	Link to endpoint (multiple)
Dose descriptor	The primary dose descriptor in this endpoint is the NOAEC. In some studies also the BMCL (benchmark concentration level). The LOAEC should be used only if NOAEC is not available.	List (picklist)
Effect level	Select the qualifier according to the key value: - if none specifically apply, leave the field empty. - if the effect level is based on "no effect seen" at the highest tested concentration, the qualifier ">" should be used and the highest tested concentration should be reported. When there is no effect observed at the highest tested concentration, and when such concentration is above the test limit dose, then it can be assumed in the further assessment process that no hazard has been identified. - if effects have been observed at the lowest tested concentration and you are not able to extrapolate an adequate dose descriptor, use the qualifier "<". Nevertheless, note that the reporting of such an effect concentration may be difficult to use appropriately in further processing of the value. As a consequence, if you can justify the extrapolation of the value to one of the proposed dose descriptors, you may do so in your assessment and explain your method in the field "Additional information".	Numeric range (half bounded)
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.	Numeric (decimal)
Species	The species reported in the selected endpoint study record should be chosen here.	List (picklist)
System	The system in which adverse effects were observed should be specified here. If adverse effects were observed in several systems, the target system(s) in which the adverse effects gives rise to highest concern should be selected, i.e. the system(s) associated with the dose descriptor.	List multi. (multi-select list)
Organ	The organ in which adverse effects were observed should be specified here. If adverse effects were observed in several organs, the target organ(s) in which the adverse effects gives rise to highest concern should be selected, i.e. the organ(s) associated with the dose descriptor.	List multi. (multi-select list)
Chronic toxicity - systemic effects		Header 2
Oral route		Header 3

Link to relevant study record(s)	Follow instructions reported in "Endpoint summary block for relevant study record"	Link to endpoint (multiple)
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.	List (picklist)
Effect level	Select the qualifier according to the key value: - if none specifically apply, leave the field empty. - if the effect level is based on "no effect seen" at the highest tested concentration, the qualifier ">" should be used and the highest tested concentration should be reported. When there is no effect observed at the highest tested concentration, and when such concentration is above the test limit dose, then it can be assumed in the further assessment process that no hazard has been identified. - if effects have been observed at the lowest tested concentration and you are not able to extrapolate an adequate dose descriptor, use the qualifier "<". Nevertheless, note that the reporting of such an effect concentration may be difficult to use appropriately in further processing of the value. As a consequence, if you can justify the extrapolation of the value to one of the proposed dose descriptors, you may do so in your assessment and explain your method in the field "Additional information".	Numeric range (half bounded)
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.	Numeric (decimal)
Species	The species reported in the selected endpoint study record should be chosen here.	List (picklist)
System	The system in which adverse effects were observed should be specified here. If adverse effects were observed in several systems, the target system(s) in which the adverse effects gives rise to highest concern should be selected, i.e. the system(s) associated with the dose descriptor.	List multi. (multi-select list)
Organ	The organ in which adverse effects were observed should be specified here. If adverse effects were observed in several organs, the target organ(s) in which the adverse effects gives rise to highest concern should be selected, i.e. the organ(s) associated with the dose descriptor.	List multi. (multi-select list)
Dermal		Header 3
Link to relevant study record(s)	Follow instructions reported in "Endpoint summary block for relevant study record"	Link to endpoint (multiple)
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.	List (picklist)

Effect level	Select the qualifier according to the key value: - if none specifically apply, leave the field empty. - if the effect level is based on "no effect seen" at the highest tested concentration, the qualifier ">" should be used and the highest tested concentration should be reported. When there is no effect observed at the highest tested concentration, and when such concentration is above the test limit dose, then it can be assumed in the further assessment process that no hazard has been identified. - if effects have been observed at the lowest tested concentration and you are not able to extrapolate an adequate dose descriptor, use the qualifier "<". Nevertheless, note that the reporting of such an effect concentration may be difficult to use appropriately in further processing of the value. As a consequence, if you can justify the extrapolation of the value to one of the proposed dose descriptors, you may do so in your assessment and explain your method in the field "Additional information".	Numeric range (half bounded)
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.	Numeric (decimal)
Species	The species reported in the selected endpoint study record should be chosen here.	List (picklist)
System	The system in which adverse effects were observed should be specified here. If adverse effects were observed in several systems, the target system(s) in which the adverse effects gives rise to highest concern should be selected, i.e. the system(s) associated with the dose descriptor.	List multi. (multi-select list)
Organ	The organ in which adverse effects were observed should be specified here. If adverse effects were observed in several organs, the target organ(s) in which the adverse effects gives rise to highest concern should be selected, i.e. the organ(s) associated with the dose descriptor.	List multi. (multi-select list)
Inhalation		Header 3
Link to relevant study record(s)	Follow instructions reported in "Endpoint summary block for relevant study record"	Link to endpoint (multiple)
Dose descriptor	The primary dose descriptor in this endpoint is the NOAEC. In some studies also the BMCL (benchmark concentration level). The LOAEC should be used only if NOAEC is not available.	List (picklist)
Effect level	Select the qualifier according to the key value: - if none specifically apply, leave the field empty. - if the effect level is based on "no effect seen" at the highest tested concentration, the qualifier ">" should be used and the highest tested concentration should be reported. When there is no effect observed at the highest tested	Numeric range (half bounded)

	concentration, and when such concentration is above the test limit dose, then it can be assumed in the further assessment process that no hazard has been identified. - if effects have been observed at the lowest tested concentration and you are not able to extrapolate an adequate dose descriptor, use the qualifier "<". Nevertheless, note that the reporting of such an effect concentration may be difficult to use appropriately in further processing of the value. As a consequence, if you can justify the extrapolation of the value to one of the proposed dose descriptors, you may do so in your assessment and explain your method in the field "Additional information".	
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.	Numeric (decimal)
Species	The species reported in the selected endpoint study record should be chosen here.	List (picklist)
System	The system in which adverse effects were observed should be specified here. If adverse effects were observed in several systems, the target system(s) in which the adverse effects gives rise to highest concern should be selected, i.e. the system(s) associated with the dose descriptor.	List multi. (multi-select list)
Organ	The organ in which adverse effects were observed should be specified here. If adverse effects were observed in several organs, the target organ(s) in which the adverse effects gives rise to highest concern should be selected, i.e. the organ(s) associated with the dose descriptor.	List multi. (multi-select list)
Repeated dose toxicity – local effects		Header 2
Dermal		Header 3
Link to relevant study record(s)	Provide here the link(s) to the study record(s) supporting the choice of the key value for assessment.	Link to endpoint (multiple)
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. "No information available" should be chosen if there is no data to conclude on repeated dose toxicity	List (picklist)
Dose descriptor	The primary dose descriptor in this endpoint is the NOAEL. In some studies also the BMDL (benchmark dose level).	List (picklist)

	The LOAEL should be used only if NOAEL is not available.	
Effect level	Select the qualifier according to the key value: - if none specifically apply, leave the field empty. - if the effect level is based on "no effect seen" at the highest tested concentration, the qualifier ">" should be used and the highest tested concentration should be reported. When there is no effect observed at the highest tested concentration, and when such concentration is above the test limit dose, then it can be assumed in the further assessment process that no hazard has been identified. - if effects have been observed at the lowest tested concentration and you are not able to extrapolate an adequate dose descriptor, use the qualifier "<". Nevertheless, note that the reporting of such an effect concentration may be difficult to use appropriately in further processing of the value. As a consequence, if you can justify the extrapolation of the value to one of the proposed dose descriptors, you may do so in your assessment and explain your method in the field "Additional information".	Numeric range (half bounded)
Study duration	Choose the duration of the selected endpoint study record. Short-term corresponds to e.g. 28-day studies, subchronic e.g. to 90-day studies and chronic usually to longer than 180-day studies.	List (picklist)
Species	The species reported in the selected endpoint study record should be chosen here.	List (picklist)
Inhalation		Header 3
Link to relevant study record(s)	Provide here the link(s) to the study record(s) supporting the choice of the key value for assessment.	Link to endpoint (multiple)
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. "No information available" should be chosen if there is no data to conclude on repeated dose toxicity	List (picklist)
Dose descriptor	The primary dose descriptor in this endpoint is the NOAEC. In some studies also the BMCL (benchmark concentration level). The LOAEC should be used only if NOAEC is not available.	List (picklist)
Effect level	Select the qualifier according to the key value: - if none specifically apply, leave the field empty. - if the effect level is based on "no effect seen" at the highest tested concentration, the qualifier ">" should be used and the highest tested concentration should be reported. When there is no effect observed at the highest tested	Numeric range (half bounded)

	concentration, and when such concentration is above the test limit dose, then it can be assumed in the further assessment process that no hazard has been identified. - if effects have been observed at the lowest tested concentration and you are not able to extrapolate an adequate dose descriptor, use the qualifier "<". Nevertheless, note that the reporting of such an effect concentration may be difficult to use appropriately in further processing of the value. As a consequence, if you can justify the extrapolation of the value to one of the proposed dose descriptors, you may do so in your assessment and explain your method in the field "Additional information".	
Study duration	Choose the duration of the selected endpoint study record. Short-term corresponds to e.g. 28-day studies, subchronic e.g. to 90-day studies and chronic usually to longer than 180-day studies.	List (picklist)
Species	The species reported in the selected endpoint study record should be chosen here.	List (picklist)
Repeated dose toxicity:other routes		Header 3
Link to relevant study record(s)	Provide here the link(s) to the study record(s) supporting the choice of the key value for assessment.	Link to endpoint (multiple)
Mode of Action Analysis / Human Relevance Framework		Header 2
	A discussion about the mode of action and the relevance of the data for human health should be provided here.	Rich text area
Justification for classification or non-classification		Header 1
	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
Additional information	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) Follow instructions reported in "Additional information– common block"	Header 1

5.3.1 Repeated dose toxicity: oral– Endpoint study record

Purpose

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.

ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral		
Name	**Instructions**	**Type**
Administrative data	Follow instructions reported in "Administrative data – common block"	Header 1
Data source	Follow instructions reported in "Data source– common block"	Header 1
Materials and methods	Follow instructions reported in "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
Limit test	Indicate if the experiment was a limit test.	Closed list
Test material	Follow instructions reported in "Test Material – common block"	Header 2
Test animals	Follow instructions reported in "Test animals – common block"	Header 2
Administration / exposure		Header 2
Route of administration	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list
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
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 provided in this list are used for specific routes of administration only.	Open list with remarks
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
Analytical verification of doses or concentrations	Indicate whether the doses or concentrations were analytically verified.	Closed list with remarks

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
Duration of treatment / exposure	Indicate duration in days, weeks or months, e.g. '104 weeks' or '90 days'.	Multi-line text
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
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.	
Dose / conc.	Enter numeric value.	Unit measure with Open List (Decimal)
Remarks	Enter any remarks related to dose / concentration values.	Multi-line text
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	Multi-line text

	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.	
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
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
Positive control	Indicate if a positive control was used and if necessary indicate purity, Lot/batch No.	Multi-line text
High dose level used	Where a test method offers flexibility in the study design, for example in relation to the choice of dose levels, the chosen study design shall ensure that the data generated are adequate for hazard identification and risk assessment. To this end, testing shall be performed at appropriately high dose levels. If dose (concentration) selection is limited by the physicochemical properties or biological effects of the test substance, justification shall be provided.	
Examinations		Header 2
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
Sacrifice and pathology	Indicate if and which examinations were performed. Also indicate the dose groups that were examined if not all.	Text template

	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.	
Optional endpoint(s)	Describe any other optional endpoint(s).	Text template
Other examinations	Describe any other examinations.	Text area
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
Model and software	Follow instructions reported in "Model and software – common block". Note: This block of fields is displayed only when "Type of information" is set to (Q)SAR.	Header 2
Any other information on materials and methods incl. tables	Follow instructions reported in "Any other information on materials and methods incl. tables – common block"	Header 2
Results and discussion		Header 1
Results of examinations	Follow instructions reported in "Results of examinations – common block"	Header 2
Effect levels	Follow instructions reported in "Effect levels – 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
Target system / organ toxicity	Follow instructions reported in "Target system/organ toxicity – common block" 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

Detailed toxicology results		Header 2
Detailed toxicology results	This block should be used to report a detailed result summary table. This block of fields is replacing the need to submit template 5.1 for the OHT in which this block of fields is implemented.	Block of fields (repeatable)
Sex	Select from drop-down list.	List (picklist)
Additional covariate	Select the type of additional covariate from the drop down list and the value for the covariate in the remarks field e.g. LitterID:Litter1. Note multiple covariates other than sex can be included by using concatenation.	List (picklist with remark
Dose / conc.	Report dose and units for the group of test animals.	Numeric (decimal including unit)
No. of animals per sex per dose	Report the number of test animals in the group (Dose group, sex and covariate combinations)	Numeric
Examination	Report the examination used to determine the results reports in the Experiment result field.	List (picklist)
Experimental result	Report the result number	Numeric (decimal)
Variation statistic	Report the measure of variability e.g. the upper and lower 95 percentile confidences intervals or standard deviation. Provide the methodology in the 'Statistics' field.	Numeric range (decimal)
Unit	Report the units for reported result	List (picklist)
Additional information about applicability domain and reliability of (Q)SAR predictions	Follow instructions reported in "Additional information about applicability domain and reliability of (Q)SAR predictions – common block"	Header 2
Any other information on results incl. tables	Follow instructions reported in "Any other information on results incl. tables – common block"	Header 2
Overall remarks, attachments	Follow instructions reported in "Overall remarks, attachments – common block"	Header 1
Applicant's summary and conclusion	Follow instructions reported in "Applicant's summary and conclusion – common block"	Header 1

5.3.2 Repeated dose toxicity: inhalation– Endpoint study record

Purpose

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.RepeatedDoseToxicityInhalation		
Name	**Instructions**	**Type**
Administrative data	Follow instructions reported in "Administrative data – common block"	Header 1
Data source	Follow instructions reported in "Data source– common block"	Header 1
Materials and methods	Follow instructions reported in "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
Limit test	Indicate if the experiment was a limit test.	Closed list
Test material	Follow instructions reported in "Test material – common block"	Header 2
Test animals	Follow instructions reported in "Test animals – common block"	Header 2
Administration / exposure		Header 2
Route of administration	Specify the route of administration by indicating in what physical form the test material was administered.	Open list
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
Vehicle	Select the vehicle used. If not available from picklist, select 'other' and specify.	Open list with remarks

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)
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
Remarks on MMAD	Enter any remarks related to the mass median aerodynamic diameter.	Multi-line text
Details on inhalation 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
Analytical verification of doses or concentrations	Indicate whether the doses or concentrations were analytically verified.	Closed list with remarks
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
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
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
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.	
Dose / conc.	Enter numeric value.	Unit measure with Open List (Decimal)

Remarks	Enter any remarks related to dose / concentration values.	Multi-line text
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
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
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
Positive control	Indicate if a positive control was used and if necessary indicate purity, Lot/batch No.	Multi-line text
Examinations		Header 2
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

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
Other examinations	Describe any other examinations.	Text area
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
Model and software	Follow instructions reported in "Model and software – common block". Note: This block of fields is displayed only when "Type of information" is set to (Q)SAR.	Header 2
Any other information on materials and methods incl. tables	Follow instructions reported in "Any other information on materials and methods incl. tables – common block"	Header 2
Results and discussion		Header 1
Results of examinations	Follow instructions reported in "Results of examinations – common block"	Header 2
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
Target system / organ toxicity	Follow instructions reported in "Target system – common block" 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
Additional information about applicability domain and	Follow instructions reported in "Additional information about applicability domain and reliability of (Q)SAR predictions – common block"	Header 2

reliability of (Q)SAR predictions		
Any other information on results incl. tables	Follow instructions reported in “Any other information on results incl. tables – common block”	Header 2
Overall remarks, attachments	Follow instructions reported in "Overall remarks, attachments – common block"	Header 1
Applicant's summary and conclusion	Follow instructions reported in “Applicant's summary and conclusion – common block”	Header 1

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

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

ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal		
Name	**Instructions**	**Type**
Administrative data	Follow instructions reported in "Administrative data – common block"	Header 1
Data source	Follow instructions reported in "Data source– common block"	Header 1
Materials and methods	Follow instructions reported in "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
Test material	Follow instructions reported in "Test material – common block"	Header 2
Test animals	Follow instructions reported in "Test animals – common block"	Header 2
Administration / exposure		Header 2
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
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
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
Analytical verification of doses or	Indicate whether the doses or concentrations were analytically verified.	Closed list with

concentrations		remarks
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
Duration of treatment / exposure	Indicate duration in days, weeks or months, e.g. '104 weeks' or '90 days'.	Multi-line text
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
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.	
Dose / conc.	Enter numeric value.	Unit measure with Open List (Decimal)
Remarks	Enter any remarks related to dose / concentration values.	Multi-line text
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	Multi-line text

	Table 1'). Note: Specific tables may be required.	
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
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
Positive control	Indicate if a positive control was used and if necessary indicate purity, Lot/batch No.	Multi-line text
Examinations		Header 2
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'). 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
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
Other examinations	Describe any other examinations.	Text area
Statistics	List parameters that were analysed and the statistical methods used; include a statement that the Reviewer considers the	Multi-line text

	analyses used to be appropriate. If inappropriate, provide alternative/rationale.	
Model and software	Follow instructions reported in "Model and software – common block". Note: This block of fields is displayed only when "Type of information" is set to (Q)SAR.	Header 2
Any other information on materials and methods incl. tables	Follow instructions reported in "Any other information on materials and methods incl. tables – common block"	Header 2
Results and discussion		Header 1
Results of examinations	Follow instructions reported in "Results of examinations – common block" Body weight and weight changes: The effects should be also considered in relation to organ weights.	Header 2
Effect levels	Follow instructions reported in "Effect levels – common block" Record the available effect levels for NO(A)EL(s), LO(A)EL(s) and other relevant dose descriptors. Copy this block of fields for entering different effect levels, based on different endpoints and/or separated for each sex. 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
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)
Target system / organ toxicity	Follow instructions reported in "Target system – common block" 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
Additional information about applicability domain and reliability of	Follow instructions reported in "Additional information about applicability domain and reliability of (Q)SAR predictions – common block"	Header 2

(Q)SAR predictions		
Any other information on results incl. tables	Follow instructions reported in "Any other information on results incl. tables – common block"	Header 2
Overall remarks, attachments	Follow instructions reported in "Overall remarks, attachments – common block"	Header 1
Applicant's summary and conclusion	Follow instructions reported in "Applicant's summary and conclusion – common block"	Header 1

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		
Name	**Instructions**	**Type**
Administrative data	Follow instructions reported in "Administrative data – common block"	Header 1
Data source	Follow instructions reported in "Data source– common block"	Header 1
Materials and methods	Follow instructions reported in "Material and methods – common block"	Header 1
Limit test	Indicate if the experiment was a limit test.	Closed list
Test material	Follow instructions reported in "Test material – common block"	Header 2
Test animals	Follow instructions reported in "Test animals – common block"	Header 2
Administration / exposure		Header 2
Route of administration	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list
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
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

Analytical verification of doses or concentrations	Indicate whether the doses or concentrations were analytically verified.	Closed list with remarks
Duration of treatment / exposure	Indicate total duration of exposure in days, weeks or months, e.g. '104 weeks' or '90 days'.	Multi-line text
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
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.	
Dose / conc.	Enter numeric value.	Unit measure with Open List (Decimal)
Remarks	Enter any remarks related to dose / concentration values.	Multi-line text
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 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
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
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	Text template

	appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	
Examinations		Header 2
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'). 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
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
Other examinations	Describe any other examinations.	Text area
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
Model and software	Follow instructions reported in "Model and software – common block". Note: This block of fields is displayed only when "Type of information" is set to (Q)SAR.	Header 2
Any other information on materials and methods incl. tables	Follow instructions reported in "Any other information on materials and methods incl. tables – common block"	Header 2
Results and discussion		Header 1
Results of examinations	Follow instructions reported in "Results of examinations – common block"	Header 2
Effect levels	Follow instructions reported in "Effect levels – 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	Header 2

	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'.	
Target system / organ toxicity	Follow instructions reported in "Target system – common block" 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.	Header 2
Additional information about applicability domain and reliability of (Q)SAR predictions	Follow instructions reported in "Additional information about applicability domain and reliability of (Q)SAR predictions – common block"	Header 2
Any other information on results incl. tables	Follow instructions reported in "Any other information on results incl. tables – common block"	Header 2
Overall remarks, attachments	Follow instructions reported in "Overall remarks, attachments – common block"	Header 1
Applicant's summary and conclusion	Follow instructions reported in "Applicant's summary and conclusion – common block"	Header 1

5.4 Genotoxicity testing – Endpoint Summary

Purpose

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 (Q)SAR 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)

ENDPOINT_SUMMARY.GeneticToxicity		
Name	**Instructions**	**Type**
Administrative data	Follow instructions reported in "Administrative data summary – common block"	Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	Confidentiality
Description of key information	Provide a brief description of the genotoxicity studies and effects.	
Key value for chemical safety assessment		Header 1
Genetic toxicity in vitro		Header 2
Link to relevant study records	The link(s) to study record(s) supporting the choice of the key value for assessment should be provided. For the genotoxicity summary this refers to all key in vitro and in vivo studies contributing to the overall weight of evidence (i.e. those of high reliability / relevance) independent of whether they report positive or negative results. Likewise, if there is more than one study record addressing the same genotoxicity endpoint (e.g. two *in vitro* gene mutation studies in bacteria) preference should be given to the one of high reliability / relevance.	Header 3
Endpoint conclusion		Header 3
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. "No information available" should be chosen if there is no data to conclude on genetic toxicity in vitro.	Closed list
Genetic toxicity in vivo		Header 2
Link to relevant study records	Follow instructions reported in "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 conclusion		Header 3
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". No information available" should be chosen if there is no data to conclude on genetic toxicity in vivo.	Closed list

Mode of Action Analysis / Human Relevance Framework		Header 2
	A discussion about the mode of action and the relevance of the data for human health should be provided here. 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	Rich text area
Justification for classification or non-classification		Header 1
	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
Additional information	Follow instructions reported in "Additional information – common block" Provide additional information related to the endpoint, for example: - In vitro studies (state the available in vitro studies and the results), - In vivo studies (state the available in vivo studies and the results) Provide an statement on the photomutagenicity potential: e.g. -Not required -Unlikely to be photomutagenic 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]	Header 1

5.4.1 In vitro studies – Endpoint study record

Purpose

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.

ENDPOINT_STUDY_RECORD.GeneticToxicityVitro		
Name	**Instructions**	**Type**
Administrative data	Follow instructions reported in "Administrative data – common block"	Header 1
Data source	Follow instructions reported in "Data source – common block"	Header 1
Materials and methods	Follow instructions reported in "Material and methods – common block" 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	Header 1
Type of assay	As appropriate supplement the information provided in field 'Endpoint' and indicate the type of assay used.	Open list
Test material	Follow instructions reported in "Test material – common block"	Header 2
Method		Header 2
Target gene	Indicate the target gene (HPRT, XPRT, TK, ATPase, other: specify) only if necessary to characterise the test system.	Multi-line text
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.	
Species / strain / cell type	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list with remarks
Details on mammalian	For robust study summaries, describe relevant details on cell cultures if applicable. Use freetext template and delete/add elements as appropriate. Enter any details	Text template

cell type (if applicable)	that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	
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
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
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
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
Test concentrations	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 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
High dose level used	Where a test method offers flexibility in the study design, for example in relation to the choice of dose levels, the chosen study design shall ensure that the data generated are adequate for hazard identification and risk assessment. To this end, testing shall be performed at appropriately high dose levels. If dose (concentration) selection is limited by the physicochemical properties or biological effects of the test substance, justification shall be provided.	
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	Text template

	solvent/vehicle. 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. 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'.	
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
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
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
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
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'. 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.	Multi select open list with remarks
Remarks	Enter any remarks related to the recorded controls as appropriate.	Text
Controls		
Details on test system and	Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for	Text template

experimental conditions	evaluating this study summary or that are requested by the respective regulatory programme.	
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
Evaluation criteria	Describe the evaluation criteria used in the study to judge if a substance is positive, negative or equivocal.	Multi-line text
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
Model and software	Follow instructions reported in "Model and software – common block". Note: This block of fields is displayed only when "Type of information" is set to (Q)SAR.	Header 2
Any other information on materials and methods incl. tables	Follow instructions reported in "Any other information on materials and methods incl. tables– common block"	Header 2
Results and discussion		Header 1
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 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 ± 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
Species / strain	Indicate the species/strain or cell type tested. Multiply this block of fields for each tester strain.	Open list with remarks
Metabolic activation	Indicate whether metabolic activation was applied or not.	Closed list
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

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
Vehicle controls validity	Indicate whether test with vehicle control(s) (i.e. vehicle without test substance,) is valid.	Open list with remarks
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
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
Positive controls validity	Indicate whether test with positive control(s), i.e. substance(s) with known genotoxicity, is valid.	Open list with remarks
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
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)
Additional information about applicability domain and reliability of (Q)SAR predictions	Follow instructions reported in "Additional information about applicability domain and reliability of (Q)SAR predictions – common block"	Header 2
Any other information on results incl. tables	Follow instructions reported in "Any other information on results incl. tables – common block"	Header 2
Overall remarks, attachments	Follow instructions reported in "Overall remarks, attachments – common block"	Header 1
Applicant's summary and conclusion	Follow instructions reported in "Applicant's summary and conclusion – common block"	Header 1

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		
Name	**Instructions**	**Type**
Administrative data	Follow instructions reported in "Administrative data – common block"	Header 1
Data source	Follow instructions reported in "Data source– common block"	Header 1
Materials and methods	Follow instructions reported in "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
Type of assay	As appropriate supplement the information provided in field 'Endpoint' and indicate the type of assay used.	Open list
Test material	Follow instructions reported in "Test material – common block"	Header 2
Test animals	Follow instructions reported in "Test animals – common block"	Header 2
Administration / exposure		Header 2
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
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
Details on exposure	Select freetext template for the respective type of study and delete/add elements as appropriate. Enter any details	Text template

	that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	
Duration of treatment / exposure	Indicate duration in days, weeks or months, e.g. '5 days' or '10 weeks'.	Multi-line text
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
Post exposure period	Indicate observation period (in days, weeks, months) after last exposure to the test material.	Multi-line text
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.	
Dose / conc.	Enter numeric value.	Unit measure with Open List (Decimal)
Remarks	Enter any remarks related to dose / concentration values.	Multi-line text
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
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
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 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. Use freetext template and delete/add elements as appropriate. Note that the list of substances provided is not exhaustive.	Text template
High dose level used	Where a test method offers flexibility in the study design, for example in relation to the choice of dose levels, the	

	chosen study design shall ensure that the data generated are adequate for hazard identification and risk assessment. To this end, testing shall be performed at appropriately high dose levels. If dose (concentration) selection is limited by the physicochemical properties or biological effects of the test substance, justification shall be provided.	
Examinations		Header 2
Tissues and cell types examined	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. 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').	Multi-line text
Details of tissue and slide preparation	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.	Text template
Evaluation criteria	Describe the evaluation criteria used in the study to judge if a substance is positive.	Multi-line text
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
Model and software	Follow instructions reported in "Model and software – common block". Note: This block of fields is displayed only when "Type of information" is set to (Q)SAR.	Header 2
Any other information on materials and methods incl. tables	Follow instructions reported in "Any other information on materials and methods incl. tables – common block"	Header 2
Results and discussion		Header 1
Test results	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'). Note: Specific tables may be required.	
Key result	This read-only field displays the key results flagged in the corresponding results table(s), if any.	Check box
Sex	Select from drop-down list.	Closed list

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
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
Vehicle controls validity	Indicate whether test with vehicle control(s) (i.e. without test substance, with/without solvent) is valid.	Open list with remarks
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
Positive controls validity	Indicate whether test with positive control(s), i.e. substance(s) with known genotoxicity, is valid.	Open list with remarks
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)
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
Additional information about applicability domain and reliability of (Q)SAR predictions	Follow instructions reported in "Additional information about applicability domain and reliability of (Q)SAR predictions – common block"	Header 2
Any other information on results incl. tables	Follow instructions reported in "Any other information on results incl. tables – common block"	Header 2
Overall remarks, attachments	Follow instructions reported in "Overall remarks, attachments – common block"	Header 1

Applicant's summary and conclusion	Follow instructions reported in "Applicant's summary and conclusion – common block"	Header 1

5.5 Long-term toxicity and carcinogenicity

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:
- 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 carcinogenicity (SANCO/12592/2012-rev. 2, 22 March 2019).
Carcinogenicity (Regulation (EU) N°283/2013, Annex Part A, point 5.5)

It is noted that repeated dose toxicity after chronic exposure was previously summarised within the carcinogenicity summary since the same study may address both carcinogenicity and long-term toxicity. Currently the summary on repeated dose toxicity after chronic (long-term) exposure should be reported under 5.3.

Create two summaries, one for rat and one for mice, the two species required for carcinogenicity testing.

ENDPOINT_SUMMARY.Carcinogenicity		
Name	**Instructions**	**Type**
Administrative data		Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	Confidentiality
Description of key information	Provide a brief description of carcinogenicity studies and effects.	
Key value for chemical safety assessment		Header 1
Carcinogenicity: via oral route		Header 2
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 conclusion	Endpoint conclusion: Carcinogenic effect observed" should be chosen if the substance was found to be carcinogenic. "No carcinogenic effect observed" should be chosen if the substance was not found to be carcinogenic in the available study(ies). "No information available" should be chosen if there is no data to conclude on carcinogenicity.	

	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 systems in which cancer was observed should be specified here. 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.	
Endpoint conclusion		
Carcinogenicity: via inhalation route		Header 2
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 conclusion	Endpoint conclusion: Carcinogenic effect observed" should be chosen if the substance was found to be carcinogenic. "No carcinogenic effect observed" should be chosen if the substance was not found to be carcinogenic in the available study(ies). "No information available" should be chosen if there is no data to conclude on carcinogenicity. 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 system that is associated with the dose descriptor.	Header 3

	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.	
Carcinogenicity: via dermal route		Header 2
Link to relevant study records		Header 3
Results		Read-only
Endpoint conclusion	Endpoint conclusion: Carcinogenic effect observed" should be chosen if the substance was found to be carcinogenic. "No carcinogenic effect observed" should be chosen if the substance was not found to be carcinogenic in the available study(ies). "No information available" should be chosen if there is no data to conclude on carcinogenicity. 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 system that is associated with the dose descriptor 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	Header 3
Mode of Action Analysis / Human Relevance Framework		Header 2
	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	Rich text area
Additional information	Follow instructions reported in "Additional information – common block" Provide additional informatoion related to the endpoint, for example: -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

	-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
	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

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		
Name	**Instructions**	**Type**
Administrative data	Follow instructions reported in "Administrative data – common block"	Header 1
Data source	Follow instructions reported in "Data source– common block"	Header 1
Materials and methods	Follow instructions reported in "Material and methods – common block" Applicable test guideline: - 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.	Header 1

	- other	
Test material	Follow instructions reported in "Test material – common block"	Header 2
Test animals	Follow instructions reported in "Test animals – common block"	Header 2
Administration / exposure		Header 2
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
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
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
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)
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
Remarks on MMAD	Enter any remarks related to the mass median aerodynamic diameter.	Multi-line text
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
Analytical verification of doses or concentrations	Indicate whether the doses or concentrations were analytically verified.	Closed list with remarks
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	Text area

	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. - 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 in days, weeks or months, e.g. '104 weeks' or '18 months'.	Multi-line text
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
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
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.	
Dose / conc.	Enter numeric value.	Unit measure with Open List (Decimal)
Remarks	Enter any remarks related to dose / concentration values.	Multi-line text
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	Multi-line text

	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.	
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
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
Positive control	Indicate if a positive control was used and if necessary indicate purity, Lot/batch No.	Multi-line text
Examinations		Header 2
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) 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
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	Text template

	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.	
Other examinations	Describe any other examinations.	Text area
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
Model and software	Follow instructions reported in "Model and software – common block". Note: This block of fields is displayed only when "Type of information" is set to (Q)SAR.	Header 2
Any other information on materials and methods incl. tables	Follow instructions reported in "Any other information on materials and methods incl. tables – common block"	Header 2
Results and discussion		Header 1
Results of examinations	Follow instructions reported in "Results of examinations – common block"	Header 2
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
Effect levels	Follow instructions reported in "Effect levels – 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	Header 2

	result', e.g. 'not determinable due to absence of adverse toxic effects'.	
Target system / organ toxicity	Follow instructions reported in "Target system – common block"	Header 2
Additional information about applicability domain and reliability of (Q)SAR predictions	Follow instructions reported in "Additional information about applicability domain and reliability of (Q)SAR predictions – common block"	Header 2
Any other information on results incl. tables	Follow instructions reported in "Any other information on results incl. tables – common block"	Header 2
Overall remarks, attachments	Follow instructions reported in "Overall remarks, attachments – common block"	Header 1
Applicant's summary and conclusion	Follow instructions reported in "Applicant's summary and conclusion – common block"	Header 1

5.6 Reproductive toxicity

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		
Name	**Instructions**	**Type**
Administrative data		Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	Confidentiality
Key value for chemical safety assessment		Header 1
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
Effects on reproductive toxicity / fertility		Header 2
Description of key information	Provide a brief description of reproductive toxicity studies and effects.	Rich text field
Link to relevant study records	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.	Header 3

Effect on fertility-reproductive toxicity: via oral route		Header 3
Endpoint conclusion	"Adverse effect observed" should be chosen if adverse reproductive effects were observed at or below the limit dose level. "No adverse effect observed" should be chosen if no adverse reproductive effects were observed at or below the limit dose level. If "No study available" is chosen, a justification needs to be provided. The selection of the dose descriptor should only refer for the specific effect on "reproductive toxicity". 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). 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. The species should be reported in the relative field.	Closed list
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)
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)
Dose descriptor	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	Picklist

	be reported in the section "Description of key information".	
Study duration	Choose the duration of the selected robust study summary.	Picklist
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.	Numeric
Species	The species reported in the selected robust study summary should be chosen here.	Open list
Quality of the whole database	The following factors should be considered: - 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).	Text
Effect on fertility-parental toxicity: via oral route		Header 3
Endpoint conclusion	"Adverse effect observed" should be chosen if adverse reproductive effects were observed at or below the limit dose level. "No adverse effect observed" should be chosen if no adverse reproductive effects were observed at or below the limit dose level. If "no study available" is chosen, a justification needs to be provided. The dose descriptor should only refer for the specific effect on "parental toxicity". 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" studies (e.g. for pesticides). 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. The species should be reported in the relative field, usually the rat.	Closed list
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)

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)
Dose descriptor	Select the dose descriptor. 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".	
Study duration	Choose the duration of the selected robust study summary. Two-generation studies (OECD 416) and 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" studies (e.g. for pesticides).	
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.	
Species	The species reported in the selected robust study summary should be chosen here.	
Quality of whole database	The following factors should be considered - 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).	
Effect on fertility-offspring toxicity: via oral route		Header 3
Endpoint conclusion	"Adverse effect observed" should be chosen if adverse reproductive effects were observed at or below the limit dose level. "No adverse effect observed" should be chosen if no adverse reproductive effects were observed at or below the limit dose level. If "no study available" is chosen, a justification needs to be provided. The selection of the dose descriptor should only refer for the specific effect on "offspring toxicity". The duration of the selected robust study summary.	Closed list

	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" 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 The species reported in the selected robust study summary should be chosen in the relative field, usually the rat.	
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)
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)
Dose descriptor	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".	Picklist
Study duration	Choose the duration of the selected robust study summary. Two-generation studies (OECD 416) and 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" studies (e.g. for pesticides).	Picklist
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.	Numeric
Species	The species reported in the selected robust study summary should be chosen here.	Open list
Quality of whole database	The following factors should be considered - Reliability and consistency across different studies (i.e. quality of testing methods, size and statistical	Text

	power of study design, biological plausibility, dose-response relationships and statistical testing).	
Effect on fertility: via inhalation route		Header 3
Endpoint conclusion	"Adverse effect observed" should be chosen if adverse reproductive effects were observed at or below the limit dose level. "No adverse effect observed" should be chosen if no adverse reproductive effects were observed at or below the limit dose level. If "no study available" is chosen, a justification needs to be provided. 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. 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. Pre-natal developmental toxicity studies (OECD 414) and screening studies for reproductive toxicity (OECD 421/422) are to be reported as "subacute" studies. 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 The species reported in the selected robust study summary should be chosen in the relative field, usually the rat.	Closed list
Dose descriptor	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".	Picklist
Study duration	Choose the duration of the selected robust study summary. Two-generation studies (OECD 416) and 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" studies (e.g. for pesticides).	Picklist
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.	Numeric

Species	The species reported in the selected robust study summary should be chosen here.	Open list
Quality of whole database	The following factors should be considered - 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).	Text
Effect on fertility: via dermal route		Header 3
Endpoint conclusion	"Adverse effect observed" should be chosen if adverse reproductive effects were observed at or below the limit dose level. "No adverse effect observed" should be chosen if no adverse reproductive effects were observed at or below the limit dose level. If "no study available" is chosen, a justification needs to be provided. 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". 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. 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 The species reported in the selected robust study summary should be chosen in the relative field.	Closed list
Dose descriptor	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".	Picklist
Study duration	Choose the duration of the selected robust study summary. Two-generation studies (OECD 416) and 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" studies (e.g. for pesticides).	Picklist

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.	Numeric
Species	The species reported in the selected robust study summary should be chosen here.	Open list
Quality of whole database	The following factors should be considered - 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).	Text
Additional information		Header 3
	Provide additional information related to the endpoint, for example: - 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.	Rich text area
Effects on developmental toxicity		Header 2
Description of key information		Header 3
	Report Information to support the developmental toxicity.	Rich text area
Link to relevant study records		Header 3
Effect on developmental toxicity: via oral route		Header 3
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 conclusion	"Adverse effect observed" should be chosen if adverse developmental effects were observed at or below the limit dose level. "No adverse effect observed" should be chosen if no adverse developmental 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	Closed list

	developmental toxicity, "no study available (further information necessary)" should be chosen. The selection of the dose descriptor should only refer for specific effect on maternal toxicity. The duration of the selected robust study summary should be: Pre-natal developmental toxicity studies(OECD 414) is to be reported as "subacute" studies 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. The species reported in the selected robust study summary should be chosen in the relative field i.e. rat or rabbits.	
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)
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)
Dose descriptor	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".	Picklist
Study duration	Choose the duration of the selected robust study summary. Two-generation studies (OECD 416) and 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" studies (e.g. for pesticides).	Picklist
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.	Numeric
Species	The species reported in the selected robust study summary should be chosen here.	Open list

Quality of whole database	The following factors should be considered - 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).	Text
Effect on developmental toxicity - maternal: via oral route		Header 3
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 two species should be reported.	
Endpoint conclusion	"Adverse effect observed" should be chosen if adverse developmental effects were observed at or below the limit dose level. "No adverse effect observed" should be chosen if no adverse developmental 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 developmental toxicity, "no study available (further information necessary)" should be chosen. The selection of the dose descriptor should only refer for the specific effect on developmental toxicity. The duration of the selected robust study summary should be: Pre-natal developmental toxicity studies(OECD 414) is to be reported as "subacute" studies. 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. The species reported in the selected robust study summary should be chosen in the relative field i.e. rat or rabbits.	Closed list
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)
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)

	- 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:'.	
Dose descriptor	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".	Picklist
Study duration	Choose the duration of the selected robust study summary. Two-generation studies (OECD 416) and 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" studies (e.g. for pesticides).	Picklist
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.	Numeric
Species	The species reported in the selected robust study summary should be chosen here.	Open list
Quality of whole database	The following factors should be considered - 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).	Text
Effect on developmental toxicity: via inhalation route		Header 3
Endpoint conclusion	"Adverse effect observed" should be chosen if adverse reproductive effects were observed at or below the limit dose level. "No adverse effect observed" should be chosen if no adverse reproductive effects were observed at or below the limit dose level. If "No study available" is chosen, a justification needs to be provided. 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". The duration of the selected robust study summary should be: Pre-natal developmental toxicity studies(OECD 414) is to be reported as "subacute" studies.	Closed list

	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. The species reported in the selected robust study summary should be chosen in the relative field i.e. rat or rabbits.	
Dose descriptor	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".	Picklist
Study duration	Choose the duration of the selected robust study summary. Two-generation studies (OECD 416) and 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" studies (e.g. for pesticides).	Picklist
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.	Numeric
Species	The species reported in the selected robust study summary should be chosen here.	Open list
Quality of whole database	The following factors should be considered - 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).	Text
Effect on developmental toxicity: via dermal route		Header 3
Endpoint conclusion	"Adverse effect observed" should be chosen if adverse reproductive effects were observed at or below the limit dose level. "No adverse effect observed" should be chosen if no adverse reproductive effects were observed at or below the limit dose level. If "No study available" is chosen, a justification needs to be provided. 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". 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	Closed list

	screening studies for reproductive toxicity (OECD 421/422) are to be reported as "subacute" studies. 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. The species reported in the selected robust study summary should be chosen in the relative field.	
Dose descriptor	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".	Picklist
Study duration	Choose the duration of the selected robust study summary. Two-generation studies (OECD 416) and 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" studies (e.g. for pesticides).	Picklist
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.	Numeric
Species	The species reported in the selected robust study summary should be chosen here.	Open list
Quality of whole database	The following factors should be considered - 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).	Text
Additional information	Provide additional information related to the endpoint, for example: - 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 3
	Provide any additional information related to the endpoint.	Rich text area
Toxicity to reproduction: other studies		Header 2
Description of key information		Header 3

	Report Information to support the toxicity on reproduction.	Rich text area
Link to relevant study records	If other studies relevant to toxicity to reproduction are available should be reported here. The specifics should be reported in the section "Description of key information".	Header 3
Additional information		Header 3
	Provide additional information related to the endpoint, for example: - 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.	Rich text area
Mode of Action Analysis / Human Relevance Framework		Header 2
	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
Additional information	Follow instructions reported in "Additional information– 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
Justification for classification or non-classification		Header 1
	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

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.ToxicityReproductionOther		
Name	**Instructions**	**Type**
Administrative data	Follow instructions reported in "Administrative data – common block"	Header 1
Data source	Follow instructions reported in "Data source– common block"	Header 1
Materials and methods	Follow instructions reported in "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
Test material	Follow instructions reported in "Test material – common block"	Header 2
Test animals	Follow instructions reported in "Test animals – common block"	Header 2
Administration / exposure		Header 2
Route of administration	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list
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
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

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
Analytical verification of doses or concentrations	Indicate whether the doses or concentrations were analytically verified.	Closed list with remarks
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 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
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
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
Duration of test	Indicate the complete duration of the test.	Multi-line text
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.	

