IUCLID for applicants

This course is meant for :
-applicants submitting pesticide dossiers under Regulation (EC) No 1107/2009 concerning the placing of plant protection products and according to the new requirements of the Transparency Regulation;
- new active substances and renewals for chemicals and microorganism, MRL applications and basic substance applications

- Overview of ECHA Cloud Services
- Overview of IUCLID Cloud
- Creating a dossier
- Submitting a dossier

Lesson 1 of 4

Overview of ECHA Cloud Services

1. How to register for and access ECHA Cloud Services and the ECHA submission portal.
2. Understanding the Legal Entity's purpose and the importance of maintaining legal entities for companies submitting under different EU legislation.
3. How to use a Foreign entity when using regulatory affairs consultants or to prepare a joint submission.

1

Welcome to ECHA Cloud Services

Who are we?

ECHA Cloud Services is a secure online platform used to distribute ECHA's IT applications into a private cloud environment.

The service is built within ECHA's IT infrastructure. The use of encrypted communication, regular security audits and updates of all the components ensures that your cloud data is safe and cannot be accessed by anyone else.

Why should you use ECHA Cloud services?

ECHA Cloud services offer you:

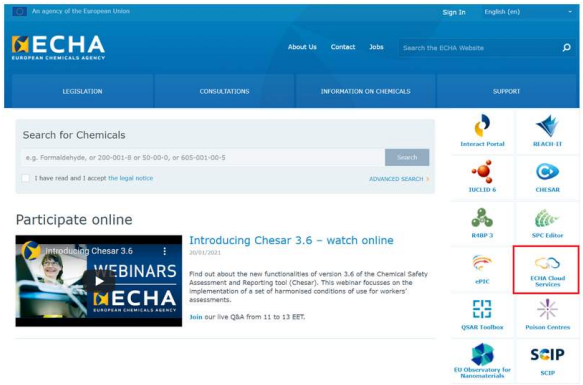
- Access from anywhere, anytime, to the latest release of the IUCLID application, maintained by ECHA;
- Regular and automated data backups by ECHA;
- Easy online collaboration. Companies can improve data security by reducing the number of local copies;
- Secure submission portal to submit EU_PPP applications to EFSA, EC and MS competent authorities
- Responsive and 24/7 online support.

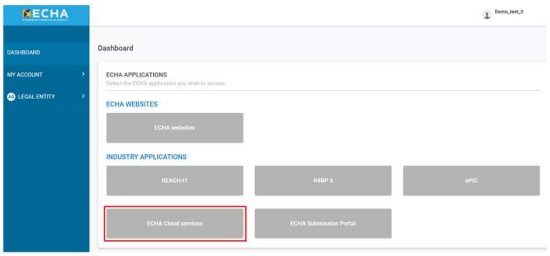
How to access ECHA Cloud Sevices

The following steps will guide you through the registration process to the ECHA account and through the subscription process to IUCLID Cloud Services, whether you already have an ECHA account or not.

Step 1

How to reach ECHA Cloud Services





ECHA Could Services are available directly for the main page of the ECHA website - https://echa.europa.eu/

To access it, click on the box highlighted above.

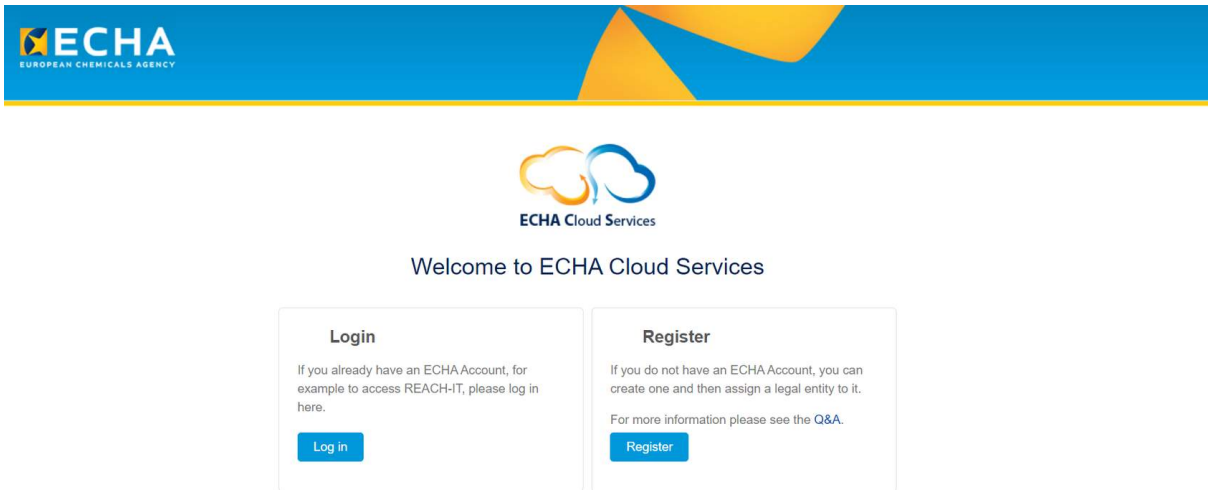
To access the cloud space, you need to **log in** using your ECHA Account credentials.

It is also possible to use a local version which can be downloaded from the link below :

https://iuclid6.echa.europa.eu/download

Step 2

How to access ECHA Cloud Services



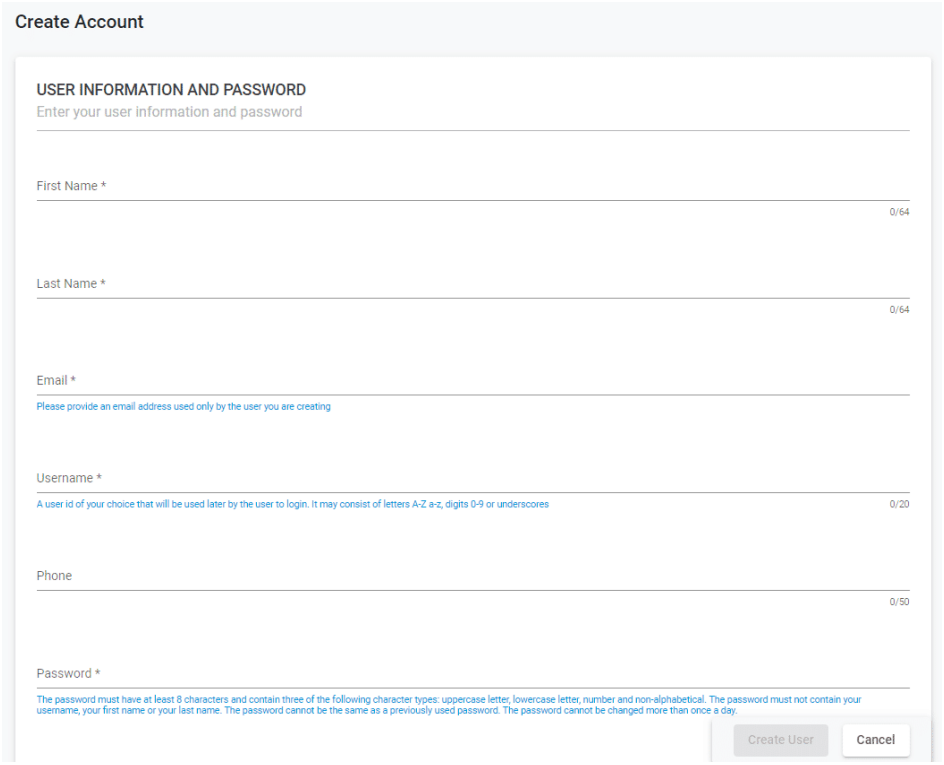
If you already have an **ECHA account,** you can directly login by entering your username & password.

Instead, if you do not have an ECHA account yet, you need t**o register** and create it first.

You would need **to create a user** and **provide information about your company.**

Step 3

How to register to ECHA Cloud Services



Fill in the form with basic user information and click on the registration **link sent via email.**

Click the links below to access the guided tutorials.

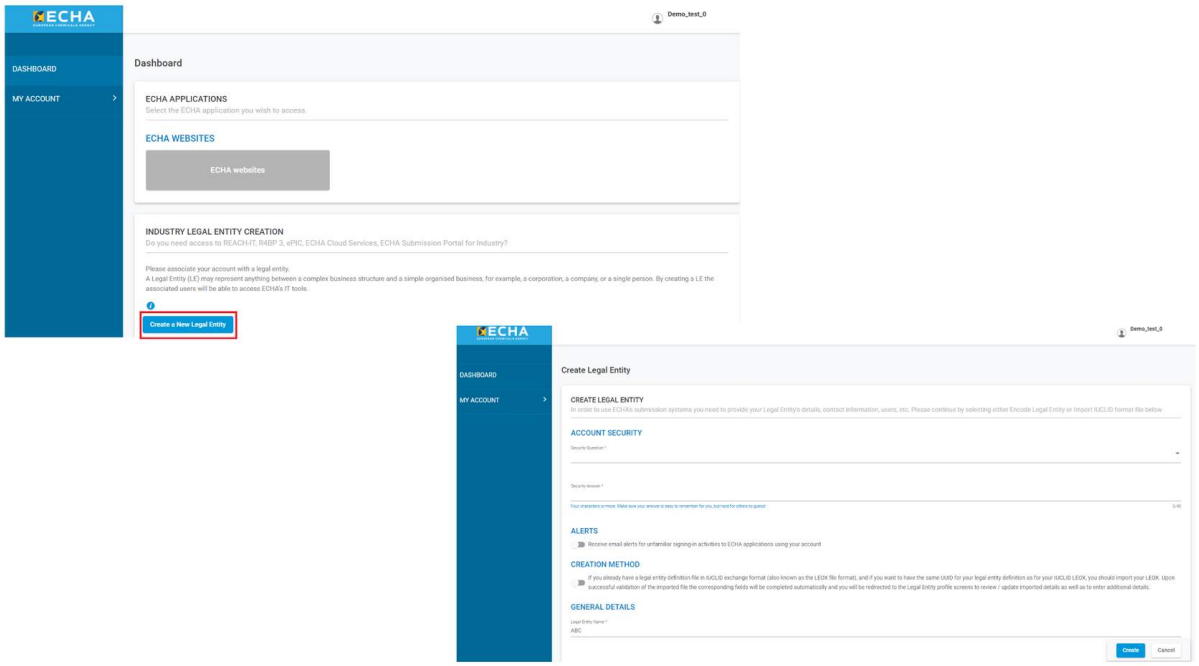
How to create a personal ECHA account

How to login and use the ECHA accounts dashboard

How to use the ECHA Accounts “Forgot Password” and “Forgot username” functionalities

Step 4

How to create a Legal entity



To use ECHA's submission tools, the user must provide the **Legal entity's details** and then add other users from the same company.

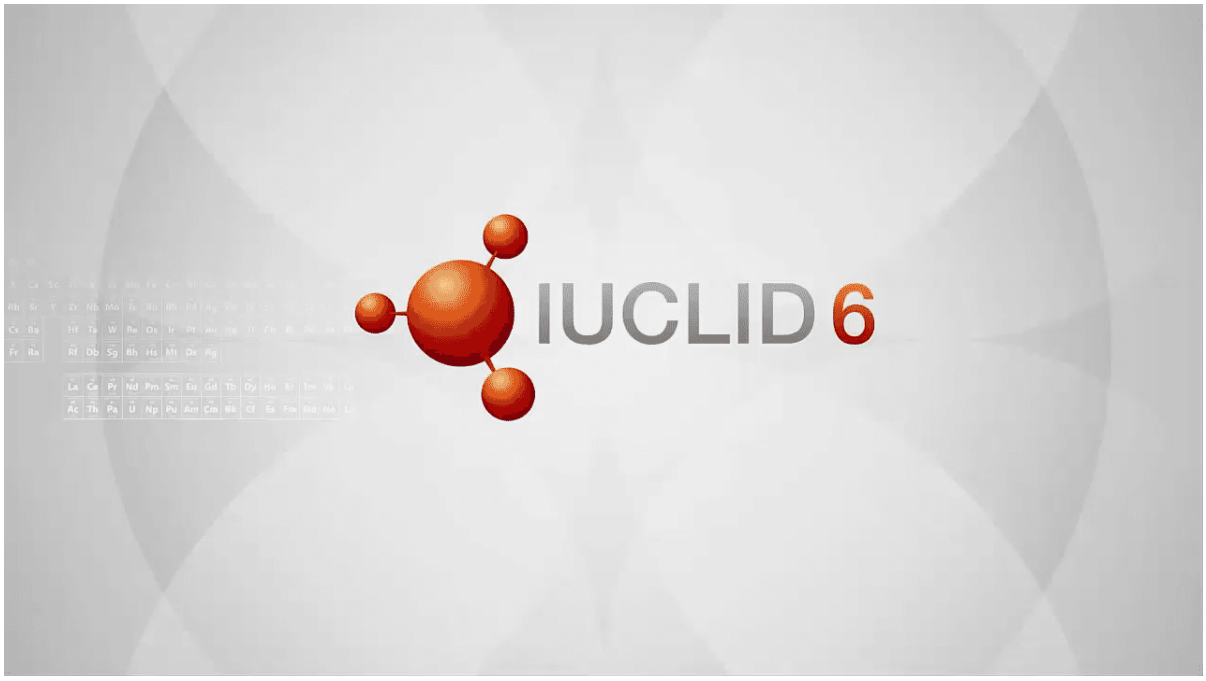
In case the company already has a legal entity, it can reuse it for EU_PPP submissions.

For more information, please read the ECHA Accounts Manual.

Click the link below to access the guided tutorial.

How to create a Legal Entity

Summary



For guided journey please watch the video.

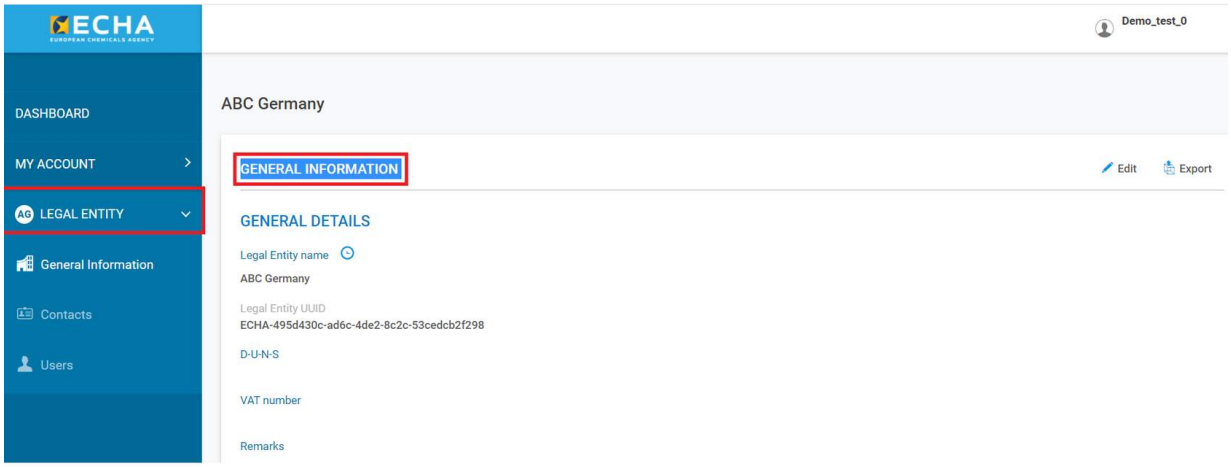
Understanding the purpose of a Legal entity

It is essential to properly manage your users' access rights for the IUCLID Cloud Service

- **A Legal entity is actually the organisation** (the submitting entity) for which the user is working. It is the dossier owner or leads applicant.