Dose / conc.	Enter numeric value.	Unit measure with Open List (Decimal)
Remarks	Enter any remarks related to dose / concentration values.	Multi-line text
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
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
Details on study design	Give details on the study design. As an option you may include an excerpt from the study report.	Text area
Statistics	List parameters that were analyzed by which test methods.	Multi-line text
	Where a test method offers flexibility in the study design, for example in relation to the choice of dose levels, the chosen study design shall ensure that the data generated are adequate for hazard identification and risk assessment. To this end, testing shall be performed at appropriately high dose levels. If dose (concentration) selection is limited by the physicochemical properties or biological effects of the test substance, justification shall be provided.	Picklist
High dose level used	Where a test method offers flexibility in the study design, for example in relation to the choice of dose levels, the chosen study design shall ensure that the data generated are adequate for hazard identification and risk assessment. To this end, testing shall be performed at appropriately high dose levels. If dose (concentration) selection is limited by the physicochemical properties or biological effects of the test substance, justification shall be provided.	
Justification for deviation from the high dose level	Provide a justification for deviating from the high dose level.	Text template
Model and software	Follow instructions reported in "Model and software – common block". Note: This block of fields is displayed only when "Type of information" is set to (Q)SAR.	Header 2
Any other information on materials and methods incl. tables	Follow instructions reported in "Any other information on materials and methods incl. tables– common block"	Header 2
Results and discussion		Header 1
Effect levels	Follow instructions reported in "Effect levels – 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	Header 2

	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'.	
Observed effects		Header 2
Additional information about applicability domain and reliability of (Q)SAR predictions	Follow instructions reported in "Additional information about applicability domain and reliability of (Q)SAR predictions – common block"	Header 2
Any other information on results incl. tables	Follow instructions reported in "Any other information on materials and methods incl. tables– common block"	Header 2
Overall remarks, attachments	Follow instructions reported in "Overall remarks, attachments – common block"	Header 1
Applicant's summary and conclusion	Follow instructions reported in "Applicant's summary and conclusion – common block"	Header 1

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.ToxicityReproduction		
Name	**Instructions**	**Type**
Administrative data	Follow instructions reported in "Administrative data – common block"	Header 1
Data source	Follow instructions reported in "Data source– common block"	Header 1
Materials and methods	Follow instructions reported in "Material and methods – common block" Applicable test guideline, e.g: Reproductive toxicity (one-/two generation studies):	Header 1

	- 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 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
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
Test material	Follow instructions reported in "Test material – common block"	Header 2
Test animals	Follow instructions reported in "Test animals – common block"	Header 2
Administration / exposure		Header 2
Route of administration	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list
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
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)
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
Remarks on MMAD	Enter any remarks related to the mass median aerodynamic diameter.	Multi-line text

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
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
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
Analytical verification of doses or concentrations	Indicate whether the doses or concentrations were analytically verified.	Closed list with remarks
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 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. - 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

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
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
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.	
Dose / conc.	Enter numeric value.	Unit measure with Open List (Decimal)
Remarks	Enter any remarks related to dose / concentration values.	Multi-line text
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 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').	Multi-line text
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
Details on study design	Include any details on the study design including a brief description on dose selection and animal	Text template

	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.	
Positive control	Indicate if a positive control was used and if necessary indicate purity, Lot/batch No.	Multi-line text
High dose level used	Where a test method offers flexibility in the study design, for example in relation to the choice of dose levels, the chosen study design shall ensure that the data generated are adequate for hazard identification and risk assessment. To this end, testing shall be performed at appropriately high dose levels. If dose (concentration) selection is limited by the physicochemical properties or biological effects of the test substance, justification shall be provided. Select as appropiate.	Open list with justification .
Justification for deviation from high dose level	Provide a justification for deviating from the high dose level.	Free text field
Examinations		Header 2
Parental animals: Observations and examinations	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'). 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'. 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
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

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
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 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
Postmortem examinations (parental animals)	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'). Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template
Postmortem examinations (offspring)	Indicate details on gross pathological and histopathological examinations. Also indicate those dose groups which were examined if not all. Use 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.	Text template
Statistics	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	Multi-line text

	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 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. 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.	
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
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
Model and software	Follow instructions reported in "Model and software – common block". Note: This block of fields is displayed only when "Type of information" is set to (Q)SAR.	Header 2
Any other information on materials and methods incl. tables	Follow instructions reported in "Any other information on materials and methods incl. tables – common block"	Header 2
Results and discussion		Header 1
Results: P0 (first parental generation)		Header 2
General toxicity (P0)		Header 3
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
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	Text area

	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
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
Mortality	Indicate whether mortality was observed and whether it was treatment-related or not.	Closed list
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
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
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
Food consumption and	Indicate whether any effects were observed and whether they were treatment-related or not.	Closed list

compound intake (if feeding study)	Select 'not examined' or 'not specified' as applicable.	
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
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
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
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
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	Text area

	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
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
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
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
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
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	Text area

	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.	
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
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
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
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
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
Description (incidence and severity)	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	Text area

	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.	
Immunological 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
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
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
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

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
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
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
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
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
Description (incidence and severity)	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. 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

	NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	
Histopathological findings: 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
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
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
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
Reproductive function / performance (P0)		Header 3
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
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	Text area

	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.	
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
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
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
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
Details on results (P0)		Header 3
	Provide any other relevant details if not entered in the specific "Description" fields for the examined parameters.	Text area
Effect levels (P0)		Header 3

Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box
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
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)
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
Sex	Select from drop-down list.	Closed list
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)
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	Open list with remarks (2000)

	- entering any additional information on the effect level by selecting 'other:'	
Target system / organ toxicity (P0)		Header 3
	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.	
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box
Critical effects observed	Flag to indicate if critical effects were observed in the study within specific organs or systems.	Closed list
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)
System	Select any specific system where toxicity was observed that is considered of biological relevance.	Open list
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
Treatment related	Flag to indicate if the effects in systems and/or organs are treatment related.	Closed list
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
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
Results: P1 (second parental generation)		Header 2
General toxicity (P1)		Header 3
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
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	Text area

	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.	
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
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
Mortality	Indicate whether mortality was observed and whether it was treatment-related or not.	Closed list
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
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
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	Text area

	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
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
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
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
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
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	Text area

	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
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
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
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
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
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

	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.	
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
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
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
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
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
Description (incidence and severity)	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	Text area

	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.	
Immunological 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
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
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
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

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
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
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
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
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
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

	NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	
Histopathological findings: 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
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
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
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
Details on results	Provide any other relevant details if not entered in the specific "Description" fields for the examined parameters.	Text area
Reproductive function / performance (P1)		Header 3
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
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	Text area

	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.	
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
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
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
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
Details on results (P1)		Header 3
	Provide any other relevant details if not entered in the specific "Description" fields for the examined parameters.	Text area
Effect levels (P1)		Header 3

Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box
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
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)
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
Sex	Select from drop-down list.	Closed list
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)
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)
Target system / organ toxicity (P1)		Header 3
	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.	
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box

Critical effects observed	Flag to indicate if critical effects were observed in the study within specific organs or systems.	Closed list
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)
System	Select any specific system where toxicity was observed that is considered of biological relevance.	Open list
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
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
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
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
Results: F1 generation		Header 2
General toxicity (F1)		Header 3
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
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
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

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
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
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
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. Please indicate if maternal toxicity is seen.	Closed list
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	Text area

	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
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
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
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
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
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	Text area

	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
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
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
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
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
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

	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.	
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
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
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
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
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
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	Text area

	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.	
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
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
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. Please indicate if maternal toxicity is seen.	Closed list
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

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
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
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
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
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
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

	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.	
Developmental neurotoxicity (F1)		Header 3
Behaviour (functional findings)	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 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.	Closed list
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
Developmental immunotoxicity (F1)		Header 3
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
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	Text area

	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.	
Details on results (F1)		Header 3
	Provide any other relevant details if not entered in the specific "Description" fields for the examined parameters.	Text area
Effect levels (F1)		Header 3
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box
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
Generation	Select the generation (e.g. 'P') the effect level refers to.	Open list
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)
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
Sex	Select from drop-down list.	Closed list
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)
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	Open list with remarks (2000)

	- entering any additional information on the effect level by selecting 'other:'	
Target system / organ toxicity (F1)		Header 3
	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.	
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box
Critical effects observed	Flag to indicate if critical effects were observed in the study within specific organs or systems.	Closed list
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)
System	Select any specific system where toxicity was observed that is considered of biological relevance.	Open list
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
Treatment related	Flag to indicate if the effects in systems and/or organs are treatment related.	Closed list
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
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
Results: F2 generation		Header 2
General toxicity (F2)		Header 3
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
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	Text area

	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.	
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
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
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
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
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

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
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
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
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
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

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
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
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
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
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
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	Text area

	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.	
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
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
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
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
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
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	Text area

	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.	
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
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
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
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
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
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	Text area

	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.	
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
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
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
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
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

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
Developmental neurotoxicity (F2)		Header 3
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
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
Developmental immunotoxicity (F2)		Header 3
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
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	Text area

	regulatory programme some form of a table(s) (predefined table) may be mandatory.	
Details on results (F2)		Header 3
	Provide any other relevant details if not entered in the specific "Description" fields for the examined parameters.	Text area
Effect levels (F2)		Header 3
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box
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
Generation	Select the generation (e.g. 'P') the effect level refers to.	Open list
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)
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
Sex	Select from drop-down list.	Closed list
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)

	always be entered in the related supplementary text field.	
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)
Target system / organ toxicity (F2)		Header 3
	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.	
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box
Critical effects observed	Flag to indicate if critical effects were observed in the study within specific organs or systems.	Closed list
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)
System	Select any specific system where toxicity was observed that is considered of biological relevance.	Open list
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
Treatment related	Flag to indicate if the effects in systems and/or organs are treatment related.	Closed list
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
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

Overall reproductive toxicity		Header 2
	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.	
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box
Reproductive effects observed	Flag to indicate if reproductive toxicity was observed in the study.	Closed list
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)
Treatment related	Flag to indicate if the reproductive effects are treatment related.	Closed list
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
Dose response relationship	Flag to indicate if the reproductive effects are in a dose-response manner.	Closed list
Relevant for humans	Flag to indicate if the reproductive effects are in a dose-response manner.	Closed list
Additional information about applicability domain and reliability of (Q)SAR predictions	Follow instructions reported in "Additional information about applicability domain and reliability of (Q)SAR predictions – common block"	Header 2
Any other information on results incl. tables	Follow instructions reported in "Any other information on results incl. tables – common block"	Header 2
Overall remarks, attachments	Follow instructions reported in "Overall remarks, attachments – common block"	Header 1
Applicant's summary and conclusion	Follow instructions reported in "Applicant's summary and conclusion – common block"	Header 1

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		
Name	**Instructions**	**Type**
Administrative data	Follow instructions reported in "Administrative data – common block"	Header 1
Data source	Follow instructions reported in "Data source (Literature Reference) – common block"	Header 1
Materials and methods	Follow instructions reported in "Material and methods – common block"	Header 1
Limit test	Indicate if the experiment was a limit test.	Closed list
Test material	Follow instructions reported in "Test material – common block"	Header 2
Test animals	Follow instructions reported in "Test animals – common block" Select species as appropriate. If not available from picklist, select 'other' and specify "i.e. rat or rabbit".	Header 2
Administration / exposure		Header 2
Route of administration	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list
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
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
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)
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
Remarks on MMAD	Enter any remarks related to the mass median aerodynamic diameter.	Multi-line text
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	Text template

	study summary or that are requested by the respective regulatory programme.	
Analytical verification of doses or concentrations	Indicate whether the doses or concentrations were analytically verified.	Closed list with remarks
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 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
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
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
Frequency of treatment	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.	Multi-line text
Duration of test	Indicate the complete duration of the test.	Multi-line text
Doses / concentrations	Enter any remarks related to dose / concentration values.	

Dose / conc.	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.	Unit measure with Open List (Decimal)
Remarks	Enter numeric value.	Multi-line text
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
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
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
Examinations		Header 2
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
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
Blood sampling	Indicate if plasma or serum were examined and the type of examinations.	Text template

	Use freetext template to indicate the volume of whole blood examined.	
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 the respective regulatory programme.	Text template
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
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
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
Model and software	Follow instructions reported in "Model and software – common block". Note: This block of fields is displayed only when "Type of information" is set to (Q)SAR.	Header 2
Any other information on materials and methods incl. tables	Follow instructions reported in "Any other information on materials and methods incl. tables – common block"	Header 2
Results and discussion		Header 1
Results: maternal animals		Header 2
General toxicity (maternal animals)	Follow instructions reported in "Results of examinations – common block"	Header 3
Maternal developmental toxicity		Header 3
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

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
Pre- and post-implantation loss	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list
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
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
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
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
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	Text area

	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.	
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
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
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
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
Changes in number of pregnant	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list
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

	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.	
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
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
Details on maternal toxic effects	Provide any other relevant details if not entered in the specific "Description" fields for the examined parameters.	Text area
Effect levels (maternal animals)	Follow instructions reported in "Effect levels – 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 3
Maternal abnormalities		Header 3
	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.	

Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box
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
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
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
Results (fetuses)		Header 2
Fetal body 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
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	Text area

	some form of a table(s) (predefined table) may be mandatory.	
Reduction in number of live offspring	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list
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
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
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
Changes in litter size and weights	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list
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

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
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
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
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
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
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

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
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
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
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
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
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
Details on embryotoxic /	Provide any other relevant details if not entered in the specific "Description" fields for the examined parameters.	Text area

teratogenic effects		
Effect levels (fetuses)	Follow instructions reported in "Effect levels – 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 3
Fetal abnormalities		Header 3
	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.	
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box
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
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
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	Text area

	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.	
Overall developmental toxicity		Header 2
	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.	
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box
Developmental effects observed	Flag to indicate if developmental toxicity was observed in the study.	Closed list
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)
Treatment related	Flag to indicate if the reproductive effects are treatment related.	Closed list
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
Dose response relationship	Flag to indicate if the reproductive effects are in a dose-response manner.	Closed list
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
Additional information about applicability domain and reliability of (Q)SAR predictions	Follow instructions reported in "Additional information about applicability domain and reliability of (Q)SAR predictions – common block"	Header 2
Any other information on results incl. tables	Follow instructions reported in "Any other information on results incl. tables – common block"	Header 2
Overall remarks, attachments	Follow instructions reported in "Overall remarks, attachments – common block"	Header 1

Applicant's summary and conclusion	Follow instructions reported in "Applicant's summary and conclusion – common block"	Header 1

5.7 Neurotoxicity studies, including delayed polyneuropathy studies

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		
Name	**Instructions**	**Type**
Administrative data		Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page"	Confidentiality
Description of key information	If all key information is provided in the linked study records, this field can be left empty. In case there is no linked study record, or in case you want to point to specific information in the linked study record, provide a summary of the key information related to the studies here.	
Key value for chemical safety assessment		Header 1
Effect on neurotoxicity: via oral route		Header 2
Link to relevant study records		Header 3
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.	Header 3
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. The	Closed list with remarks

	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".	
Effect level	Select the qualifier according to the key value: - if none specifically apply, leave the field empty. - if the effect level is based on "no effect seen" at the highest tested concentration, the qualifier ">" should be used and the highest tested concentration should be reported. When there is no effect observed at the highest tested concentration, and when such concentration is above the test limit dose, then it can be assumed in the further assessment process that no hazard has been identified. - if effects have been observed at the lowest tested concentration and you are not able to extrapolate an adequate dose descriptor, use the qualifier "<". Nevertheless, note that the reporting of such an effect concentration may be difficult to use appropriately in further processing of the value. As a consequence, if you can justify the extrapolation of the value to one of the proposed dose descriptors, you may do so in your assessment and explain your method in the field "Additional information".	Range with closed list (Decimal)
Study duration	Choose the duration of the selected endpoint study record. Short-term corresponds to e.g. 28-day studies, subchronic e.g. to 90-day studies and chronic usually to longer than 180-day studies	List (picklist)
Species	The species reported in the selected endpoint study record should be chosen here.	List (picklist)
Effect on neurotoxicity: via dermal route		Header 2
Link to relevant study records		Header 3
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.	Header 3
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. 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".	Closed list with remarks
Effect level	Select the qualifier according to the key value: - if none specifically apply, leave the field empty. - if the effect level is based on "no effect seen" at the highest tested concentration, the qualifier ">" should be used and the highest tested concentration should be reported. When there is no effect observed at the highest tested concentration, and when such	Range with closed list (Decimal)

	concentration is above the test limit dose, then it can be assumed in the further assessment process that no hazard has been identified. - if effects have been observed at the lowest tested concentration and you are not able to extrapolate an adequate dose descriptor, use the qualifier "<". Nevertheless, note that the reporting of such an effect concentration may be difficult to use appropriately in further processing of the value. As a consequence, if you can justify the extrapolation of the value to one of the proposed dose descriptors, you may do so in your assessment and explain your method in the field "Additional information".	
Study duration	Choose the duration of the selected endpoint study record. Short-term corresponds to e.g. 28-day studies, subchronic e.g. to 90-day studies and chronic usually to longer than 180-day studies	List (picklist)
Species	The species reported in the selected endpoint study record should be chosen here.	List (picklist)
Effect on neurotoxicity: via inhalation route		Header 2
Link to relevant study records		Header 3
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.	Header 3
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. 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".	Closed list with remarks
Effect level	Select the qualifier according to the key value: - if none specifically apply, leave the field empty. - if the effect level is based on "no effect seen" at the highest tested concentration, the qualifier ">" should be used and the highest tested concentration should be reported. When there is no effect observed at the highest tested concentration, and when such concentration is above the test limit dose, then it can be assumed in the further assessment process that no hazard has been identified. - if effects have been observed at the lowest tested concentration and you are not able to extrapolate an adequate dose descriptor, use the qualifier "<". Nevertheless, note that the reporting of such an effect concentration may be difficult to use appropriately in further processing of the value. As a consequence, if you can justify the extrapolation of the value to one of the	Range with closed list (Decimal)

	proposed dose descriptors, you may do so in your assessment and explain your method in the field "Additional information".	
Study duration	Choose the duration of the selected endpoint study record. Short-term corresponds to e.g. 28-day studies, subchronic e.g. to 90-day studies and chronic usually to longer than 180-day studies	List (picklist)
Species	The species reported in the selected endpoint study record should be chosen here.	List (picklist)
Mode of Action Analysis / Human Relevance Framework		Header 2
	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	Rich text area
Justification for classification or non-classification		Header 1
	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
Additional information	Follow instructions reported in "Additional information – common block" Provide additional information related to the endpoint, for example: - 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 descritptor (e.g. NOAEL) - Additional studies (e.g. delayed neurotoxicity, developmental neurotoxicity) (mention study results.), and dose descritptor (e.g. NOAEL) If there is no additional information to be reported this field may be left empty.	Header 1

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		
Name	**Instructions**	**Type**
Administrative data	Follow instructions reported in "Administrative data – common block"	Header 1
Data source	Follow instructions reported in "Data source– common block"	Header 1
Materials and methods	Follow instructions reported in "Material and methods – common block" Applicable test guideline, e.g. "OECD 424 Method B.43".	Header 1
Test guideline		
Limit test	Indicate if the experiment was a limit test.	Closed list
Test material	Follow instructions reported in "Test material – common block"	Header 2
Test animals	Follow instructions reported in "Test animals – common block"	Header 2
Administration / exposure		Header 2
Route of administration	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list
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
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)
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
Remarks on MMAD	Enter any remarks related to the mass median aerodynamic diameter.	Multi-line text
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

Analytical verification of doses or concentrations	Indicate whether the doses or concentrations were analytically verified.	Closed list with remarks
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 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. - 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
Duration of treatment / exposure	Indicate duration in days, weeks or months, e.g. '28 days' or '18 months'.	Multi-line text
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
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.	
Dose / conc.	Enter numeric value.	Unit measure with Open List (Decimal)
Remarks	Enter any remarks related to dose / concentration values.	Multi-line text

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 motor activity testing, the same individual animals should have been evaluated at all scheduled time points. 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.	Multi-line text
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
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. 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.	Text template

	Any pilot study data (including biomarker data, such as cholinesterase 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
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
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
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 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 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).	Text template
Sacrifice and (histo)pathology	Indicate details on gross pathological and histopathological examinations. Also indicate those dose groups which were examined. 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

	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). Narrative accompanying such tabular data should address the toxicological significance of the results and not repeat what is presented in the table(s). Specific guidance for acute or subchronic neurotoxicity: 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? Specific guidance for developmental neurotoxicity studies: see freetext template. Tables are optional, particularly for postmortem examinations of the offspring and the specific morphometric measures taken.	
Other examinations	Describe any other examinations.	Text area
Positive control	Briefly describe the positive control data cited, and its acceptability for use with the current study. 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). 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	Multi-line text

	animals per test group should not be greater than that 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
Model and software	Follow instructions reported in "Model and software – common block". Note: This block of fields is displayed only when "Type of information" is set to (Q)SAR.	Header 2
Any other information on materials and methods incl. tables	Follow instructions reported in "Any other information on materials and methods incl. tables – common block"	Header 2
Results and discussion		Header 1
Results of examinations	Follow instructions reported in "Results of examinations – common block"	Header 2
Effect levels	Follow instructions reported in "Effect levels – common block"	Header 2
Target system / organ toxicity	Follow instructions reported in "Target system – common block"	Header 2
Additional information about applicability domain and reliability of (Q)SAR predictions	Follow instructions reported in "Additional information about applicability domain and reliability of (Q)SAR predictions – common block"	Header 2
Any other information on results incl. tables	Follow instructions reported in "Any other information on results incl. tables – common block"	Header 2
Overall remarks, attachments	Follow instructions reported in "Overall remarks, attachments – common block"	Header 1
Applicant's summary and conclusion	Follow instructions reported in "Applicant's summary and conclusion – common block"	Header 1

5.8 Other toxicological studies – Endpoint Summary

Other toxicological studies – 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 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

ENDPOINT_SUMMARY.AdditionalToxicologicalInformation		
Name	**Instructions**	**Type**
Administrative data		Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page"	Confidentiality
Link to relevant study records	Provide here the link(s) to the study record(s) supporting the choice of the key value for assessment.	Cross-reference: ENDPOINT_STUDY_RECORD.AdditionalToxicologicalInformation
Description of key information	Provide a brief description of additional toxicological studies and effects.	Text (rich-text area)
Additional information	Follow instructions reported in "Additional information–common block" Provide additional information related to the endpoint, for example: - 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. If there is no additional information to be reported this field may be left empty.	Header 1

	See IUCLID templates for PPP Risk Assessment - Template 5.4 - Template summary table on the assessment of the toxicological profile of metabolites [http://doi.org/10.5281/zenodo.4557353]"	

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.

ENDPOINT_STUDY_RECORD.AdditionalToxicologicalInformation		
Name	**Instructions**	**Type**
Administrative data	Follow instructions reported in "Administrative data – common block"	Header 1
Data source	Follow instructions reported in "Data source– common block"	Header 1
Materials and methods	Follow instructions reported in "Material and methods – common block"	Header 1
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, hematoxicity, hepatotoxicity, mechanistic studies, methaemoglobinaemia, nephrotoxicity, phototoxicity, respiratory irritation, splenic toxicity, or toxicogenomics.	Multi-line text
Test material	Follow instructions reported in "Test material – common block"	Header 2
Model and software	Follow instructions reported in "Model and software – common block". Note: This block of fields is displayed only when "Type of information" is set to (Q)SAR.	Header 2
Any other information on materials and	Follow instructions reported in "Any other information on materials and methods incl. tables – common block"	Header 2

methods incl. tables		
Results and discussion		Header 1
Additional information about applicability domain and reliability of (Q)SAR predictions	Follow instructions reported in "Additional information about applicability domain and reliability of (Q)SAR predictions – common block"	Header 2
Any other information on results incl. tables	Follow instructions reported in "Any other information on results incl. tables – common block"	Header 2
Overall remarks, attachments	Follow instructions reported in "Overall remarks, attachments – common block"	Header 1
Applicant's summary and conclusion	Follow instructions reported in "Applicant's summary and conclusion – common block"	Header 1

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		
Name	**Instructions**	**Type**
Administrative data		Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page"	Confidentiality
Description of key information	Provide a brief description of the immunotoxicity studies and effects.	
Key value for chemical safety assessment		Header 1

Effect on immunotoxicity: via oral route		Header 2
Link to relevant study records	Provide here the link(s) to the study record(s) supporting the choice of the key value for assessment.	Link
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. 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". Define the duration of the selected robust study summary. The species reported in the selected robust study summary should be reported in the relative field .	Header 3
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. 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".	Closed list with remarks
Effect level	Select the qualifier according to the key value: - if none specifically apply, leave the field empty. - if the effect level is based on "no effect seen" at the highest tested concentration, the qualifier ">" should be used and the highest tested concentration should be reported. When there is no effect observed at the highest tested concentration, and when such concentration is above the test limit dose, then it can be assumed in the further assessment process that no hazard has been identified. - if effects have been observed at the lowest tested concentration and you are not able to extrapolate an adequate dose descriptor, use the qualifier "<". Nevertheless, note that the reporting of such an effect concentration may be difficult to use appropriately in further processing of the value. As a consequence, if you can justify the extrapolation of the value to one of the proposed dose descriptors, you may do so in your	Range with closed list (Decimal)

	assessment and explain your method in the field "Additional information".	
Study duration	Choose the duration of the selected endpoint study record. Short-term corresponds to e.g. 28-day studies, subchronic e.g. to 90-day studies and chronic usually to longer than 180-day studies	List (picklist)
Species	The species reported in the selected endpoint study record should be chosen here.	List (picklist)
Effect on immunotoxicity: via dermal route		Header 2
Link to relevant study records	Provide here the link(s) to the study record(s) supporting the choice of the key value for assessment.	Link
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. 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". Define the duration of the selected robust study summary. The species reported in the selected robust study summary should be reported in the relative field .	Header 3
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. 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".	Closed list with remarks
Effect level	Select the qualifier according to the key value: - if none specifically apply, leave the field empty. - if the effect level is based on "no effect seen" at the highest tested concentration, the qualifier ">" should be used and the highest tested concentration should be reported. When there is no effect observed at the highest tested concentration, and when such concentration is above the test limit dose, then it can be assumed in the further assessment process that no hazard has been identified. - if effects have been observed	Range with closed list (Decimal)

	at the lowest tested concentration and you are not able to extrapolate an adequate dose descriptor, use the qualifier "<". Nevertheless, note that the reporting of such an effect concentration may be difficult to use appropriately in further processing of the value. As a consequence, if you can justify the extrapolation of the value to one of the proposed dose descriptors, you may do so in your assessment and explain your method in the field "Additional information".	
Study duration	Choose the duration of the selected endpoint study record. Short-term corresponds to e.g. 28-day studies, subchronic e.g. to 90-day studies and chronic usually to longer than 180-day studies	List (picklist)
Species	The species reported in the selected endpoint study record should be chosen here.	List (picklist)
Effect on immunotoxicity: via inhalation route		Header 2
Link to relevant study records	Provide here the link(s) to the study record(s) supporting the choice of the key value for assessment.	Link
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. 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".	Closed list with remarks
Effect level	Select the qualifier according to the key value: - if none specifically apply, leave the field empty. - if the effect level is based on "no effect seen" at the highest tested concentration, the qualifier ">" should be used and the highest tested concentration should be reported. When there is no effect observed at the highest tested concentration, and when such concentration is above the test limit dose, then it can be assumed in the further assessment process that no hazard has been identified. - if effects have been observed at the lowest tested concentration and you are not able to extrapolate an adequate dose descriptor, use the qualifier "<". Nevertheless, note that the reporting of such an effect concentration may be difficult to use appropriately in further processing of the value. As a consequence, if you can justify the extrapolation of the value to one of the proposed dose descriptors, you may do so in your assessment and explain your method in the field "Additional information".	Range with closed list (Decimal)
Study duration	Choose the duration of the selected endpoint study record. Short-term corresponds to e.g. 28-day studies, subchronic e.g. to 90-day studies and chronic usually to longer than 180-day studies	List (picklist)

Species	The species reported in the selected endpoint study record should be chosen here.	List (picklist)
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. 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". Define the duration of the selected robust study summary. The species reported in the selected robust study summary should be reported in the relative field .	Header 3
Mode of Action Analysis / Human Relevance Framework		Header 2
	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	Rich text area
Justification for classification or non-classification		Header 1
	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
Additional information	Follow instructions reported in "Additional information – common block"	Header 1

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		
Name	**Instructions**	**Type**
Administrative data	Follow instructions reported in "Administrative data – common block"	Header 1
Data source	Follow instructions reported in "Data source – common block"	Header 1
Materials and methods	Follow instructions reported in "Material and methods – common block"	Header 1
Limit test	Indicate if the experiment was a limit test.	Closed list
Test material	Follow instructions reported in "Test material – common block"	Header 2
Test animals	Follow instructions reported in "Test animals – common block"	Header 2
Administration / exposure		Header 2
Route of administration	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list
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
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)
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
Remarks on MMAD	Enter any remarks related to the mass median aerodynamic diameter.	Multi-line text
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
Analytical verification of doses or concentrations	Indicate whether the doses or concentrations were analytically verified.	Closed list with remarks
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	Text area

	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 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.	
Duration of treatment / exposure	Indicate duration in days, weeks or months, e.g. '28 days' or '18 months'.	Multi-line text
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
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.	
Dose / conc.	Enter numeric value.	Unit measure with Open List (Decimal)
Remarks	Enter any remarks related to dose / concentration values.	Multi-line text
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	Multi-line text

	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.	
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
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
Examinations		Header 2
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. 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'). 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
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
Cell viabilities	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.	Text template

Humoral immunity examinations	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: '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.' 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 erythrocytes on day...IgM titers in serum were determined ... days after immunization.'	Text template
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
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 cytolysis).'	Text template
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	Text template

	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 harvest on day 3, the cells were pulsed with 3H-thymidine for 18-24 hours.' 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.'	
Other examinations	Describe any other examinations.	Text area
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
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
Model and software	Follow instructions reported in "Model and software – common block". Note: This block of fields is displayed only when "Type of information" is set to (Q)SAR.	Header 2
Any other information on materials and methods incl. tables	Follow instructions reported in "Any other information on materials and methods incl. tables – common block"	Header 2
Results and discussion		Header 1

Results of examinations	Follow instructions reported in "Results of examinations – common block"	Header 2
Specific immunotoxic examinations		Header 3
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
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
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
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
Specific cell-mediated immunity	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
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

Non-specific cell-mediated immunity	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
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
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.	Closed list
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
Other findings	Report results related to pathogenicity, infectiveness or clearance in studies with micro-organisms	Closed list
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
Effect levels	Follow instructions reported in "Effect levels – common block"	Header 2
Target system / organ toxicity	Follow instructions reported in "Target system – common block"	Header 2

Additional information about applicability domain and reliability of (Q)SAR predictions	Follow instructions reported in "Additional information about applicability domain and reliability of (Q)SAR predictions – common block"	Header 2
Any other information on results incl. tables	Follow instructions reported in "Any other information on results incl. tables – common block"	Header 2
Overall remarks, attachments	Follow instructions reported in "Overall remarks, attachments – common block"	Header 1
Applicant's summary and conclusion	Follow instructions reported in "Applicant's summary and conclusion – common block"	Header 1

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		
Name	**Instructions**	**Type**
Administrative data	Follow instructions reported in "Administrative data summary – common block" Provide a brief description of the relevant study and effects	Header 1
Additional information	Follow instructions reported in "Additional information – common block"	Header 1

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		
Name	**Instructions**	**Type**
Administrative data	Follow instructions reported in "Administrative data – common block"	Header 1
Data source	Follow instructions reported in "Data source– common block"	Header 1
Materials and methods	Follow instructions reported in "Material and methods – common block"	Header 1

	Applicable test guideline: OECD 503 study on metabolism.	
Limit test	Indicate if the experiment was a limit test.	Closed list
Test material	Follow instructions reported in "Test material – common block"	Header 2
Test animals	Follow instructions reported in "Test animals – common block"	Header 2
Route of exposure	Indicate to which route of exposure the information or description of experimenta study refers to.	Open list with remarks
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
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
Analytical verification of doses or concentrations	Indicate whether the doses or concentrations were analytically verified.	Closed list with remarks
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 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

Duration of treatment / exposure	Indicate duration in days, weeks or months, e.g. '5 days' or '10 weeks'.	Multi-line text
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
Post exposure period	Indicate observation period (in days, weeks, months) after last exposure to the test material.	Multi-line text
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.	
Dose / conc.	Enter numeric value.	Unit measure with Open List (Decimal)
Remarks	Enter any remarks related to dose / concentration values.	Multi-line text
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
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
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
Examinations		Header 2
Observations and examinations	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	Text template

performed and frequency	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.	
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
Other examinations	Describe any other examinations.	Text area
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
Model and software	Follow instructions reported in "Model and software – common block". Note: This block of fields is displayed only when "Type of information" is set to (Q)SAR.	Header 2
Any other information on materials and methods incl. tables	Follow instructions reported in "Any other information on materials and methods incl. tables – common block"	Header 2
Results and discussion		Header 1
Results of examinations	Follow instructions reported in "Results of examinations – common block"	Header 2
Effect levels	Follow instructions reported in "Effect levels – common block"	Header 2
Target system / organ toxicity	Follow instructions reported in "Target system – common block"	Header 2
Additional information about applicability domain and reliability of (Q)SAR predictions	Follow instructions reported in "Additional information about applicability domain and reliability of (Q)SAR predictions – common block"	Header 2
Any other information on results incl. tables	Follow instructions reported in "Any other information on results incl. tables – common block"	Header 2

Overall remarks, attachments	Follow instructions reported in "Overall remarks, attachments – common block"	Header 1
Applicant's summary and conclusion	Follow instructions reported in "Applicant's summary and conclusion – common block"	Header 1

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		
Name	**Instructions**	**Type**
Administrative data	Follow instructions reported in "Administrative data – common block"	Header 1
Data source	Follow instructions reported in "Data source – common block"	Header 1
Materials and methods	Follow instructions reported in "Material and methods – common block" Applicable test guideline: OECD 229, OECD 230, OECD 231, OECD 234.	Header 1
Test type		Text
Limit test	Indicate if the experiment was a limit test.	Closed list
Test material	Follow instructions reported in "Test material – common block"	Header 2
Test animals	Follow instructions reported in "Test animals – common block"	Header 2
State	Select as appropriate.	Closed list
Administration / exposure		Header 2
Route of administration	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list

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
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 provided in this list are used for specific routes of administration only.	Open list with remarks
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
Analytical verification of doses or concentrations	Indicate whether the doses or concentrations were analytically verified.	Closed list with remarks
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
Duration of treatment / exposure	Indicate duration in days, e.g. '7 days'.	Multi-line text
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
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.	
Dose / conc.	Enter numeric value.	Unit measure with Open List (Decimal)
Remarks	Enter any remarks related to dose / concentration values.	Multi-line text
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
Control animals	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.	Multi select open list with remarks
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
Positive control	Uterotrophic Bioassay: Indicate data from the Baseline Positive Control Test and periodic positive control data (reference oestrogen: 17α-ethinyl estradiol). Hershberger Bioassay: Indicate that a reference androgen agonist (Testosterone Propionate) or a reference androgen antagonist (Flutamide) have been used.	Multi-line text
Examinations		Header 2

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
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
Other examinations	Describe any other examinations.	Text area
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
Model and software	Follow instructions reported in "Model and software – common block". Note: This block of fields is displayed only when "Type of information" is set to (Q)SAR.	Header 2
Any other information on materials and methods incl. tables	Follow instructions reported in "Any other information on materials and methods incl. tables – common block"	Header 2
Results and discussion		Header 1
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

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
Results of examinations	Follow instructions reported in "Results of examinations – common block"	Header 2
Effect levels	Follow instructions reported in "Effect levels – 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
Additional information about applicability domain and reliability of (Q)SAR predictions	Follow instructions reported in "Additional information about applicability domain and reliability of (Q)SAR predictions – common block"	Header 2
Any other information on results incl. tables	Follow instructions reported in "Any other information on results incl. tables – common block"	Header 2
Overall remarks, attachments	Follow instructions reported in "Overall remarks, attachments – common block"	Header 1
Applicant's summary and conclusion	Follow instructions reported in "Applicant's summary and conclusion – common block"	Header 1

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.

<table>
<tr><td>*Report **apical knowledge** …*

ßßß</td><td colspan="2">*Report **mechanistic knowledge** …*</td></tr>
<tr><td rowspan="2">For effects on biotic systems, use:

OHTs 41 to 57

For health effects, use:

OHTs 58 to 84 & 86</td><td>*In a regulatory context: If Mechanistic Knowledge was generated according to an OECD Test Guideline for which an (apical) endpoint OHT[12] was created*

ßßß</td><td>*In all other cases*

ßßß</td></tr>
<tr><td>Use the

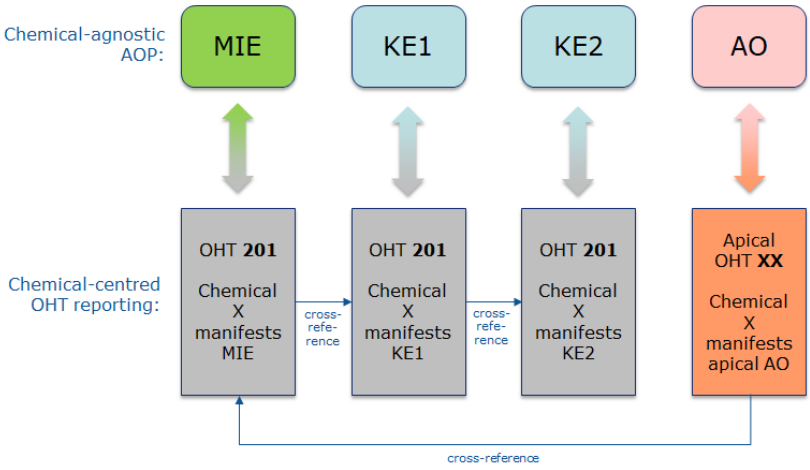
suitable endpoint OHT,

and there, use the mechanism-oriented fields, if available, else use appropriate other fields.</td><td>Use

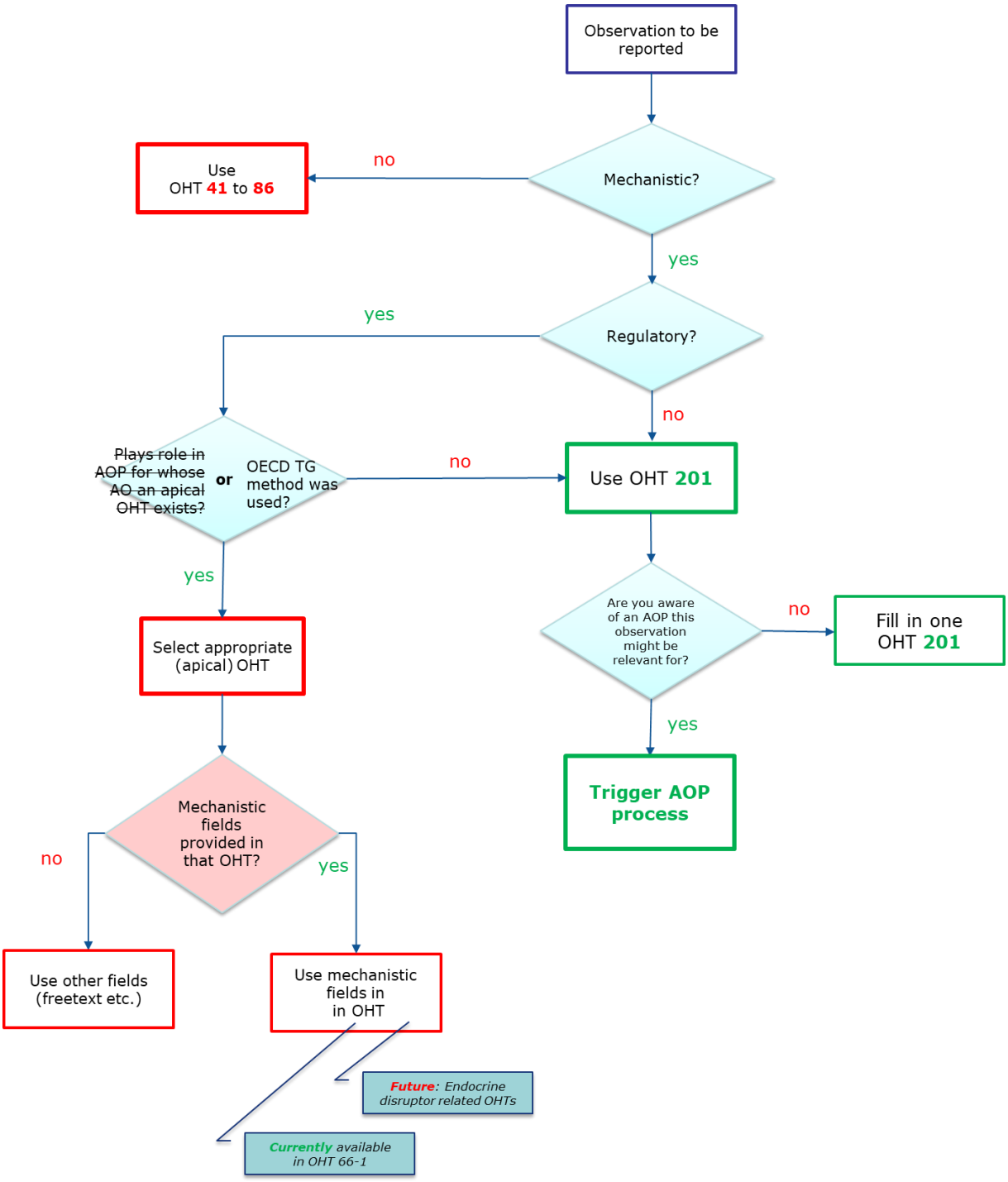
OHT 201</td></tr>
</table>

[12] Example: future endocrine disruptor related TG methods

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:

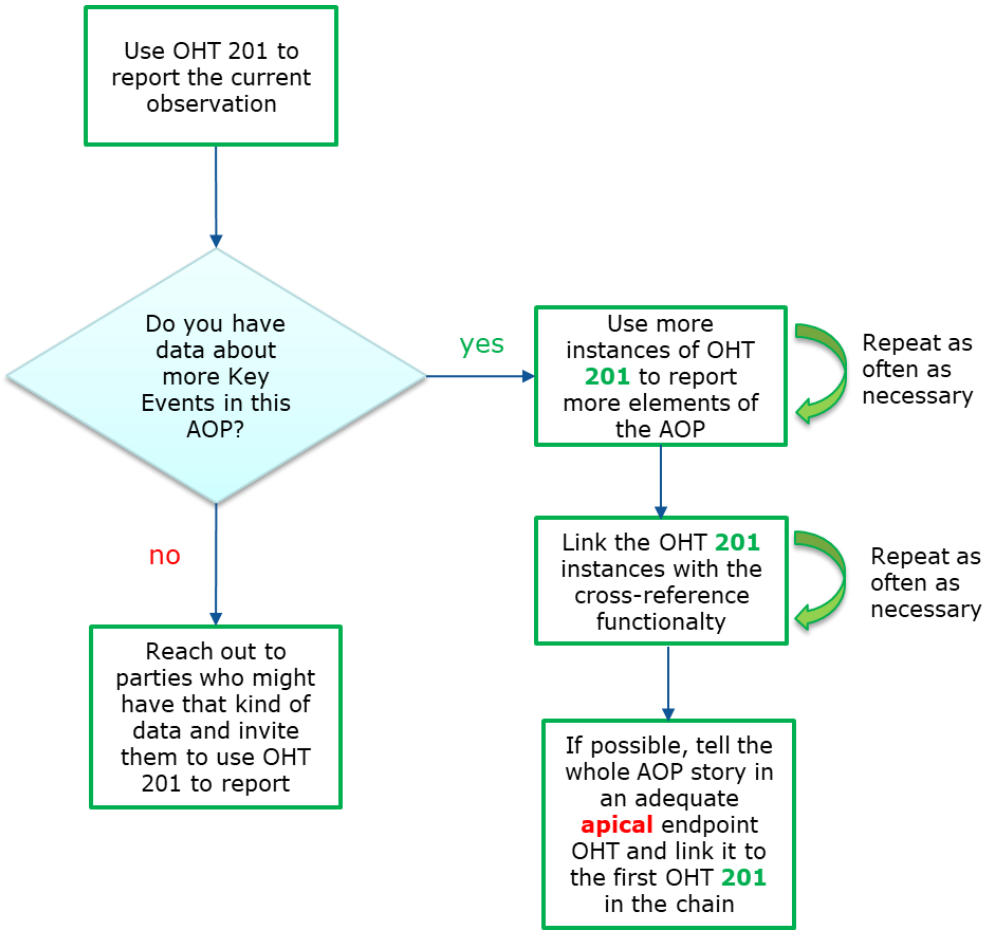


Overview Flowcharts



See next page for "AOP Process"

AOP Process



FLEXIBLE_RECORD.IntermediateEffects		
Name	**Instructions**	**Type**
Administrative data		Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	Confidentiality
Type of information	Select the appropriate type of study performed that provides the mechanistic information. Select 'in vitro' for any type of in vitro study. Select 'in chemico' for assays using cell- / tissue-free laboratory models.	Picklist with remarks

	Select 'in silico' for e.g. a (Q)SAR model. If the information is taken from a handbook or review article, select the relevant item, e.g. 'in vitro', 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, e.g. in case of an in vivo study or when reporting read across data.	
Study period: start date	If applicable indicate the period during which the study was conducted, i.e. start and end date. For (Q)SAR predictions, add date of QPRF. 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.	Date
Study period: end date	Indicate end date	Date
Remarks	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 which the test system is alive/growing) may have to be specified for some toxicology endpoints.	Text
Reliability	Enter an appropriate reliability score.	Picklist
Rationale for reliability incl. deficiencies	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. For (Q)SAR results (i.e. 'Type of information' is '(Q)SAR'), reliability scores are associated to the uncertainty of the result as described in the OECD (Q)SAR Assessment Framework.	Picklist with remarks
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	Block of fields

	for selecting a standard reason from the picklist and optionally to add free text explanation in the related supplementary text field.	
Reason / purpose for cross-reference	Select the appropriate reason of the cross-reference, i.e.: - adverse outcome pathway (AOP) (in case the mechanistic 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 - 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)	Picklist with remarks
Study objective(s) / purpose / aim	Specify the objective, purpose and/or aim of the study explaining clearly why the study was performed and what (regulatory) question is answered. For example: - 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.	Text
Data source	Follow instructions reported in "Data source – common block"	
Effect identification	Describe the mechanism that can be measured with the method 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,	Header 1

	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). 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. 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 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). For each effect identified with a process, object and action (P/O/A), the results can be reported in the reporting section. Please use the following P/O/A for existing OECD test guidelines and methods. TG442C, DPRA, kinetic DPRA, and ADRA: protein binding / - / increase TG442D, Keratinosens: keratinocyte activation / aldo-keto reductase family 1 member C2 (AKR1C2) / increase TG442D, Lusens: keratinocyte activation / NAD(P)H dehydrogenase [quinone] 1 (NQ01) / increase TG442E, h-CLAT: cell activation / CD54 molecule (intercellular adhesion molecule 1) / increase and cell activation / CD86 molecule / increase TG442E, U-SENS: cell activation / CD54 molecule (intercellular adhesion molecule 1) / increase	

	TG442E, IL8 LUC: cell activation / interleukin 8 (IL8) / increase TG455, ERTA STTA, VM7Luc and ERα CALUX: nuclear receptor activity / estrogen receptor alpha / increase, agonism and nuclear receptor activity / estrogen receptor alpha / decrease, antagonism TG456, H295R Steroidogenesis Assay: steroid hormone biosynthetic process / estradiol / alteration and steroid hormone biosynthetic process / testosterone / alteration TG458, ARTA STTA, AR-CALUX and 22Rv1/MMTV GR-KO: nuclear receptor activity / androgen receptor / increase, agonism and nuclear receptor activity / androgen receptor / decrease, antagonism TG493, hrER binding FW assay and CERI assay: Nuclear receptor binding / estrogen receptor alpha / binder–non binder	
P/O/A details		Block of fields (repeatable)
Process	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). 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	Picklist with remarks

	(GO). For most terms there will be several options. It is therefore important to also copy the preferred ontology identifier into the remarks field. 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 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	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). 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. 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). For most terms there will be several options. It is therefore important to also copy the preferred ontology identifier into the remarks field. More than one object can be provided e.g. when changes of more than one biomarker is measured.	Picklist with remarks
Action	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. 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. Select the Action that best describes the effect	Picklist with remarks

	observed or select 'other' to specify the action and provide a term	
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.	Text
Context	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. Copy this block of fields for referring to different target systems if applicable. For a given system, multiple organs can be selected.	Block of fields (repeatable)
System	Select the specific system where the observed effect(s) play a role. More than one 'Context' item can be created.	Picklist
Organ	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'.	Multi-select list
Remarks	Include any remarks as appropriate.	Text
Method used	Indicate if the study was conducted according to a test guideline. If no test guideline was explicitly followed, but the methodology used is equivalent or similar to a specific guideline, you can indicate 'equivalent or similar to guideline' in the 'Qualifier' field preceding the field 'Method used'.	Block
Qualifier	Select appropriate qualifier, i.e.: - '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 a guideline was not available or an available guideline was not used. If so, fill in field 'Principle of the method').	Picklist
Method used	The method names are only visible when 'according to guideline' is selected. In the remarks field, you can enter the specific test guideline (if applicable) and version number, In case 'equivalent or similar to guideline' was selected, provide any remarks as applicable, particularly: - 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.	Picklist
Deviations	In case a test guideline or other standardised method was used, indicate if there are any deviations. Briefly	Picklist

	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.	
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.	Picklist
Other quality systems, standards or guidance followed	Indicate whether the study was conducted following a laboratory-specific quality system or standard such as the OECD guidance on Good In Vitro Method Practice (OECD GIVIMP). Other quality systems, not listed, may be added under 'other'. When selecting OECD GIVIMP, the submitter ensures that the following elements (if applicable) are documented and/or reported: The purpose of the study. Test and control items: The chemical name, CAS-number lot/batch number of the test and control items. The purity, stability homogeneity, solubility and solvent/vehicle of the test and control item was stated or is traceable according to information given regarding manufacturer and lot/batch number. In case of mixtures, the composition of different constituents. In case of nanomaterials, clear identification of the tested nanomaterial (e.g. particle size, shape, particle size distribution, surface area, coating). Test System: The in vitro test system (e.g. tissue or organ fragment / organ explant/ dissociated cells / primary cells culture/ continuous or finite cell line/ stem cells/ complex culture system/ re-differentiated cells/ sub-cellular fractions like cytosol and microsomes/ proteins) was described, justified and characterised to confirm/authenticate the identity. The source or supplier of the test system. Metabolic competence of the test system was described. The number of passages of the test system used,. The test system mass, volume, or dimensions. The type of media used. The use of serum or animal free chemically-defined alternatives. The use of growth factors was described. The use of antibiotics. The incubation temperature, humidity and CO2. All measures taken to avoid or screen for contamination by mycoplasma, bacteria, fungi and virus were described.	Picklist

	Apparatus, materials and reagents: The apparatus was described. The limit of detection or limit of quantitation of the apparatus. The materials and reagents. The culture dimensions (mm2 or ml). The use of animal-derived materials or reagents (e.g. Trypsin, antibodies, collagen, Matrigel etc.). The use of fully animal-free materials and reagents. Test item treatment: The test item concentrations/dose levels. Biological fluid characterisation was described (quantification of proteins and cells/tissue present). Binding to biological fluid and culture material. Test system number, density, dimension, quantity used during treatment. The duration of treatment. The number of replicates per concentration/dose. The number of times the experiment was repeated (independent biological runs). Data collection and analysis: The experimental design and layout (e.g. plate layout) and relevant acceptance criteria. The time points for data collection. The effect of the test item on cytotoxicity was measured. Other observations that may impact the results (e.g. autofluorescence, absorbance by the test system). Details on calculation of results. All results were clearly presented, including negative and failed runs. The statistical methods and software used. A clear description on how to interpret read outs, evaluation/data interpretation criteria and criteria for decision-making was given. Funding and competing interests: The funding sources for the study. Any competing interests were disclosed or it was explicitly stated that the authors did not have any competing interests. Information on the overall availability of the IPR protected components, including whether they are commercially available or require a Material Transfer Agreement or other licensing agreements. (See OECD Guiding principles on good practices for the availability/distribution of protected elements in OECD test guidelines).	
Attached background material		
Type	Classify the type of attachment uploaded e.g the 'Full study report'.	Open list
Attached (confidential) document	Attach any document that provides information on the method used, such as the SOP, protocol, QMRF or a scientific publication. The original file only needs to be attached here if the non-confidential file uploaded under "Attached (sanitised)	Single file attachment

	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.	
Attached (sanitised) documents for publication	Attach any document that provides information on the method used, such as the SOP, protocol, QMRF or a scientific publication. Any 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. 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.	Single File Attachment
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
Test material	Follow instructions reported in "Test Material – common block"	Header 1
Test system		Header 2
Type of test system	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). Examples of physical chemical based test systems: serum protein, peptide, enzyme. Select complex biological test system for example in case of: 3D model, induced pluripotent stem cells, organ on a chip, co-cultures, etc. 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.	Picklist with remarks
Test system identity	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: - Source / supplier	Picklist with remarks

	- Catalogue / batch number - Species and strain (as relevant) of the origin of the test system. 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.	
Genetic modification of the test system	When applicable, provide the following information on the genetic modification: - Gene inserted - Gene species (e.g. human, rat, mouse) - Additional information on modification	Picklist with remarks
Details of the test system	TEST SYSTEM DESCRIPTION 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): For cell lines: - 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: MEDIA USED and incubation conditions - Type and composition of media, including use of serum and antibiotics: - Incubation conditions such as CO2 concentration, humidity level, temperature, if applicable:	Text template
Metabolic competence of the test system	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. 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:	Picklist with remarks

	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.	
Detection method		Header 2
Detection method used	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.	Picklist with remarks
Details on detection method	Quantitative analytical methods: '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 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. Freetext template: Option 1: Semi or non-quantitative detection methods SEMI OR NON-QUANTITATIVE DETECTION METHODS Instrument type and model: Option 2 Option 2: Quantitative analytical methods QUANTITATIVE ANALYTICAL METHODS Instrument type and model:	Text template

	COMPOUND (ANALYTE): ... - 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: INTERFERING SUBSTANCE(S): STABILITY OF PARENT AND TRANSFORMATION PRODUCTS AT VARIOUS STAGES OF ANALYSIS: PROBLEMS / PRECAUTIONS: - Special problems encountered: - Precautions to be taken during: - analysis of samples: - handling of samples: - storage of samples: TOTAL TIME FOR COMPLETION:	
Test design		Header 2
Test material preparation		Header 3
Vehicle / solvent	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. In case a solvent is used that is different from those recommended in the in vitro method Standard	Picklist with remarks

	Operating Procedure or test guideline, a justification for the choice must be provided.	
Dilution steps / dose intervals	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. 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%. Freetext template: DILUTION STEPS PERFORMED Provide the following information (where available): - Dilution steps from 'stock solution' in the vehicle/solvent including the final % of vehicle/solvent in the exposure medium - Dose intervals in case of dose range - Number of concentrations prepared	Text template
Control and reference items		Header 3
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'.	Picklist
Controls / reference items	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. 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.	Block of fields (repeatable)
Type of controls used	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. See (GIVIMP, OECD guidance document 286 in the series on testing and assessment). Solvent / vehicle controls consist of solvent or vehicle alone, without test item (test material), and otherwise	Picklist

	treated in the same way as the treatment groups. Negative / untreated controls consist of culture medium without solvent / vehicle or test item, and otherwise treated in the same way as the treatment groups. True negative controls include items (e.g. chemicals) with known lack of activity. Positive controls include items with known activity. Reference items are substances with known activity, used as basis for comparison with the test item (test material).	
Description of reference and control items used	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. If 'other:' is selected, provide the name and identity (CAS number) in the additional text field. For each selection (including the 'other:'), provide purity (%) and concentration (range or single concentration) in the field 'Remarks'.	Picklist with remarks
Remarks	Additional information, such as solvents used.	Text
Experimental conditions		Header 3
Number of replicates	Provide the number of replicates per concentration and the number of independent experiments performed. For each experiment, valid or invalid, results should be reported. NUMBER OF REPLICATIONS: - Number of replicates per concentration (single, duplicate, triplicate) - Number of independent experiments	Text template
Experimental 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. 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. Concentration of biological test systems is usually expressed as cell density (amount of cells/cm2 or cells/ml seeded) or confluence (%). Concentration of physical chemical test systems is	Text template

	usually expressed in mg/ml or molarity. Incubation conditions are e.g. temperature, CO2, concentration, humidity level, etc. A vessel can e.g. be a test tube or cell culture plates with 24, 96 or 384 wells. Freetext template: METHOD OF TREATMENT/ EXPOSURE: - 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) TREATMENT AND HARVEST SCHEDULE: - 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) - Incubation conditions - Vessel type used for exposure - OTHER:	
Number of replicates	Provide the number of replicates per concentration and the number of independent experiments performed. For each experiment, valid or invalid, results should be reported.	Text template
Experimental 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. Consult the programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) thereof. Concentration of biological test systems is usually expressed as cell density (amount of cells/cm2 or cells/ml seeded) or confluence (%). Concentration of physical chemical test systems is usually expressed in mg/ml or molarity. Incubation conditions are e.g. temperature, CO2, concentration, humidity level, etc.	Text template

	A vessel can e.g. be a test tube or cell culture plates with 24, 96 or 384 wells.	
Additional analysis: e.g. cytotoxicity assay or other	This picklist was established on basis of GIVIMP annex I (OECD, 2018). Select the viability assay used to measure cytotoxicity: 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.). In the remarks field any additional information can be provided.	Picklist with remarks
Data analysis		Header 3
Acceptance criteria for the test material results	Add the criteria used to decide if the results of a test material are accepted or not (e.g. variability of triplicate values < 20% and minimum 6 valid concentrations). This is usually described in test guidelines and not in non-test guidelines. Definition of 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). For cell-based methods, the acceptance criteria should include the level of cytotoxicity or other type of interference that is accepted / not accepted. Any free text explanation can be given to specify which criteria exist for acceptance of results, e.g. related to reference and control substances or vehicle/solvent control, cytotoxicity or other interference, capturing of full dose-response, minimum/maximum response to be observed or outliers. Freetext template: Provide a description or list of the study acceptance criteria:	Text template
Data calculation and statistics	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. 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.	Text template

	Example of data calculation and statistical analysis performed: 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. Specify if outlier analysis is performed and what (statistical) method was used to exclude values. Calculations performed - Statistical methods used - Where relevant, provide the method used to exclude outliers.	
Evaluation / data interpretation criteria	Describe the evaluation criteria used in the study to judge if the test material is positive, negative or equivocal. For example: 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'. h-CLAT: When the RFI of CD86 is equal to or greater than 150% in at least one tested concentration (with cell viability ≥ 50%), the result for the test material is positive. The EC150 value is calculated where possible. DPRA: The mean of cystein and lysine depletion is: Less than 6.38%: minimal reactivity. Between 6.38% and 22.62%: low reactivity Between 22.62% and 42.47%: moderate reactivity. More than 42.47%: high reactivity. Consider also precipitation and co-elution. Evaluation / data interpretation criteria: - Results will be expressed as:	Text template
Any other information on materials and methods incl. tables	Follow instructions reported in "Any other information on materials and methods incl. tables - common block"	Header 2
Results and discussion		Header 1
Test results		Header 2
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	Block of fields (Repeatable)

	guideline or if different concentration ranges were tested. 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. Set this flag if a key observation should be identified for the conclusion section.	
Details of the effect identification	Select the Process/Object/Action combination for which you will report the data. For each combination a dedicated results section can be completed.	Link to repeatable entry
Key result	Set this flag if a key observation should be identified for the conclusion section.	Check box
Concentration selection of the test material	For data interpretation it is important to know on what basis the highest concentration tested was selected. 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. Example for TG442E (h-CLAT) Highest concentration to be used is either of the following concentrations: - 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. Any free text explanation can be given in the adjacent text field to justify the dose level selected.	Picklist with remarks
Concentration range tested	Indicate the lowest and highest concentration tested. 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.	Numeric range
Number of replicates and outliers	Specify the number of replicates per concentration and if any values were excluded after outlier analysis.	Text template

	- Number of replicates: - Information on outlier removal: - Impact of outlier removal on the results:	
Parameter and result		Block of fields repeatable
Parameter	This picklist displays either the parameters specific to the selected method, or general parameters in case another method is used. 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. For guideline methods, all relevant parameters are listed. 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. 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.). Explanation of some parameters: 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. 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. 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. 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..	Picklist with remarks

	CL, in vitro, INT is in vitro intrinsic (metabolic) clearance.	
Result for the parameter	Provide the result for the selected parameter and select the appropriate unit.	Numeric
Other observations		Block of fields (repeatable)
Observation	Indicate other observations that are important for results interpretation such as information on cytotoxic concentrations, precipitation observed at specific 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'). Note: Specific tables may be required. Consult the programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) thereof.	Picklist with remarks
Concentration	Provide the result for other observations and select the appropriate unit.	Numeric range
Results for the test material	The options in the picklist are derived from existing in vitro OECD test guidelines. Indicate the result of the test conducted. 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'. Example of results from TG442C, DPRA: - Minimal reactivity - Low reactivity - Moderate reactivity - High reactivity	Picklist with remarks
Acceptance of results	Select the element for which acceptance criteria exist and indicate in the remarks field if the results are valid or invalid. 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.	Multi-select list with remarks
Remarks on results	This field can be used for: - explaining expert judgement, in case it was applied;	Text

	- 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.	
Attached material		Block of fields (repeatable)
Type of attachment	Choose the type of document from the picklist or select 'other:'. 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. 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.	Multi-select list with remarks
Attachment	Attach the document indicated in the field "Type of attachment".	Attachment
Overall remarks, attachments	Follow instructions reported in "Overall remarks, attachments – common block"	Header 1
Applicant's summary and conclusion		Header 1
Interpretation of results / observations		Header 2
Overall results and conclusion	Provide the overall result for the test material, on basis of one or more experiments and all observations reported in this template. Convey a clear statement on the mechanistic information obtained. Add the effect concentration in the next fields. Example from h-CLAT: The RFI of CD86 is greater than 150% at 2 tested concentrations (with cell viability ≥	Text template

	50%) in 2 of 2 experiments. Therefore the test material is activating dendritic cells and is a possible skin sensitizer.	
Type of result	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.	Picklist with remarks
Effect concentration	Where available, provide the effect concentration taking into account results from more than one experiment. Explanation of some parameters: 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. 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. 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. 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.	Picklist with remarks
Concentration	Provide the effect concentration and select the appropriate unit.	Numeric range
Remarks	Include any remarks as appropriate.	Text
Executive summary		Header 2
	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 the corresponding document. You may also provide information on other existing data or studies that confirm the results obtained. 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.	Text

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?)

ENDPOINT_SUMMARY.ExposureRelatedObservationsHumans		
Name	**Instructions**	**Type**
Administrative data	Follow instructions reported in "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
Additional information	Follow instructions reported in "Additional information – 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

5.9.1 Medical surveillance on manufacturing plant personnel and monitoring studies– Endpoint study record

Purpose

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		
Name	**Instructions**	**Type**
Administrative data	Follow instructions reported in "Administrative data – common block"	Header 1
Data source	Follow instructions reported in "Data source – common block"	Header 1
Reference	Follow instructions reported in "Literature reference – common block"	Literature reference list
Materials and methods	Follow instructions reported in "Material and methods – common block"	Header 1
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). - 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.	Open list with remarks
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.	Multi select open list

	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.	
Test material	Follow instructions reported in "Test material – common block"	Header 2
Test material information	Follow instructions reported in "Test material – common block"	Entity reference field
Method		Header 2
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
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
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
Model and software	Follow instructions reported in "Model and software – common block". Note: This block of fields is displayed only when "Type of information" is set to (Q)SAR.	Header 2
Any other information on materials and methods incl. tables	Follow instructions reported in "Any other information on materials and methods incl. tables – common block"	Header 2
Results and discussion		Header 1
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
Additional information about applicability domain and reliability of (Q)SAR predictions	Follow instructions reported in "Additional information about applicability domain and reliability of (Q)SAR predictions – common block"	Header 2
Any other information on results incl. tables	Follow instructions reported in "Any other information on results incl. tables – common block"	Header 2
Overall remarks, attachments	Follow instructions reported in "Overall remarks, attachments – common block"	Header 1

Applicant's summary and conclusion	Follow instructions reported in "Applicant's summary and conclusion – common block"	Header 1

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.

ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther		
Name	**Instructions**	**Type**
Administrative data	Follow instructions reported in "Administrative data – common block"	Header 1
Data source	Follow instructions reported in "Data source– common block"	Header 1
Materials and methods	Follow instructions reported in "Material and methods – common block"	Header 1
Type of study / information	Briefly indicate the type of information (which does not fit into any of the specific chapter.)	Multi-line text
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
Test material	Follow instructions reported in "Test material – common block"	Header 2
Method		Header 2
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
Details on study design	Describe the study design including any relevant information from a study report, publication or other	Text area

	source. Include or attach tables or excerpts from study report as appropriate.	
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
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
Model and software	Follow instructions reported in "Model and software – common block". Note: This block of fields is displayed only when "Type of information" is set to (Q)SAR.	Header 2
Any other information on materials and methods incl. tables	Follow instructions reported in "Any other information on materials and methods incl. tables – common block"	Header 2
Results and discussion		Header 1
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
Additional information about applicability domain and reliability of (Q)SAR predictions	Follow instructions reported in "Additional information about applicability domain and reliability of (Q)SAR predictions – common block"	Header 2
Any other information	Follow instructions reported in "Any other information on results incl. tables – common block"	Header 2

on results incl. tables		
Overall remarks, attachments	Follow instructions reported in "Overall remarks, attachments – common block"	Header 1
Applicant's summary and conclusion	Follow instructions reported in "Applicant's summary and conclusion – common block"	Header 1

5.9.3 Direct observations – Endpoint study record

Purpose

Available reports from the open literature, relating to clinical cases and poisoning incidents, 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		
Name	**Instructions**	**Type**
Administrative data	Follow instructions reported in "Administrative data – common block" For micro-organisms, direct observations and clinical cases should be considered as supporting information.	Header 1
Data source	Follow instructions reported in "Data source– common block"	Header 1
Reference	Follow instructions reported in "Literature reference – common block"	Literature reference list
Materials and methods	Follow instructions reported in "Material and methods – common block"	Header 1
Study type	Select type of medical data.	Open list with remarks
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
Test material	Follow instructions reported in "Test material – common block"	Header 2
Test material information	Follow instructions reported in "Test material – common block"	Entity reference field
Method		Header 2

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
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
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
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
Reason of exposure	Indicate the reason of exposure e.g. intentional or occupational unitentional.	Open list
Exposure assessment	Indicate whether the exposure was measured or estimated.	Closed list with remarks
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
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
Medical treatment	Indicate if and what medical treatment exposed / intoxicated persons received.	Text area
Model and software	Follow instructions reported in "Model and software – common block". Note: This block of fields is displayed only when "Type of information" is set to (Q)SAR.	Header 2
Any other information on materials and methods incl. tables	Follow instructions reported in "Any other information on materials and methods incl. tables – common block"	Header 2
Results and discussion		Header 1

Clinical signs	Describe any relevant signs and symptoms observed.	Text area
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
Effectivity of medical treatment	Indicate whether and during what time intoxicated persons responded to medical treatment.	Text area
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
Additional information about applicability domain and reliability of (Q)SAR predictions	Follow instructions reported in "Additional information about applicability domain and reliability of (Q)SAR predictions – common block"	Header 2
Any other information on results incl. tables	Follow instructions reported in "Any other information on results incl. tables – common block"	Header 2
Overall remarks, attachments	Follow instructions reported in "Overall remarks, attachments – common block"	Header 1
Applicant's summary and conclusion	Follow instructions reported in "Applicant's summary and conclusion – common block"	Header 1

5.9.4 Epidemiological studies – Endpoint study record

Purpose

Provide data of relevant epidemiological studies, if available.