- In IUCLID, a Legal entity is used to store information about a party or person involved in a chemical substance, mixture, or product life-cycle. Can use a Legal entity to identify the party responsible for a certain activity, such as the manufacturing or importing of a mixture.

- Once the Legal entity has been created, it is important to maintain **accurate Legal entity information** and **keep them up to date**, especially for companies performing business in **different countries** and operating under **different EU legislation**.

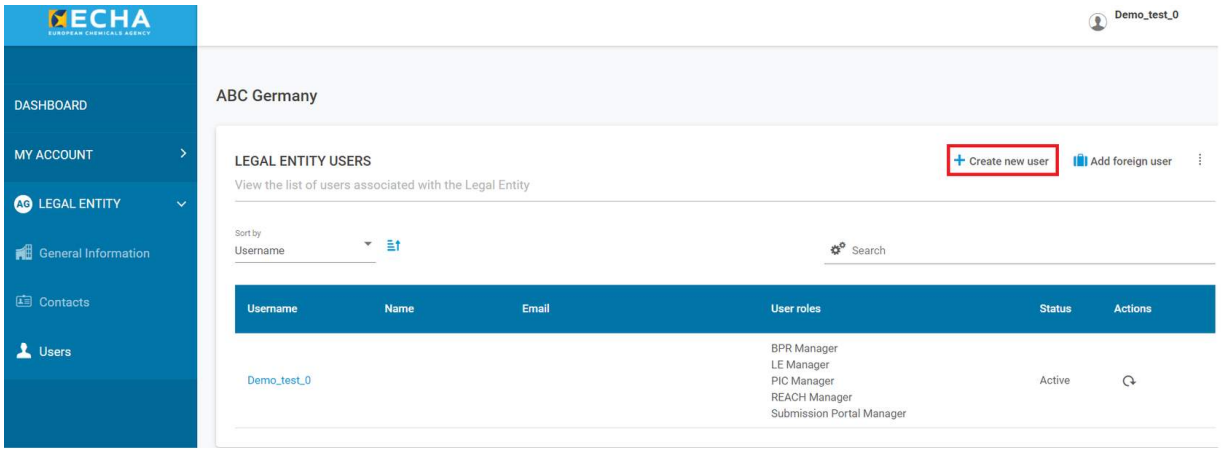


How to add new users

If you wish that other persons in your organisation have access to ECHA Cloud Services, you can **add new users** under your existing ECHA account.

The cloud bar (on the top of the screen) contains a menu with several functionalities, including **MANAGE ACCOUNT**! This is where you can manage all information regarding your Legal entity account.

From here, you can **add new users, edit users' account details and assign specific roles** to them.
*Note: to add a user, the person must already have an **ECHA account**.*



Click the link below to access the guided tutorial.

How to create users in a Legal Entity (company) as a Legal Entity Manager

3

How to add a foreign entity

If you want to work with people from other organisations (and different legal entities), you add them as foreign entities

- If you have an IUCLID account and want others to contribute, or don't have the data, or you want to assign a task to someone else, you may add **a foreign user from a 3rd party or a consultant.**

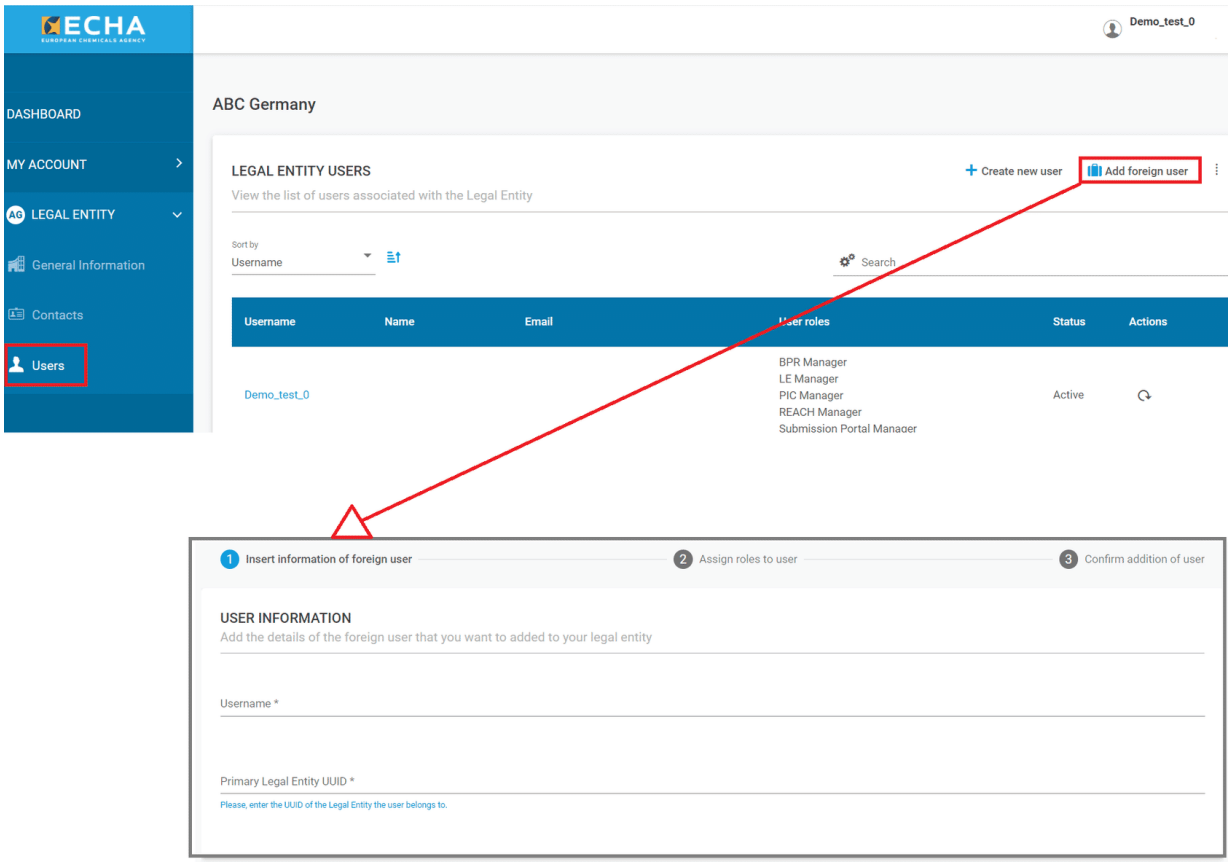
- A Legal Entity manager can assign roles and give permissions to a third-party organisation in case there is ongoing a **joint submission**

Adding a foreign entity

The cloud bar (on the top of the screen) contains a menu with several functionalities, including **MANAGE ACCOUNT**!

From here, you can **add a foreign entity, edit entities' account details** and **assign specific roles** to them.

*Note: to add a user, the person must already have an **ECHA account**.*

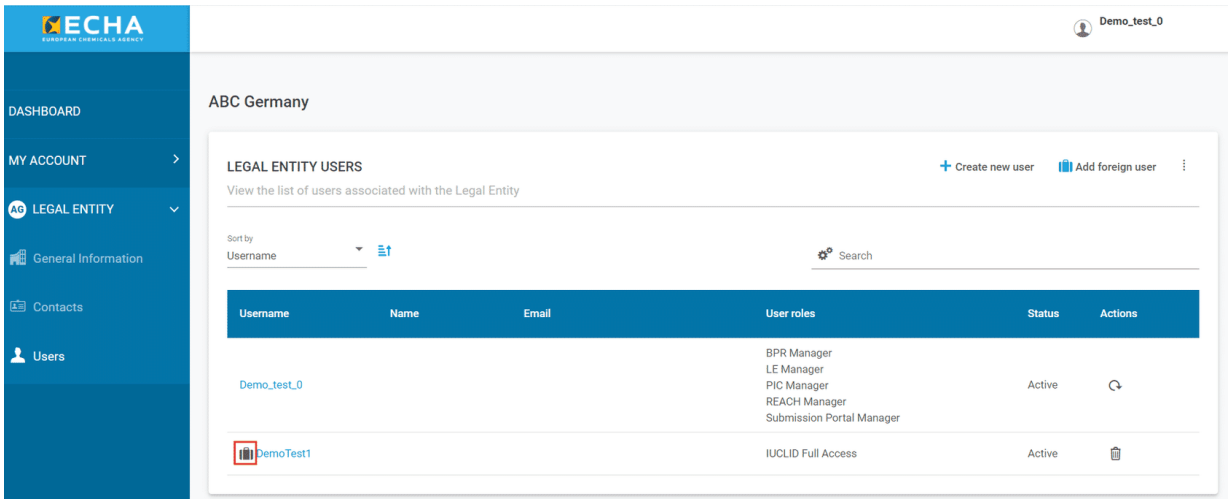


Click the link below to access the guided tutorial.

[How to assign roles and include a foreign account to a legal entity]

A foreign user can perform actions on behalf of the company that permits him to use an account from their own ECHA account.

The foreign users are easily noted in the legal entity user list - ' the suitcase' icon indicates a foreign user.


ECHA
EUROPEAN CHEMICALS AGENCY
Demo_test_0
DASHBOARD
MY ACCOUNT
AG LEGAL ENTITY
General Information
Contacts
Users
ABC Germany
LEGAL ENTITY USERS
View the list of users associated with the Legal Entity
Create new user
Add foreign user
Sort by
Username
Search
Username
Name
Email
User roles
Status
Actions
Demo_test_0
BPR Manager
LE Manager
PIC Manager
REACH Manager
Submission Portal Manager
Active
DemoTest1
IUCLID Full Access
Active

Overview of IUCLID Cloud

Objectives

Throughout this module, you will get familiar with the following concepts:

1. How to register for and access IUCLID Cloud Service
2. Which are the key concepts of an IUCLID dossier

1

Welcome to IUCLID Could Services

What is IUCLID?

IUCLID (International Uniform Chemical Information Database) is the software to record, store, maintain and exchange data on chemical substances' intrinsic and hazard properties. It is a key software application for regulatory bodies and the chemical industry used in the implementation of various regulatory programmes.

What is IUCLID used for?

IUCLID is built as a platform meant to provide regulatory authorities and industry with tools to manage information on chemicals, using a common format, facilitating the reuse and exchange of the data.

IUCLID distribution

There are different ways of distributing IUCLID.

Note! Regardless of the application chosen, the interface is the same.

DESKTOP: for a single user, on his/her own computer
https://iuclid6.echa.europa.eu/download

SERVER: hosted on a server, shared with multiple users
https://iuclid6.echa.europa.eu/download

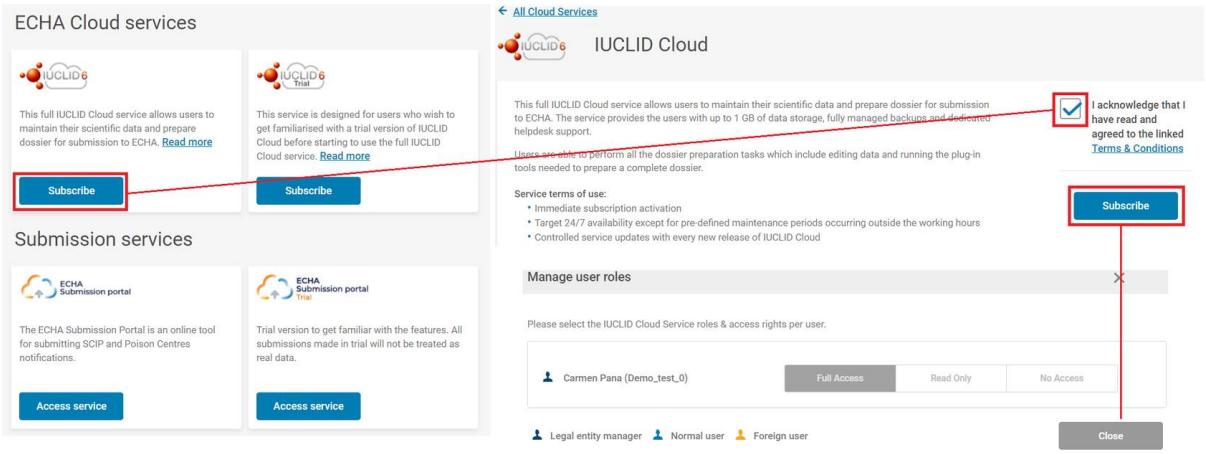
CLOUD: ECHA Cloud Services, hosted by ECHA. The current storage allocation for IUCLID cloud services is 5GB per instance.

How to access IUCLID Cloud services

Before you start working with IUCLID, it is important that you get familiar with how the **application** information is structured

Step 1

Subscription



After accessing the ECHA Cloud platform, you can now **subscribe** to the cloud services made available by ECHA.

To access **IUCLID Cloud Services,** the user has first to **subscribe** to it.

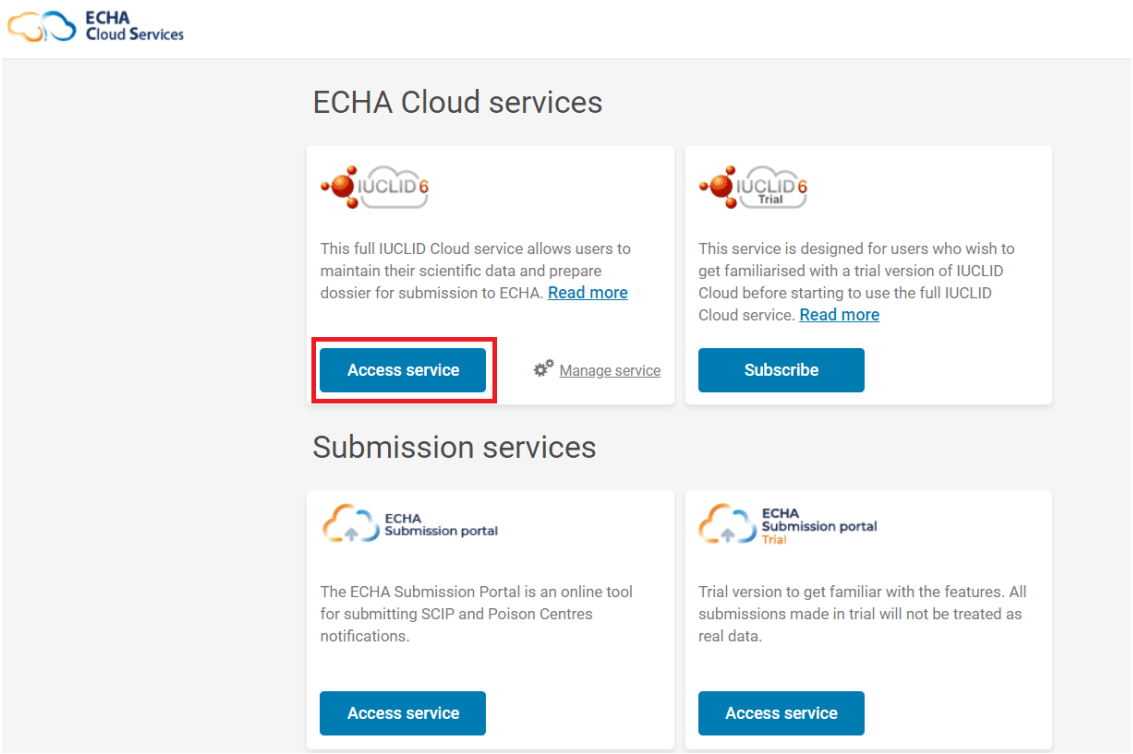
Remember to read and accept terms & conditions!

Once acknowledged, the subscription starts! … it will take a few minutes for the process to update the database.

After that, the services are ready to be accessed and used!

Step 2

Regular access



Once you have subscribed, you can access your cloud service at any time.

Key concepts of an IUCLID dossier

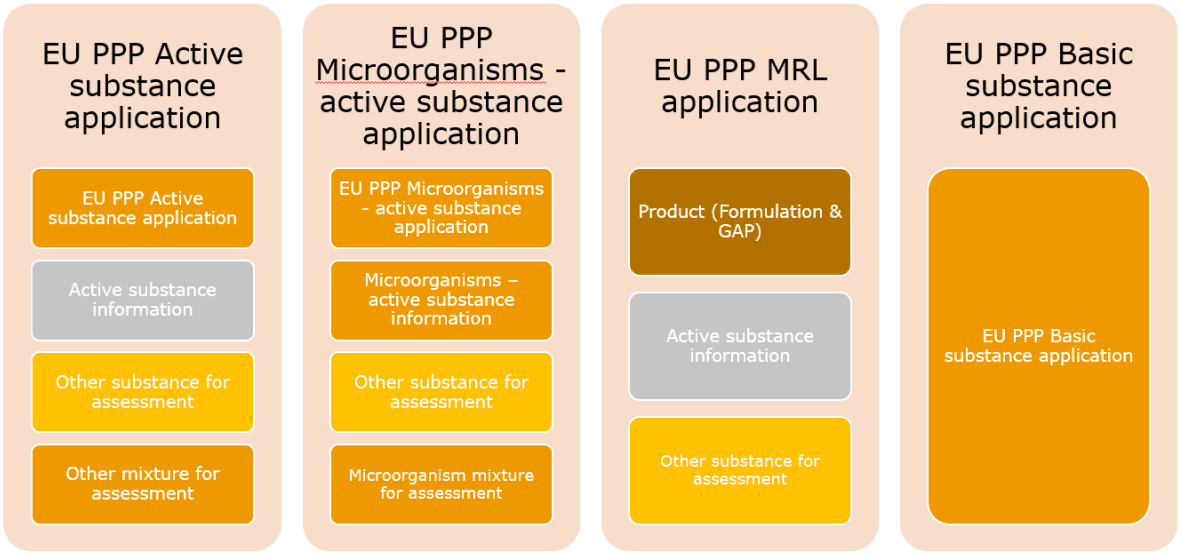
A **Dossier** is used to submit data to a regulatory authority to satisfy a legal obligation arising from legislation.

EU_PPP Dossiers are created from a Mixture/Product dataset and can contain one of more substance datasets.

A Dossier contains:

- a **read-only copy** of a **header** for storing administrative data,

- a **read-only copy** of a **product dataset**, an active substance dataset and, in some cases, other substance datasets (e.g. metabolite information).



What is a dataset?

A **dataset** is a **collection of documents** related to a particular chemical substance or grouping of chemical substances/micro-organism. It can be of the following types: Substance, Mixture/Product, Template.

A dataset represents the **raw format documents / set of data** still in an **editable version**.

All **EU PPP dossiers** start from a mixture of the dataset.

Mixture/Product dataset

A **Mixture/Product** is a type of entity in IUCLID **used to store information on a chemical substance/micro-organism** considered to be in a regulatory context, either a mixture, a product,

Active substance dataset

'Can link the **active substance dataset** to the Mixture/Product dataset by completing the Mixture/Composition document, which describes the formulation.

Fixed records

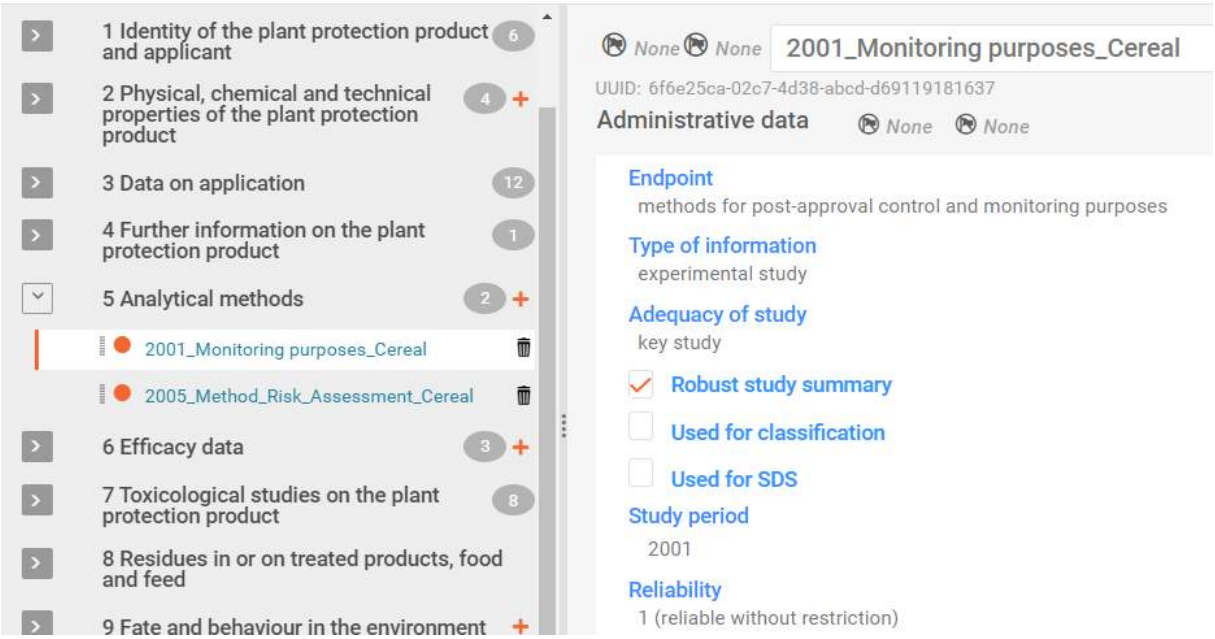
A **fixed record** is created in a section where there can be only one record.

Flexible Records

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

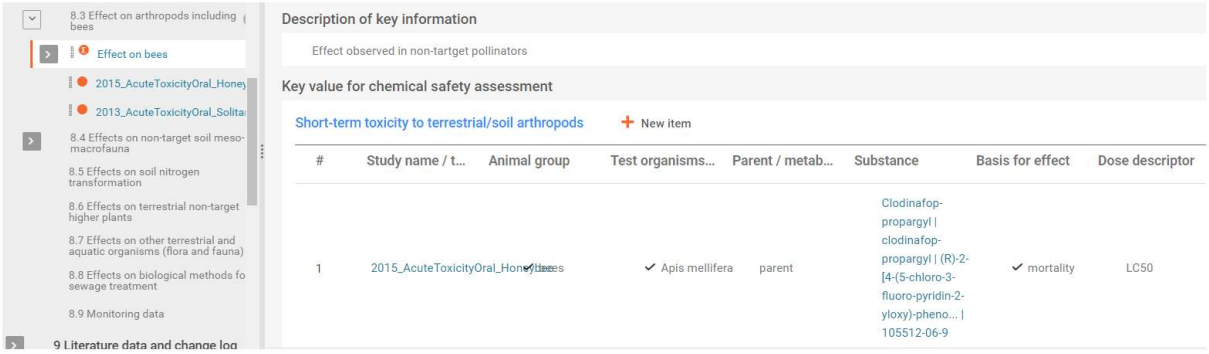
Endpoint Study Records

An **endpoint study record** provides a **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.
All entries under the OECD (https://www.oecd.org/ehs/templates/harmonised-templates.htm) are endpoint study records.



Endpoint Summaries

An **endpoint summary** presents the conclusion on the endpoint and key safety assessment values derived from the submitted endpoint study records.
An endpoint summary **contains links** to the endpoint study records in the field Link to relevant study records(s).



Which are IUCLID entities?

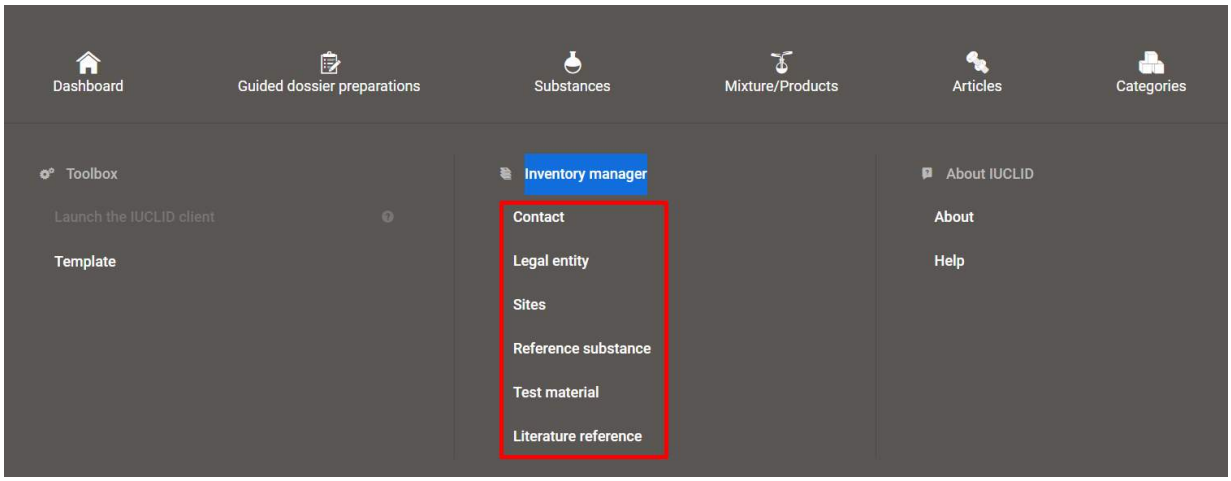
In IUCLID, an Entity is usually an inventory of information **linked to and reused** by any document.

Entities in IUCLID are software objects used to store data and have a particular purpose, depending on the type of entity.

Here is the list of reusable **IUCLID entities** that can be managed through the **Inventory Manager**:

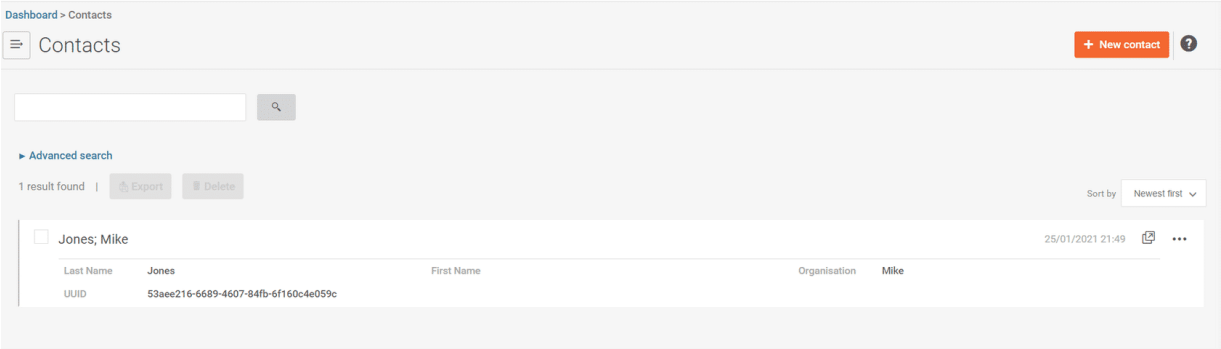
- Contact
- Legal entity
- Sites

- Referenced substance
- Test material
- Literature reference



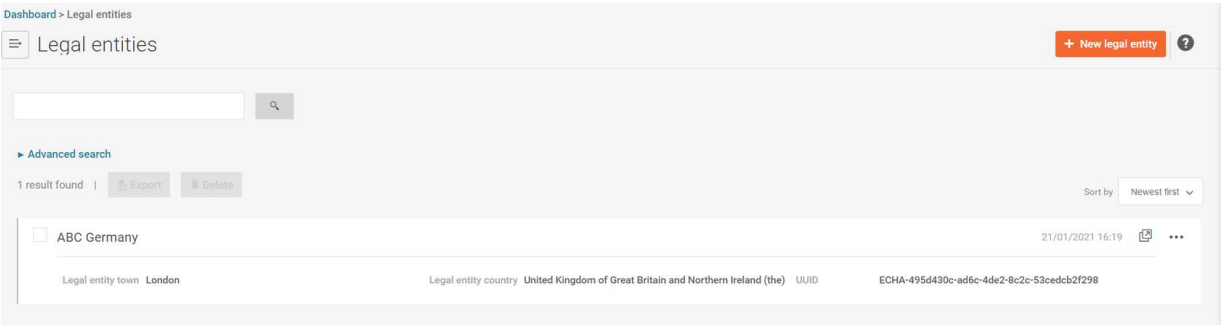
CONTACTS | LEGAL ENTITY | SITES | REFERENCE SUBSTANCE | TES

Contact is an entity that is used **to record the contact details of a particular person**. One can also use it to record something about a **person's role in a process**, such as the competent person responsible for a safety data sheet (SDS).
Using Contacts **removes the need to re-enter details** where a particular person is involved across multiple processes and Substances.
A Contact can be either **edited or created** from the place within a document or entity that links to it.