ENDPOINT_STUDY_RECORD.EpidemiologicalData		
Name	**Instructions**	**Type**
Administrative data	Follow instructions reported in "Administrative data – common block"	Header 1

Data source	Follow instructions reported in "Data source – common block"	Header 1
Materials and methods	Follow instructions reported in "Material and methods – common block"	Header 1
Study type	Select appropriate study type.	Open list with remarks
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
Test material	Follow instructions reported in "Test material – common block"	Header 2
Method		Header 2
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
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
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 a 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 a attach a table and refer to respective Table no.	Text template
Exposure assessment	Indicate whether the exposure was measured or estimated. For robust study summaries or as requested by the	Closed list with remarks

	regulatory programme, provide further details in the following freetext field.	
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
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
Model and software	Follow instructions reported in “Model and software – common block”. Note: This block of fields is displayed only when “Type of information” is set to (Q)SAR.	Header 2
Any other information on materials and methods incl. tables	Follow instructions reported in "Any other information on materials and methods incl. tables – common block"	Header 2
Results and discussion		Header 1
Results	Provide exposure data as available. Give numbers of cases for each effect/disease/parameter under consideration, 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').	Text template

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
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
Effect levels	Follow instructions reported in Effect Level	Header 2
Target system/organ toxicity	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.	Header 3
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
Critical effects observed	Flag to indicate if critical effects were observed in the study within specific organs or systems.	Closed list
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)
System	Select any specific system where toxicity was observed that is considered of biological relevance.	Open list
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
Treatment related	Flag to indicate if the effects in systems and/or organs are treatment related.	Closed list
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
Target system / organ toxicity		
Additional information about applicability domain and reliability of (Q)SAR predictions	Follow instructions reported in "Additional information about applicability domain and reliability of (Q)SAR predictions – common block"	Header 2

Any other information on results incl. tables	Follow instructions reported in “Any other information on results incl. tables – common block”	Header 4
Overall remarks, attachments	Follow instructions reported in "Overall remarks, attachments – common block"	Header 1
Applicant's summary and conclusion	Follow instructions reported in “Applicant's summary and conclusion – common block”	Header 1

6. Residues in or on treated products, food and feed - Endpoint summary

General note on instructions for section 6: please follow the instructions for the common blocks reported in the relevant chapter of this manual, **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		
Name	**Instructions**	**Type**
Administrative data		Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page".	Confidentiality
Description of key information	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. 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 of the application; (ii) the main substantive arguments. 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.	Header 1
Additional information		Header 1

	Provide information related to the assessment of the endpoint, for example: - any endpoint specific information relevant for the interpretation of the results - the rationale for the choice of the key study(ies) and the choice for the key value that characterises the endpoint - information on the potential data gaps and the quality of the whole database for this endpoint - relevance of the results for the risk assessment (e.g. in case no effects have been observed at the limit dose) - the rationale for any user-derived values for the key result for assessment (for example, if a corrected value or a geometric mean is reported) - any additional information such as epidemiological data or higher tier testing (e.g. mesocosm studies or field studies) when relevant If there is no additional information to be reported, this field may be left empty.	Rich text area
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 not here.	Header 2
Attached confidential document	Provide the original version of any document that contains confidential material.	Single file attachment
Attached (sanitised) documents for publication	Same as above with sanitized version for the document(s).	Attachments list
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

6.1 Storage stability of residues

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		
Name	**Instructions**	**Type**
Administrative data		Header 1

	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	Confidentiality
Link to relevant study record(s)		Header 1
Study name / type	Provide here the link to the most relevant study (or studies) from which the key value(s) for the storage stability of residues is/are derived.	Endpoint reference list
Results		Read-only
Description of key information		Header 1
	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").	Rich text area
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).	Block of fields (Repeatable)
Category	Select the matrix to which the key results apply (e.g. commodities with "high water content"). Category defined according to OECD TG 506.	Open list with remarks
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
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
Substance(s)	Link (cross reference) to the substance(s) indicated in the above field.	Entity reference list
Temperature (°C)	Indicate the temperature tested in the study in degrees Celcius (e.g. -18°C).	Decimal

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)
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)
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 common moiety, use the same field to explain.	Multi-line text
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.	Block of fields (Repeatable)
Category	Select category from the list	Open list with remarks
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
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
Substance(s)	Link (cross reference) to the substance(s) indicated in the above field.	Entity reference list
Temperature (°C)	Indicate the temperature tested in the study in degrees Celcius (e.g. -18°C).	Decimal
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	Unit measure with

	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.	Closed List (Decimal)
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)
Remarks	Please report the same text as for stability in plant for the similar field.	Multi-line text
Additional information	Follow instructions reported in "Additional information – common block"	Header 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		
Name	Instructions	Type
Administrative data	Follow instructions reported in "Administrative data – common block"	Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	Confidentiality
Data source	Follow instructions reported in "Data source – common block"	Header 1
Materials and methods	Follow instructions reported in "Material and methods – common block"	Header 1
Product type	Indicate the product type addressed by the information entered in this record.	List
Test material	Follow instructions reported in "Test material – common block"	Header 2
Radiolabelling	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.	Open list with remarks

	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.	
Study design		Header 2
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
Details on stored commodities	Provide detailed description of commodities / matrices stored (whether raw or processed).	Text area
Storage temperature	Specify the storage temperature.	Unit measure with Closed List (Decimal)
Duration of storage	Specify the total duration of the storage.	Unit measure with Closed List (Decimal)
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 supplementary remarks field. . You can choose the corresponding picklist item and give an explanation in the supplementary remarks field.	Multi select closed list with remarks (2000)
Sampling and analytical methodology		Header 2
Details on sample collection	Include details on sampling time (age of raw commodity in days at each sampling time), number of samples/replicates. Use freetext templateand delete/add elements as appropriate.	Text template
Details on sample handling and preparation	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. 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 whether samples contain incurred residues or if samples were spiked/fortified with the active	Text template

	substance/metabolites; whether samples were homogenised or not. Use "insert existing templates" and delete/add elements as appropriate. E.g. *RAC* samples were homogenized and fortified with *test material* at about *X* mg/kg.	
Details on analytical methodology	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) 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').	Text template
Model and software	Follow instructions reported in "Model and software – common block". Note: This block of fields is displayed only when "Type of information" is set to (Q)SAR.	Header 2
Any other information on materials and methods incl. tables	Follow instructions reported in "Any other information on materials and methods incl. tables - – common block"	Header 2
Results and discussion		Header 1
Residue data	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.	
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 which MRLs apply according to Annex I of Reg. (EC) No 396/2005.	Open list
Other details on test commodity	As appropriate, provide details on the test commodity analysed.	Multi-line text
Fortification date (day 0)	Enter the date when the sample was fortified and put into storage (day 0)	Date
Storage removal date (day X)	Enter the date when the stored sample was removed from storage for analysis (day X)	Date

Sample ID	Provide the code of the sample if any.	Text
Sample description	Include a description of the sample.	Text
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)
Fortification rate / spike level of stored sample	Enter the fortification level for the sample.	Unit measure with Open List (Decimal)
Analyte measured	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 mutiple analytes (if any). If only one analyte (e.g. parent compound) is analysed in the study, there is no need to repeat this block.	
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. 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 refered 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.	Entity reference field

Extraction date	Enter the date of extraction.	Date
Analysis date	Enter the date of extraction.	Date
Method ID	Identify the analytical method that was used to obtain this result. This should cross-reference with the method(s) described in the method portion of this template).	Text
Residue level	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. Copy this block of fields for recording the results of mutiple analytical repetitions, and report the mean of analytical repetitions after the repeated blocks.	
Analysed sample ID	Report the sample number/ID that was measured.	Text
Residue level	Report the measured level of the residue mentioned afore.	Unit measure with Open List (Decimal)
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
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)
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
Procedural recovery	Enter the result of the procedural recoveries for the given commodity at a given storage period. Copy this block of fields for recording the results of mutiple analytical repetitions, and report the mean of analytical repetitions after the repeated blocks.	Block of fields (Repeatable)
Control Sample ID	Report the control sample number/ID that was used to measure the procedural recovery.	Text

Procedural recovery control (%)	Enter the percentage of the procedural recovery determined in freezer storage stability control sample.	Decimal
Mean procedural recovery control (%)	Enter the mean percentage, from the repeated analytical repetitions, of the procedural recovery for freshly spiked control sample.	Decimal
Storage stability of residues (Sample Integrity)	Briefly describe the conditions, which residues of [parent and/or metabolites] appeared to be [stable or [decreased or increased] by [percentage]]. Example: 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 Please make one statement per commodity. (Optional) Provide graph of residue stability in matrix as applicable as percent recovery over time, in an attachment (in the block below).	Text area
Transformation products	Indicate whether transformation products occurred and were identified in this study. If yes, provide information on 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
Identity of transformation products	Use this repeatable block of fields for specifying the transformation products found and their parent compound(s).	
No.	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
Reference substance	Indicate the identity of the compound (transformation product or test substance) using an appropriate identifier, e.g. CAS number, CAS name, IUPAC name. 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
Parent compound(s)	If the compound is a transformation product, link to the identity of the substance that is characterised as the parent of this transformation product. Link to multiple parent substances if applicable.	Entity reference field

	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.	
Maximum occurrence (%)	Indicate the maximum occurrence of the transformation product in %.	Numeric (decimal including unit)
Additional information about applicability domain and reliability of (Q)SAR predictions	Follow instructions reported in "Additional information about applicability domain and reliability of (Q)SAR predictions – common block"	Header 2
Any other information on results incl. tables		Header 2
	In this field, you can enter any other remarks on the 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. NB: According to OECD 506 guidance correction for day zero recovery and/or procedural recovery is not recommended. Other formats can be used provided that all information requested in OECD TG 506 is reported and that they are readable by the system.	Rich text area
Overall remarks, attachments	Follow instructions reported in "Overall remarks, attachments – common block"	Header 1
Applicant's summary and conclusion	Follow instructions reported in "Applicant's summary and conclusion – common block"	Header 1
Conclusions	The assessment and conclusion of the applicant should be reported here.	Text area
Executive summary	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. Example: Samples of [ground or whole crop/matrix] 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]. At each storage interval, [analytes] were determined using Method [Method ID], a [describe method]. Acceptable [method validation and] concurrent recoveries were reported for [matrices]	Rich text area

	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]. 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].	

6.2 Metabolism, distribution and expression of residues

6.2.1 Metabolism of residues in plants and in rotational crops

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		
Name	Instructions	Type
Administrative data		Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	Confidentiality
Description of key information		Header 1
	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 metabolites),	Rich text area

	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.	Block of fields (Repeatable)
Link to relevant studies	Provide here the link to the relevant study(ies) corresponding to the created row.	Endpoint reference list
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
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
Treatment type	Indicate the type of treatment (e.g. foliar) tested in the study. If different types of treatments were tested in the same study, please create a separate row for each of the treatment type.	Multi select open list with remarks
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
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
Remarks	Use this field to report any additional useful information that is not covered by the fields above.	Text area
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.	Block of fields (Repeatable)
Link to relevant studies	Provide here the link to the relevant study(ies) corresponding to the created row.	Endpoint reference list
Crop groups	Picklist (based on representative crop groups defined in OECD TG 502): Indicate the metabolism crop group 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.	Open list

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
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
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
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 interception accordingly.	Multi-line text
Additional information		Header 1
	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
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.	Block of fields (Repeatable)
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
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 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.	Attachments list
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

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 requirement 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		
Name	**Instructions**	**Type**
Administrative data	Follow instructions reported in "Administrative data – common block" Note: when selecting the relevant endpoint from picklist, for metabolism studies in primary crops, please use the option "metabolism of residues in crops")	Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	Confidentiality
Data source	Follow instructions reported in "Data source– common block"	Header 1

	Note: the XML-file created with the MSS-composer should be attached in the literature reference.	
Materials and methods	MATERIALS AND METHODS 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.	Header 1
Background information	Mandatory field in the study record.	Rich text area
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
Test guideline	Mandatory field in the study record. 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'. Add one block of fields for each guideline when more than one guideline is followed (e.g. US EPA in addition to OECD guideline).	Block of fields (repeatable)
Qualifier	Mandatory field in the study record. Select appropriate qualifier, i.e. - '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	Mandatory field in the study record. Select the applicable test guideline, e.g. 'OECD TG 501' (for primary crops) or 'OECD TG 502' (for 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'.	Open list

	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. 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'.	
Version / remarks	Mandatory field in the study record. In this text field, you can enter any remarks as applicable, particularly: - 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
Deviations	Mandatory field in the study record. 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
Principles of method if other than guideline	Mandatory field in the study record. 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 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. 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. If the free text template for (Q)SAR is selected, indicate the (Q)SAR 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. Details should be entered in appropriate distinct fields of section MATERIALS AND METHODS if available. Also	Text template

	provide a justification for using this method if appropriate.	
GLP compliance	Mandatory field in the study record. 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.	Closed list with remarks
Test material	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.	Header 2
Test material information	Mandatory field in the study record.	Entity reference field
Additional test material information	If relevant.	Entity reference field
Specific details on test material used for the study	Mandatory field in the study record.	Text template
Specific details on test material used for the study (confidential)	Mandatory field in the study record.	Text template
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
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).	Block of fields (repeatable)
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
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
Radiochemical purity (%)	Mandatory field in the study record.	Range (Decimal)

	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).	
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)
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)
Remarks	Field not mandatory. Use this field to enter any remarks.	Text
Crop information		Header 2
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).	Block of fields (repeatable)
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 template
Test site and soil properties		Header 2
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
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.	Block of fields (repeatable)
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
Environmental conditions		Header 2
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

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
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
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
Application		Header 2
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).	Block of fields (repeatable)
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
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
Sampling and analysis of crop plants		Header 2
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
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
Details on identificatio	Field not mandatory in the study record.	Text area

n and characterisation	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).	
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).	Block of fields (repeatable)
Sampling and analysis of soil		Header 2
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
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
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
Model and software	Follow instructions reported in "Model and software – common block". Note: This block of fields is displayed only when "Type of information" is set to (Q)SAR.	Header 2
Any other information on materials and methods incl. tables	Follow instructions reported in "Any other information on materials and methods incl. tables – common block" 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. 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
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.	Header 1

	However, the fields marked as "mandatory" shall be fulfilled to ensure a minimum structured data and to make best use of the report generator.	
Total radioactive residues		Header 2
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).	
Quantitation	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
TRR results	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).	Block of fields (repeatable)
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
Extraction, characterisation, and distribution of residues		Header 2
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).	
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
Storage stability of residues		Header 2
Summary of storage conditions	Field not mandatory in the study record. This information shallbe reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Block of fields (repeatable)
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
Summary of radioactive residues in crops		Header 2

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).	Block of fields (repeatable)
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
Summary of radioactive residues in soil		Header 2
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).	Block of fields (repeatable)
Proposed metabolic pathway		Header 2
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).	Block of fields (repeatable)
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
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
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
Additional information about applicability domain and reliability of (Q)SAR predictions	Follow instructions reported in "Additional information about applicability domain and reliability of (Q)SAR predictions – common block"	Header 2
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	Header 2

	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.	
Overall remarks, attachments		Header 1
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
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).	
Illustration (picture/graph)		Image
Applicant's summary and conclusion	Follow instructions reported in "Applicant's summary and conclusion – common block"	Header 1
Conclusions	Mandatory field in the study record. Write here the Applicant's conclusion of the metabolism study in context of the application.	Text area
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

Links to support material:

Please find specific instructions on who 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

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		
Name	**Instructions**	**Type**
Administrative data		Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	Confidentiality
Link to relevant study record(s)		Header 1
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
Description of key information	Please make a statement whether the nature of residues in commodities of animal 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. 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].	Header 1
		Rich text area

Comparable to metabolism in rats	Indicate whether the metabolism observed in ruminants is similar to rats, use the remarks field to justify the conclusion or to highlight any key differences.	Multi select open list with remarks
Key value for chemical safety assessment		Header 1
Time to reach plateau (milk) in days	Report the time to reach plateau in milk in days	Numeric (integer)
Time to reach plateau (eggs) in days	Report the time to reach plateau in eggs in days	Numeric (integer)
Additional information		Header 1
	Provide additional information related to the endpoint, for example: - 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.	Rich text area
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.	Block of fields (repeatable)
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
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 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.	Attachments list
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

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 requirement 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		
Name	**Instructions**	**Type**
Administrative data	Follow instructions reported in "Administrative data – common block"	Header 1
Data source	Follow instructions reported in "Data source– common block" Note:The XML-file created with the MSS-composer should be attached in the litterature reference.	Header 1
Materials and methods	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	Header 1

	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
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
Type of study	Mandatory field in the study record	Open list
Test guideline	Mandatory field in the study record	
Qualifier	Mandatory field in the study record	Closed list
Guideline	Mandatory field in the study record	Open list
Version / remarks	Mandatory field in the study record	Multi-line text
Deviations	Mandatory field in the study record	Closed list with remarks
Test guideline	Mandatory field in the study record	Block of fields (Repeatable)
Principles of method if other than guideline	Mandatory field in the study record.	Text template
GLP compliance	Mandatory field in the study record.	Closed list with remarks
Test material	Follow instructions reported in "Test material – common block" 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.	Header 2
Test material information	Mandatory field in the study record	Entity reference field
Additional test material information	If relevant	Entity reference field
Specific details on test material used for the study	Mandatory field in the study record	Text template
Specific details on test material used for thestudy (confidential	Mandatory field in the study record.	Text template
Radiolabelling	Mandatory field in the study record. Indicate if labelled or non-labelled test material was used. Details on labelled material	Open list with remarks

	should be described in field 'Details on test material'.	
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).	Block of fields (repeatable)
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
SMILES notation	Mandatory field in the study record. This information shall also bereported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Multi-line tex
Radiochemical purity(%)	Mandatory field in the study record. This information shall also bereported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Range (Decimal)
Specific activity as received	Mandatory field in the study record. This information shall also bereported 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)
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)
Remarks	Field not mandatory.Use this field to enterany remarks	Text
Radiolabelled test material		
Test animals		Header 2
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).	Block of fields (repeatable)
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
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).	Block of fields (repeatable)
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	Text area

	information is available in the XML-file attached to this record).	
Administration / exposure		Header 2
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).	Block of fields (repeatable)
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
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
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
Analysis of feed and water	Field not mandatory in the study record. This information canbe reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Multi-line text
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
Sampling and analysis		Header 2
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).	Block of fields (repeatable)
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
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
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

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).	Block of fields (repeatable)
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
Model and software	Follow instructions reported in "Model and software – common block". Note: This block of fields is displayed only when "Type of information" is set to (Q)SAR.	Header 2
Any other information on materials and methods incl. tables	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. 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
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
Total radioactive residues		Header 2
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).	Block of fields (repeatable)
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
TRR results	Field not mandatory in the study record. This information shall be reported via the MSS composer (please make sure that this	Block of fields (repeatable)

	information is available in the XML-file attached to this record).	
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
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).	Block of fields (repeatable)
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).	Block of fields (repeatable)
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
Extraction, characterisation, and distribution of residues		Header 2
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).	Block of fields (repeatable)
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
Storage stability of residues		Header 2
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	Block of fields (repeatable)
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
Summary of characterisation and identification of radioactive residues		Header 2
Characterisation and identification	Field not mandatory in the study record. This information shall be reported via the MSS composer (please make sure that this	Block of fields (repeatable)

of radioactive residues	information is available in the XML-file attached to this record).	
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
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
Proposed metabolic pathway		Header 2
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).	Block of fields (repeatable)
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
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
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
Additional information about applicability domain and reliability of (Q)SAR predictions	Follow instructions reported in "Additional information about applicability domain and reliability of (Q)SAR predictions – common block"	Header 2
Any other information on results incl. tables		Header 2
	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 section. In addition, the fields	Rich text field

	'Overall remarks' and 'Executive summary' allow rich text entry.	
Overall remarks, attachments		Header 1
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
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).	attachment
Illustration (picture/graph)		Image
Applicant's summary and conclusion	Follow instructions reported in "Applicant's summary and conclusion – common block"	Header 1

Links to support material:

Please find specific instructions on who 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		
Name	**Instructions**	**Type**
Administrative data		Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	Confidentiality
Description of key information		Header 1
	Enter a short description of the most relevant endpoint data. Only information on studies for primary crops should be described here. Information on rotational crops should be reported in a separate endpoint summary record. 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 trials", following the instructions below.	Rich text area
Endpoint	From the picklist select the relevant endpoint addressed by this summary. Here: "residue in crops (field trials)".	Closed list with remarks
Summary of residues data from the supervised residue trials	Repeat this block to create one "new item" per relevant GAP under assessment.	Block of fields (repeatable)
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
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
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)

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 commodity(ies) 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.	Multiselect open list
Commodity(ies) used in the residue trials	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) 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.	Multi select open list
Residue levels: RD RA	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]. For example: <0.01; <0.01; 0.01; 0.05; 0.05; 0.05; 0.05; 0.05 mg/kg.	Multi-line text
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
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

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)
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)
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)
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)
MRL derived	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`. Not mandatory for commodities exclusively used as feed items (e.g. wheat straw).	Unit measure with Closed List (Decimal)
MRL at LOQ?	Tick this check box if the MRL derived correspond to the LOQ for enforcement.	Check box
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)
Remarks	Please insert here any other remarks, if necessary, relevant for the residue trials data. If the results reported in the block refer to 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.	Text area
Summary of residues data from the supervised residue trials		
Additional information		Header 1
	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
Attached background material	Add any additional document that support the above key results (e.g. calculation tables, graphs).	
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
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	Attachments list

	multiple data sets here: https://www.oecd.org/env/ehs/pesticides-biocides/oecdmaximumresiduelimitcalculator.htm. If additional calculators (e.g. Kruskal-Wallis.xls to compare dataset) were used in the assessment, they should also be uploaded here The uploaded file should not contain confidential material.	
Remarks		Text

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		
Name	**Instructions**	**Type**
Administrative data		Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	Confidentiality
Description of key information		Header 1
	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. 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:	Rich text area

	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 the maximum soil concentration expected for the active substance (and its soil metabolites), considering the use pattern on primary crop under assessment. - as to whether those studies can be used to derive MRL and risk assessment values (HR and STMR). Respective detailed parameters and results on the eventual available key trials used for risk assessment should be reported in the detailed table below.	
Endpoint	From the picklist select the relevant endpoint addressed by this summary. Here: "residues in rotational crops (limited field studies)"	Closed list with remarks
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.	Block of fields (repetable)
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
Relevant GAP	This entry refers to GAP linked to the endoint values reported in this table. 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 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.	MultiLineText 2000
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 of 365d) the residue results are considered.	Unit measure with Closed List (Decimal)
Commodity(ies) for which MRL and risk assessment	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.	Multi select open list

values are derived	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.	
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. 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.	Multi select open list
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
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 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
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
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)
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)

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)
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)
MRL derived	If MRL is derived, please enter here the MRL as derived from the submitted residue trials for the commodit(y)ies listed under `Commodity(ies) for which MRL and risk assessment values are derived`. Not mandatory for commodities exclusively used as feed items (e.g. wheat straw).	Unit measure with Closed List (Decimal)
MRL at LOQ?	Tick this check box if the MRL derived correspond to the LOQ for enforcement.	Check box
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)
Remarks	Please insert here any other remarks, if necessary. Please specify which eventual mitigation measures were considered to derive the endpoints above. Indicate whether a rotational crop was planted/sown following a treatment and harvest of primary crop. 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). Please elaborate on the approach used to derive the MRL proposal and risk assessment values for rotational crops and indicate if any extrapolations are proposed.	Text area
Summary of residues data from the supervised residue trials		Block of fields (repeatable)
Additional information		Header 1
	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
Attached background material	Add any additional document that support the above key results (e.g. calculation tables, graphs).	
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

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
Remarks		Text

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 cops 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		
Name	**Instructions**	**Type**
Administrative data	Follow instructions reported in "Administrative data – common block"	Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	Confidentiality
Data source	Follow instructions reported in "Data source (Literature Reference) – common block"	Header 1
Materials and methods	Follow instructions reported in "Material and methods – common block"	Header 1
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
Test material	Follow instructions reported in "Test material – common block"	Header 2

Analytical methods		Header 2
Analytical method	"This block of fields can be repeated to cover each analytical methods used to analyse samples (including soil). All combinations of: - analytical method - analysed matrix and - analysed substance should be defined to use them in block "Residue".	Block of fields (repeatable)
Method ID	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. 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.	Text
Related information	Select the record containing the related study summary of the used analytical method and its validation data are described, thus creating a link. If the study record referred to was duly compiled and contain the data on method validation, further information is not required	Endpoint reference field
Details on analytical methods	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'. 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 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	Text template

	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.	
Combinations of substance and analysed sample portion	Define for each analytical method all relevant combinations of analysed substance and - analysed matrix to use them in block "Residue levels".	Block of fields (repeatable)
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. 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.	Entity reference field
Analysed sample portion ID	Enter applicants internal code for the analysed sample portion.	Text
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	Text

	give weights of peel and pulp), aspirated grain fractions are separated from grain.	
Fortification	This block of fields can be repeated to cover each 'Fortification level'.	Block of fields (repeatable)
Fortification level	Enter the fortification level.	Unit measure with Open List (Decimal)
Recovery (%)	Enter the percentage of recovery.	Decimal
Residue trials	This section 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
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'. Please use the repeatable block to report individual trial information. Copy this block of fields for recording the results of each sampling. Note: in case of large dataset, applicants can opt for reporting the detailed residue trial information directly in the Excel file Residues trial table to be attached in the field "Attached sanitized documents". Any additional information which is relevant for the residue trial but not captured in the Excel residue trial tables should be reported in the field `Any other information on materials and methods, incl.tables`.	Block of fields (repeatable)
Trial ID no.	Insert the trial specific, unequivocal identification code For example, Company Internal Code	Text
Geographic location and soil characteristics		Header 3
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
Geographic location	Trial specific information.	Text

Trial deviation	List any deviations which may impact the trial results or study conclusions.	Text
Year	Indicate the year in which the first GLP data are collected in trial. Trial may extend over several years.	Integer
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
Geographic region	Select the geographic region of the country.	Closed list
State/Province	Select the state/province as applicable depending on the selected country or territory.	Open list
County	Indicate the county as applicable.	Text
City	Indicate the city and the postal code as applicable.	Text
GPS coordinates	Provide the GPS coordinates as applicable. Use any of the following units and formats to specify the latitude and longitude: - 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
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
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
Crop grouping (primary)		Open list
Crop group	Select the crop group from drop-down list. If not listed, select 'other fruit:', 'other vegetables:' or 'other:' and specify.	Open list with remarks

Crop	Enter the EPPO name of crop, see EPPO Plant Protection Thesaurus. at http://eppt.eppo.org	Text
Crop code	Enter the EPPO Code, see EPPO Plant Protection Thesaurus. at http://eppt.eppo.org	Text
Crop variety	Specify the crop variety used in the study, e.g. blood orange.	Text
Replant no. (1, 2)	List the consecutive numbers of the replanting. i.e. 1st crop replant = 1, 2nd crop replant = 2.	Integer
Date of planting	Enter the date of planting.	Date
Date of seeding	Enter the date of planting.	Date
Date of flowering (beginning)	Enter the date of the beginning of flowering.	Date
Date of flowering (end)	Enter the date of the end of flowering.	Date
Date of harvest (beginning)	Enter the date of the beginning of harvest.	Date
Date of harvest (end)	Enter the date of the end of harvest.	Date
Crop plant back interval	Specify the time in days after application.	Text
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 application), temperature data.	Text template
Soil characterization	Describe the soil type.	Multi-line text
Other details on test crops	Include other details on test crops.	Text area
Plot description		Header 3
Plot	This block of fields can be repeated to cover each plot. It includes the nested repeatable blocks 'Application' and 'Sampling'.	Block of fields (repeatable)
Plot ID	Unequivocal plot identification e.g. consecutive number.	Text
Control plot	Indicate if this plot is a "control plot".	Closed list

Corresponding control plot ID	Plot ID of the corresponding control plot. A control plot could be used in different test plots.	Text
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
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
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 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').	Text template
Application		Header 4
Application	This block of fields can be repeated to cover each application of a given plot.	Block of fields (repeatable)
Application no. (1, 2)	List the consecutive numbers of the applications. i.e. 1st crop replant = 1, 2nd crop replant = 2. In the case of seed treatment, the sowing of the seeds is the first application.	Integer
Bare soil	For crop rotational studies indicate if the application was on bare soil or not.	Closed list

Growth stage code (BBCH) at application	Enter the code of the BBCH-scale system or an intervall of two codes separated by "-" eg. 99 or 99-99.	Text
Growth stage description at application	Enter the description of the growth stage at application.	Text
Date of application	Enter the date of application.	Date
Method of application	Select the method of application.	Open list
Seeding rate	Enter the seeding rate.	Unit measure with Open List (Decimal)
Thousand grain weight	Enter the thousand grain weight.	Unit measure with Open List (Decimal)
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.	
Test material information	Select the appropriate Test Material Information (TMI) record. If not available in the repository, create a new one. You may also copy (clone) an existing TMI record, edit it and store it as new TMI. To change the link to an existing TMI, click the Delete button, then the Link button and proceed as described above. Depending on the purpose of the reporting or data submission, the information that must be provided may change. As a minimum, the chemical name, identifier and/or CAS number and molecular weight must be provided. For (Q)SAR results the TMI record is intended as the input for the (Q)SAR model (chemical identifiers and/or parameters).	Entity reference field
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
Formulation type	Select the formulation type.	Open list

Trade name	Provide the trade name, company developmental code or other.	Text
Active ingredients (a.i.)	This block of fields can be repeated to cover each test item for a given application.	
Related substance information	Each component should be cross referenced to a 'Real' Substance definition in IUCLID.	Entity reference field
Name of a.i.	Indicate the name of the active ingredient, trade name or company developmental code or other.	Multi-line text
Nominal a.i. content	Indicate the nominal a.i. content of the test substance.	Unit measure with Open List (Decimal)
Applied amount (actual)	State the actual application rate, anticipated/targeted use rate (label rate) of the test material (formulated product).	Unit measure with Open List (Decimal)
Amount a.i./seed (actual)	Indicate the amount a.i./seed (actual).	Unit measure with Open List (Decimal)
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)
Adjuvant added	Indicate the additive type, additive name, content added in spray volume (%), actual additive amount.	Multi-line text
Amount of water used in spray application (nominal)	Indicate the amount of water used in spray application (nominal).	Unit measure with Open List (Decimal)
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
Sampling		Header 4
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

	text template and delete/add elements as appropriate.	
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
Sampling and analysis of soil		Header 4
Details on sampling of soil	If soil residues were determined, include details on the sampling, sampling method and handling and preparation of samples. 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.	Text template
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 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: ANALYTICAL METHODOLOGY - 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 t analytical methods if 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	Text template

	which you refer to them in the text (e.g. '... see Table 1').	
Any other information on materials and methods incl. tables	In this field, you can enter any information on materials and methods, for which no distinct field is availableYou 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 on the sampling, sampling method and handling and preparation of soil samples.	Header 2
	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
Results and discussion		Header 1
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 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	Text area

	present studies are covered by the most limiting storage conditions for which stability of the relevant residues has been demonstrated.	
Summary of residues	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.	Header 2
Sampling and residues	Enter a consecutive sampling number and 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.	Block of fields (repeatable)
Trial ID no.	Trial specific, unequivocal identification code. For example, Company Internal Code.	Text
Plot ID	Unequivocal plot identification, e.g. consecutive number (already used in block "Plot description").	Text
Sampling ID	Unique sample identification code.	Text
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
Growth stage code (BBCH) at sampling	Enter the code of the BBCH-scale system or an intervall of two codes separated by "-" eg. 99 or 99-99.	Text
Growth stage description at sampling	Enter the code of the BBCH-scale system and a description of the growth stage at application.	Text
Date of sampling	Enter the date of sampling.	Date
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
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 and Types are included with all their groups: - 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,	Open list

	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). The field should be empty, if no appropiate Sampled material / commodity could be found in the Codex Classification of Foods and Animal Feeds.	
Sampled material / commodity (Field RAC sample) description	Specify the sampled material / commodity.	Text
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.	Block of fields (repeatable)
Method ID	Identify the analytical method that was used to obtain this result. This should cross-reference with Method ID in the block "Analytical methods".	Link to repeatable entry
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. 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 refered 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.	Entity reference field
Analysis sample portion ID	Include "Analysed sample portion ID" which was defined in block "Analytical methods".	Text
Extraction date	Enter the date of extraction.	Date

Analysis date	Enter the date of analysis.	Date
Storage stability factor	Factor that allows for the correction of residue results in cases were 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 which are corrected for recovery.	Decimal
Use of storage stability factor	e.g., linear, first-order, etc	Text
Correction by storage stability	Nor relevant for PPP applications. The correction by Storage Stability Factor was done?	Closed list
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
Correction by recovery	Nor relevant for PPP applications. The correction by recovery was done?	Closed list
Reference portion	Specify for which part of plant or commodity the residue is calculated	Multi-line text
Residue level (measured)	Enter the result as measured (i.e. based on the measured analyte), without re-calculation and correction for storage stability. 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)
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
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. Note: Depending on the relevant regulation corrected data may be provided in addition, but	Range with open list (Decimal)

	not instead of measured data. This refers also to data which are corrected for recovery. 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.	
Residue level (calculated and corrected)	Not relevant for PPP applications. Enter the result expressed as the calculated analyte (e.g. acid expressed as carboxylic ester), after correction for storage stability and/or recovery. 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. 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)
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)
Any other information on results incl. tables		Header 2
	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.	Rich text area
Overall remarks, attachments	Follow instructions reported in "Overall remarks, attachments – common block"	Header 1
Applicant's summary and conclusion		Header 1
Interpretation of results	Select applicable conclusion from the picklist	Open list with remarks (2000)
Conclusions	The assessment and conclusion of the applicant should be reported here.	Text area
Executive summary	The assessment and conclusion of the applicant should be reported here. Briefly summarise the relevant aspects of the study(ies) including the conclusions reached. If a specific format is prescribed, copy it from the	Rich text area

	corresponding document or upload it if provided as htm or html document. 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 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 [commodities] with increasing PHIs. 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 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.]	

6.4 Feeding studies – Flexible summary

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 1: 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.

Note 2: this document is also relevant to report dietary burden for different fish species and MRL proposal for fish and fish products.

<table>
<tr><th colspan="3">FLEXIBLE_SUMMARY.ResiduesInLivestock</th></tr>
<tr><th>Name</th><th>Instructions</th><th>Type</th></tr>
<tr><td>Administrative data</td><td></td><td>Header 1</td></tr>
<tr><td></td><td>Use this field to set flags for confidentiality and regulatory purpose(s).

For further information see:
“User Guide: submission of confidentiality requests” available under the IUCLID software section of the Toolkit page.</td><td></td></tr>
<tr><td>Description of the key information</td><td>Use this field to report the input values used to calculate the median and max dietary burden. The input values should be reported in a table (use the function create table in the rich text area). Please do not use merged cells in the table (see example below).

<table>
<tr><th>Feed commodity</th><th>Input value for median DB</th><th>Comment</th><th>Input value for maximum DB</th><th>Comment</th></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
</table></td><td>Rich text area</td></tr>
<tr><td>Key value for chemical safety assessment</td><td></td><td>Header 1</td></tr>
<tr><td>Dietary burden</td><td>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.
This document is also relevant for fish and fish products.</td><td>Block of fields (Repeatable)</td></tr>
<tr><td>RD RA (plant/feed)</td><td>Provide the plant risk assessment residue definition (valid for all plants including feed and processed feed item) for which this dietary burden is calculated.</td><td>Multi-line text</td></tr>
<tr><td>Animal species</td><td>Select the animal species, which the calculated dietary burden refers to.</td><td>Closed list</td></tr>
</table>

	The picklist contains also relevant fish species, to be used if an assessment of residues levels in fish and fish products is performed.	
Median dietary burden	Report the Median dietary burden (mg/kg bw per day) calculated for the selected animal species.	Unit measure with Closed List (Decimal)
Maximal dietary burden	Report the Maximal dietary burden (mg/kg bw per day) calculated for the selected animal species.	Unit measure with Closed List (Decimal)
Median dietary burden	Report the Median dietary burden (mg/kg dry matter) calculated for the selected animal species.	Unit measure with Closed List (Decimal)
Maximal dietary burden	Report the Maximal dietary burden (mg/kg dry matter) calculated for the selected animal species.	Unit measure with Closed List (Decimal)
Trigger exceeded?	Conclude ("Yes" or "No") whether the trigger value is exceeded according to the relevant data requirement.	Closed list
Remarks	Additional remarks on the calculated dietary burden result for the given species.	Text area
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.	Block of fields (repeatable)
Link to relevant study record(s)	Link to the relevant study record.	Endpoint reference list
Commodity(ies) for which MRL and risk assessment values are derived	Please select from the picklist the commodity(ies) of animal origin for which MRL and risk assessment values are derived in this block. In case the same MRL and RA values risk assessment values are derived for different commodities, a multi-selection is possible (e.g. sheep and goat muscles). The picklist contains also relevant commodities for fish products, to be selected if MRLs are proposed on fish and fish products.	Multiselect open list
Highest residue RD-RA	Enter the highest residue according to the residue definition for risk assessment. [default unit "mg/kg"]	Unit measure with Closed List (Decimal)

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)
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)
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)
MRL derived	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"]. All MRLs should be listed as basis for the decision on the MRL proposal to be reported in the summary report MRL.	Unit measure with Closed List (Decimal)
MRL at LOQ?	Tick this check box if the MRL derived correspond to the LOQ for enforcement.	Check box
Provisional	If proposed MRL and risk assessment values are provisional ("yes"), clarify the reason in the additional remark field.	Closed list with remarks (2000)
Remarks	This field can be used to report any further additional remark regarding the calculated MRL and risk assessment values, that could not be reported in the above table.	Text area
Conversion factor (CF)	Conversion factor between enforcement and risk assessment derived from the results of the feeding study.	Decimal
Additional information		Header 1
	Follow instructions reported in "Additional information – common block" Provide additional information related to the endpoint, for example: - information on the potential data gaps - relevance of the results for the risk assessment	Rich text area

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		
Name	**Instructions**	**Type**
Administrative data	Follow instructions reported in "Administrative data – common block" Note: Select relevant endpoint from picklist, here: ”Residues in livestock”.	Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: “User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	Confidentiality
Data source	Follow instructions reported in "Data source– common block"	Header 1
Materials and methods	Follow instructions reported in “Material and methods – common block”	Header 1
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
Product type	Indicate the product type addressed by the information entered in this record.	Open list with remarks

Type of study	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. Most frequent options in the context EU PPP assessments: "livestock feeding"	Open list
Test guideline	Follow instructions reported in "Material and methods – common block"	Block of fields (repeatable)
Test material	Follow instructions reported in "Test material – common block"	Header 2
Test animals		Header 2
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
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 housing including size of enclosures, individual vs. group housing, food and water containers, temperature, lighting, and waste handling. TEST ANIMALS: Include information on breed, age, weight, stage of development, health status and condition of test animals.	Text template
Details on dietary regime	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'). The following information should be addressed: - Composition of diet: Describe the diet of animals during acclimation and the dosing period regarding: (1) Types of feed (e.g.,	Text template

	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 treatment group basis throughout the study. - Water: Report water consumption - Acclimation period: specify	
Administration / exposure		Header 2
Treatment type (route of exposure)	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. Most frequent options in the context EU PPP assessments: Oral: "capsule" or "applied on feed"	Multi select open list
Frequency of dosing	The frequency of application / dosing if the test material is not incorporated into the total diet or feed. 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.	Multi-line text
Dosing duration	Indicate the total length of the dosing period (e.g. 20 days).	Unit measure with Open List (Decimal)
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).	Block of fields (repeatable)
Dose / conc.	Enter numeric value with unit (recommended "mg/kg bw/day".	Unit measure with Open List (Decimal)
Remarks	Enter any remarks related to dose / concentration values, e.g. feeding level.	Multi-line text
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.	Text template

	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'). 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. 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. 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'. DOSING REGIME: Using an appropriate predefined table indicate the dosing regimen used.	
No. of animals per dose group	Report the number of animals per dose group, e.g. "3 cows per feeding level".	Multi-line text
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
Further details on study design		Header 2
Further details on study design	Include any further relevant details on the study design.	Text area
Details on sampling and analytical methods	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'). The following information should be addressed: IN-LIFE SAMPLING - 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.	Text template

	- Amount of milk and number of eggs produced during normal production: Provide data as indicated. - Urine, faeces, cage wash collected: For feed-through pesticides, include data on urine, feces and cage wash. POST-SLAUGTHER SAMPLING - Mode of sacrifice: Describe - 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. - Tissue harvested and their weights: Indicate the tissues taken after sacrifice, their type (e.g., thigh muscle, omental fat, etc.), and their weights. - Specification of and combining of samples from different animals: Indicate if pooling was done (usually acceptable for poultry, but not ruminants). SAMPLE HANDLING AND PREPARATION: Describe the handling of tissues, eggs and milk between sample collection and storage addressing at least following items: - 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: ANALYTICAL METHODOLOGY 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. In the study record created for this method (and its validation) in Section 4 of the dossier, the following information is expected: - 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.	
Model and software	Follow instructions reported in "Model and software – common block". Note: This block of fields is displayed only when "Type of information" is set to (Q)SAR.	Header 2
Any other information on materials and methods incl. tables	Follow instructions reported in "Any other information on materials and methods incl. tables– common block"	Header 2
	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
Results and discussion		Header 1
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	Text area

	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 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	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. Copy this block of fields for each different sampling instance.	Block of fields (repeatable)
Animal No.	Results should be associated to each animal individually. Therefore, please enter here the Animal No to which the following results correspond. For example, if three different goats were used in a lactating goat 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.	Multi select closed list
Feeding level	Specify the feeding level, typically 1, 2 or 3.	Integer
Dose (mg/kg bw)	Specify the dose in mg/kg bw.	Decimal
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
Sampling date	Report the days after the first dose or the actual date in ISO 8601 format (e.g. 2021-05-22).	Text
Sampling time	Report phase of the day the sampling took place, for milk/egg sampling.	Open list

Slaughter interval	Report time between last dose and sacrifice, for tissue.	Unit measure with Open List (Decimal)
Additional information on the sampling procedure	Report any additional information regarding the sampling procedure, if applicable.	Multi-line text
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.	Block of fields (repeatable)
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. 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 refered 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.	Entity reference field
Residue level	Enter the result as measured (i.e. based on the measured analyte), without re-calculation and correction for storage stability. Copy this block of fields for recording the results of analytical repeatitions. The mean calculated from all analytical repeatitions should be reported after this repeatable block.	Block of fields (repeatable)

Analysed sample ID	Report the sample number/ID that was measured.	Text
Residue level	Report the measured level of the residue mentioned afore. [Typical unit :"mg/kg"]	Range with open list (Decimal)
Mean residue level	Enter the mean residue level of the replicates data provided above [Typical unit :"mg/kg"]	Unit measure with Open List (Decimal)
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
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 study, please ignore this field..	Unit measure with Open List (Decimal)
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
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 refer to them in the text (e.g. '... see Table 1').	Text area
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,	Text area

	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').	
Additional information about applicability domain and reliability of (Q)SAR predictions	Follow instructions reported in "Additional information about applicability domain and reliability of (Q)SAR predictions – common block"	Header 2
Any other information on results incl. tables		Header 2
	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.	Rich text area
Overall remarks, attachments	Follow instructions reported in "Overall remarks, attachments – common block"	Header 1
Applicant's summary and conclusion	Follow instructions reported in "Applicant's summary and conclusion – common block"	Header 1
Conclusions	Enter any conclusions if applicable in addition to the information given in fields 'Key results' and 'Interpretation of results' (if any).	Text area
Executive summary	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.] 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 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	Rich text area

	frozen conditions. Adequate storage stability data are therefore available to support the storage conditions and intervals for samples in the current study. 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]. 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 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.]	