CONTACTS | LEGAL ENTITY | SITES | REFERENCE SUBSTANCE | TES

In IUCLID, a **Legal entity** is used **to store information about a party or person** involved in a chemical substance, mixture, or product life-cycle.
Can use a Legal entity to **identify the party** responsible for a certain activity, such as the manufacturing or importing of a substance.
The creation and editing of a Legal entity are done from the point where the Legal entity is referred to in a dataset.
Must enter the name of the Legal entity, but the other fields are optional. The type of the Legal entity and other names are for information purposes.



CONTACTS | LEGAL ENTITY | SITES | REFERENCE SUBSTANCE | TES

An entity **site** is an entity used to associate a Legal or a Foreign entity, and therefore its associated entities, with a **physical location.**
This **can have important legal implications**, especially where the country is concerned.
A Legal entity site must have a name, a value in the field Site to indicate the physical location, and can be associated with a Legal entity.
The creation and editing of a Legal entity site are done from the point where the Legal entity site is referred to in a dataset.
One should report each manufacturing plant's name and report address in which the plant protection product and active substance are manufactured and reported in the Site entities.

CONTACTS | LEGAL ENTITY | SITES | REFERENCE SUBSTANCE | TES

A **Reference substance** is an entity used to **define a particular molecular structure** or **narrow range of molecular structures** that may re-use the definition.
A Reference substance **contains chemical identifiers and structural information**.

Chemicals: Identity of the active substance – ISO common name and synonyms, Chemical name following IUPAC and CA nomenclature, CAS Reg number EC number, molecular and structural formula, molar massMicroorganisms: Identity of the microorganism – Name, taxonomy, species description and strain characterisation.

Reference substances are efficient because some chemical substances frequently appear across multiple Substances and Mixture/products. Besides, Reference substances **can be shared and exchanged among instances and users** of IUCLID.

UUID: fe4e2639-841d-48ff-9ece-dd1cb4ceeb28

Reference substance name*
Impurity A

IUPAC name
2-(trichloromethylsulfanyl)isoindole-1,3-dione

Description
None

Inventory

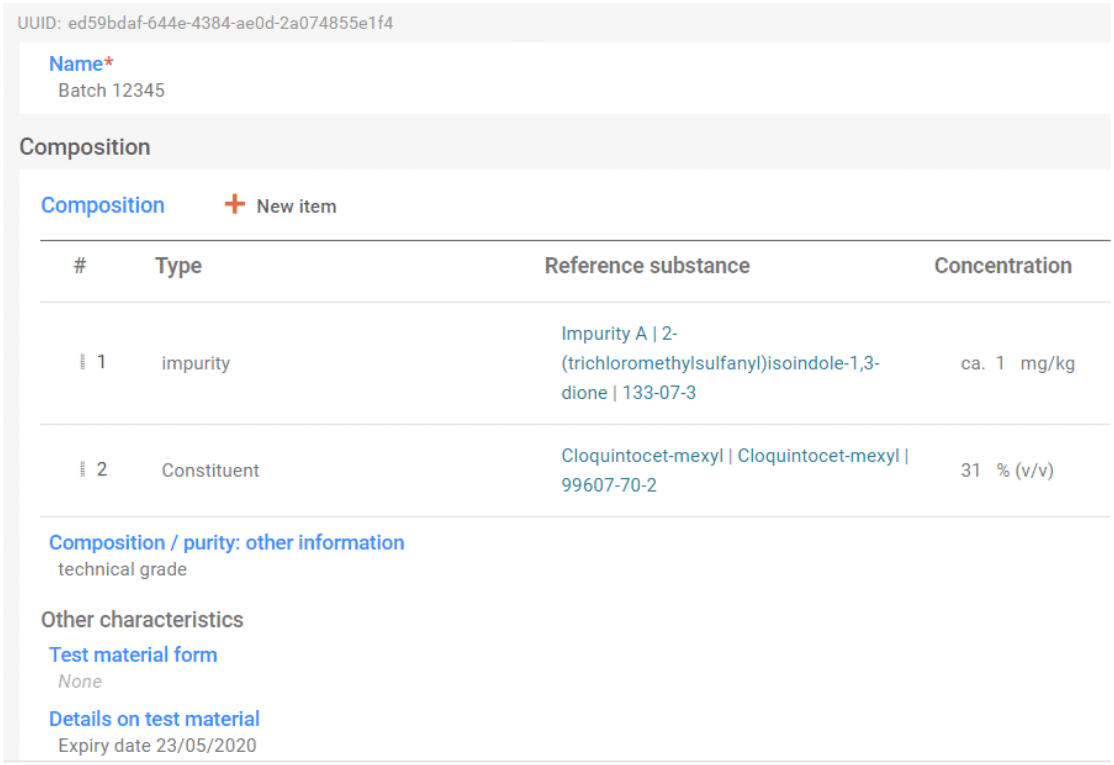
Inventory number
EC / 205-088-6 / N-(trichloromethylthio)phthalimide / 133-07-3 / C9H4Cl3NO2S

No inventory information available - Justification
None

CAS number
133-07-3

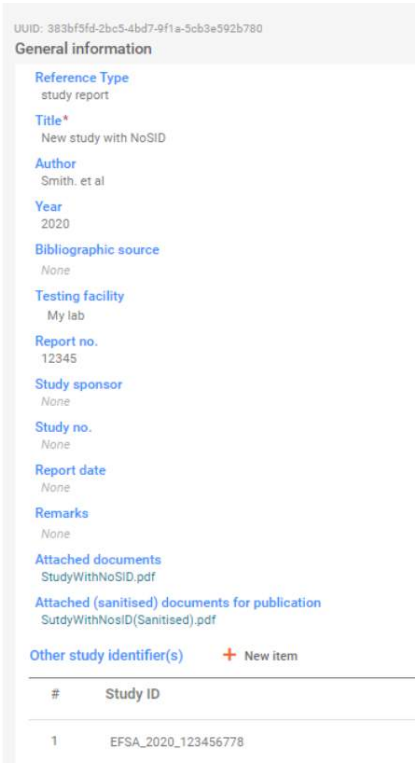
CAS name
None

Test materials is an entity used to **describe the material on which a physical test has been performed.**
A Test material entity can **describe the composition** of the batch used in a study, plus a **description of the physical form** and **some extra information** that may be considered confidential, such as information on impurities.
The **correct use of Test material** will provide the evaluator with an overview of which batches have been used in the studies submitted in the dossier.'



CONTACTS	LEGAL ENTITY	SITES	REFERENCE SUBSTANCE	TES

A **Literature reference** is an entity that **identifies a particular document** that contains information on a Substance or a Mixture/Product.
A **Literature reference** is an entity that **contains the bibliographic metadata** and the full report for each piece of evidence included in the dossier.
The creation and editing of a Literature reference are done from the point where the Literature reference is referred to in a dataset.
It is important to **create** a Literature reference for **all studies** used as evidence in the dossier. If a study has been notified in the **Notification of Studies Database**, it must be reported in the Literature Reference 'Study ID' field.
The **full study repor**t should be uploaded in the literature reference with a **sanitised version.**



Dossier header

A **Dossier header** is a set of fields used to store administrative information relevant to data submission under a particular regulation.

The dossier header specifies the regulatory context and the purpose of the application.

The Working context determines the fields present.

EU_PPP Mixture/Product dataset has a Dossier header associated with it which can be edited at any time, including during Dossier creation.

When a Dossier is created, a r**ead-only copy of the Dossier header** is placed into the Dossier.

Note: there is a direct dependency between the Working context - Table of Content -Dossier header

During Dossier creation, the first step is to review and/or edit the Dossier header.

Lesson 3 of 4

Creating a dossier

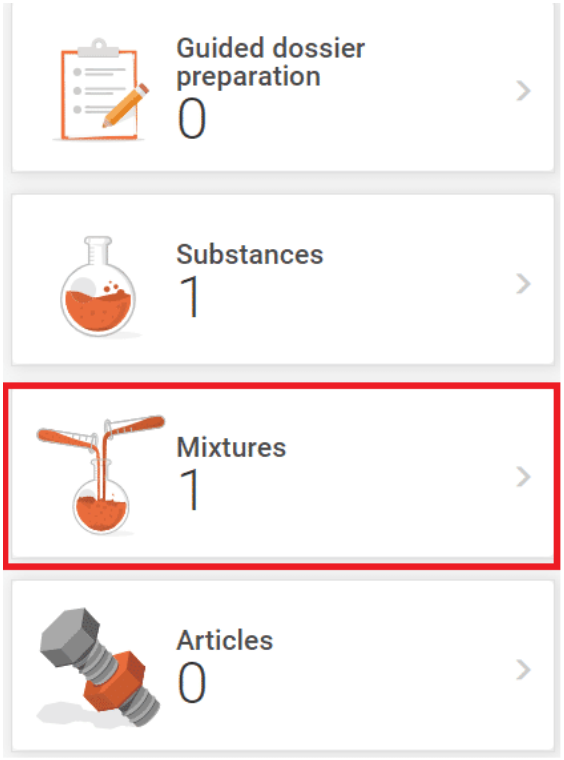
1. How to add a new mixture / product
2. Selecting the "Working context"
3. How to add an active substance dataset and a metabolite dataset
4. How to access the Table of content and edit it to complete your dossier
5. What is the dossier header and where you can find it?
6. How to create a dossier

1

How to add a new mixture / product

Step 1

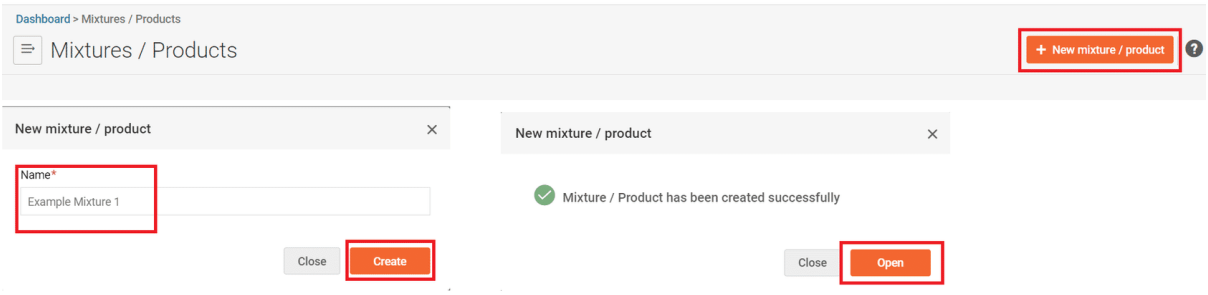
Mixture/product



The **mixture product** can be access from the dashboard.

Step 2

How to add your mixture/ product in IUCLID



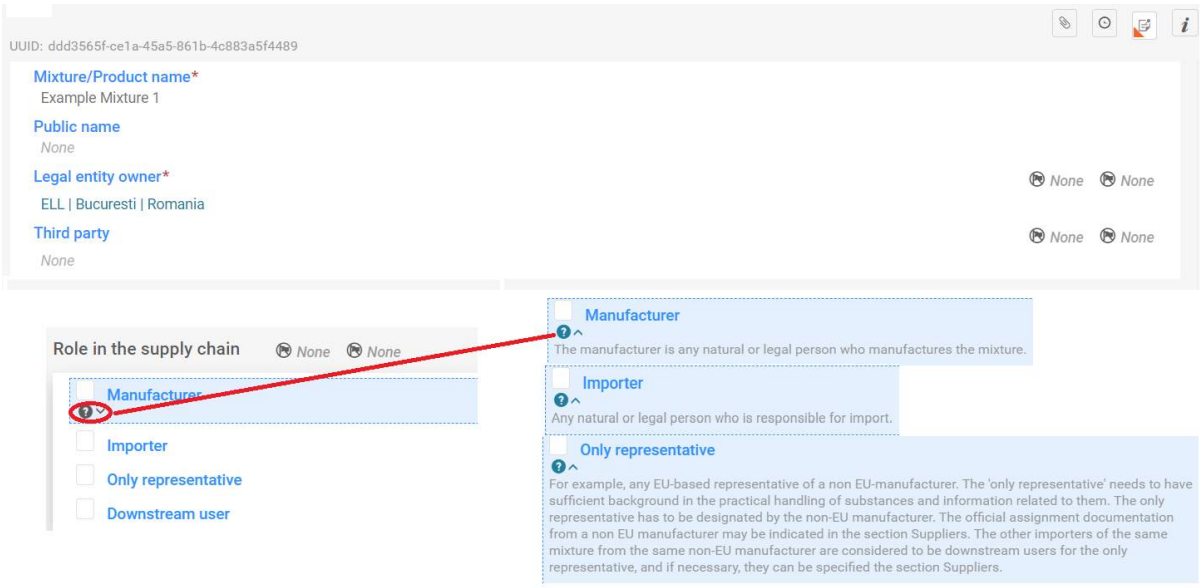
For you to be able to create your dossier, you need to **start from a mixture/product.**

After inserting the naming of your mixture, the dataset needs to be completed.

So it would be best if you opened the mixture to fill in the required information.

Step 3

How to complete your information about the mixture/product



To complete your mixture product dataset, you need t**o complete these fields.**

The name (mandatory field) is already filled in from the moment when you create your mixture. Is the name of the mixture dataset given by the user during the creation.

One may enter the public name (optional field) in case such a name exists.

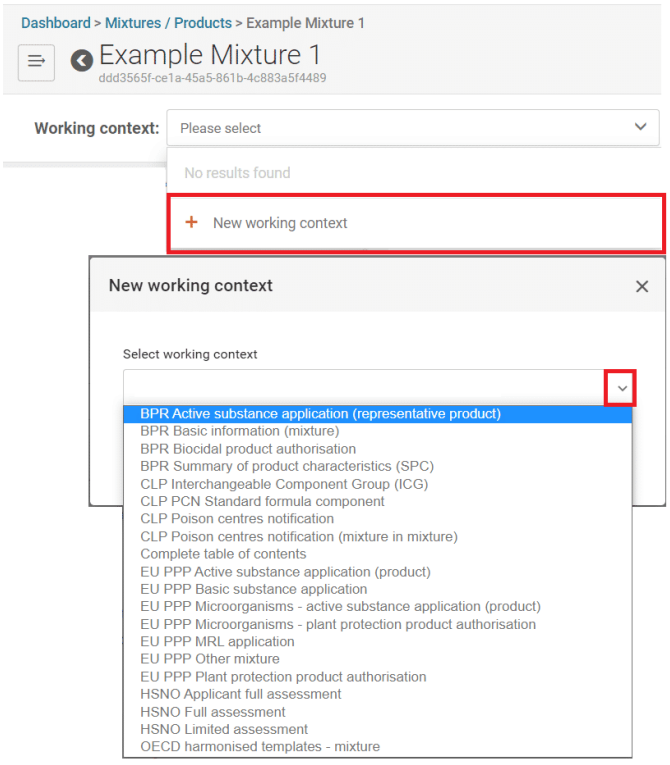
The legal entity (mandatory field) is, in fact, the working legal entity (the master one) for which you are submitting the dossier and is synchronised with the login.

The third-party (optional field) may be filled if the organisation appoints a third party representative to create the dataset.

To better understand, you can click on the "support" button (each role is explained, being easier for you to make the right choice).

Step 1

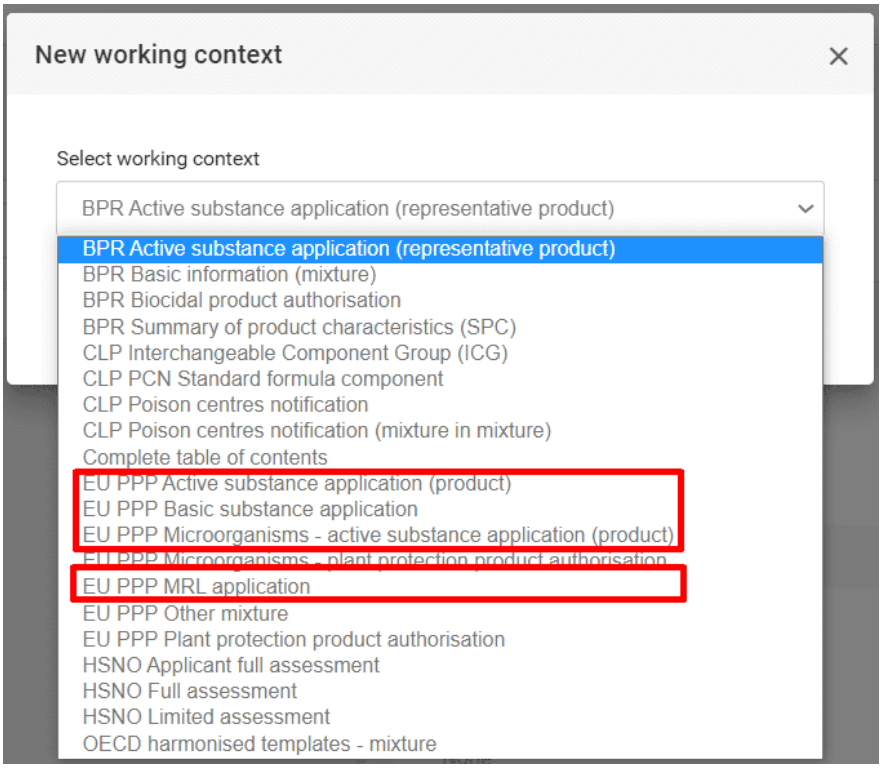
How to add the Working context



To create your dossier, you need to select the correct working context. You can do this action from the field "Working context."

Step 2

What is the right working context for your dossier

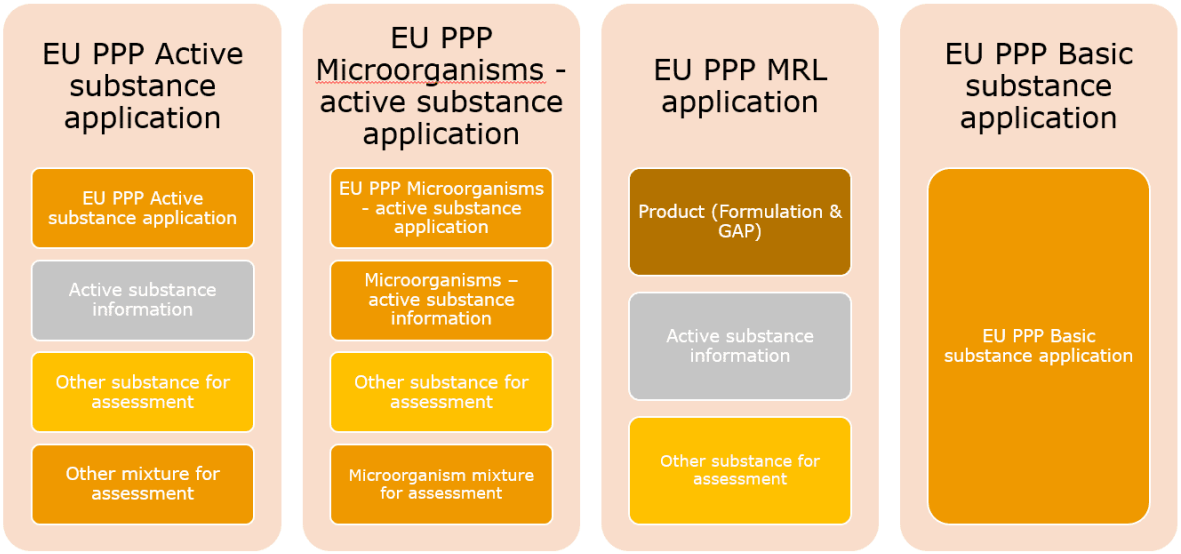


The working context includes the Table of Contents and the IUCLID documents needed to meet the regulatory data requirements (see links below).

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

https://ec.europa.eu/food/plant/pesticides/approval_active_substances_en

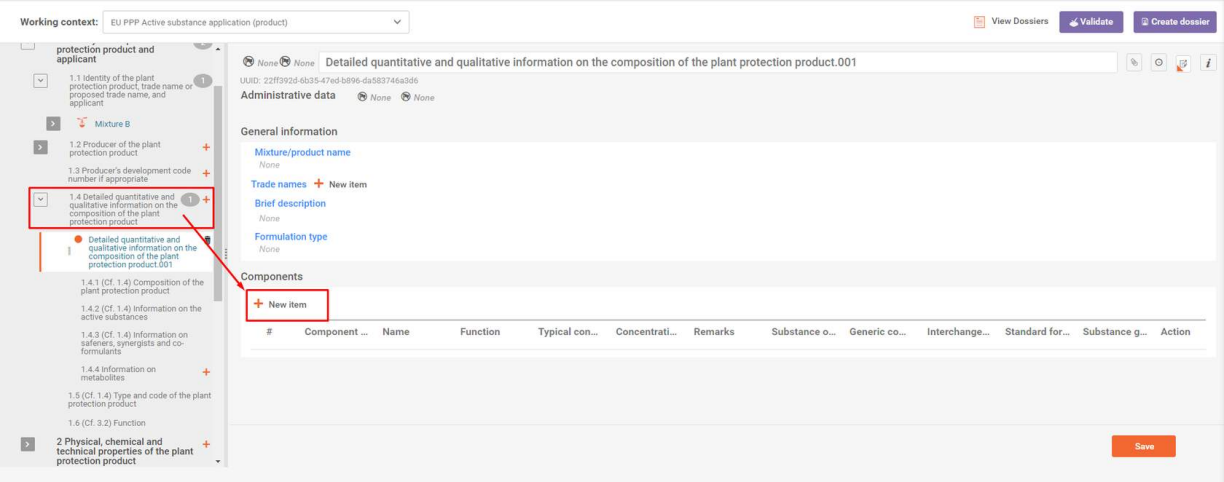
The working contexts that EFSA accepts are the ones highlighted above - EU PPP.'



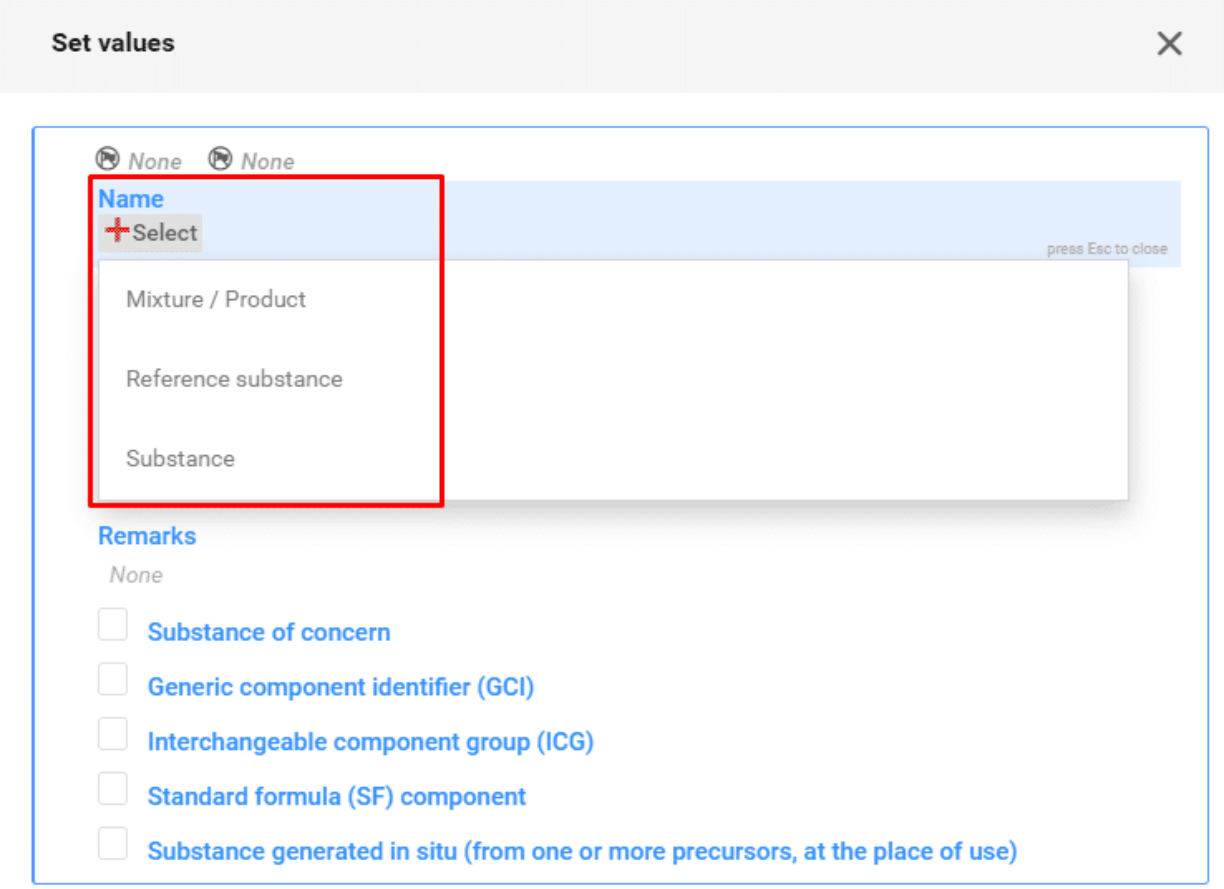
3

How to add an active substance dataset and a metabolite dataset

Once the mixture is created, you need to describe the formulation. Can create a **new mixture composition** in **section 1.4**



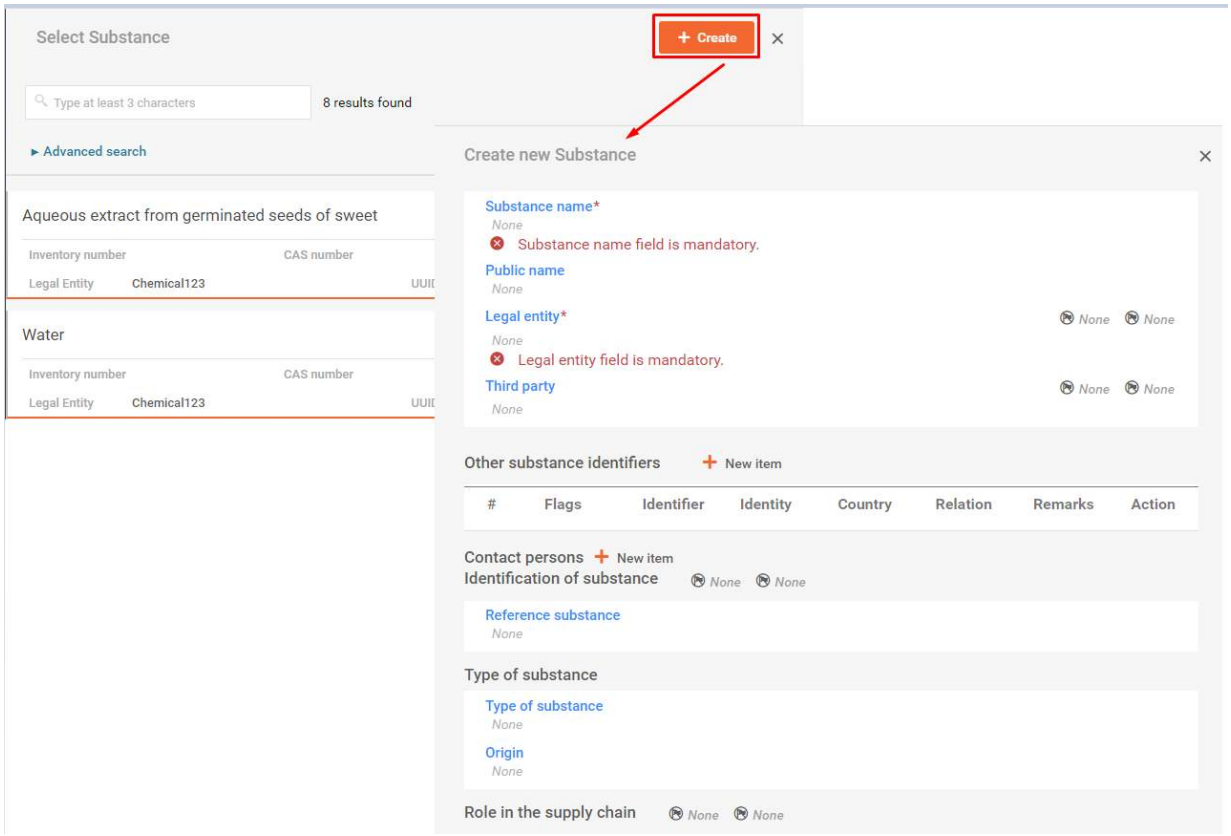
By adding a new item, you can include the **active substance and the concentration** in the formulation.