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		
Name	**Instructions**	**Type**
Administrative data		Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	Confidentiality
Description of key information		Header 1
	Please make a statement whether: 1) the nature of residues in processed commodities was sufficiently investigated 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. 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.	Rich text area

	Key results used for the risk assessment should be reported in the detailed tables below.	
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).	Block of fields (Repeatable)
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
Conditions	Select the standard hydrolysis conditions (e.g. sterilisation) for which a conclusion can be derived.	Multi select open list with remarks (2000)
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)
Processing factors	Repeat this block to create one box per combination raw agricultural commodity (RAC)/processed commodity (PC) for which processing factors could be derived. This section can also be used to capture the distribution of residues in peel/pulp by derivation of process factor pulp/RAC.	Block of fields (Repeatable)
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
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. The term RAC means the same as "primary food commodity" or "primary feed commodity". Indicate the raw agricultural commodity (RAC) for which the processing factor is derived (e.g. apple). If not available, select 'other:' and specify.	Open list with remarks (2000)
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)

	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
Median processing factor: RD MO	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): PF MO = [residue concentration in Processed Com] RD MO/ [residue concentration in RAC] RD MO This factor is valid for the combination `procedure/commodity`, which was investigated in the processing study. 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). 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.	Decimal
Median processing factor: RD RA	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: PF RA = [residue concentration in Processed Com] RD RA/ [residue concentration in RAC] RD MO. 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 definition in processed commodity.	Decimal

Remarks	Please enter any additional remark for the processing factor, for example if the processing factor is tentative.	Multi-line text
Additional information	Follow instructions reported in "Additional information – common block"	Header 1

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		
Name	**Instructions**	**Type**
Administrative data	Follow instructions reported in "Administrative data – common block" Note: Select relevant endpoint from picklist: - Nature of the residues in processed commodities: high temperature hydrolysis. Or - Nature of the residues in processed commodities: other. If `other` is selected, please specify in the remark field the type of the study.	Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	Confidentiality
Data source	Follow instructions reported in "Data source– common block"	Header 1

Materials and methods	Follow instructions reported in “Material and methods – common block”	Header 1
Product type	Indicate the product type addressed by the information entered in this record. Leave field empty if not applicable.	Open list with remarks
Test material	Follow instructions reported in "Test material – common block"	Header 2
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

Study design		Header 2
Teststrategies	Brief description of testing guideline conditions used.	Text area
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, 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.	Text template
Sampling and		Header 2

analytical methodology		
Details on sample handling and storage con	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

Conditions		
Details on analytical method	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 method validation, further information is not required. 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 flow diagram should be submitted. 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').	Text template

Model and software	Follow instructions reported in "Model and software – common block". Note: This block of fields is displayed only when "Type of information" is set to (Q)SAR.	Header 2
Any other information on materials and methods incl.		Header 2

cl.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.	Rich text area
Results and discussion	Identify all major components of TRR and specify the 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.	Header 1
Total radioactive resid	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.	Block of fields (repeatable)

ues (TRR)		
TRR component no.	Enter consecutive numbering of the components of TRR.	Closed list
Sample ID	Please report here the sampled ID.	Text area
Storage stability (Sample Int	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 procedures for harvested samples to be described in field 'Details on sampling handling and storage conditions'. 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'). Note: Specific tables may be required. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.	Text area

egrity)		
Test conditions	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.	Open list with remarks (2000)
Identity of TRR component	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
TRR concentrati	Enter the concentration of the component expressed as active ingredient equivalents (preferably use mg/L).	Unit measure with Open List (Decimal)

on		
TRR (%)	Enter the percentage of the component (%TRR).	Decimal
Fortification level	Enter the concentration of the sample before hydrolysis (preferably use mg/L).	Unit measure with Open List (Decimal)
TRR (%) prior hydrolysis	Enter the percentage of the initial TRR concentration of the sample before hydrolysis. Calculation based on field 'Fortification Level'.	Decimal
Other details	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

IsonTRRs		
Metabolicpathway	Discuss the routes of degradation observed and describe the metabolic pathways and/or attach figures in field “Illustration (picture/graph)”	Rich text area
Metabolicnap(picture/graph)	Optionally upload a picture of the metabolic pathways depicted in the study.	Image
Append		Header 2

ix: Metabolites and their parents in treatment groups		
Metabolite	Use this repeatable block of fields for specifying the metabolites/transformation products found and their parent compound(s).	Block of fields (repeatable)

Substreatmentgroups		
ID No.	Select a consecutive number for the test substance and to each metabolite/transformation product from drop-down list. 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.	Open list with remark
Identityofcompound	Indicate the identity of the compound (metabolite/transformation product or test substance) using an appropriate identifier, e.g. CAS number, CAS name, IUPAC name. 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
Parentcompo	If the compound is a metabolite/transformation product, link to the identity of the substance that is characterised as the parent of this transformation product. Link to multiple parent substances if applicable. 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

und(s)		
Testconditions	Specify the test condition(s) under which the metabolite is retrieved.	Multi select open list with remarks (2000)
Expertise	Indicate if the metabolite and its relationship has been expertly specified or not.	Closed list
Typeofexpertise	If expert judgment applies, indicate the type of expertise. Multiple selection is possible. Select "expert:" and "decision:" and enter text.	Multi select closed list with remark
Additionalinf	Follow instructions reported in "Additional information about applicability domain and reliability of (Q)SAR predictions – common block"	Header 2

orn ati ona bou t app lic abi lit y don ain and rel iab ili ty of (Q) SAR pre dic		

tions		
Anyotherinformationonresultsincl.tables		Header 2
	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. Note: One rich text editor field each is provided for the MATERIALS AND METHODS	Rich text area

	and RESULTS section. In addition the fields 'Overall remarks' and 'Executive summary' allow rich text entry.	
Overall remarks, attachments	Follow instructions reported in "Overall remarks, attachments – common block"	Header 1
Applicant's summary and conclus	Follow instructions reported in "Applicant's summary and conclusion – common block"	Header 1

ion		
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
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 substance/metabolite] was investigated in standard hydrolysis study simulating [include here the process, temperature, pH] conditions. 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.	Rich text area

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		
Name	**Instructions**	**Type**
Administrative data	Follow instructions reported in "Administrative data – common block" Note: Select relevant endpoint from picklist: magnitude of residues in processed commodities	Header 1
Data source	Follow instructions reported in "Data source– common block"	Header 1
Materials and methods	Follow instructions reported in "Material and methods – common block"	Header 1
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
Test material	Follow instructions reported in "Test material – common block"	Header 2
Study design		Header 2
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 commodity" or "primary feed commodity". Select the raw agricultural commodity (RAC). If not available, select 'other:' and specify.	Open list
Details on test commodity	Include details on the test commodity, including a description of the general condition (e.g. immature/mature, green/ripe, fresh/dry). Use existing template and delete/add elements as appropriate.	Text template
Sample processing	Briefly describe how the RAC was processed into the processed commodity(ies). As appropriate and relevant, attach or upload the processing flow chart in 'Illustration (picture/graph)'.	Text area
Further details on study design	Include any further relevant details on the study design. Use existing templates and delete/add elements as appropriate.	Text template
Sampling and analytical methodology		Header 2

Details on sample collection	Include details on sampling time (age of raw commodity in days), number of samples/replicates. Use existing templates and delete/add elements as appropriate.	Text template
Details on sample handling and preparation	Include details on the sample handling and preparation. Use existing template and delete/add elements as appropriate. The following information should be addressed: handling and shipping of commodities, storage conditions, length of storage, any preparation done prior to extraction.	Text template
Details on analytical methodology	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. 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 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.	Text template
Model and software	**Follow instructions reported in Model and software" -common block. Note: This block of fields is displayed only when "Type of information" is set to (Q)SAR.**	Header 2
Any other information on materials and methods incl. tables	Follow instructions reported in "Any other information on materials and methods incl. tables– common block"	Header 2

	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
Results and discussion		Header 1
Additional information about applicability domain and reliability of (Q)SAR predictions	Follow instructions reported in ”Additional information about applicability domain and reliability of (Q)SAR predictions – common block“	Header 2
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
Residues in RAC prior to processing		Header 2
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 below “Attached background material”	Block of fields (repeatable)
Date of sub-sample	Report date	Date

Analysis sample ID	Provide the code of the analysis sample if any.	Text
Analysis sample description	Include a description of the analysis sample.	Text
Analyte measured		Block of fields (repeatable)
Analyte identity	Click the Link button to navigate to the Substances Inventory and select the relevant substance name for indicating the identity. f not available in the inventory, create a new one.	Entity reference field
Extraction date	Enter the date of extraction	Date
Analysis date	Report date of analysis	Date
Method ID	Identify the analytical method that was used to obtain this result. This should cross-reference with the method(s) described in the method portion of this template.	Text
Storage stability factor	Optional; default value = 1. Factor that allows for the correction of residue results in cases were 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 which are corrected for recovery.	Decimal
Use of factor	e.g., linear, first-order, etc	Text
Correction by storage stability	Indicate whether the correction by Storage Stability Factor was done or not	Closed list
Recovery	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
Correction by recovery	Indicate whether the correction by recovery was done or not	Closed list
Reference portion	Specify for which part of plant or commodity the residue is calculated	Multi-line text
Residue level (measured)	Enter the result as measured (i.e. based on the measured analyte), without re-calculation and correction for storage stability. 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)
Residue level (calculated)	Not needed	Range with closed list (Decimal)
Residue level (calculated and corrected)	Not needed	Range with closed list (Decimal)

Residues in processed fractions (PF) and aspirated grain fractions (AGF)		Header 2
Processing information	Description of processing method(s). 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.	Multi-line text
Processed fraction	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. 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"	Block of fields (repeatable)
Processed fraction (PF sample)	Specify the processed fraction to which the residue data summarised in the nested repeatable block 'Analyte measured' refer	Open list
PF sample no.	Report Unique sample identification code.	Text
Date of processing	Enter the date of processing. dd/mm/yyyy	Date
Analysis sample ID	Provide the code of the analysis sample if any	Text
Analysis sample description	Include a description of the analysis sample.	Text
Analyte measured	Specify residue level of each analyte determined for a given processed fraction. Copy this block of fields for recording the results of repetitions and for multiple analytes.	Block of fields (repeatable)
Analyte identity	Click the Link button to navigate to the Substances Inventory and select the relevant substance name for indicating the identity . If not available in the inventory, create a new one.	Entity reference field
Extraction date	Enter the date of extraction.	Date
Analysis date	Enter the date of analysis.	Date
Method ID	Identify the analytical method that was used to obtain this result. This should cross-reference with the method(s) described in the method portion of this template.	Text
Storage stability factor	Optional; default value = 1. Factor that allows for the correction of residue results in cases were analytes are not stable throughout the	Decimal

	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 which are corrected for recovery.	
Use of factor	e.g., linear, first-order, etc	Text
Correction by storage stability	Indicate whether the correction by Storage Stability Factor was done or not	Closed list
Recovery	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
Correction by recovery	Indicate whether the correction by recovery was done or not	Closed list
Reference portion	Specify for which part of plant or commodity the residue is calculated	Multi-line text
Residue level (measured)	Enter the result as measured (i.e. based on the measured analyte), without re-calculation and correction for storage stability. 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)
Residue level (calculated)	Not needed	Range with closed list (Decimal)
Residue level (calculated and corrected)	Not needed	Range with closed list (Decimal)
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".	
AGF analysis sample	Include a description of the AGF analysis sample.	Text
Date of AGF sample	Enter the date of the AGF sample.	Date
Analysis sample ID	Provide the code of the analysis sample if any.	Text
Analyte measured		Block of fields (repeatable)
Analyte identity	Click the Link button to navigate to the Substances Inventory and select the relevant substance name for indicating the identity . If	Entity reference field

	not available in the inventory, create a new one.	
Extraction date	Enter the date of extraction.	Date
Analysis date	Enter the date of analysis.	Date
Method ID	Identify the analytical method that was used to obtain this result. This should cross-reference with the method(s) described in the method portion of this template.	Text
Storage stability factor	Optional; default value = 1. Factor that allows for the correction of residue results in cases were 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 which are corrected for recovery.	Decimal
Use of factor	e.g., linear, first-order, etc	Text
Correction by storage stability	Indicate whether the correction by Storage Stability Factor was done or not	Closed list
Recovery	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
Correction by recovery	Indicate whether the correction by recovery was done or not	Closed list
Residue level (measured)	Enter the result as measured (i.e. based on the measured analyte), without re-calculation and correction for storage stability. 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)
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. 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. 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)
Residue level (calculated and corrected)	Enter the result expressed as the calculated analyte (e.g. acid expressed as carboxylic ester), after correction for storage stability and/or recovery. 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. Enter a single numeric value in the first numeric field if you select no qualifier or	Range with closed list (Decimal)

	'>', '>=' 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.	
Distribution of residues	Report quantitative information on the recovery of the residue from the processed commodities.	Text area
Any other information on results incl. tables		Header 2
	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.	Rich text area
Overall remarks, attachments		Header 1
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 document. Use this field only if strictly necessary i.e. when no other specific fields such as repeatable blocks exist in the document to enter the data of interest. 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
Attachments	Attach any background document that cannot be inserted in any rich text editor field, particularly image files. Copy this block of fields for attaching more than one file.	Block of fields (repeatable)
Type	Specify the type of attachment inserted. Full study reports should be uploaded in the Literature reference entity	
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.	Attachments list
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	Attachments list

	Template 6.5 (http://doi.org/10.5281/zenodo.4621130)]. The uploaded file should not contain confidential material.	
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.	
Applicant's summary and conclusion		Header 1
Conclusions	The assessment and conclusion of the applicant should be reported here.	Text area
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 treatment. The [RAC samples] were processed into [processed food/feed fractions] using [simulated commercial practices]. 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. 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]. 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.	Rich text area

6.7 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.

NOTE: Only one summary per dataset shoud be created. If different residue definitions are proposed for different crops or different types of use, they should be reported in the repeatable blocks.

ENDPOINT_SUMMARY.ResidueFood		
Name	**Instructions**	**Type**
Administrative data		Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	Confidentiality
Description of key information		Header 1
	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
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	Block of fields (repeatable)
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
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
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

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 01, expressed as parent).	Multi-line text
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
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)
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
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.	Block of fields (repeatable)
Commodity type	Indicate if the residue definition for monitoring is proposed for raw commodities (unprocessed) and/or for processed commodities. If the residue definition is for processed commodities, indicate the type of process (baking/brewing/boiling, pasteurisation, sterilisation) covered by the residue definition in the remarks. If the same monitoring residue definition is proposed for raw and processed commodities, both items can be selected to report the same residue definition in the same line.	Multi select open list with remarks
Metabolism group	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
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
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
Monitoring residue definition LOQ (mg/kg)	Limit of quantification (LOQ) for the residue definition for monitoring and enforcement	Decimal

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)
Remarks	Any additional remarks regarding the proposed RD monitoring (e.g. common RD with other substance(s)…)	Multi-line text
Validated method	Indicate if a validated method for Monitoring (including inter-laboratory validation ILV) is available for the proposed residue definition.	Check box
Link to validated method	Link to the study describing method for monitoring and its validation	Endpoint reference field
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".	
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
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. r all tissues of ruminants and pigs), multi-selection feature can be used.	Multi select open list with remarks
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 01, expressed as parent).	Multi-line text
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
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)
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
Food of animal origin residue	Use the repeatable block to create as many rows as necessary to reflect the residue definition(s) for monitoring for each	Block of fields (repeatable)

definition monitoring	combination "animal commodity/provisional or not".	
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
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
Processing	Indicate if the monitoring residue definition is also relevant for processed commodities and indicate the type of processed commodity(ies) in the remarks.	Closed list with remarks (2000)
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
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
Monitoring residue definition LOQ (mg/kg)	Limit of quantification (LOQ) for the residue definition for monitoring and enforcement	Decimal
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)
Remarks	Any additional remarks regarding the proposed RD monitoring (e.g. common RD with other substance(s)…)	Multi-line text
Validated method	Indicate if a validated method for Monitoring (including inter-laboratory validation ILV) is available for the proposed residue definition.	Check box
Link to validated method	Link to the study describing method for monitoring and its validation	Endpoint reference field
Additional information	Follow instructions reported in "Additional information – common block"	Header 1

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		
Name	**Instructions**	**Type**
Administrative data		Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	Confidentiality
Description of key information		Header 1
	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. 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. Describe if relevant, the possible presence of pesticide residues arising from sources other	Rich text area

<table>
<tr><td></td><td>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.

Describe the method and results, if cumulative exposure to more than one active substance has been performed.

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.

Use this field to report the input values used to perform the chronic and acute risk assessments.
The input values should be reported in a table (use the function create table in the rich text area). Please do not use merged cells in the table (see example below).

<table>
<tr><td>Commodity</td><td>Input value for chronic RA</td><td>Comment</td><td>Input value for acute RA</td><td>Comment</td></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
</table>
</td><td></td></tr>
<tr><td>Exposure from dietary sources</td><td>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.</td><td>Header 2</td></tr>
<tr><td>Model</td><td>Select PRIMO version (e.g. “PRIMo 3.1”) if ‘other’ is selected provide details in the remarks</td><td>Open list with remarks</td></tr>
<tr><td>Food domain</td><td>Specify the food domain/class of the substance</td><td>Picklist with remarks</td></tr>
<tr><td>Residue definition(s) for risk assessment</td><td>Specify the compound(s), e.g., parent + metabolite(s), that are considered in the present exposure assessment.</td><td>Text</td></tr>
<tr><td>Toxicological reference values</td><td>Please select the document (from the mammalian toxicology section) where are reported the toxicological reference values (ADI and ARfD) relevant for this risk assessment.</td><td>Endpoint reference field</td></tr>
</table>

Chronic exposure		Header 3
Exposure asumption	Specify if TMDI or IEDI calculations.	Pick list with remarks
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
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 RD RA (e.g. if the tRV is 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).	Unit measure with Open List (Decimal)
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)
Total exposure (% of ADI)	Please report the value of the highest calculated chronic (among all surveys/populations) as % of ADI.	Decimal
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
Contribution of commodities		Block of fields (repeatable block)
Commodity - chronic exposure	Commodities of plant and animal origin available for the PRIMo calculations (to assess the chronic exposure):	Open list
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)
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 calculated chronic exposures among all surveys/populations).	Decimal
Population / Survey	Please report the name of the survey/population for which the highest chronic	Open list with remarks

	exposure was identified. This information is available in PRIMo excel file.	
Acute exposure		Header 3
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
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 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).	Unit measure with Open List (Decimal)
Commodity - acute exposure	Commodities of plant and animal origin for which an acute exposure can be calculated in PRIMo:	Open list
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)
Exposure (% of ARfD)	Please report the acute exposure as % of ARfD calculated for the commodity(ies) under assessment. Please report the highest IESTI	Decimal
Exposure from other sources (drinking water)		Header 2
	Exposure from other sources (drinking water). Please report in the Table the additional contribution to consumer intake through drinking water resulting from groundwater metabolites expected to be present above 0.75 µg/L. Indicate any metabolites included in the exposure assessment. Report PECgw 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.	Rich text area

Additional information	Follow instructions reported in "Additional information – common block" 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. 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]. The uploaded file should not contain confidential material.	Header 1

Links to support material:

FAO Manual (FAO, 2016): http://www.fao.org/3/i5452e/i5452e.pdf

6.10 Other studies – Endpoint summary

Other studies – Endpoint summary

ENDPOINT_SUMMARY.AdditionalInformationOnResiduesInFoodAndFeedingstuffs		
Name	**Instructions**	**Type**
Administrative data		Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	Confidentiality
Link to relevant study record(s)	Provide here the link(s) to the study record(s) supporting the choice of the key value for assessment. The study(ies) giving rise to the highest concern should be chosen. The following factors, among others, should be taken into account when the study record is selected: quality of the study (e.g. Klimisch score), type of study (e.g. duration, experimental design, observed effects), whether or not the study is GLP. Please provide your rationale for the selection of the relevant study record in the field "Additional information".	Header 1
Description of key information		Header 1
	If all key information is provided in the linked study records, this field can be left empty. In case there is no linked study record, or in case you want to point to specific information in the linked study record, provide a summary of the key information related to the studies here. The summary could include, for example: - the test type - the test guideline used (and any deviations from it) - the test organism - the exposure duration - other contextual information on the origin of the key value	Rich text area
Additional information	Provide a brief description of additional study(ies) and of the key conclusions derived from this/these study(ies).Follow instructions reported in "Additional information – common block"	Header 1

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		
Name	**Instructions**	**Type**
Administrative data	Follow instructions reported in "Administrative data – common block" Note: Select from picklist 'additional information on residue chemistry'	Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	Confidentiality
Data source	Follow instructions reported in "Data source– common block"	Header 1
Materials and methods	Follow instructions reported in "Material and methods – common block" Note: "Product type" field is 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.	Header 1
Test material	Follow instructions reported in "Test material – common block"	Header 2
Model and software	Follow instructions reported in "Model and software – common block". Note: This block of fields is displayed only when "Type of information" is set to (Q)SAR.	Header 2
Any other information on materials and methods incl. tables		Header 2
	Follow instructions reported in "Any other information on materials and methods incl. tables – 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	Rich text area

	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.	
Results and discussion		Header 1
Details on results	Provide any other relevant details if not entered in the specific "Description" fields for the examined parameters.	Text area
Additional information about applicability domain and reliability of (Q)SAR predictions	Follow instructions reported in "Additional information about applicability domain and reliability of (Q)SAR predictions – common block"	Header 2
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
Overall remarks, attachments	Follow instructions reported in "Overall remarks, attachments – common block"	Header 1
Applicant's summary and conclusion	Follow instructions reported in "Applicant's summary and conclusion – common block"	Header 1

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		
Name	**Instructions**	**Type**
Administrative data		Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	Confidentiality
Link to relevant study record(s)		Header 1
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
Description of key information		Header 1
	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. 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: - A residue at or above the LOQ (a value of 0.05 mg/kg or lower is 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.	Rich text area

Additional information	Follow instructions reported in "Additional information – common block"	Header 1

6.10.1 Effect on the residue level in pollen and bee products – Endpoint study record

Purpose

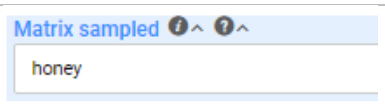
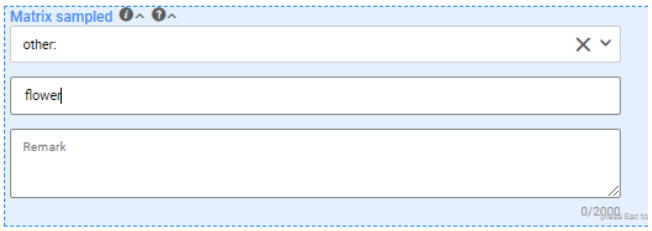
Studies to determine the residue in pollen and bee products for human consumption resulting from residues taken up by honeybees from crops at blossom.

ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities		
Name	**Instructions**	**Type**
Administrative data	Follow instructions reported in "Administrative data – common block"	Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	Confidentiality
Endpoint	Select relevant endpoint from picklist: - residues in honey - residue in nectar - residues in pollen - residues in other bee products If the MRL application is done to request an MRL in honey, the relevant endpoint to be selected is "residue in honey". If residues in flowers/upper part of the plant or nectar are used to support an MRL in honey, the relevant point is also "residue in honey" because the overall purpose is to derive an MRL in honey.	Closed list with remarks
Data source	Follow instructions reported in "Data source (Literature Reference) – common block"	Header 1
Materials and methods	Follow instructions reported in "Material and methods – common block"	Header 1
Test guideline	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'. Copy this block of fields for specifying more than one guideline (e.g. US EPA in addition to OECD guideline).	
Guideline	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 SANTE/11956/2016 rev. 9".	Open list

Test material	Follow instructions reported in "Test material – common block"	Header 2
Study design	Please report the study design in the proposed structure below.	Header 2
Study type	Use the picklist to define the study type (field trials, syrup feeding tests, tunnel trials). If different types of study are reported in the same study report, please create one study record per study type. If residues trials are performed to analyse residues in flowers/upper part of the plant or nectar, to support an MRL in honey, these trials should be considered as "field trials", specifying in the remark field "residues in nectar/flowers are measured". If trials are performed as rotational crops trials (measuring residues in honey or any other matrices), these trials should be considered as "field trials", specifying in the remark field "rotational crops".	Open list with remarks
Number of trials	Report the number of trials available in the study.	Numeric (integer)
Trial parameters	Use this block of fields to report detailed parameters for each trial.	
Trial number	Assign consecutive numbers to each trial (e.g. 1, 2, 3) and report the parameters for each trial below.	Closed list with remarks
Trials site	Only relevant for tunnel and field trials. Specify the trial site (e.g. geographical location). Specify: Country – Region - City – Postal code	Text area
Duration of trial	Indicate the duration of the trials using the appropriate unit. For honey trials, the duration goes from the day when the honeybee colony is exposed to the a.s. (e.g. the colony is fed with treated syrup or placed in the treated tunnel/field) until honey sample collection. For crop field trials, the duration goes from the treatment day until (flower/upper part of the plant or nectar) sample collection.	Unit measure with Closed List (Decimal)
Tunnel size/ Field size	For syrup or tunnel trials, report here the tunnel size. For field trials, report here the field size. Size should be reported in m^2 or in hectares.	Unit measure with Closed List (Decimal)
Method of application/ administration	For syrup trials: Please provide information on administration of the test substance, such as number of days of administration of the spiked feeding solution, volume of the feeding solution.	Text area

	The concentration level should be reported in the specific field below. For tunnel and field trials: Describe how the test substance is applied and the crops used in the study (report the mode of application, the growth stage of the crops at application…). The number of applications and the application rate should be reported in the specific fields below.	
Dose/ concentration	For syrup trials only: Indicate the dose or concentration levels applied and the basis of quantity used. Conversion of the dose / conc. values to the relevant unit used for the effect levels may be required. Enter numeric value.	Unit measure with Closed List (Decimal)
Number of applications	For tunnel and field trials only. Report the number of individual applications.	Numeric (integer)
Application rate (active ingredient) (actual)	For tunnel and field trials only: Report the actual application rate of the active ingredient (if more than one application is performed, the single rate per application should be reported here).	Unit measure with Closed List (Decimal)
Remarks	Enter any remarks related to dose / concentration values, e.g. feeding level that could not be reported in the above fields. For field trials performed as rotation crops trials, please report here the additional relevant parameters: application on bare soil or not, Plant back interval (PBI), type of soil…	Text area
Trial parameters		
Additional study design details	Provide additional information on the study to assess compliance with guidelines and reliability/reproducibility of the results. Text prompts are provided for each study design. For syrup feeding test: Percentage of sugar in feeding solution For tunnel trials: Details on control plot Distance between trial sites (km) For field trials: Details on control plot No flowering crops within a 2 to 3 km radius? (500 m radius in the case of less-attractive flowering crops compared to the treated crop). Distance between trial sites (km) Details on pollen traps and methods to determine honey source	Text template

Any other information on materials and methods incl. tables	Follow instructions reported in "Any other information on materials and methods incl. tables – 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.	Header 2
		Rich text area
Results and discussion		Header 1
Colony health	Report a general statement on colony health observations taken during the study.	Text area
Honey sample size	Report the sizes of the samples used in the study. A range of values is expected to cover the size of all the relevant samples used in the study.	Range with closed list (Decimal)
Storage of samples	Report the number of days the samples were stored for. As only one value can be reported to cover the storage conditions of all the relevant samples used in the study, please report the max storage length from all samples.	Unit measure with Closed List (Decimal)
Percentage water content in honey	For field studies report the % water content to demonstrate that the honey has reached commercial maturity. A range of values is expected to cover all the relevant samples used in the study.	Range (Decimal)
Residue data	Specify residue level of each analyte determined for this sampling instance. Copy this block of fields for recording the results of repetitions (each trial) and for multiple analytes.	
Trial number	Refer to the trial number defined in material and methods. (e.g. for trial #1 defined in material and methods, report #1 in this field and report the results corresponding to trial #1 in this block of fields). Several lines can be created for the same trial, to report data from different samples and/or for different analytes.	Closed list
Analysed sample ID	Report the sample number/ID that was measured.	Text area
Result type	Specify if the results correspond to the treated sample or the control sample. Results for the treated samples are mandatory. Results for the control samples are mandatory if above LOQ. If control samples remain below LOQ, this can be included as a general statement in the field "remarks" of the present block.	Closed list with remarks
Matrix sampled	Select the matrix analysed from the drop-down list.	Open list with remarks

	 If residues in flowers/upper part of the plant or nectar were measured in support of an MRL application in honey, use the option "other" and specify the matrix field below (e.g. nectar, flowers, upper part of the plant…). 	
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
Residue level	Report the measured level of the residue trial mentioned afore using the relevant unit (typically "mg/kg").	Range with open list (Decimal)
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. If control samples remain below LOQ, this could be included as a general statement in this field.	Text area
Residue data		
Key results	Use this block of fields to report the key values (median, highest residues) per matrix according to the relevant residue definition(s).	
Matrix	Select the matrix from the drop-down list.	Open list with remarks

Median value	Specify the median value (from all available results) calculated for the relevant residue definition (e.g. parent compound and/or metabolite(s)), for the residue definition for enforcement and risk assessment purposes.	Range with open list (Decimal)
Highest value	Specify the highest value (from all available results) calculated for the relevant residue definition (e.g. parent compound and/or metabolite(s)), for the residue definition for enforcement and risk assessment purposes.	Range with open list (Decimal)
Residue definition	Provide the residue definition for which the key values are calculated.	Text area
Enforcement / risk assessment	Specify if the key values are derived for the residue definition for enforcement and/or for the residue definition for risk assessment.	Multi select open list with remarks
Key results		
Any other information on results incl. tables	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. The results of the study can be also presented in a table format. In particular the following points must be addressed: - 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
		Rich text area
Overall remarks, attachments	Follow instructions reported in "Overall remarks, attachments – common block"	Header 1
Applicant's summary and conclusion		Header 1
Conclusions	The assessment and conclusion of the applicant should be reported here.	Text area
Executive summary	Briefly summarise the relevant aspects of the study including the 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: 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].	Rich text area

	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]. [Bee product] samples were collected at [conditions of sampled product (maturity, water content (%) etc.] at [crop growth stage]. Residues of [active substance/metabolites] were present at the level of [xx] mg/kg in control samples of [bee product]/not present in control samples of [bee product] above the LOQ of [xx] mg/kg in control samples. In [bee product] the residues of [active substance/metabolites] were present at the level of [xx] mg/kg. 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. 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].	

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.

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		
Name	**Instructions**	**Type**
Administrative data		Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page"	Confidentiality
Description of key information	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 Group the main findings from the relevant endpoint level summaries and provide conclusions on the available information for the hazard assessment.	
Additional information	Follow instructions reported in "Additional information – 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

7.1 Fate and behaviour in soil

7.1.1 Route and rate of degradation in soil, aerobic and anaerobic (laboratory studies)

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.