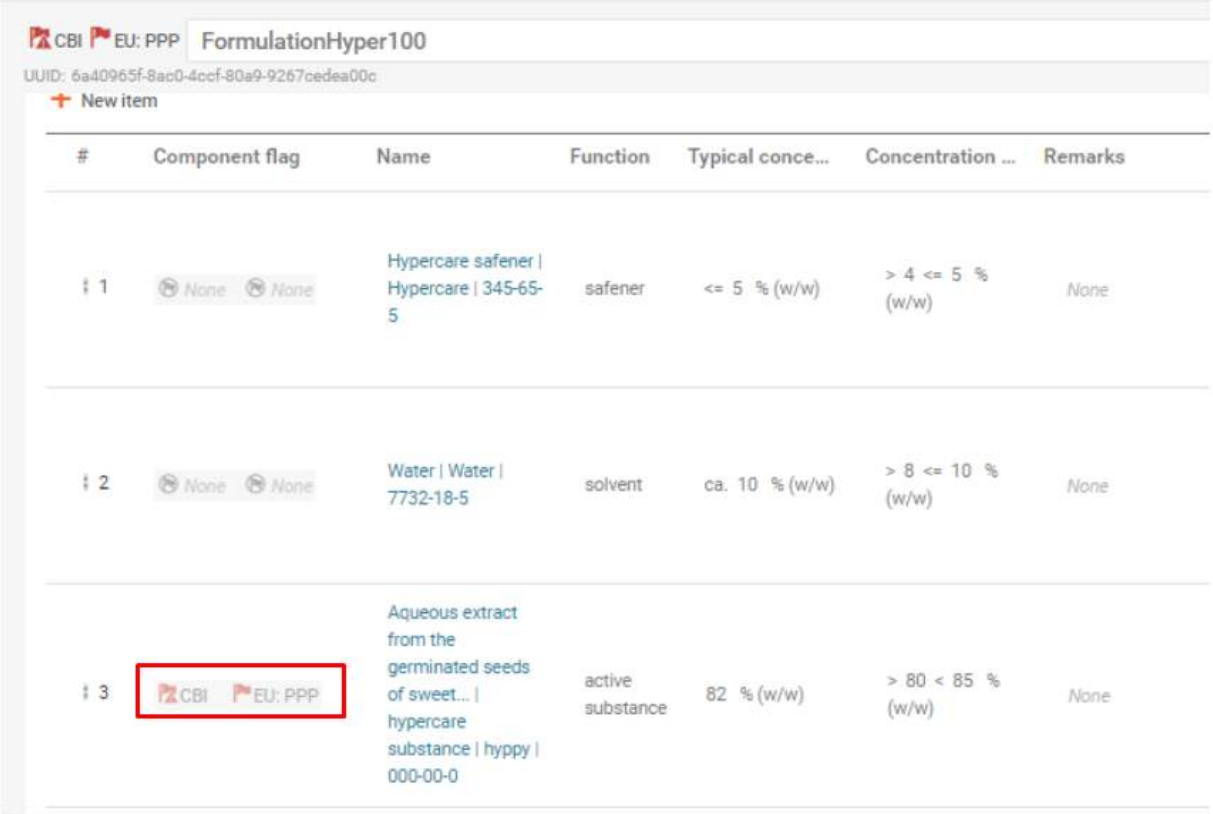
For the component with the **'active substance'** function, must select a **Substance** dataset.

For the other components, if **Substance** is selected, a dataset is available to **report studies** where this substance was used as the **test material.**

If there are no additional studies for a component, then should select a **Reference substance**.



If a component in the **formulation/preparation** is not available in the **list of substances or reference substances,** you can **create a new one**.



If you want to set this information **confidential,** you can set a **flag to confidential** and justify it.

Practical Arrangements on confidentiality

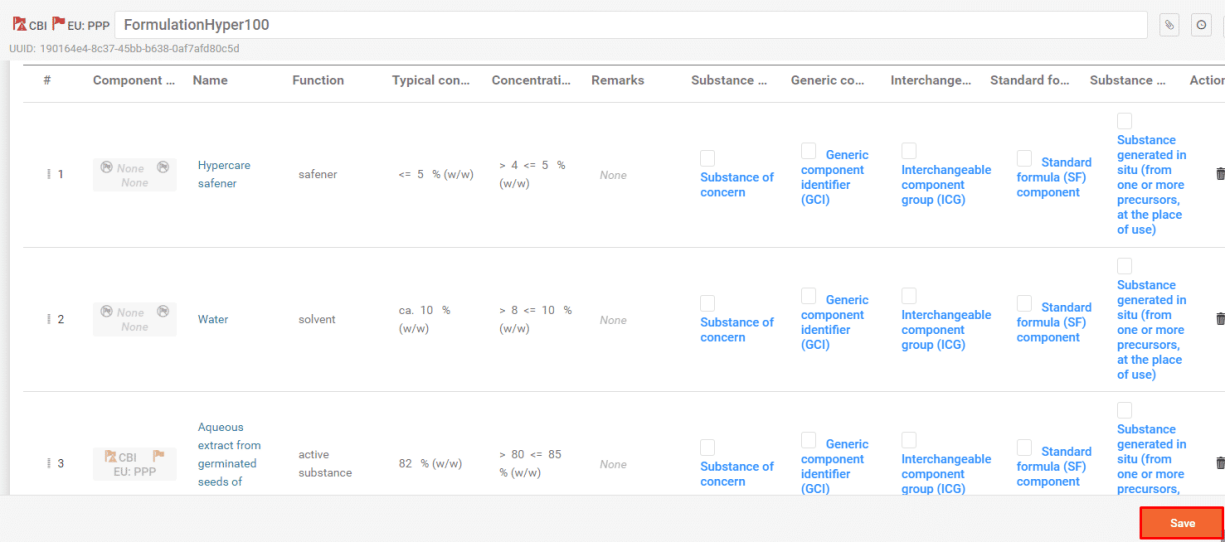
- **New Active Substances** - decision is issued by RMS
- **Article 16 Renewals** - decision is issued by EFSA
- **MRLs** - decision is issued by EFSA

Underlying principles

- **Transparency** is the rule, and **confidentiality** the exception
- **Confidentiality requests** must be kept to a minimum and may relate only to items on closed positive list set out in Article 63 of

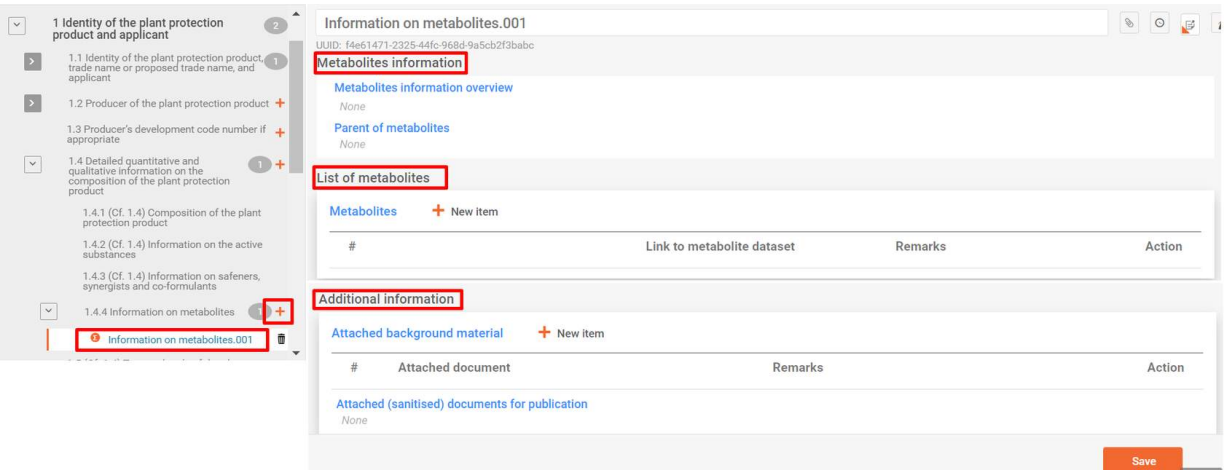
Practical Matters

- **Confidentiality Requests** are submitted through IUCLID and to be granted only after assessment by EFSA/RMS -> detailed justification is paramount
- Applicants are urged to use "**Dissemination**



Once the formulation is **complete**, click on the '**Save**' button.

Information on metabolites (Section 1.4.4)



By clicking on "+", a metabolites information (flexible summary) document is generated. In this document, you can report the parent compound and list the relevant metabolites. If there are studies where the metabolite is the test material, select the appropriate substance; otherwise, select the appropriate reference substance.

4

How to access the Table of content and edit it

After selecting the working context, the **Table of Contents** is shown with all the documents needed to meet your application's data requirements.

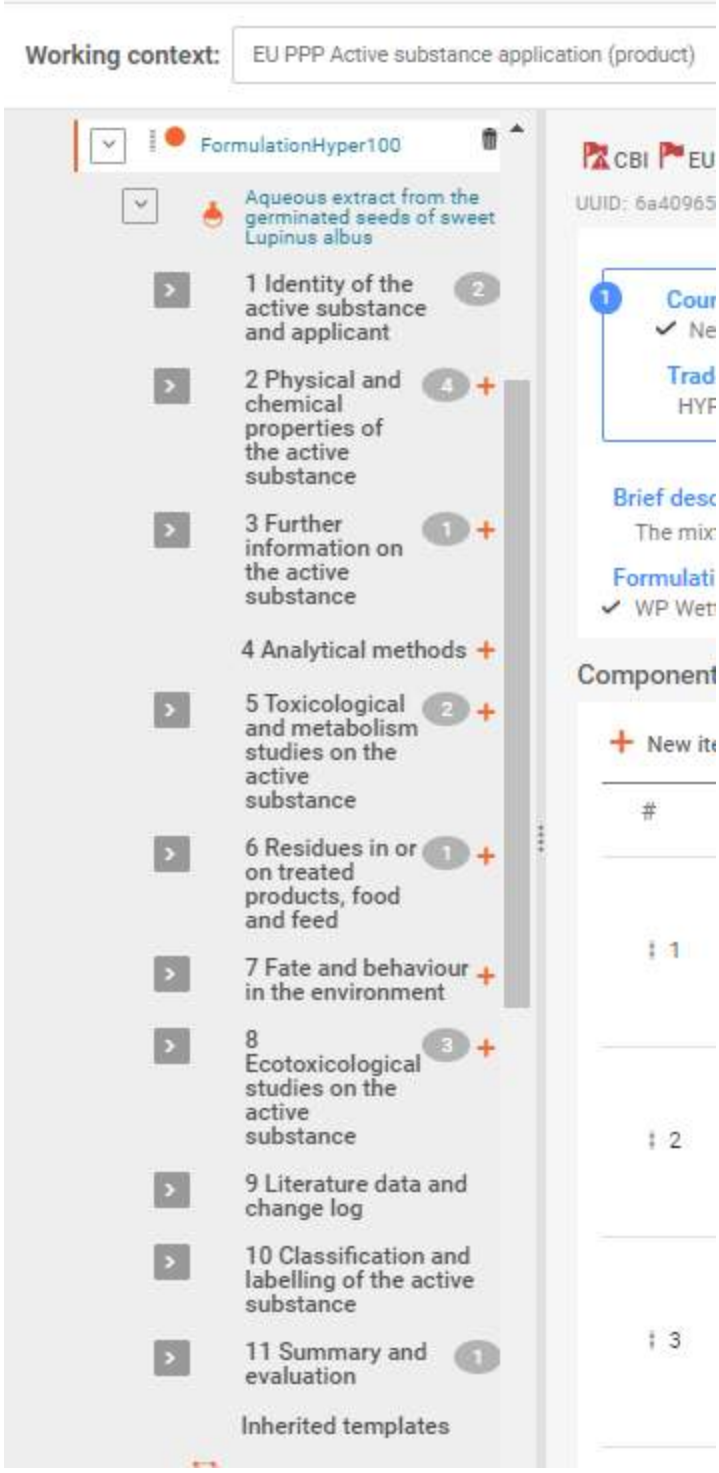
For **each working context**, you will have a **specific table of content.**

You'll need to create your documents for the defined TOC (Table of Contents).

The full TOC is displayed when you click the arrows. The documents that you'll need to add are displayed in the correspondent fields.

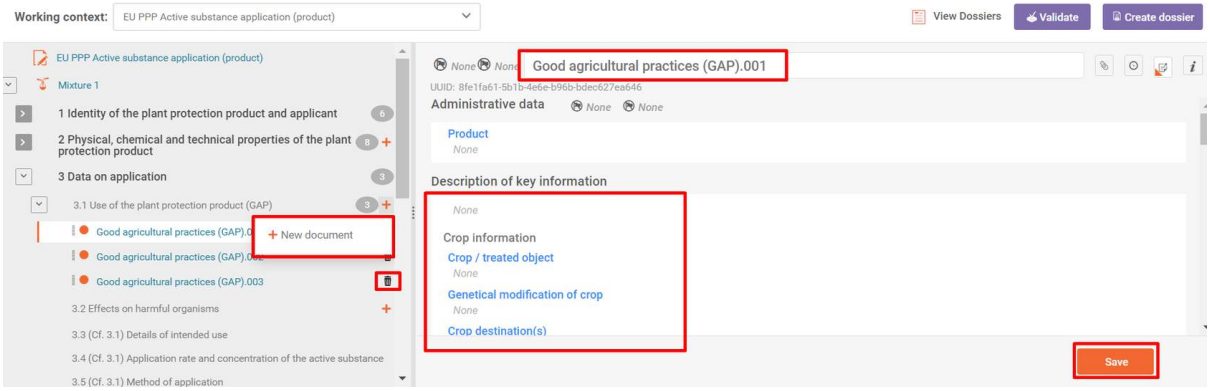
If you want to **reuse the information in a different working context** (e.g. to use information from a new active substance application in an MRL application), **switch the working context.** The information will be presented in the MRL application format.

Use the **Validation assistant** to check if you need to add some more documents to meet the data requirements.


Working context:
EU PPP Active substance application (product)
FormulationHyper100
Aqueous extract from the germinated seeds of sweet Lupinus albus
1 Identity of the active substance and applicant
2
2 Physical and chemical properties of the active substance
4
3 Further information on the active substance
1
4 Analytical methods
5 Toxicological and metabolism studies on the active substance
2
6 Residues in or on treated products, food and feed
1
7 Fate and behaviour in the environment
8 Ecotoxicological studies on the active substance
3
9 Literature data and change log
10 Classification and labelling of the active substance
11 Summary and evaluation
1
Inherited templates
CBI
EU
UUID: 6a40965
Brief desc
The mix
Formulati
WP Wet
Component
New it
#
1
2
3

Step 1

How can you complete the TOC (table of content)



After you click on the '+' sign to create a new document, the page on the right opens.'

The **name** of the document can be easily edited from the field highlighted.

It is recommended to use the following naming convention: Year of study_Endpoint_Additional relevant context. An example of a relevant context would be crop or species. It is recommended not to use author names.

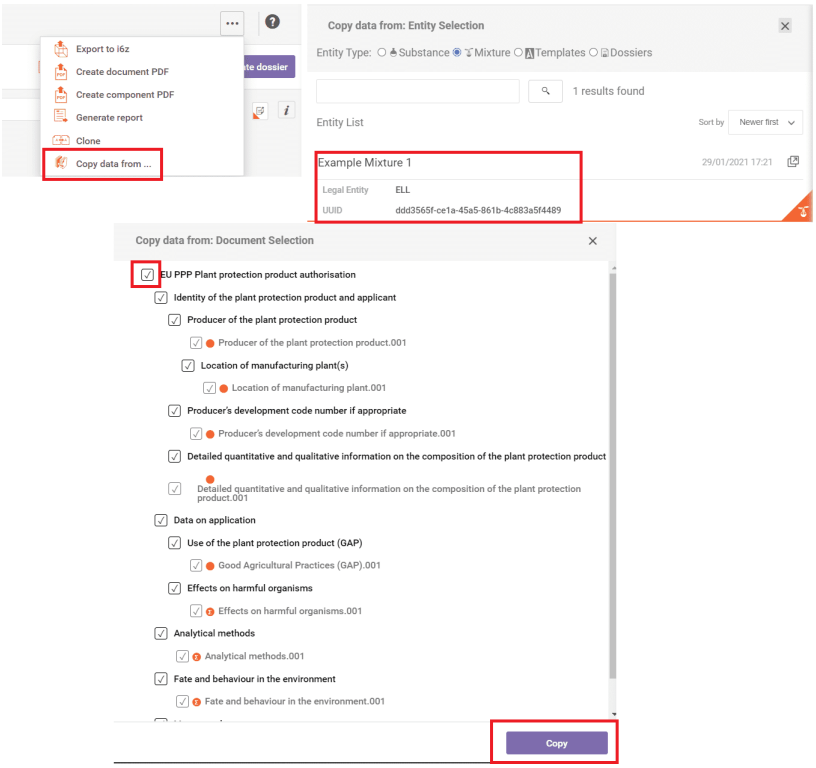
Complete all relevant fields. See EU_PPP manuals for more information on completing IUCLID documents.

By clicking the "**Save**" button, your information is saved in the document.

If you make a mistake, you can **delete** the document from the button displayed in TOC.

Step 2

How can you copy the datasets from another mixture



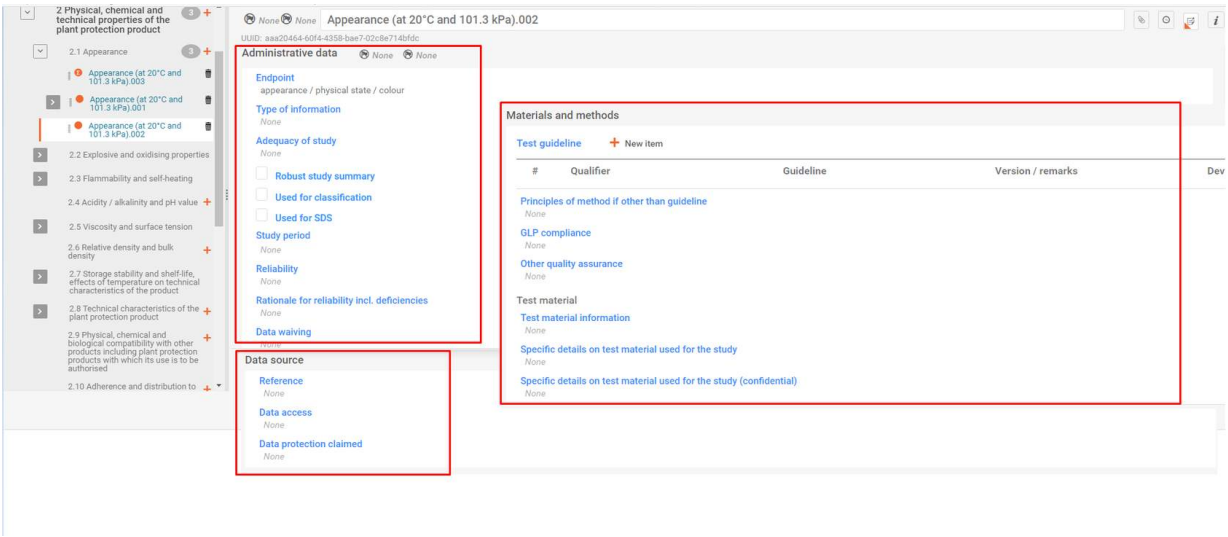
You can easily copy the documents from another mixture by accessing the "**Copy data from...**" button.

You can now select the documents that need to be copied.

Endpoint study records

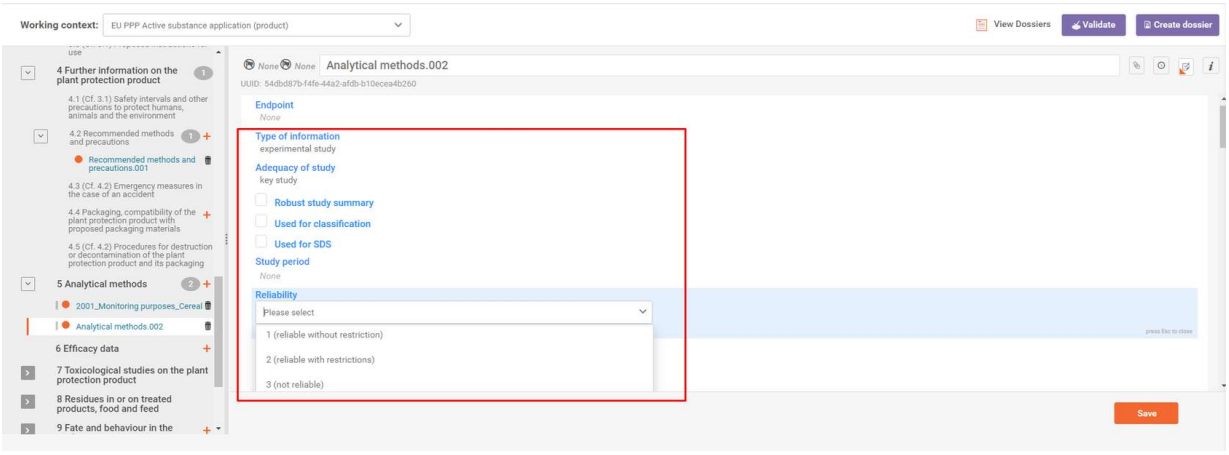
An endpoint study record provides a **template** with predefined fields where data is entered to describe a study carried out within the subject area defined by the section's title. All entries

under the OECD harmonised templates are endpoint study records.



General information

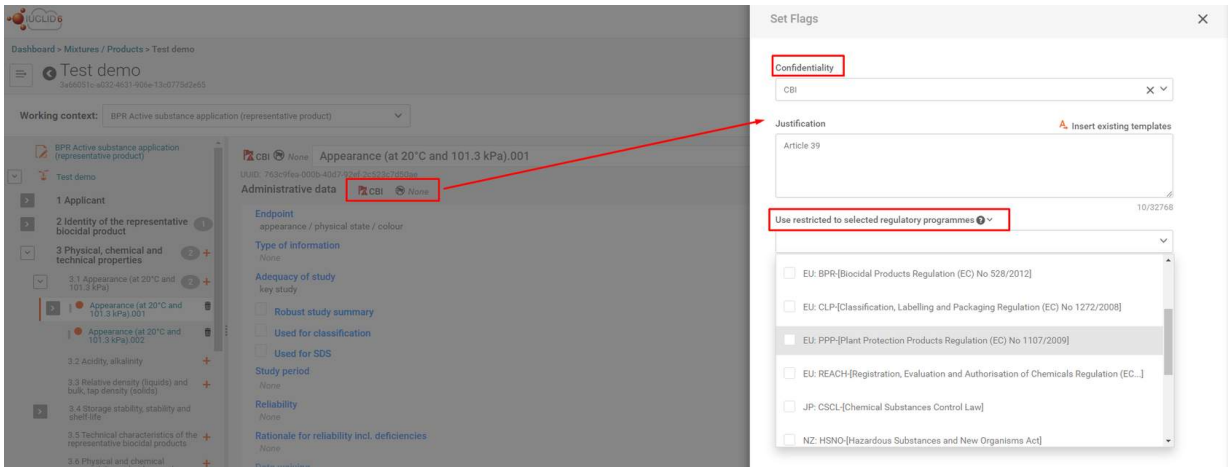
Endpoint study records usually consist of the data entry blocks: '**Administrative data**', '**Data source**', '**Materials and methods**', '**Test material**'.



'Administrative data' block

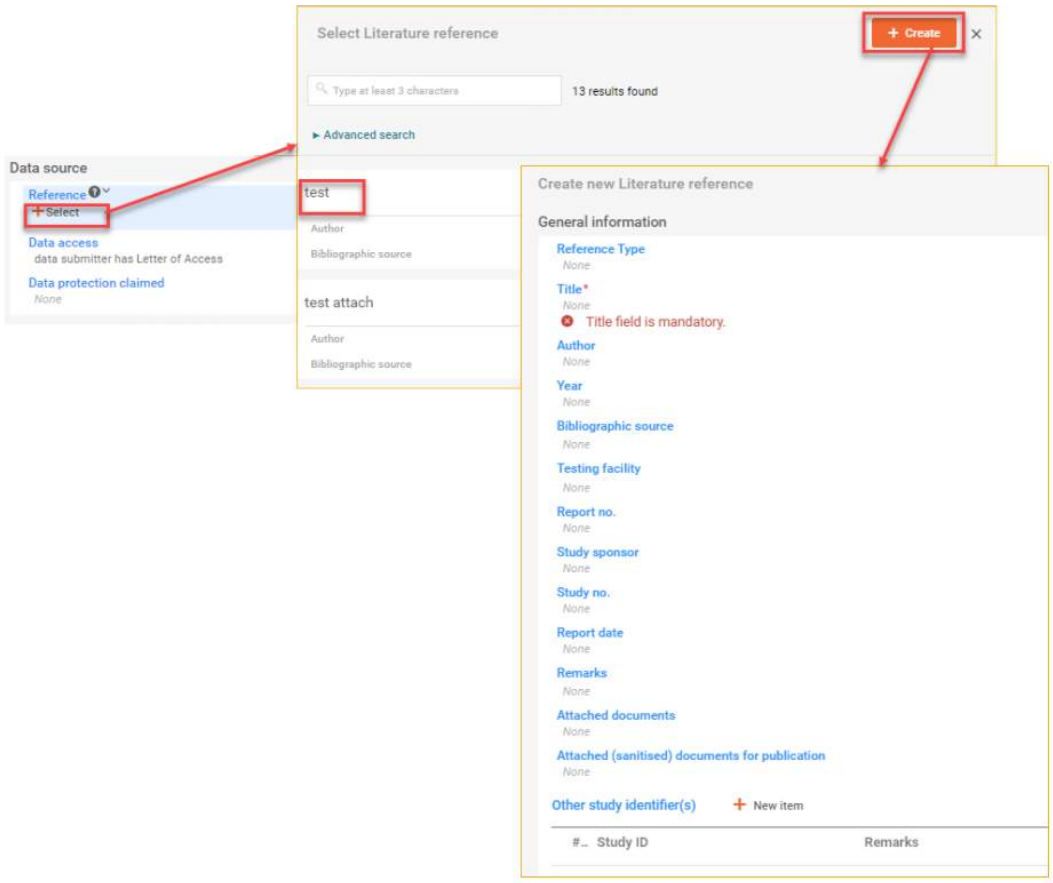
Make a selection (e.g. ‘key study’) in the field ‘**Adequacy of study**’ using the drop-down list by clicking in the field.

Also, select the fields ‘**Type of information**’ and ‘**Reliability**’ using the dropdown lists by clicking in the relevant field.



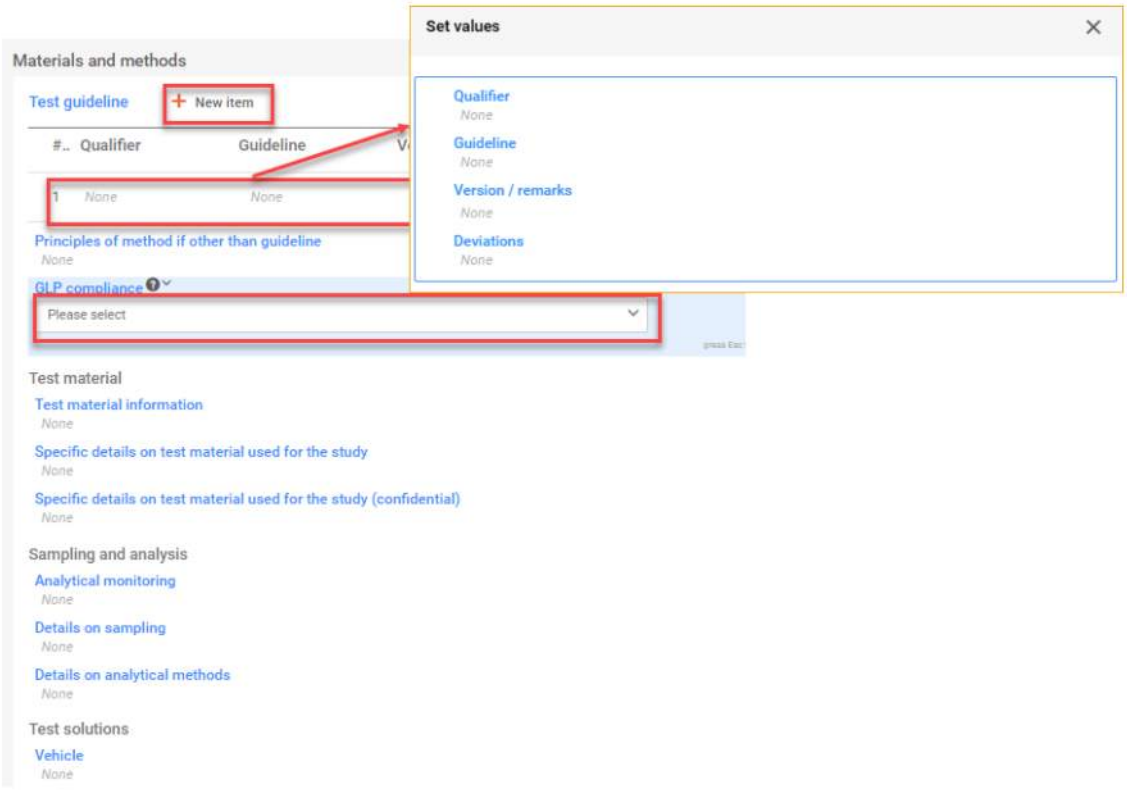
Setting a confidentiality flag

When a document is created, no flags are set. To edit a flag, click on either of the **flag icons** in its pair. The **flag for confidentiality** and the **flag for the regulatory programme** is edited from the same page, as shown in the figure below.