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

ENDPOINT_SUMMARY.BiodegradationInSoil		
Name	**Instructions**	**Type**
Administrative data		Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page"	Confidentiality
Description of key information		Header 1
	If all key information is provided in the linked study records, this field can be left empty. In case there is no linked study record, or in case you want to point to specific information in the linked study record, provide a summary of the key information related to the studies here. The summary could include, for example: - the test type - the test guideline used (and any deviations from it) - the test organism - the exposure duration - other contextual information on the origin of the key value	Text area
Key value for chemical safety assessment		Header 1
Biodegradation in soil for	Provide the values relevant for the exposure assessment of the substance.	Header 2

exposure assessment	In case degradation is found to be pH dependent, two DT50 values might need to be provided, depending on the regulatory context.	
Link to relevant study record(s)	Provide the link(s) to the study record(s) supporting the choice of the key value for assessment. The study(ies) giving rise to the highest concern should be chosen. The following factors, among others, should be taken into account when the study record is selected: quality of the study (e.g. Klimisch score), type of study (e.g. duration, experimental design, observed effects), whether or not the study is GLP. Please provide your rationale for the selection of the relevant study record in the field "Additional information".	Link to endpoint
DT50	Include here DT50 value (d) which is expected to be taken into account when estimating exposure. Depending on the regulatory context you may report a worst case DT50 or for example a geometric mean of various values available, once normalised to the exposure assessment temperature.	Unit measure with Closed List (Decimal)
at the temperature of	Enter the reference temperature of the soil in the laboratory test system for the DT50 value used for exposure assessment.	Unit measure with Closed List (Decimal)
pH condition	For pH dependent degradation, indicate the relevant pH condition of the provided DT50 value. Indicate acidic pH or basic pH.	Closed list
pH dependence	Where relevant, indicate if degradation is pH dependent. Indicate yes or no.	Closed list
DT50	For pH dependent degradation, two DT50 values (d) might need to be provided, depending on the regulatory context. Here you may include the second DT50 value (d), to be taken into account when estimating exposure.	Unit measure with Closed List (Decimal)
at the temperature of	Enter the reference temperature of the soil in the laboratory test system for the DT50 value used for exposure assessment.	Unit measure with Closed List (Decimal)
pH condition	For pH dependent degradation, indicate the relevant pH condition of the provided DT50 value. Indicate acidic pH or basic pH.	Closed list
Biodegradation in soil for persistence assessment	Provide here values relevant for the persistence assessment of the substance.	Header 2

Link to relevant study record(s)	Provide the link(s) to the study record(s) supporting the choice of the key value for assessment. The study(ies) giving rise to the highest concern should be chosen. The following factors, among others, should be taken into account when the study record is selected: quality of the study (e.g. Klimisch score), type of study (e.g. duration, experimental design, observed effects), whether or not the study is GLP. Please provide your rationale for the selection of the relevant study record in the field "Additional information".	Link to endpoint
DT50	Indicate the DT50 value used for persistence assessment. For first order kinetics DT50 = half-life.	Unit measure with Closed List (Decimal)
DT90	Indicate the DT90 value used for persistence assessment.	Unit measure with Closed List (Decimal)
Temperature of the test system	Indicate the temperature of the soil in the laboratory test system used to derive the DT50 and DT90 values.	Unit measure with Closed List (Decimal)
Route of biodegradation	Depending on the regulatory context, you can indicate here the key study(ies) for the route of biodegradation.	Header 2
Link to relevant study record(s)	Provide here the link(s) to the study record(s) supporting the choice of the key value for assessment. The study(ies) giving rise to the highest concern should be chosen. The following factors, among others, should be taken into account when the study record is selected: quality of the study (e.g. Klimisch score), type of study (e.g. duration, experimental design, observed effects), whether or not the study is GLP. Please provide your rationale for the selection of the relevant study record in the field "Additional information".	Link to endpoint
Information on transformation products		Header 1
Information on transformation products	Provide here the identity and some key values of the transformation products that require further consideration for risk assessment. Repeat this block of fields for each relevant compound.	Block of fields (repeatable)
Link to relevant study record(s)	Provide here the link(s) to the study record(s) supporting the choice of the key value for assessment. The study(ies) giving rise to the highest concern should be chosen. The following factors, among others, should be taken into account when the	Link to endpoint

	study record is selected: quality of the study (e.g. Klimisch score), type of study (e.g. duration, experimental design, observed effects), whether or not the study is GLP. Please provide your rationale for the selection of the relevant study record in the field "Additional information".	
Identity of the transformation product	Indicate the identity of the transformation product observed in the test.	
Kinetic formation fraction	Provide here the arithmetic mean of the kinetic formation fractions (f. f. kf /kdp) of the transformation product.	
Maximum occurrence	Indicate the percentage (%) of maximum occurrence of the relevant transformation product observed in the parent-dosed study.	
Additional information	Follow instructions reported in "Additional information common block"	Header 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		
Name	**Instructions**	**Type**
Administrative data	Follow instructions reported in "Administrative data – common block"	Header 1
Data source	Follow instructions reported in "Data source – common block"	Header 1
Materials and methods	Follow instructions reported in "Material and methods – common block" Applicable test guideline:	Header 1

	Microbial PesticideTest GuidelinesOPPTS 885.5200Expression in aTerrestrial Environment	
Test type	Indicate whether the study was a field trial or laboratory study.	Open list
Test material	Follow instructions reported in "Test material – common block"	Header 2
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
Study design		Header 2
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
Continuous darkness	Indicate if the study was performed in continuous darkness	Check box
Soil classification	Select as cited in the study report. If not available from picklist, select 'other:' and specify.	Open list with remarks
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
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.	
Soil no.	Select a consecutive soil number from drop-down list if more than one soil types were used.	Closed list
Soil type	Select from drop-down list.	Open list
% 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)
% 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)
% 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)
% 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)
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)
pH measured in	Indicate the medium in which pH was measured (e.g. calcium chloride solution, water).	

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)
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)
% 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)
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
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.	
Soil No.	Select a consecutive soil number from drop-down list if more than one soil types were used.	Closed list
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)
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).	
Soil No.	Select a consecutive soil number from drop-down list if more than one soil types were used.	Closed list
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)

Based on	From drop-down list, select the parameter on which the initial concentration is based.	Open list with remarks
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
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 template
Experimental conditions	For each soil type, indicate the environmental conditions during the test if available or assumed in the model, if estimated.	
Soil No.	Select a consecutive soil number from drop-down list if more than one soil types were used.	Closed list
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
Humidity	Indicate soil humidity in % moisture content or g water/100g soil dry weight.	Text
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
Experimental conditions		
Details on experimental conditions	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 template
Model and software	Follow instructions reported in "Model and software – common block". Note: This block of fields is displayed only when "Type of information" is set to (Q)SAR.	Header 2
Any other information on materials and methods incl. tables	Follow instructions reported in "Any other information on materials and methods incl. tables – common block"	Header 2
Results and discussion		Header 1

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.	
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose or for inclusion in the list of endpoints.	Check box
Soil No.	Select a consecutive soil number from drop-down list if more than one soil types were used.	Closed list
Sampling date	Enter the date the sample was taken	Date
Sampling time	Enter numeric value.	Unit measure with Closed List (Decimal)
% 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)
% Non extractable residues	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)
% Mineralisation (% 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)
% 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)
% Recovery	Enter numeric value.	Decimal
St. dev.	Enter numeric value.	Decimal
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)
Material (mass) balance		
Mineralization rate (in CO2)	Enter mineralization rate (in CO2).	Decimal
% 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.	
Parent / transformation product	Indicate if the result reported is for the active substance/parent or the transformation product.	Closed list
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
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box
Soil No.	Select a consecutive soil number from drop-down list if more than one soil types were used.	Closed list
Sampling date	Enter date when the sample was taken	Date
Sampling time	Enter numeric value.	Unit measure with Closed List (Decimal)
% 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)
St. dev.	Enter numeric value.	Decimal
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
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)
Disappearance time (DT) of parent compound	For each soil type, include value (or range if reported so) of DT50 and indicate the type of the DT50 (For first order kinetics DT50 = half-life). If relevant, also indicate the DT90 value (or range if reported so) and the DT50 value as normalised to reference conditions.	
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box
Soil No.	Select a consecutive soil number from drop-down list if more than one soil types were used.	Closed list
Parameter	Indicate if you are reporting a DT50 value, a DT50 value normalised to reference conditions or a DT90 value. For the normalised values, you can specify which reference conditions were used and how the	Closed list

	normalisation was carried out (e.g. using a Q10 of 2.58 and Walker equation coefficient of 0.7) in the remark field.	
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 closed list (Decimal)
St. dev.	Enter numeric value.	Decimal
Type of kinetics and method of calculation	Select the type of kinetics from the drop-down list. You can indicate the kinetics equation used in the remark field (e.g. SFO, DFOP).	Closed list
Type of value	Select from drop-down list.	Open list
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)
Chi-square (χ^2) error	Chi-square error of the kinetic model used for deriving the reported DT value. Deviations between observed and calculated values for each separate model relative to the uncertainty of the measurements.	Decimal
p-value (t-test)	Provide the result of the t-test to evaluate the confidence in the parameter estimates. The parameter is considered significantly different from zero if the probability is smaller than 0.05 ($p<0.05$), i.e. considering a 5 % significance level. Alternatively, the 95% confidence interval can be reported when kinetic parameters do not allow a t-test to be completed.	Decimal
Kinetic parameters	Please provide here the kinetic parameters and their values that are relevant to the kinetic model used for deriving the reported DT value. Depending on the kinetic model, the relevant kinetic parameters could be e.g. alpha, beta, g, k, k1, k2 or tb.	Open text (2000)
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)
Disappearance time (DT) 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	Closed list with remarks

	entered in field 'Any other information on results incl. tables'.	
Transformation products	Provide information on the transformation products observed in the parent-dosed study. 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'.	
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose or for inclusion in the list of endpoints.	Check box
ID no.	For easier distinction, you can assign consecutive numbers to the test substance (i.e. #1) and to each metabolite (i.e. #2, #3, etc.).	Open list with remarks
Identity of compound	Indicate the identity of the compound (transformation product or test substance) using an appropriate identifier, e.g. CAS number, CAS name, IUPAC name. 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.	
Parent compound(s)	If the compound is a transformation product, link to the identity of the substance that is characterised as the parent of this metabolite. Link to multiple parent substances if applicable. 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.	
Soil No.	Select a consecutive soil number from drop-down list if more than one soil types were used.	Closed list
Kinetic formation fraction	Indicate the kinetic formation fraction (f. f. kf/kdp) of the transformation product, as derived from the parent-dosed study.	Decimal
Maximum occurrence (%)	Indicate the maximum occurrence of the transformation product as observed in the parent-dosed study.	Decimal
Timepoint of maximum occurrence observed in days	Indicate the time point in days when the maximum occurrence of the transformation product was observed in the parent-dosed study.	Integer
Parameter	Indicate if you are reporting a DT50 value, a DT50 value normalised to reference conditions or a DT90 value. For the normalised values, you can specify which reference conditions were used and how the normalisation was carried out (e.g. using a Q10 of 2.58 and Walker equation coefficient of 0.7) in the remark field.	Closed list with remarks
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 with closed list

	range use both numeric fields together with the appropriate qualifier(s) if applicable.	(Decimal)
St. dev.	Enter numeric value.	Decimal
Type of kinetics and method of calculation	Select the type of kinetics from the drop-down list. You can indicate the kinetics equation used in the remark field (e.g. SFO, DFOP).	Closed list with remarks
Type of value	Select from drop-down list.	Closed list
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)
Chi-square (χ^2) error	Chi-square error of the kinetic model used for deriving the reported DT value. Deviations between observed and calculated values for each separate model relative to the uncertainty of the measurements.	Decimal
p-value (t-test)	Provide the result of the t-test to evaluate the confidence in the parameter estimates. The parameter is considered significantly different from zero if the probability is smaller than 0.05 ($p<0.05$), i.e. considering a 5 % significance level. Alternatively, the 95% confidence interval can be reported when kinetic parameters do not allow a t-test to be completed.	Range (Decimal)
Kinetic parameters	Provide here the kinetic parameters and their values that are relevant to the kinetic model used for deriving the reported DT value. Depending on the kinetic model, the relevant kinetic parameters could be e.g. alpha, beta, g, k, k1, k2 or tb.	Open text (2000)
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
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 CO2 has been detected in volatile traps.	Closed list with remarks
Volatile metabolites	Indicate whether volatile metabolites were found or not. Include any explanations in field 'Details on results' as appropriate.	Closed list with remarks
Residues	Indicate whether residues were found or not. Include any explanations in field 'Details on results' as appropriate.	Closed list with remarks
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	Text template

	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 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
Additional information about applicability domain and reliability of (Q)SAR predictions	Follow instructions reported in "Additional information about applicability domain and reliability of (Q)SAR predictions – common block"	Header 2
Any other information on results incl. tables	Follow instructions reported in "Any other information on results incl. tables – common block"	Header 2
Overall remarks, attachments	Follow instructions reported in "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
Kinetic evaluation	Upload Kinetic evaluation (visual and statistical) 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
Applicant's summary and conclusion	Follow instructions reported in "Applicant's summary and conclusion – common block"	Header 1

7.1.2 Route and rate of degradation in soil

7.1.2.1 Route of degradation in soil (soil photolysis) – Endpoint summary

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

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

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		
Name	**Instructions**	**Type**
Administrative data		Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page"	Confidentiality
Link to relevant study record(s)		Header 1
Link to relevant study record(s)	Provide here the link(s) to the study record(s) supporting the choice of the key value for assessment. The study(ies) giving rise to the highest concern should be chosen. The following factors, among others, should be taken into account when the study record is selected: quality of the study (e.g. Klimisch score), type of study (e.g. duration, experimental design, observed effects), whether or not the study is GLP. Please provide your rationale for the selection of the relevant study record in the field "Additional information".	Link to endpoint
Description of key information		Header 1

	If all key information is provided in the linked study records, this field can be left empty. In case there is no linked study record, or in case you want to point to specific information in the linked study record, provide a summary of the key information related to the studies here. The summary could include, for example: - the test type - the test guideline used (and any deviations from it) - the test organism - the exposure duration - other contextual information on the origin of the key value	
Key value for chemical safety assessment		Header 1
DT50 for phototransformation in soil		Unit measure with Closed List (Decimal)
Additional information	Follow instructions reported in "Additional information – 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

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		
Name	**Instructions**	**Type**
Administrative data	Follow instructions reported in "Administrative data – common block"	Header 1
Data source	Follow instructions reported in "Data source– common block"	Header 1
Materials and methods	Follow instructions reported in "Material and methods – common block" Applicable test guideline: - EPA Guideline Subdivision N 161-3 (Photodegradation Studies on Soil) - OECD Guideline draft (Phototransformation of Chemicals on Soil Surfaces) - SETAC (1995) - Procedures for assessing the environmental fate and ecotoxicity for pesticides 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
Test material	Follow instructions reported in "Test Material – common block"	Header 2

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
Study design		Header 2
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
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
Details on sampling	Enter details on sampling regime and method. Use free text template as appropriate.	Text template
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 template
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 francaise) / USDA (US Department of Agriculture) / WRB (World Reference Base for Soil Resources) / or other (to be specified).	Text template
Light source	Select light source used.	Open list with remarks
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)
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)

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
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
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.	
Duration	Enter numeric value.	Unit measure with Closed List (Decimal)
% Moisture	Enter numeric value.	Decimal
Temp.	Enter numeric value.	Unit measure with Closed List (Decimal)
Initial conc. measured	Enter numeric value.	Unit measure with Open List (Decimal)
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
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
Computational methods	Enter details on computational methods used to calculate relevant parameters.	Multi-line text
Model and software	Follow instructions reported in "Model and software – common block". Note: This block of fields is displayed only when "Type of information" is set to (Q)SAR.	Header 2

Any other information on materials and methods incl. tables	Follow instructions reported in "Any other information on materials and methods incl. tables – common block"	Header 2
Results and discussion		Header 1
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
Test performance	Report on any unusual observations during test, deviations from test procedure or any other information affecting results.	Multi-line text
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').	
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
Value	Enter numeric value.	Unit measure with Open List (Decimal)
Remarks	Enter any remarks related to the recorded value as appropriate.	Text
Spectrum of substance		
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.	

Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose or for inclusion in the list of endpoints.	Check box
Soil No.	Select a consecutive soil number from drop-down list if more than one soil types were used.	Closed list
Sampling time	Enter numeric value.	Unit measure with Closed List (Decimal)
Sampling conditions	Enter a value	Open list with remarks
% 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)
% Non extractable residues	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)
% Mineralisation (% 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)
% 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)
% Recovery	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)
St. dev.	Enter numeric value.	Decimal
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)
Material (mass) balance		
% Degradation	Specify percentage of degradation or range and sampling time. Copy this block of fields for recording results at different test conditions.	

Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box
% 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)
St. dev.	Enter numeric value.	Decimal
Sampling time	Enter numeric value.	Unit measure with Closed List (Decimal)
Test condition	If results at different test conditions are reported, specify test condition (e.g. different temperatures). Otherwise leave this subfield empty.	Text
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)
% Degradation		
Quantum yield (for direct photolysis)	Give the reaction quantum yield of the test substance (values between 0 and 1).	Decimal

Disappearance time (DT) of parent compound	Include value (or range if reported so) of DT50 and indicate the type of the DT50 (For first order kinetics DT50 = half-life). For water-sediment systems repeat this block of fields for each compartment. If relevant, also indicate the DT90 value (or range if reported so) and the DT50 value as normalised to reference conditions.	
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box
Soil No.	Select a consecutive soil number from drop-down list if more than one soil types were used.	Closed list
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
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 closed list (Decimal)

St. dev.	Enter numeric value.	Decimal
Type of kinetics and method of calculation	Select the type of kinetics from the drop-down list. You can indicate the kinetics equation used in the remark field (e.g. SFO, DFOP).	Open list
Type of value	Select from drop-down list.	Closed list
Temp.	Enter numeric value.	Unit measure with Closed List (Decimal)
Chi-square (χ^2) error	Chi-square error of the kinetic model used for deriving the reported DT value. Deviations between observed and calculated values for each separate model relative to the uncertainty of the measurements.	Numeric
p-value (t-test)	Provide the result of the t-test to evaluate the confidence in the parameter estimates. The parameter is considered significantly different from zero if the probability is smaller than 0.05 ($p<0.05$), i.e. considering a 5 % significance level. Alternatively, the 95% confidence interval can be reported when kinetic parameters do not allow a t-test to be completed.	Range
Kinetic parameters	Please provide here the kinetic parameters and their values that are relevant to the kinetic model used for deriving the reported DT value. Depending on the kinetic model, the relevant kinetic parameters could be e.g. alpha, beta, g, k, k1, k2 or tb.	Text area
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)
Disappearance time (DT) 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
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'.	

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
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
Parent compound(s)	If the compound is a transformation product, link to the identity of the substance that is characterised as the parent of this transformation product. Link to multiple parent substances if applicable. 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	
Maximum occurrence (%)	Indicate the maximum occurrence of the transformation product.	
Identity of transformation products		
Details on results	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'). Explanations on free text prompts: TEST CONDITIONS: If the test conditions were not maintained, describe any anomalies or problems encountered. HALF-LIFE: Include a table with detailed results for dark and irradiated samples including Regression equation, r²' and DT90 if available. 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. As appropriate attach Figure showing the pathway of photo transformation of the test substance. SUPPLEMENTARY EXPERIMENT: Briefly describe the results of the supplementary experiment, if any.	Text template

Results with reference substance	Indicate whether the results with the reference substance(s) are valid.	Multi-line text
Additional information about applicability domain and reliability of (Q)SAR predictions	Follow instructions reported in "Additional information about applicability domain and reliability of (Q)SAR predictions – common block"	Header 2
Any other information on results incl. tables	Follow instructions reported in "Any other information on results incl. tables – common block"	Header 2
Overall remarks, attachments	Follow instructions reported in "Overall remarks, attachments – common block"	Header 1
Applicant's summary and conclusion	Follow instructions reported in "Applicant's summary and conclusion – common block"	Header 1

7.1.2.2 Rate of degradation in soil (field studies)

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.
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 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.

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.

Name	Instructions	Type
Administrative data		Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page"	Confidentiality
Description of key information		Header 1

	If all key information is provided in the linked study records, this field can be left empty. In case there is no linked study record, or in case you want to point to specific information in the linked study record, provide a summary of the key information related to the studies here. The summary could include, for example: - the test type - the test guideline used (and any deviations from it) - the test organism - the exposure duration - other contextual information on the origin of the key value	Text
Key value for chemical safety assessment		Header 1
Biodegradation in soil for exposure assessment	Provide here values relevant for the exposure assessment of the substance. In case degradation is found to be pH dependent, two DT50 values might need to be provided, depending on the regulatory context.	Header 2
Link to relevant study record(s)	Provide here the link(s) to the study record(s) supporting the choice of the key value for assessment. The study(ies) giving rise to the highest concern should be chosen. The following factors, among others, should be taken into account when the study record is selected: quality of the study (e.g. Klimisch score), type of study (e.g. duration, experimental design, observed effects), whether or not the study is GLP. Please provide your rationale for the selection of the relevant study record in the field "Additional information".	Link to endpoint
DT50	Include here the value for DT50 which is expected to be taken into account when estimating exposure. Depending on the regulatory context you may report a worst case DT50 or for example a geometric mean of various values available, once normalised to the exposure assessment temperature.	Numeric range
at the temperature of	Indicate the reference temperature of the DT50 value used for exposure assessment.	Decimal

pH condition	For pH dependent degradation, indicate the relevant pH condition of the provided DT50 value.	Closed list
pH dependence	Where relevant, indicate if degradation is pH dependent.	Closed list
DT50	For pH dependent degradation, two DT50 values might need to be provided, depending on the regulatory context. Here you may include the second DT50 value, to be taken into account when estimating exposure.	Numeric range
at the temperature of	Indicate the reference temperature of the DT50 value used for exposure assessment.	Decimal
pH condition	For pH dependent degradation, indicate the relevant pH condition of the provided DT50 value.	Closed list
Biodegradation in soil for persistence assessment	Provide here values relevant for the persistence assessment of the substance.	Header 2
Link to relevant study record(s)	Provide here the link(s) to the study record(s) supporting the choice of the key value for assessment. The study(ies) giving rise to the highest concern should be chosen. The following factors, among others, should be taken into account when the study record is selected: quality of the study (e.g. Klimisch score), type of study (e.g. duration, experimental design, observed effects), whether or not the study is GLP. Please provide your rationale for the selection of the relevant study record in the field "Additional information".	Link to endpoint
DT50	Indicate the DT50 value used for persistence assessment. For first order kinetics DT50 = half-life.	Numeric range
DT90	Indicate the DT90 value used for persistence assessment.	Numeric range
Temperature of the test system	Indicate the temperature of the soil in the test system used to derive the DT50 and DT90 values.	Decimal
Route of biodegradation	Depending on the regulatory context, you can indicate here the key study(ies) for the route of biodegradation.	Header 2
Link to relevant study record(s)	Provide here the link(s) to the study record(s) supporting the choice of the key value for assessment. The study(ies) giving rise to the highest concern should be chosen. The following factors, among others, should be taken into account when the study record is selected: quality of the study (e.g. Klimisch score), type of study (e.g. duration, experimental design, observed effects), whether or not the study is GLP. Please provide your rationale for the selection of the relevant study record in the field "Additional information".	Link to endpoint

Information on transformation products		Header 1
Information on transformation products	Provide here the identity and some key values of the transformation products that require further consideration for risk assessment. Repeat this block of fields for each relevant compound	
Link to relevant study record(s)	Provide here the link(s) to the study record(s) supporting the choice of the key value for assessment. The study(ies) giving rise to the highest concern should be chosen. The following factors, among others, should be taken into account when the study record is selected: quality of the study (e.g. Klimisch score), type of study (e.g. duration, experimental design, observed effects), whether or not the study is GLP. Please provide your rationale for the selection of the relevant study record in the field "Additional information".	Link to endpoint
Identity of the transformation product	Indicate the identity of the transformation product observed in the test.	
Kinetic formation fraction	Provide here the arithmetic mean of the kinetic formation fractions (f. f. kf /kdp) of the transformation product.	Decimal
Maximum occurrence	Indicate the maximum occurrence of the relevant transformation product observed in the parent-dosed study.	Decimal
Additional information	Follow instructions reported in "Additional information – common block" 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. The EFSA DegT50Endpoint Selector excel file can be uploaded here.	Header 1

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

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 % (DegT50field and DegT90field), 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		
Name	**Instructions**	**Type**
Administrative data	Follow instructions reported in "Administrative data – common block"	Header 1
Data source	Follow instructions reported in "Data source – common block"	Header 1
Materials and methods	Follow instructions reported in "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
Type of measurement	Indicate the type of measurement applied.	Multi-line text
Media	Indicate the media investigated.	Multi-line text
Test material	Follow instructions reported in "Test Material – common block"	Header 2
Model and software	Follow instructions reported in "Model and software – common block". Note: This block of fields is displayed only when "Type of information" is set to (Q)SAR.	Header 2
Any other information on materials and methods incl. tables	Follow instructions reported in "Any other information on materials and methods incl. tables – 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.	Header 2

	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.	
Results and discussion		Header 1
Half-life of parent compound / 50% disappearance time (DT50)	For each soil type, include value (or range if reported so) of DT50 and indicate the type of the DT50 (For first order kinetics DT50 = half-life).If relevant, also indicate the DT90 value (or range if reported so) and the DT50 value as normalised to reference conditions.	
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
Soil No.	Select a consecutive soil number from drop-down list if more than one soil types were used.	Picklist
Parameter	Indicate if you are reporting a DT50 value, a DT50 value normalised to reference conditions or a DT90 value. For the normalised values, you can specify which reference conditions were used and how the normalisation was carried out (e.g. using a Q10 of 2.58 and Walker equation coefficient of 0.7) in the remark field.	Closed list with remarks
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.	Decimal with a range
St. dev.	Enter numeric value.	Decimal
Type of kinetics and method of calculation	Select the type of kinetics from the drop-down list. You can indicate the kinetics equation used in the remark field (e.g. SFO, DFOP).	Closed list with remarks
Type of value	Select from drop-down list.	Closed list
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.	Decimal

Chi-square (χ^2) error	Chi-square error of the kinetic model used for deriving the reported DT value. Deviations between observed and calculated values for each separate model relative to the uncertainty of the measurements.	Decimal
p-value (t-test)	Provide the result of the t-test to evaluate the confidence in the parameter estimates. The parameter is considered significantly different from zero if the probability is smaller than 0.05 ($p<0.05$), i.e. considering a 5 % significance level. Alternatively, the 95% confidence interval can be reported when kinetic parameters do not allow a t-test to be completed.	Decimal
Kinetic parameters	Please provide here the kinetic parameters and their values that are relevant to the kinetic model used for deriving the reported DT value. Depending on the kinetic model, the relevant kinetic parameters could be e.g. alpha, beta, g, k, k1, k2 or tb.	Text (2,000 char)
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:'	Text (2,000 char)
Half-life of parent compound / 50% disappearance time (DT50)		
Transformation products	Provide information on the transformation products observed in the parent-dosed study. 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'.	
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose or for inclusion in the list of endpoints.	Check box
ID no.	For easier distinction, you can assign consecutive numbers to the test substance (i.e. #1) and to each metabolite (i.e. #2, #3, etc.).	Closed list
Identity of compound	Indicate the identity of the compound (transformation product or test substance) using an appropriate identifier, e.g. CAS number, CAS name, IUPAC name.	Link to entity

	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.	
Parent compound(s)	If the compound is a transformation product, link to the identity of the substance that is characterised as the parent of this metabolite. Link to multiple parent substances if applicable. 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.	Link to entity
Soil No.	Select a consecutive soil number from drop-down list if more than one soil types were used.	Closed list
Kinetic formation fraction	Indicate the kinetic formation fraction (f. f. kf/kdp) of the transformation product, as derived from the parent-dosed study.	Decimal
Maximum occurrence (%)	Indicate the maximum occurrence of the transformation product as observed in the parent-dosed study.	Decimal
Timepoint of maximum occurrence observed in days	Indicate the time point in days when the maximum occurrence of the transformation product was observed in the parent-dosed study.	Integer
Parameter	Indicate if you are reporting a DT50 value, a DT50 value normalised to reference conditions or a DT90 value. For the normalised values, you can specify which reference conditions were used and how the normalisation was carried out (e.g. using a Q10 of 2.58 and Walker equation coefficient of 0.7) in the remark field.	Closed list with remarks
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.	Decimal with a range
St. dev.	Enter numeric value.	Decimal
Type of kinetics and method of calculation	Select the type of kinetics from the drop-down list. You can indicate the kinetics equation used in the remark field (e.g. SFO, DFOP).	Closed list with remarks
Type of value	Select from drop-down list.	Closed list
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.	Decimal with a range
Chi-square (χ^2) error	Chi-square error of the kinetic model used for deriving the reported DT value. Deviations between observed and calculated values for each separate model relative to the uncertainty of the measurements.	Decimal

p-value (t-test)	Provide the result of the t-test to evaluate the confidence in the parameter estimates. The parameter is considered significantly different from zero if the probability is smaller than 0.05 ($p<0.05$), i.e. considering a 5 % significance level. Alternatively, the 95% confidence interval can be reported when kinetic parameters do not allow a t-test to be completed.	Decimal with a range
Kinetic parameters	Provide here the kinetic parameters and their values that are relevant to the kinetic model used for deriving the reported DT value. Depending on the kinetic model, the relevant kinetic parameters could be e.g. alpha, beta, g, k, k1, k2 or tb.	Open text
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.	Open text
Additional information about applicability domain and reliability of (Q)SAR predictions	Follow instructions reported in "Additional information about applicability domain and reliability of (Q)SAR predictions – common block"	Header 2
Any other information on results incl. tables	Follow instructions reported in "Any other information on results incl. tables – common block" For chemicals the table presenting the kinetic fitting must be included here The following information should be included Substance, Soil, Kinetic model, Mo, χ2, %-error, Prob>t, Lower CI, Upper CI, DT50 and DT90 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)	Header 2
Overall remarks, attachments	Follow instructions reported in "Overall remarks, attachments – common block"	Header 1
Kinetic evaluation	Upload Kinetic evaluation (visual and statistical)	Attachments list
Applicant's summary and conclusion	Follow instructions reported in "Applicant's summary and conclusion – common block"	Header 1

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.
Provide a brief description of relevant studies and effects.
Reference can also be made to the results of aged sorption studies if available.

ENDPOINT_SUMMARY.AdsorptionDesorption		
Name	**Instructions**	**Type**
Administrative data		Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page"	Confidentiality
Link to relevant study record(s)		Header 1
	Provide here the link(s) to the study record(s) supporting the choice of the key value for assessment. The study(ies) giving rise to the highest concern should be chosen. The following factors, among others, should be taken into account when the study record is selected: quality of the study (e.g. Klimisch score), type of study (e.g. duration, experimental design, observed effects), whether or not the study is GLP. Please provide your rationale for the selection of the relevant study record in the field "Additional information".	Link to endpoint
Description of key information		Header 1
	If all key information is provided in the linked study records, this field can be left empty. In case there is no linked study record, or in case you want to point to specific information in the linked study	

	record, provide a summary of the key information related to the studies here. The summary could include, for example: - the test type - the test guideline used (and any deviations from it) - the test organism - the exposure duration - other contextual information on the origin of the key value	
Key value for chemical safety assessment		Header 1
Koc	Report here the Koc value used for the chemical safety assessment. A Koc at 20 °C and neutral pH is usually expected.	Decimal
at the temperature of	Enter the reference temperature of the soil in the laboratory test system for the Koc value used for the chemical safety assessment.	Decimal
Other adsorption coefficients	If the value for Koc is missing, provide information on other adsorption coefficients.	
Type	Select additional adsorption coefficients. Other can be used in case of a coefficient value which is not in the list	Open list
Value	The expected value to be provided here is the logarithm of a Kp value expressed in L/kg. The expected unit to refer to is therefore L/kg.	Decimal
at the temperature of		Unit measure with Closed List (Decimal)
Additional information	Follow instructions reported in "Additional information – 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° 284/2013, Annex Part A, point 9.1.2.1) is recommended.	Header 1

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		
Name	**Instructions**	**Type**
Administrative data	Follow instructions reported in "Administrative data – common block"	Header 1
Data source	Follow instructions reported in "Data source– common block"	Header 1
Materials and methods	Follow instructions reported in "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 field can be used for query purposes.	Header 1
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
Test material	Follow instructions reported in "Test Material – common block"	Header 2
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
Study design		Header 2
Test temperature	Indicate test temperature values measured during test. Include range, mean, standard deviation and unit.	Multi-line text
HPLC method		Header 3
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
Batch equilibrium or other method		Header 3
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	Closed list with remarks

	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
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
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.	
Matrix no.	Select a consecutive number from drop-down list if more than one matrix type were used.	Closed list
Matrix type	Select from drop-down list.	Open list
% 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)
% 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)
% 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)
% 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)
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)
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)
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)
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 option, include or attach an excerpt from the study report.	Text template
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
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.	
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
Duration	Enter numeric value.	Unit measure with Closed List (Decimal)
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 with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)
pH	Enter the initial pH.	Decimal
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)
Remarks	Enter any remarks related to the duration of the adsorption equilibration.	Text
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.	
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
Duration	Enter numeric value.	Unit measure with Closed List (Decimal)
Conc. of adsorbed test mat.	Enter a numeric value.	Unit measure with Open List (Decimal)
pH	Enter the initial pH.	Decimal
Temp.	Enter a numeric value.	Unit measure with Closed List (Decimal)
Remarks	Enter any remarks related to the duration of the adsorption equilibration.	Text
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
Model and software	Follow instructions reported in "Model and software – common block". Note: This block of fields is displayed only when "Type of information" is set to (Q)SAR.	Header 2
Any other information on materials and methods incl. tables	Follow instructions reported in "Any other information on materials and methods incl. tables – common block"	Header 2
Results and discussion		Header 1
Adsorption coefficient		
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box
Sample No.	Select a consecutive sample number from drop-down list if more than one matrix types were used.	Closed list
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

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)
pH	Enter numeric value.	Decimal
Temp.	Enter numeric value.	Unit measure with Closed List (Decimal)
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
% 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)
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)
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.	
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box
Sample No.	Select a consecutive sample number from drop-down list if more than one matrix types were used.	Closed list
Phase system	Indicate the compartment-water system or select 'other:' and specify.	Open list with remarks
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
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)
Temp.	Enter numeric value.	Unit measure with Closed List (Decimal)
pH	Enter numeric value.	Decimal

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
% 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)
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)
Partition coefficients		
Results: HPLC method		Header 2
Details on results (HPLC method)	For the HPLC method only, include further data as indicated in the freetext template.	Text template
Results: Batch equilibrium or other method		Header 2
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 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
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
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	Multi-line text

	table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').	
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 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
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.	
Sample no.	Select a consecutive sample number from drop-down list if more than one matrix types were used.	Closed list
Duration	Enter numeric value.	Unit measure with Closed List (Decimal)
% 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)
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)
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.	
Sample no.	Select a consecutive sample number from drop-down list if more than one matrix types were used.	Closed list
Duration	Enter numeric value.	Unit measure with Closed

		List (Decimal)
% 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)
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)
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
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'.	
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
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
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
Statistics	Indicate the parameters analyzed, the statistical method used and the statistical test performed.	Multi-line text
Additional information about applicability domain and reliability of	Follow instructions reported in "Additional information about applicability domain and reliability of (Q)SAR predictions – common block"	Header 2

(Q)SAR predictions		
Any other information on results incl. tables		Header 2
	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
Overall remarks, attachments	Follow instructions reported in "Overall remarks, attachments – common block"	Header 1
Applicant's summary and conclusion	Follow instructions reported in "Applicant's summary and conclusion – common block"	Header 1

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		
Name	**Instructions**	**Type**
Administrative data	Follow instructions reported in "Administrative data – common block"	Header 1
Data source	Follow instructions reported in "Data source– common block"	Header 1
Materials and methods	Follow instructions reported in "Material and methods – common block" Applicable test guideline:	Header 1

	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	
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 picklist, use 'other:' and include an appropriate description. 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. Fill in fields for Administrative data and Data source as appropriate.	Open list
Media	Indicate the media addressed.	Open list
Test material	Follow instructions reported in "Test Material – common block"	Header 2
Model and software	Follow instructions reported in Model and software" -common block. Note: This block of fields is displayed only when „Type of information" is set to (Q)SAR.	Header 2
Any other information on materials and methods incl. tables	Follow instructions reported in "Any other information on materials and methods incl. tables – common block"	Header 2
Results and discussion		Header 1
Additional information about applicability domain and reliability of (Q)SAR predictions	Follow instructions reported in „Additional information about applicability domain and reliability of (Q)SAR predictions – common block"	Header 2
Any other information on results incl. tables	Follow instructions reported in "Any other information on results incl. tables – common block"	Header 2
Overall remarks, attachments	Follow instructions reported in "Overall remarks, attachments – common block"	Header 1

Applicant's summary and conclusion	Follow instructions reported in "Applicant's summary and conclusion – common block"	Header 1

7.1.4 Mobility in soil, leaching and lysimeter studies – Endpoint summary

Purpose

Conclude on the mobility and leaching potential of the active substance, metabolites, breakdown and reaction products
Where studies are provided for more than one endpoint separate summaries can be created for each endpoint.

ENDPOINT_SUMMARY.OtherDistributionData		
Name	**Instructions**	**Type**
Administrative data	Provide a brief description of relevant studies and effects.	Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page"	Confidentiality
Link to relevant study record(s)		Header 1
Link to relevant study record(s)	Provide here the link(s) to the study record(s) supporting the choice of the key value for assessment. The study(ies) giving rise to the highest concern should be chosen. The following factors, among others, should be taken into account when the study record is selected: quality of the study (e.g. Klimisch score), type of study (e.g. duration, experimental design, observed effects), whether or not the study is GLP. Please provide your rationale for the selection of the relevant study record in the field "Additional information".	Link to endpoint
Description of key information		Header 1
	If all key information is provided in the linked study records, this field can be left empty. In case there is no linked study record, or in case you want to point to specific information in the linked study record, provide a summary of the key information related to the studies here. The summary could include, for example: - the test type - the test guideline used (and any deviations from it) - the test organism - the exposure duration	

	- other contextual information on the origin of the key value	
Additional information	Follow instructions reported in "Additional information" – 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 / 7.1.4.3 and Regulation (EU) N° 284/2013, Annex Part A, points 9.1.2.2 / 9.1.2.3) is recommended If there is no additional information to be reported this field may be left empty.	Header 1

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

Provide sufficient data to evaluate the mobility and leaching potential of metabolites, breakdown, and reaction products.

ENDPOINT_STUDY_RECORD.OtherDistributionData		
Name	**Instructions**	**Type**
Administrative data	Follow instructions reported in "Administrative data – common block"	Header 1
Data source	Follow instructions reported in "Data source (Literature Reference) – common block"	Header 1
Materials and methods	Follow instructions reported in "Material and methods – common block" Applicable test guideline: OECD Test Guideline 312: Leaching in Soil Columns.	Header 1
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 picklist, use 'other:' and include an appropriate description. 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. Fill in fields for Administrative data and Data source as appropriate.	Open list
Media	Indicate the media addressed.	Open list
Test material	Follow instructions reported in "Test material – common block"	Header 2
Model and software	Follow instructions reported in "Model and software – common block". Note: This block of fields is displayed only when "Type of information" is set to (Q)SAR.	Header 2
Any other information on materials and methods incl. tables	Follow instructions reported in "Any other information on materials and methods incl. tables – common block"	Header 2
Results and discussion		Header 1
Additional information about applicability domain and reliability of (Q)SAR predictions	Follow instructions reported in "Additional information about applicability domain and reliability of (Q)SAR predictions – common block"	Header 2

Any other information on results incl. tables	Follow instructions reported in "Any other information on results incl. tables – common block"	Header 2
Overall remarks, attachments	Follow instructions reported in "Overall remarks, attachments – common block"	Header 1
Applicant's summary and conclusion	Follow instructions reported in "Applicant's summary and conclusion – common block"	Header 1

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 and change log – Flexible record

9.1 Literature data

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		
Name	**Instructions**	**Type**
Administrative data	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	Header 1
		Confidentiality
Link to relevant studies	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. An appropriate Endpoint Study Record should be completed for each relevant study and the literature reference included in the data source section.	Header 1
Literature reference(s)		Literature reference list
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 plant protection products containing the active substance and dealing with side-effects on health, the environment and non-target species	Rich text area
Overall summary of the literature search	Summary of the methodology used to retrieve relevant studies on side-effects on health, the environment and non-target species. Report the criteria used to classify the references as being clearly non-relevant (e.g. not related to pesticides).	Rich text area

	Report the criteria used to assess the reliability of the studies.	
Search strategy	Indicate how the literature search was carried out.	Header 1
Bibliographic databases used in the literature review and search results	A description each of the search strategies used in the literature review	
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
Date of search	Provide the date when the search was performed using the database.	Date
Time window of the literature search	The period covered in the literature search e.g. 2010 to 2020	Text
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
Filters	Indicate if filters were applied in the search. If yes is selected the filters applied must be described	Closed list with remarks
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
Number of hits	The number of hits for the search in each database/source	Integer
Number of hits after refinement	The number of hits after refinement, if applicable	Integer
Number of hits after duplicate removal	The number of hits after duplicate removal	Integer
Evaluation of the review		Header 1
Records retrieved	The number of records retrieved when the results for the searches above where combined	Integer
Records after removal of duplicates	Total number of summary records retrieved after removing duplicates from all database searches	Integer
Records after rapid assessment	Report the number of records retained after title/abstract screening	Integer
Records after detailed assessment	Report the number of records retained after full text screening	Integer

Reliable studies	Report the number of records retained after the reliability assessment	Integer
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
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	
Literature reference	Link a reference to the excluded publication.	Literature reference list
Exclusion reason	Reason for not including publication in dossier (based on relevance and reliability criteria).	Multi-line text
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
Additional information	Any other information needed to interpret the results for the literature research. Indicate here criteria for selected studies: a) Studies that provide data for establishing or refining risk assessment parameters. (b) Studies relevant for the data requirement but in the opinion of the applicant provide only supplementary information c) Studies for which relevance cannot be clearly determined.	Rich text area
Attached background material	Upload supporting files e.g. bibliographic metadata	
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
Remarks	Indicate the source of the contents of the file and the format type.	Text
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

9.2 Change log

Purpose

To facilitate the automated generation of the "List of Literature references" report (field 'Previously used')

FLEXIBLE_RECORD.ChangeLog		
Name	**Instructions**	**Type**
General information		Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	Confidentiality
Summary	Provide any additional explanation needed to facilitate the compilation of the final list of the tests and studies relied upon and whether the study was already submitted in the framework of national authorisations.	Rich text area
Change log		Header 1
Change log entries	Create an entry in the table for each test or study	
Link to document	Select each of the IUCLID documents included in the dataset	Endpoint reference field
Status	For each of the documents indicate if the document is 'new', 'previously used' 'obsolete' or 'updated'	Closed list
Remark	Indicate for which data point the study was previously used	Multi-line text
Change log entries		

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.

FLEXIBLE_RECORD.AssessmentOtherAuthorities		
Name	**Instructions**	**Type**
Administrative data		Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	Confidentiality
Assessments in Europe	In this section, provide information on previous or ongoing evaluations in Europe.	Header 1
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)
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)
Other product safety assessments	In this section provide information on previous or ongoing evaluations in Europe under regulations other than Biocides or Veterinary Medicines	
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
Status	Select the status of the application and provide details on the nature of the application	Open list with remarks (2000)
Other product safety assessments		
Existing residue definitions		Header 2
Monitoring purposes (plant)	Check the current existing RD in the EU MRL data base. The field refers to the enforcement residue definition of plant 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.	Multi-line text

Risk assessment (plant)	The field refers to the risk assessment residue definitions for plant commodity/ies for which the MRL application is submitted. If different risk assessment residue definitions are set in different plant commodities under consideration, this shall be indicated. If for processed commodities residue definitions differ from residue definitions in raw agricultural commodity (RAC), this shall be indicated. If for rotational crops the residue definition differs from the residue definition in primary crops, this shall be indicated. Available in EFSA ccl and Registration reports	Multi-line text
Monitoring purposes (animal)	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. If different enforcement residue definitions are set in different commodities under consideration, this shall be indicated. Please check the current existing RD in the EU MRL data base.	Multi-line text
Risk assessment (animal)	The field refers to the risk assessment residue definitions for animal commodity/ies for which the MRL application is submitted. If different risk assessment residue definitions are set in different commodities under consideration, this shall be indicated. Available in EFSA ccl and Registration reports	Multi-line text
Remarks	Any comment on the existing RD for risk assessment (e.g. provisional, clarify the source, data gaps, …)	Multi-line text
EFSA paramCode		
RD paramCode	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) EFSA paramCodes can be downloaded or accessed by the EFSA catalogue browser application	Text
Existing MRL		Header 2
EU MRL	List the existing EU MRLs for the active substance. Existing MRLs should be listed for all crops reported in the GAP.	
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
MRL value	Enter the MRL value in mg/kg	Unit measure with Closed

		List (Decimal)
Residue definition monitoring	Enter the enforcement residue definition in the commodity/ies for the MRL	Multi-line text
Remarks	Any comment on the existing MRL (provisional, confirmatory data required.)	Multi-line text
Assessments outside Europe	In this section provide information on previous or ongoing evaluations **outside of Europe**	Header 1
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
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
Other product safety assessments	In this section provide information on previous or ongoing evaluations outside Europe under regulations other than Biocides or Veterinary Medicines	
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
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
Existing residue definitions	Enter the enforcement residue definitions for the MRL in the exporting country if they differ from those listed above	Header 2
Monitoring purposes (plant)	The field refers to the enforcement residue definition in the exporting country for plant 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.	Multi-line text
Risk assessment (plant)	The field refers to the risk assessment residue definition in in the exporting country in the plant 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. 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.	Multi-line text
Monitoring purposes (animal)	The field refers to the enforcement residue definition in the exporting country for the animal commodity/ies for which the MRL application is submitted.	Multi-line text

	If different enforcement residue definitions are set in different commodities under consideration, this shall be indicated.	
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
Remarks	Any comment on the existing RD for risk assessment (e.g., provisional, clarify the source, data gaps, …)	Multi-line text
Existing MRL in the exporting country		Header 2
Exporting country MRL		
Country	Select the exporting country from the list	Multi select open list
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
MRL value	If MRL setting processes are established in exporting countries. If MRL setting processes are not established in exporting countries, specify if Codex residue limit (CXL) is applicable. If there are no CXL and no MRL in the exporting country, report 'not relevant' and specify the reason in remark box.	Unit measure with Closed List (Decimal)
Residue definition monitoring	Enter the enforcement residue definition of plant commodity/ies for the MRL	Multi-line text
Remarks	Any additional remark on the MRL in the exporting country. If MRL setting processes are not established in exporting countries, specify if Codex residue limit (CXL) is applicable. If no CXL and no MRL in the exporting country, report 'not relevant' and specify the reason in remark box.	Multi-line text
Additional information	This section is only relevant for MRL applications	Header 1
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

Evidence of registration in the exporting country (remark)	Clarification should be given in remark field if no evidence can be provided.	Multi-line text
Evidence of registration in the exporting country attached	Upload attachments with vidence of registration in the exporting country (these attachments will be published and should not contain confidential information)	Attachment list
Type	Specify the type of attachment inserted, for example the 'full study report'.	Picklist
Attached (confidential) document	An electronic copy of the full study report or other documents can be attached as Word, pdf or other file types.	Single File Attachment
Attached (sanitised) documents for publication	An electronic copy of a public (non-confidential) version of the full study report or other relevant documents can be attached. This attachment should be sanitised if needed.	Single File Attachment
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
Registered use pattern in the exporting country		Header 2
Type	Specify the type of attachment inserted, for example the 'full study report'.	Picklist
Attached (confidential) document	An electronic copy of the full study report or other documents can be attached as Word, pdf or other file types.	Single File Attachment
Attached (sanitised) documents for publication	An electronic copy of a public (non-confidential) version of the full study report or other relevant documents can be attached. This attachment should be sanitised if needed.	Single File Attachment
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 (255 char.)
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
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
Legislation in the exporting country concerning the MRL attached	Upload copies of the Legislation in the exporting country concerning the MRL	Attachments list

Type	Specify the type of attachment inserted, for example the 'full study report'.	Picklist
Attached (confidential) document	An electronic copy of the full study report or other documents can be attached as Word, pdf or other file types.	Single File Attachment
Attached (sanitised) documents for publication	An electronic copy of a public (non-confidential) version of the full study report or other relevant documents can be attached. This attachment should be sanitised if needed.	Single File Attachment
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

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

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		
Name	**Instructions**	**Type**
Administrative data		Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	Confidentiality
Complementary information	Select the type of bibliography or supporting documentation. This field is relevant for basic substance applications.	icklist with remarks
Reports and administrative information		Header 1
Reports and administrative information		
Type of report	Indicate the type of document that has been uploaded e.g. 'Document C Existing or proposed labels'	Multi-line text
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-confidential file. This file will not be published.	Single file attachment
Attached (sanitised) document for publication	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.	Single file attachment

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 bibliographic information should be completed and the PDF uploaded in the literature reference entity This would include 'Safety datasheets' 'Scientific opinions of national/international regulatory bodies'	Header 1
References		Literature reference list
Additional information		Header 1
Additional information	Overall summary of the main conclusions for the substance or mixture can be entered here	Rich text area

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

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		
Name	**Instructions**	**Type**
Administrative data		Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	Confidentiality
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
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
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
		Rich text area
Step 1: Exclusion of degradation products of no concern	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.	Header 2
		Rich text area

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
		Rich text area
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 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.	Header 2
		Rich text area
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 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.	Header 2
		Rich text area

Stage 3 of Step 3: Screening for toxicity	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.	Header 2
		Rich text area
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
		Rich text area
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/L12 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
		Rich text area
Additional information	Follow instructions reported in "Discussion (Header 1) – common block" Provide additional information related to the endpoint, for example: - 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
	Provide any additional information related to the endpoint.	Rich text area

Attached background material		Repeatable block
Attached confidential document	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. Provide any additional documents relevant for the submission, not already provided under the methods or results section or in the full study report. Examples are: - 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 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.	Single file attachment
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. 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
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

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.11)

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		
Name	**Instructions**	**Type**
Administrative data		Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	Confidentiality
ED assessment		Header 1
Assessment of ED for humans (T-modality)		Header 2
Assessment of the lines of evidence		Header 3

Have T-mediated parameters been sufficiently investigated?	Provide an assessment for the following information by specifying if the T-mediated adversity in humans has been sufficiently investigated (or not) and the rationale	Closed list with remarks
Lines of evidence for adverse effects	List the relevant lines of evidence for adversity (also using a tabular representation). Example: WoE for T-mediated adversity • 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 (l**ikely lead toxic effect**)	Rich text area
Lines of evidence for endocrine activity	List the relevant lines of evidence for endocrine activity (also using a tabular representation). Example: WoE for T-mediated endocrine activity • 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.	Rich text area

<table>
<tr><td></td><td>

- Increase at week 16 only in TSH (measured in rat and mouse) were observed in mouse.

</td><td></td></tr>
<tr><td>WoE for adversity and endocrine activity</td><td>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.</td><td>Text area</td></tr>
<tr><td>Has endocrine activity been sufficiently investigated?</td><td>Provide an assessment for the following information by specifying if the T-mediated endocrine activity in humans has been sufficiently investigated (or not) and the rationale.</td><td>Closed list with remarks</td></tr>
<tr><td>Selection of relevant scenario</td><td>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.

Under the conditions as specified above, the selection of scenario 2(iii) is not applicable.

Selection of relevant scenario
<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>
</table>
</td><td>Closed list with remarks</td></tr>
</table>

	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. 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." 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'.				Header 3
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'.				
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
Event type	Indicate the event type e.g. MIE, KE1, KE2, KEn, …, AO.				Multi-line text
Event description	Description of the event e.g. TSH; increased or Nuclear receptor activation (liver).				Multi-line text
Supporting evidence	Supporting evidence at the Lowest Observable Adverse Effect Level e.g. One-generation study (64.6 mg/kg/day in dam).				Multi-line text

<table>
<tr><td>Link to relevant study records</td><td>Link to the reference entity for the supporting evidence.</td><td>Literature reference list</td></tr>
<tr><td>Postulated MoA</td><td></td><td></td></tr>
<tr><td>Empirical support</td><td>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
<table>
<tr><th></th><th>MIE CAR-PXR activation</th><th>KE1 Phase I /Phase II catabolic activation</th><th>KE2 ↓serum concentration of T4</th><th>KE 3 ↑ 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></td><td>Rich text area</td></tr>
<tr><td>Conclusion on MoA analysis</td><td>The conclusion of the MoA analysis should be presented in a tabular form.
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.</td><td>Rich text area</td></tr>
</table>

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	String, 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

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	
Identified uncertainties	Describe each uncertainty related to the both MoA analysis and assessment of the lines of evidence.	Text area
Justification	Characterize the overall impact of the source of uncertainty on the assessment conclusion	Text area
Uncertainty analysis		
Assessment of ED for humans (EAS-modality)		Header 2
Assessment of the lines of evidence		Header 3
Have EAS-mediated parameters been sufficiently investigated?	Provide an assessment for the following information by specifying if the EAS-mediated adversity in humans has been sufficiently investigated (or not) and the rationale	Closed list with remarks
Lines of evidence for adverse effects	List the relevant lines of evidence for adversity (also using a tabular representation). Example: WoE for EAS-mediated adversity • 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.	Rich text area

	• 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.	
Lines of evidence for endocrine activity	List the relevant lines of evidence for endocrine activity (also using a tabular representation). Example: WoE for EAS-mediated endocrine activity • Several *in vitro* assays providing evidence indicative of anti-androgenic activity. • 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.	Rich text area
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
Has endocrine activity been sufficiently investigated?	Provide an assessment for the following information by specifying if the EAS-mediated endocrine activity in humans has been sufficiently investigated (or not) and the rationale.	Closed list with remarks
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. Under the conditions as specified above, the selection of scenario 2(iii) is not applicable.	Closed list with remarks

Selection of relevant scenario

Example: Selection of relevant scenario

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

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." 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'.	
MoA analysis	The following fields should be completed only for scenarios 1b, 2a(i) and 2b. 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." 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'.	Header 3
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.	
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
Event type	Indicate the event type e.g. MIE, KE1, KE2, KEn, …, AO.	Multi-line text
Event description	Description of the event e.g. LH; increased or Leydig cells hyperplasia	Multi-line text
Supporting evidence	Supporting evidence at the Lowest Observable Adverse Effect Level e.g. One-generation study (64.6 mg/kg/day in dam).	Multi-line text
Link to relevant study records	Link to the reference entity for the supporting evidence.	Literature reference list
Postulated MoA		

Empirical support

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

	MIE	**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/kg bw per day (rat)					117 weeks ++	117 weeks ++
23 mg/kg bw per day (rat)					24-52 weeks +	
31.26 mg/kg bw per day (rat)					26 weeks +	26 weeks +
100 mg/kg bw per day (rat)		13 weeks ++		13 weeks ++		
200 mg/kg bw per day (rat)			2 weeks ++			

Rich text area

<table>
<tr><td></td><td></td><td></td></tr>
<tr><td>Conclusion on MoA analysis</td><td>The conclusion of the MoA analysis should be presented in a tabular form.
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

<table>
<tr><td></td><td>MIE to KE1
Androgen receptor to decreased testosterone</td><td>KE1 to KE2
Decreased testosterone to increased LH</td><td>KE2 to KE3/4
Increased LH to
Leydig cell hyperplasia</td><td>KE4 to AO
Leydig tumors</td></tr>
<tr><td>Biological plausibility</td><td>STRONG: well documented that anti-androgenic activity leads to ↓ testosterone</td><td>STRONG: ↓ testosterone induces negative feedback to hypothalamus to ↑ LH production</td><td>STRONG: LH induces Leydig cells to produce Testosterone. This over time can lead to hyperplasia</td><td>STRONG: It is known that a continuum exists between epithelial cell hyperplasia and tumors</td></tr>
<tr><td>Empirical support</td><td colspan="2">WEAK:
Dose and time concordance were compromised by the dose selection and study design (selected parameters, hormones, and length of the study)</td><td></td><td>STRONG: dose and temporal concordance observed in several rat studies</td></tr>
<tr><td>Essentiality</td><td colspan="4">No data</td></tr>
<tr><td>Consistency</td><td colspan="4">Particularly Leyding cells hyperplasia and tumors have been observed in several studies. Also AR</td></tr>
</table>
</td><td>Rich text area</td></tr>
</table>

		anti-androgenic activity supported by several *in vitro* 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
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		
Identified uncertainties	Describe each uncertainty related to both MoA analysis and assessment of the lines of evidence.		Text area
Justification	Characterize the overall impact of the source of uncertainty on the assessment conclusion		Text area
Uncertainty analysis			
Assessment of ED for non-target organisms (T-modality)			Header 2
Assessment of the lines of evidence			Header 3
Have T-mediated parameters been sufficiently investigated?	Provide an assessment for the following information by specifying if the T-mediated adversity in non-target organisms has been sufficiently investigated (or not) and the rationale.		Closed list with remarks

<table>
<tr><td>Lines of evidence for adverse effects</td><td>List the relevant lines of evidence for adversity (also using a tabular representation).</td><td>Rich text area</td></tr>
<tr><td>Lines of evidence for endocrine activity</td><td>List the relevant lines of evidence for endocrine activity (also using a tabular representation).</td><td>Rich text area</td></tr>
<tr><td>WoE for adversity and endocrine activity</td><td>Based on the lines of evidence presented above, the overall WoE for adversity and endocrine activity should be reported. This is needed to the select the relevant scenario and to decide if it is possible to conclude without performing a MoA analysis.</td><td>Text area</td></tr>
<tr><td>Has endocrine activity been sufficiently investigated?</td><td>Provide an assessment for the following information by specifying if the T-mediated endocrine activity in non-target organisms has been sufficiently investigated (or not) and the rationale.</td><td>Closed list with remarks</td></tr>
<tr><td>Selection of relevant scenario</td><td>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.

Under the conditions as specified above, the selection of scenario 2(iii) is not applicable.

Example: Selection of relevant scenario
<table>
<tr><td>Adversity based on T-mediated parameters</td><td>Positive mechanistic OECD CF level 2/3 Test</td><td>Scenario</td><td>Next step of the assessment</td></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>
</table></td><td>Closed list with remarks</td></tr>
</table>

	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. 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." 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'.				Header 3
Postulated MoA	Based on the assessed lines of evidence described above, postulate the MoA. In case it is concluded that the available				

<table>
<tr><td></td><td>information is not sufficient to postulate the MoA, this conclusion should be reflected here.</td><td></td></tr>
<tr><td>Name of postulated MoA</td><td>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.
.</td><td>Multi-line text</td></tr>
<tr><td>Event type</td><td>Indicate the event type e.g. MIE, KE1, KE2, KEn, …, AO.</td><td>Multi-line text</td></tr>
<tr><td>Event description</td><td>Description of the event e.g. Change in Thyroid histopathology</td><td>Multi-line text</td></tr>
<tr><td>Supporting evidence</td><td>Supporting evidence at the Lowest Observable Adverse Effect Level e.g. Amphibian metamorphosis assay (AMA), 5 mg/l</td><td>Multi-line text</td></tr>
<tr><td>Link to relevant study records</td><td>Link to the reference entity for the supporting evidence.</td><td>Literature reference list</td></tr>
<tr><td>Postulated MoA</td><td></td><td></td></tr>
<tr><td>Empirical support</td><td>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

<table>
<tr><th></th><th>MIE
TPO inhibition</th><th>KE1
change in thyroid histopayhology</th><th></th><th></th><th></th><th>AO
Delayed development /time to metamorphosis</th></tr>
<tr><td>In vitro</td><td>+++</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><td></td></tr>
<tr><td>LAGDA</td><td></td><td>16 weeks +++ (interim sacrifice)</td><td></td><td></td><td></td><td>16 weeks+++ (interim sacrifice)</td></tr>
</table>
</td><td>Rich text area</td></tr>
</table>

<table>
<tr>
<td>Conclusion on MoA analysis</td>
<td>The conclusion of the MoA analysis should be presented in a tabular form.
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
<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="5">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</td></tr>
<tr><td>Analogy</td><td colspan="5">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="5">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>
</td>
<td>Rich text area</td>
</tr>
<tr>
<td>Uncertainty analysis</td>
<td></td>
<td>Header 3</td>
</tr>
</table>

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.	
Identified uncertainties	Describe each uncertainty related to both MoA analysis and assessment of the lines of evidence.	Text area
Justification	Characterize the overall impact of the source of uncertainty on the assessment conclusion	Text area
Uncertainty analysis		
Assessment of ED for non-target organisms (EAS-modality)		Header 2
Assessment of the lines of evidence		Header 3
Have EAS-mediated parameters been sufficiently investigated?	Provide an assessment for the following information by specifying if the EAS-mediated adversity in non-target organisms has been sufficiently investigated (or not) and the rationale	Closed list with remarks
Lines of evidence for adverse effects	List the relevant lines of evidence for adversity (also using a tabular representation).	Rich text area
Lines of evidence for endocrine activity	List the relevant lines of evidence for endocrine activity (also using a tabular representation).	Rich text area
WoE for adversity and	Based on the lines of evidence presented above, the overall WoE for adversity and endocrine activity should be reported. This is needed to the select the relevant scenario and to decide if it is possible to conclude without performing a MoA analysis.	Text area

<table>
<tr><td>endocrine activity</td><td></td><td></td></tr>
<tr><td>Has endocrine activity been sufficiently investigated?</td><td>Provide an assessment for the following information by specifying if the EAS-mediated endocrine activity in non-target organisms has been sufficiently investigated (or not) and the rationale.</td><td>Closed list with remarks</td></tr>
<tr><td>Selection of relevant scenario</td><td>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.

Under the conditions as specified above, the selection of scenario 2(iii) is not applicable.

Example: Selection of relevant scenario

<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</td></tr>
</table>
</td><td>Closed list with remarks</td></tr>
</table>

				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. 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." 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'.				Header 3
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. A tabular representation can also be reported here. If the postulated MoA is a non-EATS MoA, please indicate it after the name of the postulated MoA.				
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
Event type	Indicate the event type e.g. MIE, KE1, KE2, KEn, …, AO.				Multi-line text
Event description	Description of the event e.g. decrease in VTG level				Multi-line text

<table>
<tr><td>Supporting evidence</td><td>Supporting evidence at the Lowest Observable Adverse Effect Level e.g. FSTRA (Fish Short-term reproduction Assay) (0.5 mg/l)</td><td>Multi-line text</td></tr>
<tr><td>Link to relevant study records</td><td>Link to the reference entity for the supporting evidence.</td><td>Literature reference list</td></tr>
<tr><td>Postulated MoA</td><td></td><td></td></tr>
<tr><td>Empirical support</td><td>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
<table>
<tr><th></th><th>MIE</th><th>KE1
↓ estradiol level</th><th>KE2
↓ VTG level</th><th>KE3
change on gonad histopathology</th><th>AO↓ Fecundity</th><th></th></tr>
<tr><td>Aromatase inhibition in vitro (AC50=29.6µM)</td><td></td><td></td><td></td><td></td><td></td><td>Aromatase inhibition in vitro (AC50=29.6µM)</td></tr>
<tr><td>0.5 µg/l Fathead minnow</td><td></td><td>++ (3 weeks)</td><td>++ (3 weeks)</td><td></td><td>++ (3 weeks)</td><td>0.5 µg/l Fathead minnow</td></tr>
<tr><td>0.558 µg/l Fathead minnow</td><td></td><td></td><td>+ (36 weeks)</td><td>+ (36 weeks)</td><td>+ (36 weeks)</td><td>0.558 µg/l Fathead minnow</td></tr>
<tr><td>1 µg/l Fathead minnow</td><td></td><td></td><td>+ 3 weeks)</td><td></td><td>+ (3 weeks)</td><td>1 µg/l Fathead minnow</td></tr>
<tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
</table></td><td>Rich text area</td></tr>
<tr><td>Conclusion on MoA analysis</td><td>The conclusion of the MoA analysis should be presented in a tabular form.
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.</td><td>Rich text area</td></tr>
</table>

Example Summary of the MoA analysis

	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	STRONG – Although the decrease	MODERATE – histopathology	STRONG – fecundity was observed

		support 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.	in estradiol 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)	changes 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	at the 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
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	
Identified uncertainties	Describe each uncertainty related to both MoA analysis and assessment of the lines of evidence.	Text area
Justification	Characterize the overall impact of the source of uncertainty on the assessment conclusion	Text area
Uncertainty analysis		
Overall conclusion ED assessment	Report under this section whether the ED criteria are met according to Regulation EU 2018/605.	Header 1
Overall conclusion ED assessment for humans		Header 2
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.	Closed list with remarks
Overall conclusion ED assessment for non-target organisms		Header 2
If ED criteria are met for humans, is the	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. Provide the reasoning behind the conclusion.	Closed list with remarks

adverse effect identified relevant for wild mammals' population?		
Does the substance meet the ED criteria for wild mammals?	Is there a biologically plausible link between endocrine activity and observed adverse effect(s) that are relevant for wild animals? Provide the reasoning behind the conclusion.	Closed list with remarks
Does the substance meet the ED criteria for non-target organisms other than wild mammals?	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? Provide the reasoning behind the conclusion.	Closed list with remarks
Additional information	Follow instructions reported in "Discussion (Header 1) – common block" Provide any additional information to support this assessment of endocrine disrupting properties Upload the Excel file, in the format for reporting the available information specified in the guidance (this excel file with be published). Appendix E.1 to the Guidance (https://doi.org/10.2903/j.efsa.2018.5311 If required, public (non-confidential) versions of other relevant documents can be attached.	Header 1

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 disrupters. 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 and common blocks

Reference substance

Purpose

A 'Reference substance' entity enables you to store identification information on a given substance or a given constituent of a substance, such as chemical names (EC name, CAS name, IUPAC name, synonyms, etc.), identity codes (EC number, CAS number), molecular and structural information.

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.

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
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see "Confidentiality of dossiers submitted via IUCLID - practical instructions for applicant". **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.	Confidentiality
Reference substance name	Indicate name of substance, microorganism, metabolite, residue, impurity or other substance included in the dossier. For the active substances the ISO common name or proposed ISO name should be reported.	Multi-line text
IUPAC name	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).	Multi-line text
Description	Specify any additional information relevant for the description of the reference substance in this field	Text template
Inventory		Header 1
Inventory number	This field can be used to select existing substances with pre-assigned EC numbers.	Entity reference list
No inventory information	Not relevant for EU PPP	Open list with remarks

available - Justification		
CAS number	Indicate CAS Registry Number	Text
CAS name	Indicate CAS name	Multi-line text
CIPAC number	Indicate CIPAC number	
Synonyms		Header 1
Synonyms	Provide in this table synonym identifiers of the reference substance, as appropriate. EFSA paramCode should be added in the table.	
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see "Confidentiality of dossiers submitted via IUCLID - practical instructions for applicant".	Confidentiality
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
Identity	Enter here the identity (name, number, code) corresponding to the identifier type selected.	Text area
Remarks	Provide additional information if relevant	Text
Molecular and structural information		Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see "Confidentiality of dossiers submitted via IUCLID - practical instructions for applicant".	Confidentiality
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
Molecular weight	Molecular weight should be reported as a single numeric value	Range (Decimal)
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
InChI	The IUPAC international chemical identifier https://cactus.nci.nih.gov or generated by ChemSketch or ChemDraw	Multi-line text
Structural formula	The structural formula for the active substance https://chem.nlm.nih.gov/chemidplus/structure3D/viewer/ ChemSketch, ChemDraw	Image
Remarks	Provide additional information if relevant. Such information may for example include an explanation to why molecular and structural	Text area

	information could not be provided due to the nature of the substance.	
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	
Structure file	Select file to be attached	Single file attachment
Remarks on structure file	Provide additional information if relevant.	Text
Related substances	Not relevant for EU PPP	Header 1
Identifier	Not relevant for EU PPP	Open list
Identity	Not relevant for EU PPP	Text area
Remarks	Not relevant for EU PPP	Text
Relation	Not relevant for EU PPP	Open list
Group / category information	Insert information about chemical groups and categories the substance belongs to.	Multi-line text

Links to support material:
CIPAC number: https://cipac.org/index.php/code-numbers/navigate-code-numbers

https://www.cas.org/support/documentation/chemical-substances

http://doi. paramCode - European Food Safety Authority. (2020). Harmonized terminology for scientific research [Data set]. Zenodo. org/10.5281/zenodo.3243215

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

Legal entity

Purpose

Submissions require a Legal entity which must 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.

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.

Note: information provided in the Legal Entity is published. Hence, no personal information relating to natural persons should be provided under these fields.

Note that 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.

Name	Instructions	Type
General information		Tab
Legal Entity name	Indicate name of the legal entity i.e. Company name	Text
Legal entity type	Select one legal entity type from the dropdown menu. If other, please include an explanation in the free text field below.	List (picklist)
Remarks	Add any additional information on the legal entity, if relevant	Text
Other names		**Block of fields (repeatable)**
Name	Other names can be specified and if needed these names can be marked as confidential	
Address		Header 1
	See Confidentiality Requests	Confidentiality
Address 1	Street address of the legal entity	Text
Address 2	Secondary address, if relevant	Text
Postal Code	Postal code of the legal entity	Text
Town	Town of the legal entity	Text
Region/State	Region/State of the legal entity	Text
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.	List (picklist)
Phone	Phone number of the legal entity (this field must not contain personal data, therefore e.g. the number of a switchboard should be provided)	Text
Fax	Fax number of the legal entity (this field must not contain personal data)	Text
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)	Text
Website	Legal entity website	Text
Legal entity 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.	Tab

	Click on New Item and set values. See Confidentiality Requests.	
Contact information	See instructions reported below under "Contact entity" common block	Tab

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

Note: contact entities must never be claimed confidential (using the confidentiality flags in the documents where they are referenced) because they are not published by default.

Name	Instructions	Type
General information		Header 1
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
Last name	Last name of the contact person. Note that this field is mandatory	Text
First name	First name of the contact person.	Text
Organisation	Name of the Organisation. Note that this field is mandatory	Text
Department	e.g. scientific department.	Text
Title	Title of the contact person (e.g. Mr.).	Text
Phone	Phone number of the contact person.	Text
Mobile	Mobile phone number of the contact person.	Text
Fax	Fax number of the contact person.	Text
Email	Email address of the contact person.	Text
Address 1	Street address of the contact person.	Text
Address 2	Secondary address, if relevant	Text
Postal code	Postal code of the street address of the contact person.	Text
Town	Town of the contact person.	Text
Region / state	Region/State of the contact person.	Text
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
Remarks	Any additional information, if relevant.	Text area

Literature reference

Purpose

The literature Reference entity should be used for storage of bibliographic metadata with attached documents including full study reports and published scientific papers and for linking studies to the Notification of Studies Database.
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).The literature Reference entity should always be linked in the "data source" section of Endpoint Study Records.

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
General information		Header 1
Reference Type	Select 'study report' for a full study report used as a data source for an endpoint study record. Select 'publication' for relevant studies identified from a literature search to address data requirements. Select 'other company data' to characterise any unpublished information from a company other than a study report. For any other select 'other:' and specify. **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 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)'.	Open list
Title	Report title of the study report, publication or other report type	Text
Author	Report author names for the study. These will be redacted from the published dossier for unpublished toxicology studies.	Multi-line text

Year	The year the report must be reported (this is used for sorting and filtering)	Integer
Bibliographic source	For published studies information on the journal and edition should be completed. This should include the DOI (Digital Object Identifier)	Text
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
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
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
Study sponsor	Information on the source of funding of the study can be provided	Text
Study number	Report the company identifier, if it differs from the laboratory report number	Text
Other study identifier(s)	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.	
Study ID type	For all studies carried out or commissioned after March 2021 for which the study notification requirement applies: - Select 'Notification of studies (NoS) ID and report the NoS ID in the 'Study ID' field below. For studies carried out or commissioned before March 2021 Select 'Notification of studies (NoS) ID and provide a justification for not providing a NoS ID in the 'Remarks' field e.g. "Study was commissioned before 27 March 2021". For rat/plant/livestock metabolism studies: - if a MSS/DER composer file is already available in the existing collections of maps (and therefore is not attached to 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 for the existing MSS/DER composer file, create an additional item and select "Master Record Identification (MRID)". - If a MSS/DER composer file is not available in the collection of maps and is submitted within the dossier, leave this field empty.	Open list
Study ID	Report the relevant identification number (e.g. the NoS ID generated from the NoS database).	Text

Remarks	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'.	Text area
Attachments		Header 1
Attachment type	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. For rat/plant/livestock metabolism studies: - if a MSS/DER composer file is newly created for this dossier (because it was not available in the existing collections of maps),.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, only the reference to the Individual MetaPath File Number (MAP-number) is required (cf. above instructions in "Other study identifier(s)").	Open list
Attached confidential document	If the applicant has selected the option "publication (copyright not owned for reproduction)" from the drop-down list pertaining to the field "GeneralInfo.ReferenceType", a full copy of the relevant publication in PDF format needs to be provided under the field "Attached confidential document". For the purposes of proactive publication, it is sufficient to provide the following bibliographic metadata in the literature reference entry enabling the retrieval of the published literature online: title, author, year and bibliographic source . No public version of the published literature must be provided. If the applicant has not selected the option "publication (copyright not owned for reproduction)" from the drop-down list pertaining to the field "GeneralInfo.ReferenceType",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	Single file attachment

	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. For rat/plant/livestock metabolism studies: - if a MSS/DER composer file is newly created for the dossier (because it was not available in the existing collections of maps) the newly created MSS/DER composer file should be attached here. - if a MSS/DER composer file is already available in the existing collections of maps it is not required to be attached here.	
Attached (sanitised) document for publication	The applicant has selected the option "publication (copyright not owned for reproduction)" from the drop-down list pertaining to the field "GeneralInfo.ReferenceType": 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. The applicant has not selected the option "publication (copyright not owned for reproduction)" from the drop-down list pertaining to the field "GeneralInfo.ReferenceType": 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. Other supporting documentation e.g. addendum can be uploaded. For rat/plant/livestock metabolism studies: - if a MSS/DER composer file is newly created for the dossier (because it was not available in the existing collections of maps) and confidentiality requests are made on the MSS.xml /DER.xml file (regarding confidential business information (CBI) or personal data (PD), a sanitised pdf version of the word report generated from the MSS/DER render function, where the items for which a confidentiality request has been submitted are blackened, must be attached here (in	Single file attachment

	case no confidentiality requests are submitted with regard to the MSS.xml /DER.xml file a pdf version without blackening for proactive publication must be attached here). if a MSS/DER composer file is already available in the existing collections of maps it is not required to be attached it here.	
Remarks	Additional remarks on the uploaded literature reference content can be added here. **Note**: if an applicant provides a sanitised/public attachment which contains personal data (and this is not an issue because the document is already publicly available), this should be mentioned in the Remarks field to avoid misunderstanding.	Text

Links to support material:

https://www.efsa.europa.eu/en/stakeholders/transparency-regulation-implementation

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) documen...
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

The Test material describes the identity of the material(s) used in a study. Each Test material entry consists of a Composition used to report the different constituents of the test material, plus additional details such as the test material form and purity. Note that the composition/purity refers to the concentration of the active substance in the plant protection product and not to the purity of the test material itself.

Test material must clearly identify the batches used as test material in the different studies included in the dossier and should be as detailed as possible. Providing accurate data for the Test material will give the evaluator an overview of which batches were used in the studies submitted in the dossier.

When carrying out toxicological, ecotoxicological, environmental and residue testing and assessment, the test material used should essentially be the same. In the case of studies in which dosing extends over a period of time (e.g. repeated dose studies), dosing shall be done using a single batch of active substance if the stability permits this. When tests are conducted using the purified active substance, the purity must be ≥ 980 g/kg of stated specification otherwise a justification must be provided if the degree of purity achieved is lower.

The test material of studies reported within the active substance dataset should have the reference substance of the active substance as a main constituent. Exceptions can be made e.g. in case of isomeric composition of the active substance.

For the product: a detailed description of the composition used shall be provided.

Name	Instructions	Type
Name	Indicate number of the batch	Multi-line text
Composition		Header 1
Type	Indicate for each component if it is a constituent, impurity or additive.	Closed list
Reference substance	Link to the reference substance for the component.	Entity reference field
Concentration	Indicate concentration of the component. For the chemical active substance and impurities this should be in g/kg.	Range with open list (Decimal)
Remarks	Specific remarks related to the concentration of the component can be reported in this field.	Multi-line text
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
Other characteristics		Header 2
Test material form	Select the form of the test material.	Open list with remarks (2000)
Details on test material	Provide the expiry date. Differences between non-radio labelled and radio labelled can be indicated in this field.	Text template

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

Links to support material:

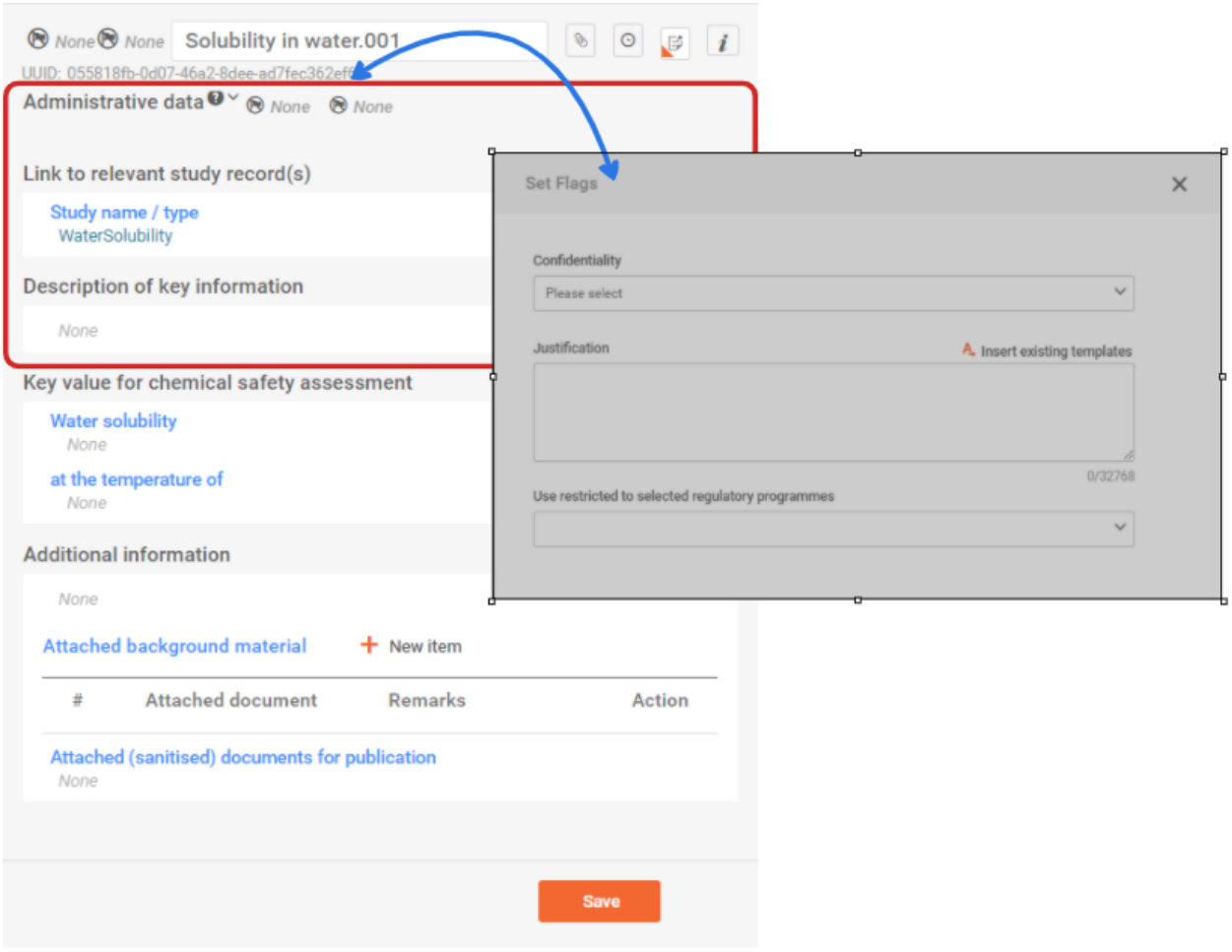
https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_guidance_equivalence-chem-substances_en.pdf

Template 1.1– Template for presentation the assessment for the equivalence of batches (https://doi.org/10.5281/zenodo.4557366)

Endpoint Summaries – Common blocks

Administrative data

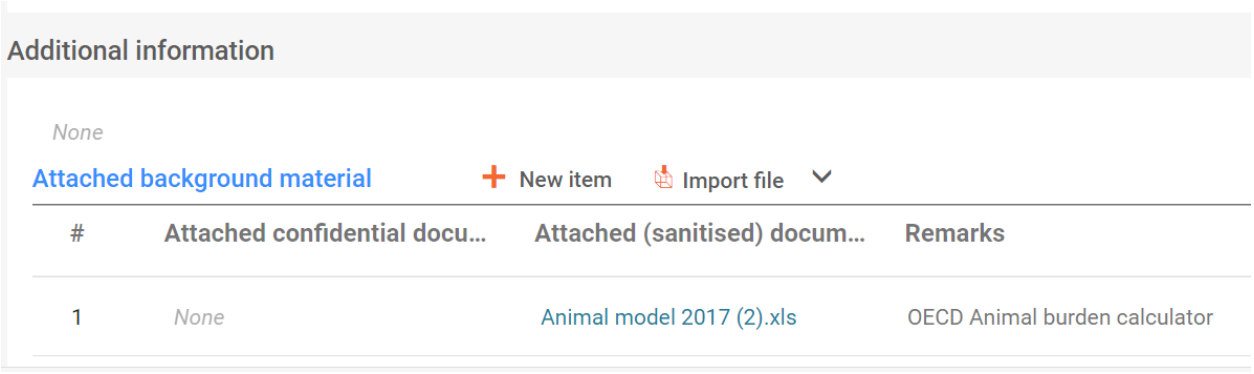
Name	Instructions	Type
Administrative data		Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page"	Confidentiality
Link to relevant study record(s)		Header 1
Link to relevant study record(s)	Provide here the link(s) to the study record(s) supporting the choice of the key value for assessment. The study(ies) giving rise to the highest concern should be chosen. The following factors, among others, should be taken into account when the study record is selected: quality of the study (e.g. Klimisch score), type of study (e.g. duration, experimental design, observed effects), whether or not the study is GLP. Please provide your rationale for the selection of the relevant study record in the field "Additional information".	Cross-reference: ENDPOINT_STUDY_RECORD.AnalyticalMethods
Description of key information		Header 1
	If all key information is provided in the linked study records, this field can be left empty. In case there is no linked study record, or in case you want to point to specific information in the linked study record, provide a summary of the key information related to the studies here. The summary could include, for example: - the test type - the test guideline used (and any deviations from it) - the test organism - the exposure duration - other contextual information on the origin of the key value	Rich text area



Additional information

Name	Instructions	Type
Additional information		Header 1
	Provide information related to the assessment of the endpoint, for example: - any endpoint specific information relevant for the interpretation of the results - the rationale for the choice of the key study(ies) and the choice for the key value that characterises the endpoint - information on the potential data gaps and the quality of the whole database for this endpoint - relevance of the results for the risk assessment (e.g. in case no effects have been observed at the limit dose) - the rationale for any user-derived values for the key result for assessment (for example, if a corrected value or a geometric mean is reported) - any additional information such as epidemiological data or higher tier testing (e.g. mesocosm studies or field studies) when relevant	Rich text area

	If there is no additional information to be reported, this field may be left empty.	
Attached background material		
Attached confidential document	Provide any additional documents relevant for the assessment of the endpoint, for example, a scientific publication. Provide the original version of any document that contains confidential material. .	Single file attachment
Attached (sanitised) documents for publication	If required, public (non-confidential) versions of other relevant documents can be attached. These attachments should be sanitised, if needed.	Single File Attachment
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
Attached background material		



Endpoint studies – Common blocks

Administrative data

Name	Instructions	Type
Administrative data		Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see "Confidentiality of dossiers submitted via IUCLID - practical instructions for applicant".	Confidentiality
Endpoint	From the picklist select the relevant endpoint addressed by this study summary. An endpoint must always be selected when entering data into an Endpoint Study Record. 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). Please note: For (Q)SAR studies, if an 'in silico' option does not exist, 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. 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.	Closed list with remarks
Type of information	Indicate 'experimental study' or 'read-across from similar mixture/product' or 'read-across from supporting substance (structural analogue or surrogate)' or 'read-across based on grouping of substances (category approach)' unless the information is retrieved from a literature search	Open list with remarks

	in this case indicate 'other': 'Study from literature search'.	
Adequacy of study	Indicate the purpose of the record selecting the adequacy in terms of usefulness for fulfilling the information requirements for the hazard/risk assessment. • 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 available to the applicant but is not taken into account because of lack of reliability or because the study is obsolete. • **Other information** is other available information which does not directly contribute to the conclusions for the setting the endpoint. 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. Where 'key study' or 'weight of evidence' is selected, the Validation assistant checks for document completeness.	Closed list
Robust study summary	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.	Check box
Used for classification	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'. If not relevant, disregard this field.	Check box
Used for SDS	Not relevant for EU-PPP	Check box
Study period: start date	Indicate the start date of the study. Note: for 'Notified' studies this should be after the date of notification.	Text
End date	Indicate the end date of the study	Text
Remark	Add remarks if relevant	Text
Reliability	The term reliability defines the inherent quality of a test report or publication.	Open list

	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). The "other:" option may be selected if this scoring system is not used. Studies indicated as key study must have a reliability score of 1 or 2. The validation check will verify consistency between 'Adequacy of study' field and 'Reliability' field (EU_PPP_007, EU_PPP_003). Further explanations on the reliability assessment can be provided in the 'Rationale for reliability incl. deficiencies' field. In terms of 'Acceptability / Reliability' Key studies and weight of evidence studies are considered to have 'Acceptability / Reliability' = Yes. A supporting study is considered to be 'Supportive only' The others are considered to have 'Acceptability / Reliability' = No.	
Rationale for reliability incl. deficiencies	Describe the rationale for the reliability score chosen considering the possible impact of deficiencies and/or implications on test results. 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. When assessing an older study against the current guideline, the current guideline can be specified in this field. Standard justifications from picklist may be sufficient in some cases. Otherwise select 'Other' and provide for additional explanation in the 'Remarks' field.	Open list with remarks (32000)
Data waiving	If no 'key study' or 'weight of evidence' study is provided for a data requirement, then data waiving must always be completed. The validation check will flag when this field must be completed (EU_PPP_013). Select the reason for data waiving or other and provide a justification in 'Justification for data waiving' field.	Closed list
Justification for data waiving	In addition to the more generic justification selected in the preceding field 'Data waiving', it is possible to provide here a more detailed justification. 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'.	Multi select open list with remarks (32000)

	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).	
Justification for type of information	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. 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. Explanations: Option 1: Type 'Waiving of standard information': 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'. Option 2: Type 'Experimental study planned / Testing proposal': 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. Option 3: Type '(Q)SAR prediction': This freetext template can be used and modified as appropriate for providing a justification for the fitness-for-purpose of (Q)SAR results according to the assessment elements of the OECD (Q)SAR Assessment Framework. Option 4: Type 'Read-across (analogue)' and Option 5: Type 'Read-across (category)' This freetext template can be used and modified as appropriate for providing a justification for read-across, particularly if it is endpoint-specific. 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.	Text template
Attached justification		Header 2

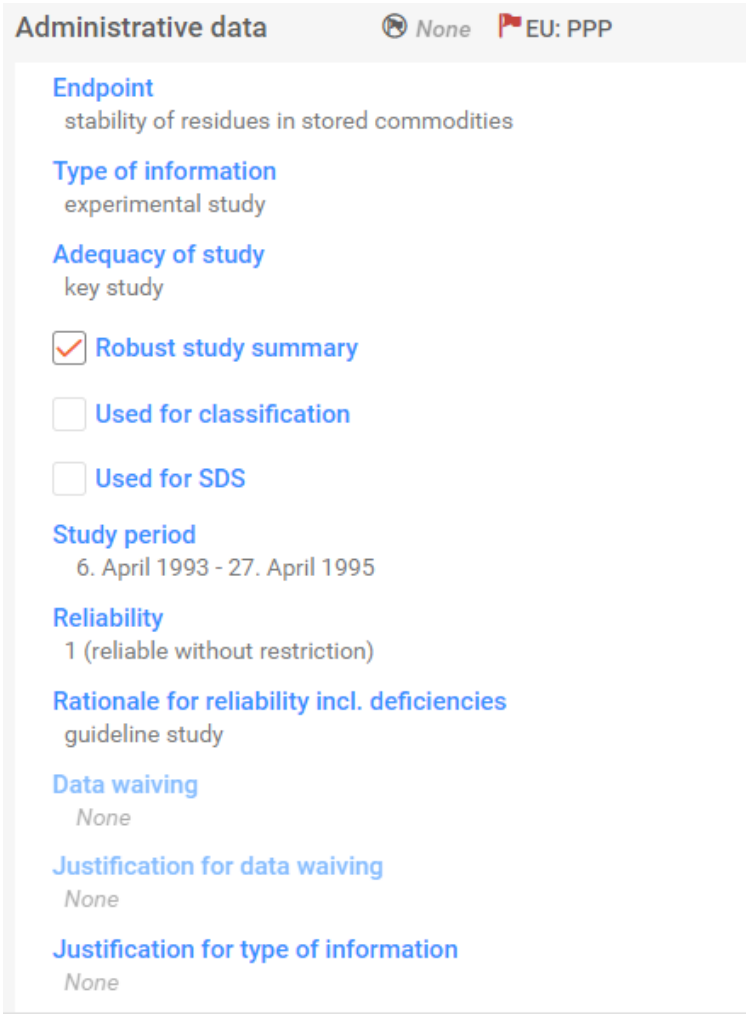
Attached justification	A document can be uploaded to support data waiving, but it is recommended to complete in full the data waiving fields. Upload file by clicking the upload icon.	Single file attachment
Reason / purpose	Indicate the reason for / purpose of the attached document. Select the relevant item from the picklist or, if none applies, select 'justification, other:' and specify.	Closed list with remarks
Cross-reference	In case the study has been reported for another data requirement use cross reference to link to the study to this section. The creation of duplicate versions of endpoint studies should be avoided. 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.	
Reason / purpose for cross-reference	Select the appropriate reason of the cross-reference, i.e. - adverse outcome pathway (AOP) (in case the 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 - 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) - defined approach for combining with results from another methods (in vitro, in chimico, in silico) - exposure-related information (for referring to a record containing exposure-related information that is used for instance to justify a data waiver) -method used in study - 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 (QMRF) (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	Open list with remarks

	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) -Weight of evidence source - other: (to be specified).	
Related information	As appropriate, select the record containing the related information, thus creating a link.	Endpoint reference field
Remarks	If relevant, add remarks	Text area

Links to support material:

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



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

Name	Instructions	Type
Data source		Header 1
Reference	Link to Literature reference Indicate the bibliographic reference of the study report or publication the study summary is based on. Provide general information such as the Title, Author, Year, Bibliographic source, Testing Facility, Report Number, Study number, Report date etc. as requested in the core template for literature search (https://www.oecd.org/ehs/templates/Generic%20elements%20for%20all%20OHTs.zip). Always enter the primary reference in the first block of fields or sort it to the first position, if there is 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 the publication(s) in addition to the reference of the original study.	Literature reference list

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
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 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, e.g. 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') Note that this field is always published so applicants are invited not to include any confidential data.	Closed list with remarks (2000)

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.

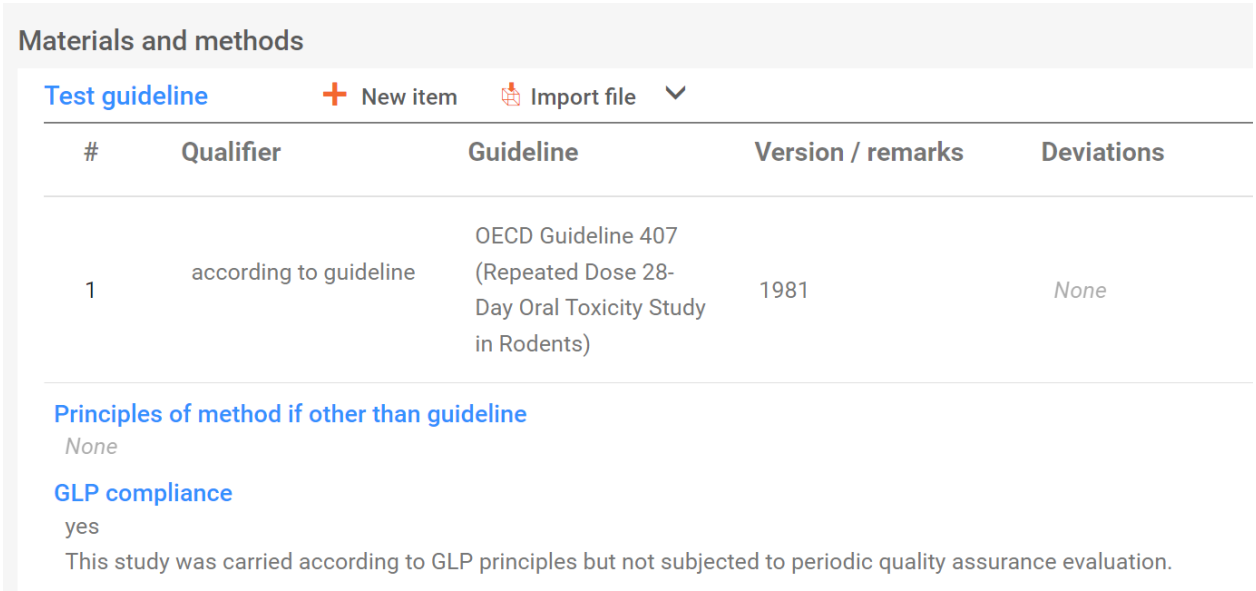
Material and methods

Name	Instructions	Type
Test guideline	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'. Copy this block of fields for specifying more than one guideline (e.g. US EPA in addition to OECD guideline).	Header
Qualifier	Select appropriate qualifier, i.e. - '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	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. Information on the version and date of the guideline used and/or any other specifics can be entered in the next field 'Version / remarks'. 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. 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'.	Open list
Version / remarks	In this text field, you can enter any remarks as applicable, particularly: - 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
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	Closed list with remarks (2000)

	duration'); details should be described in the respective fields of the section MATERIALS AND METHODS.	
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 the available pre-defined freetext template. 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 MATERIALS AND METHODS if available. Also provide a justification for using this method if appropriate.	Text template
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
Other quality assurance	Indicate any non-GLP quality assurance system adhered to, if any.	Open list with remarks
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

Links to support material:

GEP https://www.eppo.int/ACTIVITIES/plant_protection_products/gep



Test material

Name	Instructions
Test material	All Test Material (TM) batches should be entered in the TM entity manager and then the appropriate TM should be selected.
Test material information	Select the appropriate **Test material**
Additional test material information	Select additional Test material entities if relevant. For example, in long term studies where more than one batch of test material has been applied or there may be differences between the labelled and unlabelled test materials.
Specific details on test material used for the study	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 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, Pesticides NAFTA or EU REACH) thereof. If applicable, relevant available information on the following items should be given: SOURCE OF TEST MATERIAL - Source and lot/batch No. of test material - Expiration date of the lot/batch - Purity test date: provide if available RADIOLABELLING INFORMATION - Radiochemical purity - Specific activity - Locations of the label - Expiration date of radiochemical substance STABILITY AND STORAGE CONDITIONS OF TEST MATERIAL - 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 TREATMENT OF TEST MATERIAL PRIOR TO TESTING - 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)

	FORM AS APPLIED IN THE TEST (if different from that of starting material) 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. FORMULATED PRODUCT (for biocides/pesticides) 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. OTHER SPECIFICS Provide any other relevant information needed for characterising the tested material. Note: for (Q)SARs results, indicate the exact input structure and input parameters."
Specific details on test material used for the study (confidential)	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 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, Pesticides NAFTA or EU REACH) thereof. If applicable, relevant available information on the following items should be given: SOURCE OF TEST MATERIAL - Source and lot/batch No. of test material - Expiration date of the lot/batch - Purity test date: provide if available RADIOLABELLING INFORMATION - Radiochemical purity - Specific activity - Locations of the label - Expiration date of radiochemical substance STABILITY AND STORAGE CONDITIONS OF TEST MATERIAL - 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 TREATMENT OF TEST MATERIAL PRIOR TO TESTING - 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) FORM AS APPLIED IN THE TEST (if different from that of starting material) 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. FORMULATED PRODUCT (for biocides/pesticides) 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. OTHER SPECIFICS Provide any other relevant information needed for characterising the tested material. Note: for (Q)SARs results, indicate the exact input structure and input parameters.

Test animals

This block of fields is found in the following IUCLID documents:
Section 5.2.1 Acute toxicity oral
Section 5.2.2 Acute toxicity dermal
Section 5.2.4.1 Skin irritation
Section 5.2.7 Acute toxicity: other routes
Section 5.3.1 Repeated dose toxicity
Section 5.3.2 Repeated dose toxicity: inhalation
Section 5.3.3 Repeated dose toxicity: dermal
Section 5.3.4 Repeated dose toxicity: other routes
Section 5.4.2 Genotoxicity in vivo
Section 5.5 Carcinogenicity
Section 5.6 Reproductive toxicity
Section 5.6.1 Generational studies
Section 5.6.2 Developmental toxicity studies
Section 5.7 Neurotoxicity
Section 5.8.2.1 Immunotoxicity
Section 5.8.2.2 Toxic effect in livestock
Section 5.8.3 Endocrine disrupting properties

Name	**Instructions**
Test animals	
Species	Select species as appropriate. If not available from picklist, select 'other' and specify.
Strain	Select strain as appropriate. If not available from picklist, select 'other' and specify.
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.
Sex	Select as appropriate. If females were used, indicate in field "Details on test animals and environmental conditions" whether nulliparous and non-pregnant.

Details on test animals or test system and environmental 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. 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 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).

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

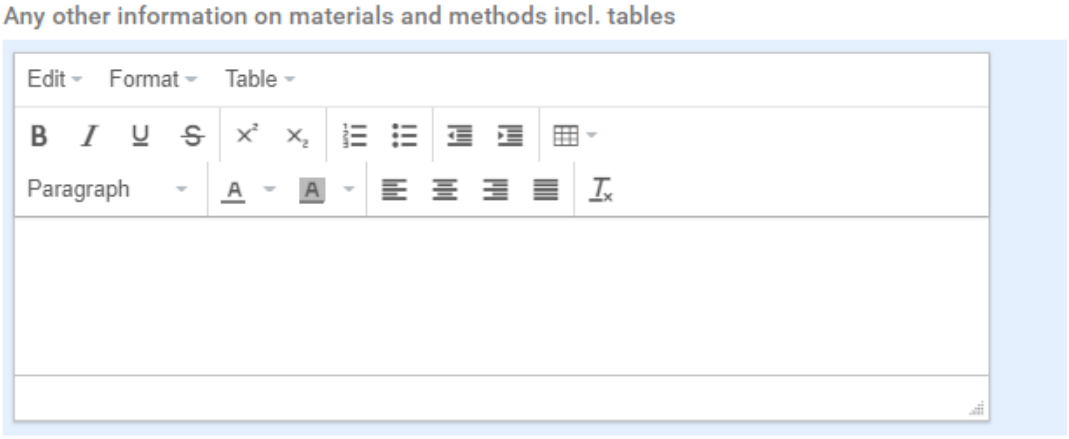
Model and software – common block

Model and software	Follow instructions reported in „Model and software" - common block. Note: This block of fields is displayed only when „Type of information" is set to (Q)SAR.	Header 2
Model name and version	Provide the name and version of the model used (e.g., ECOSAR v.1.0).	Text
Software name and version	Provide the name and version of the software used (e.g., OECD (Q)SAR Toolbox v.4.6).	Text
Remarks	Specify the exact model settings used to generate the (Q)SAR results. Indicate information on accessibility	Text

	of the models (e.g., how can the model be accessed, is the model freely or commercially available).	

Any other information on materials and methods incl. tables

Name	Instructions	Type
Any other information on materials and methods incl. tables		Header
	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 field



Additional information about applicability domain and reliability of (Q)SAR predictions – common block

Aged sorption EU-PPP

Magnitude of residues in processed commodities (OHT 85-9)

Name	Instructions	Type
Additional information about applicability domain and	Follow instructions reported in „Additional information about applicability domain and reliability of (Q)SAR predictions – common block“	Header 2

reliability of (Q)SAR predictions		
Fit with the applicability domain	Indicate if the structure fits with the applicability domain of the model as defined by the model developers.	Picklist with remarks
Justification for the fit with the applicability domain	Justify the assessment of the fit of the structure with the applicability domain. Indicate if there is any additional known limitation of the applied model, not included in the applicability domain definition, that may influence the reliability of the prediction.	Text (2,000 char.)
Fit with the space defined by the training set of the model	Indicate if the structure fits with the physicochemical, structural and response spaces defined by the training set of the model.	Picklist with remarks
Mechanistic and metabolic considerations	Indicate mechanistic and metabolic considerations relevant for the predictions, if applicable.	Text (2,000 char.)

Results of examinations

This block of fields is found in the following IUCLID documents:
Section 5.3.1 Repeated dose toxicity: oral
Section 5.3.2 Repeated dose toxicity: inhalation
Section 5.3.3 Repeated dose toxicity: dermal
Section 5.3.4 Repeated dose toxicity: other routes
Section 5.5 Carcinogenicity
Section 5.7 Neurotoxicity

Name	Instructions	Type
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
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
Dermal irritation (field available only for 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

Description (incidence and severity) (<u>field available only for dermal study</u>)	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
Mortality	Indicate whether mortality was observed and whether it was treatment-related or not.	Closed list
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
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
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
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
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

	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 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
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
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
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
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
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	Text area

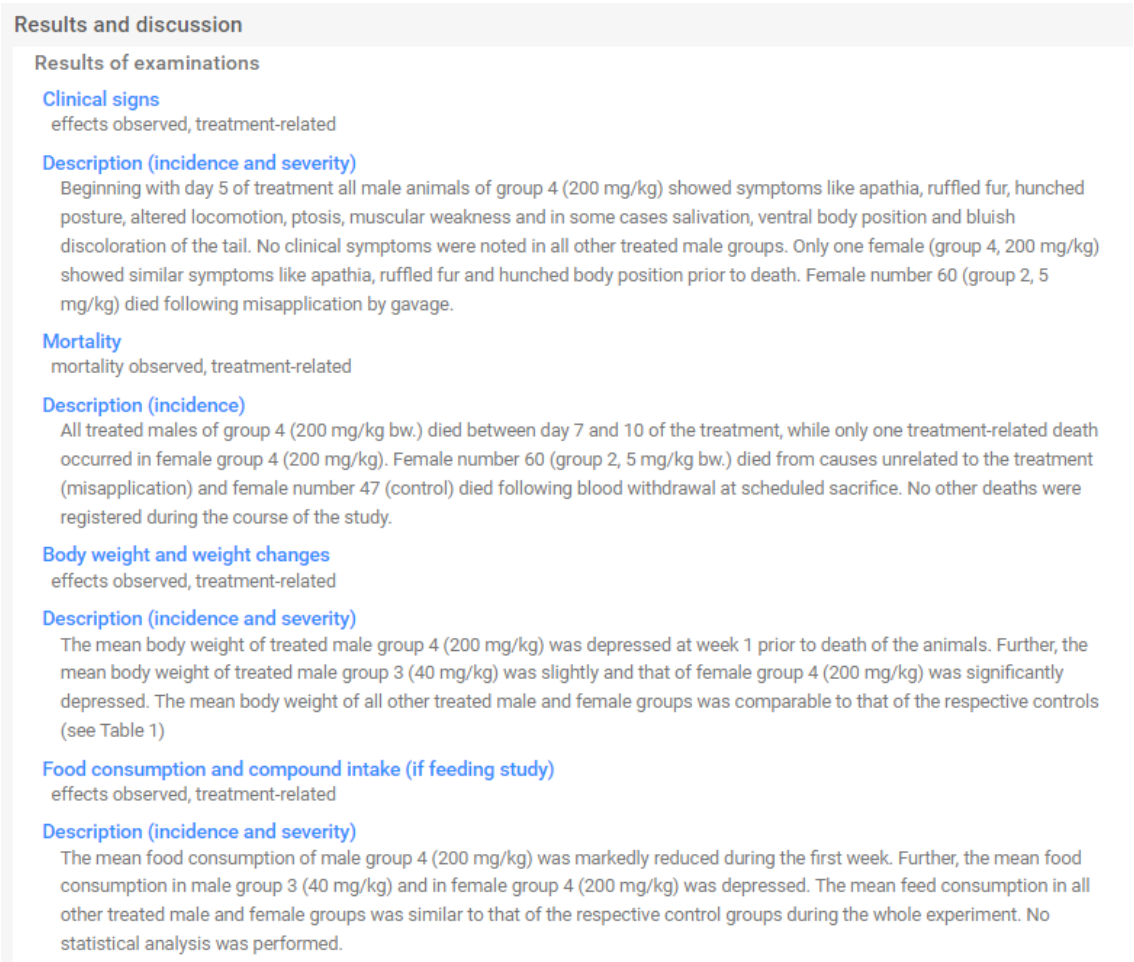
	results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	
Haematological 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
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
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
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
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
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	Text area

	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.	
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
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
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
Description (incidence and severity)	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 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
Immunological 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
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	Text area

	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.	
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
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
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
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
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
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	Text area

	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.	
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
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
Histopathological findings: 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
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
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
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	Text area

	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.	
Details on results	Provide any other relevant details if not entered in the specific "Description" fields for the examined parameters.	Text area


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

This block of fields is found in the following IUCLID documents:
Section 5.3.1 Repeated dose toxicity: oral
Section 5.3.2 Repeated dose toxicity: inhalation
Section 5.3.3 Repeated dose toxicity: dermal
Section 5.3.4 Repeated dose toxicity: other routes
Section 5.5 Carcinogenicity
Section 5.7 Neurotoxicity
Section 5.6 Reproductive toxicity

Section 5.6.2 Developmental toxicity studies
Section 5.9.4 Epidemiological data

Name	Instructions	Type
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
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'.	Closed list with remarks
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. The following units should only be used in the case of microbial active substances: - cells - CFU (colony-forming unit) - ITU (International Toxic Unit) - IU (International Unit) - OB (occlusion bodies) - spores	Range with closed list (Decimal)
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
Sex	Select from drop-down list.	Closed list
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)

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)

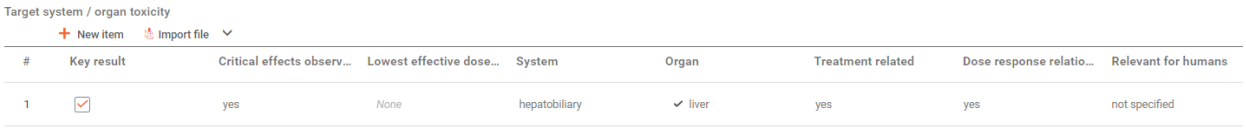
Target system/organ toxicity

This block of fields is found in the following IUCLID documents:
Section 5.3.1 Repeated dose toxicity: oral
Section 5.3.2 Repeated dose toxicity: inhalation
Section 5.3.3 Repeated dose toxicity: dermal
Section 5.3.4 Repeated dose toxicity: other routes
Section 5.5 Carcinogenicity
Section 5.7 Neurotoxicity
Section 5.9.4 Epidemiological data

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.

Name	Instructions	Type
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
Critical effects observed	Flag to indicate if critical effects were observed in the study within specific organs or systems.	Closed list
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)
System	Select any specific system where toxicity was observed that is considered of biological relevance.	Open list
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
Treatment related	Flag to indicate if the effects in systems and/or organs are treatment related.	Closed list
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

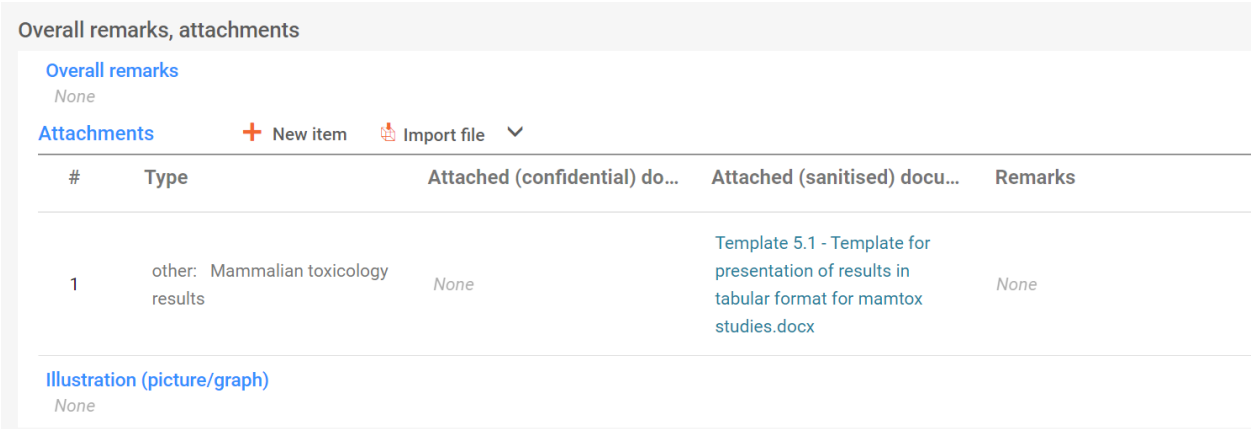
Relevant for humans	Flag to indicate if the effects observed and reported in systems and/or organs on the basis of animal experiments are also relevant for humans. Choose "no" from the picklist if the effects in target system/organ are species specific and not relevant for humans.	Closed list



Overall remarks, attachments

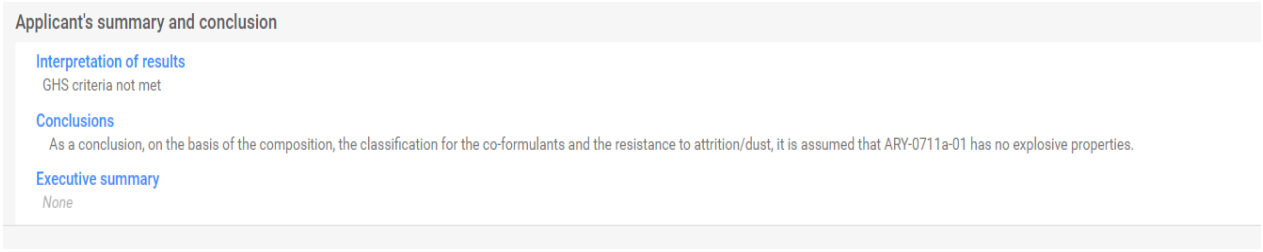
Name	Instructions	Type
Overall remarks, attachments		Header 1
Overall remarks	In this field, you can enter any overall remarks or transfer free text from other databases. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing document. Use this field only if strictly necessary i.e. when no other specific fields such as repeatable blocks exist in the document to enter the data of interest. 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
Attachments	Attach any background document that cannot be inserted in any rich text editor field, particularly image files. Copy this block of fields 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
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
Attached (sanitised)		Single File Attachment

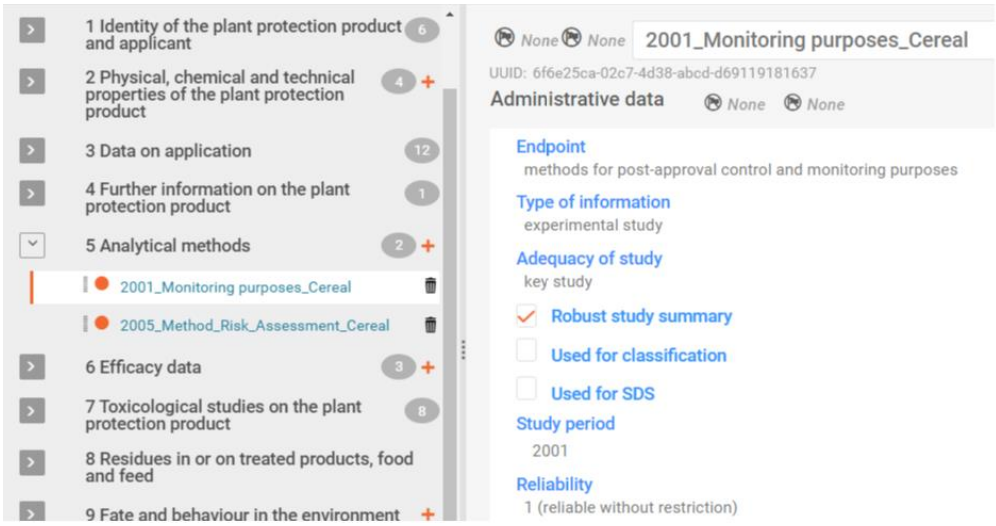
documents for publication	Provide any additional documents relevant for the submission, not already provided under the literature reference entity. For test guidelines that provide a reporting template (data analysis file), that file must be completed and can be uploaded here if not yet done in the results section. See IUCLID templates for PPP Risk Assessment Templates on EFSA Knowledge Junction (zenodo). 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. 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.	
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



Applicant's summary and conclusion

Name	Instructions	Type
Applicant's summary and conclusion		Header 1
Interpretation of results	This field is present ONLY in document 6.3 Magnitude of resdiues in plants" (OHT 85-5): Indicate overall interpretation of test results with regard to expected residues in crop commodities as given in the study report or as concluded by the submitter. You can give an explanation in the supplementary remarks field, e.g. for indicating at what plant back interval residues are taken up by rotational crop, i.e. in which crop fractions and at what levels, or for indicating if conclusions originally reported were changed by submitter. For more detailed discussion of test results, use field 'Conclusions'.	Closed list with remarks (2000)
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
Executive summary	If relevant for the respective regulatory programme, briefly summarize 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.	Rich text area




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
2001_Monitoring purposes_Cereal
2005_Method_Risk_Assessment_Cereal
6 Efficacy data
3
7 Toxicological studies on the plant protection product
8
8 Residues in or on treated products, food and feed
9 Fate and behaviour in the environment
None None
2001_Monitoring purposes_Cereal
UUID: 6f6e25ca-02c7-4d38-abcd-d69119181637
Administrative data
None None
Endpoint
methods for post-approval control and monitoring purposes
Type of information
experimental study
Adequacy of study
key study
Robust study summary
Used for classification
Used for SDS
Study period
2001
Reliability
1 (reliable without restriction)

-
-