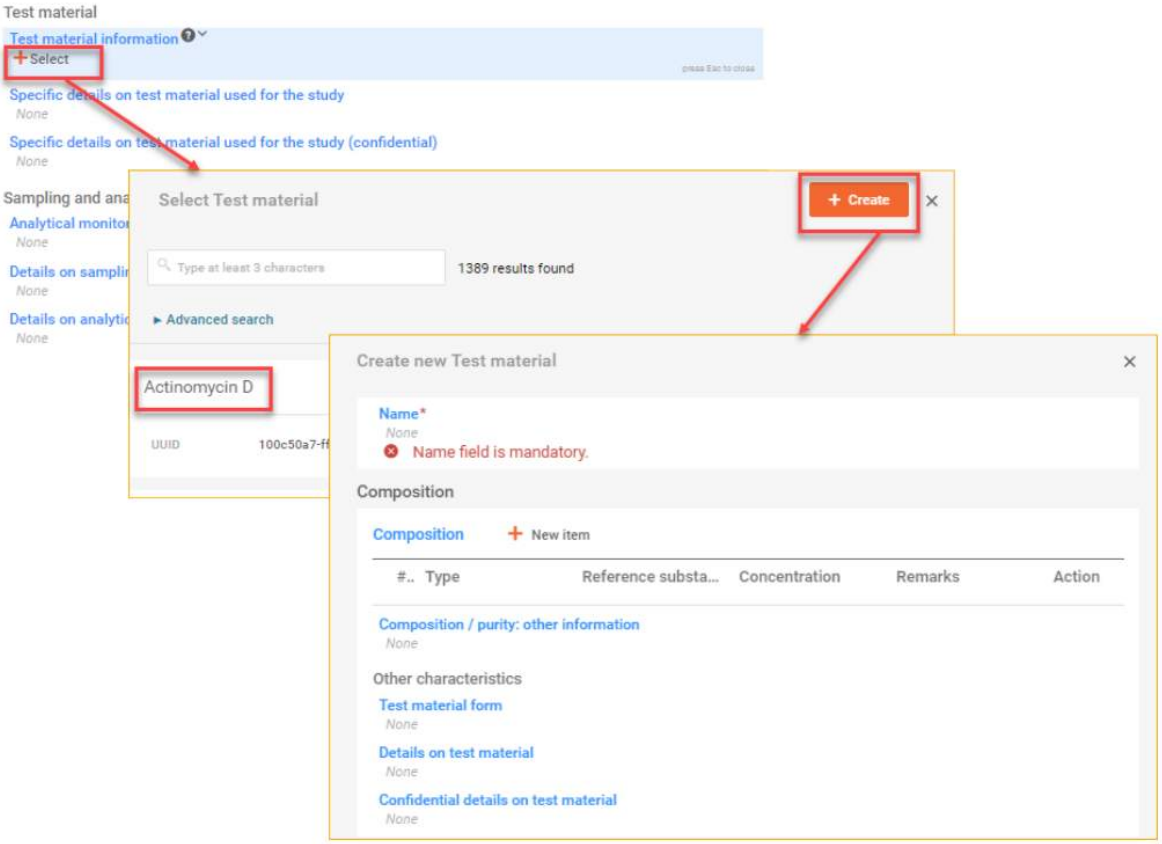
'Data Source' block

To indicate literature reference under **'Reference',** click **'+ Select'** in the field. The '**Select Literature reference**' page is opened. Search for the relevant reference and then click on the title; this will add the reference to your data source.



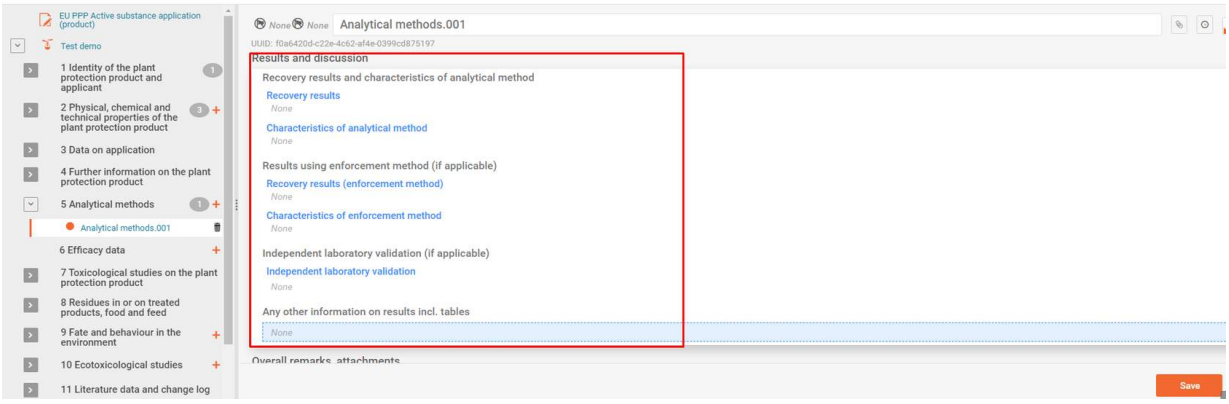
‘Materials and Methods’ block

Fill in all the necessary fields, ensuring you supply information on the **method of testing** in the table ‘**Test guideline**’, in the field ‘**Guideline**’. Achieve this by firstly adding lines to the existing tables using the ‘**+ New item**’ button



Add details on the test material.

To indicate **test material** under '**Test material information**', click '**+ Select**'. Select the correct test material from the list or **create new test material.**

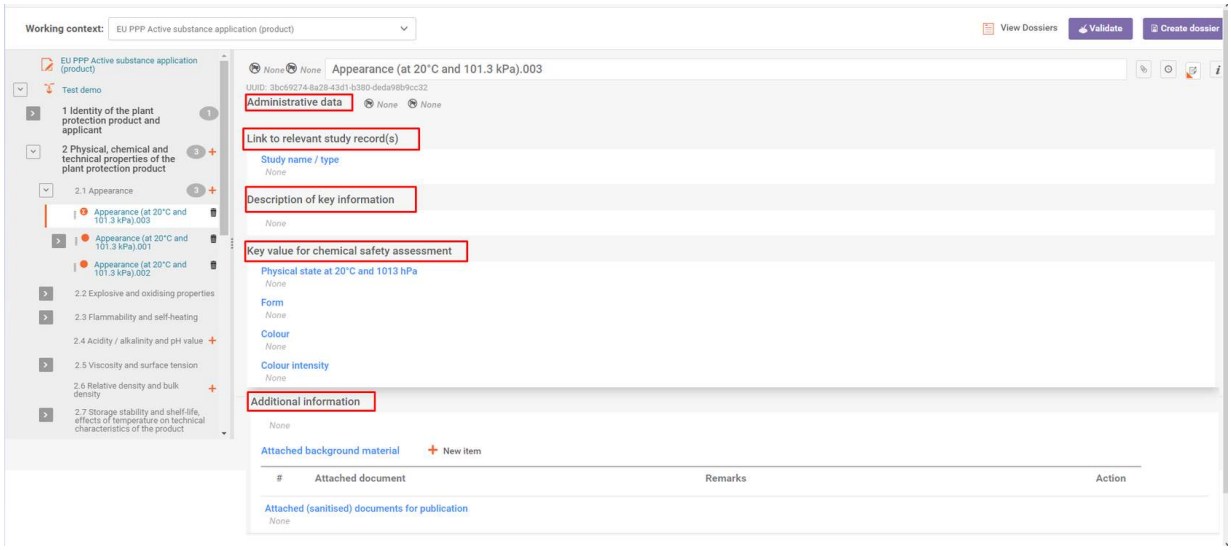


'Results and Discussions' block

For this block, the fields that must be **filled in** are **specific** for each endpoint. Information should primarily be reported in the fields defined for **reporting that result**. However, in rare cases where these basic fields cannot be completed, an explanatory text must be provided in the field **'Any other information on results incl. tables'.**

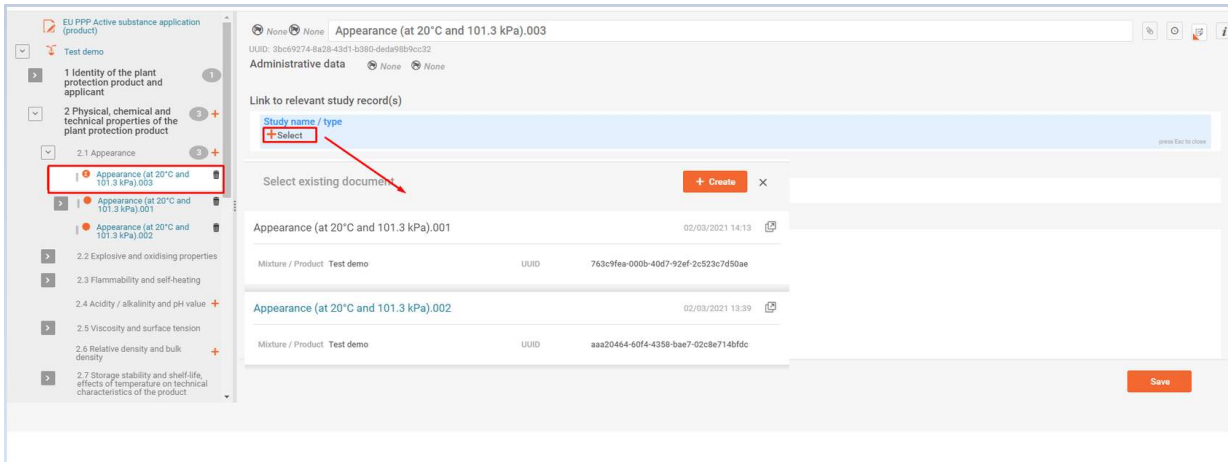
Endpoint study summaries

An endpoint study summary should summarise the evaluation made on all the data entered in the endpoint study records. An endpoint summary should **focus** on the most important **results and conclusions** and justify certain studies' use.



General information

Endpoint summaries usually consist of the data entry blocks: '**Administrative data**', '**Link to relevant study record(s)**', '**Description of key information**', '**Key value for chemical safety assessment**', and '**Additional information**'.



Complete the endpoint study summary

You can fill each field using the drop-down lists with pre-selected responses, add entries to the existing tables, or type text into the free text fields.

There is the possibility to link the summarised data to a specific endpoint study record. Achieve this by clicking the '**+ Select**' button and selecting the appropriate **endpoint study record** from the appearing page.

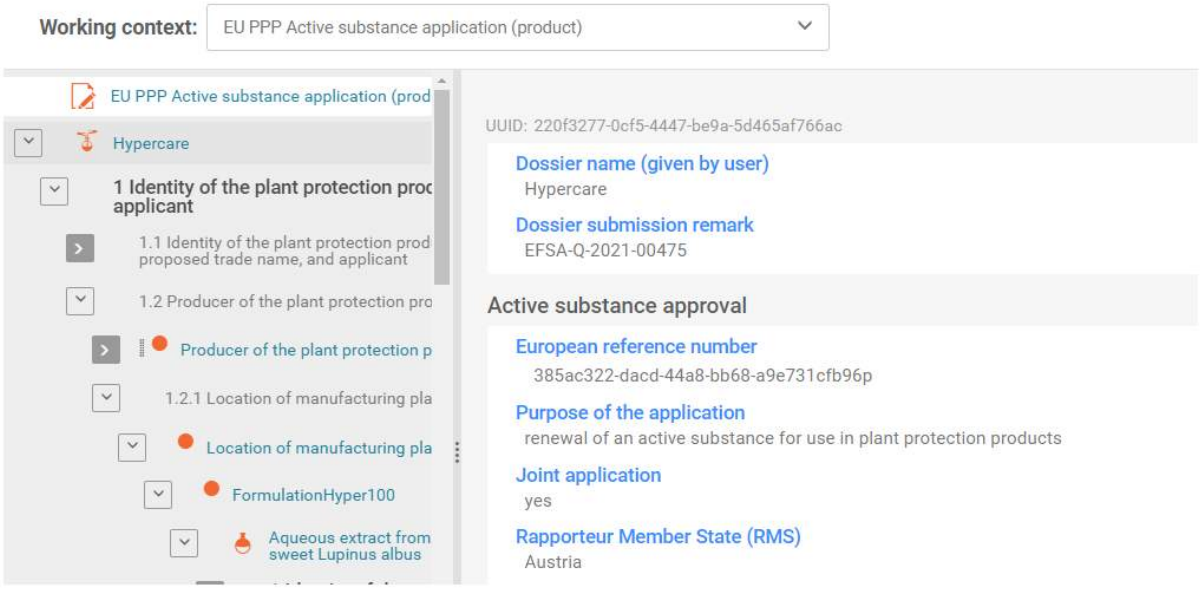
5

What is the dossier header and where you can find it?

You can access the **dossier header** from the button with the working context you've selected in the previous steps.

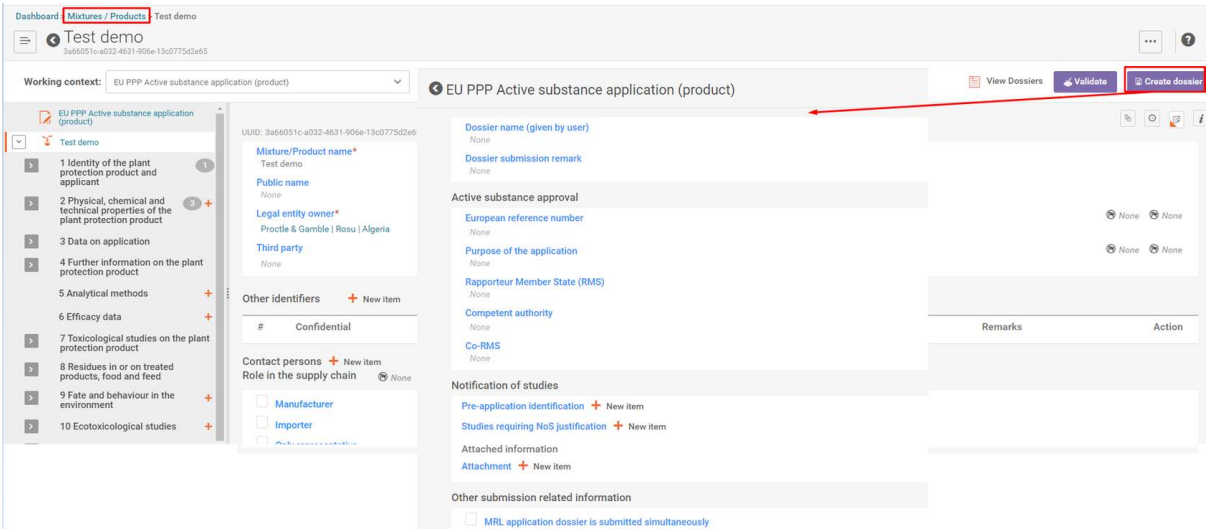
The dossier header contains the administrative data for **your submission**, you need to provide full information and a submission type that would be accepted.

After you finish completing the dossier header is necessary to save the information.


Working context:
EU PPP Active substance application (product)
EU PPP Active substance application (prod
Hypercare
1 Identity of the plant protection proc
applicant
1.1 Identity of the plant protection prod
proposed trade name, and applicant
1.2 Producer of the plant protection pro
Producer of the plant protection p
1.2.1 Location of manufacturing pla
Location of manufacturing pla
FormulationHyper100
Aqueous extract from
sweet Lupinus albus
UUID: 220f3277-0cf5-4447-be9a-5d465af766ac
Dossier name (given by user)
Hypercare
Dossier submission remark
EFSA-Q-2021-00475
Active substance approval
European reference number
385ac322-dacd-44a8-bb68-a9e731cfb96p
Purpose of the application
renewal of an active substance for use in plant protection products
Joint application
yes
Rapporteur Member State (RMS)
Austria

Step 1

How to create a dossier

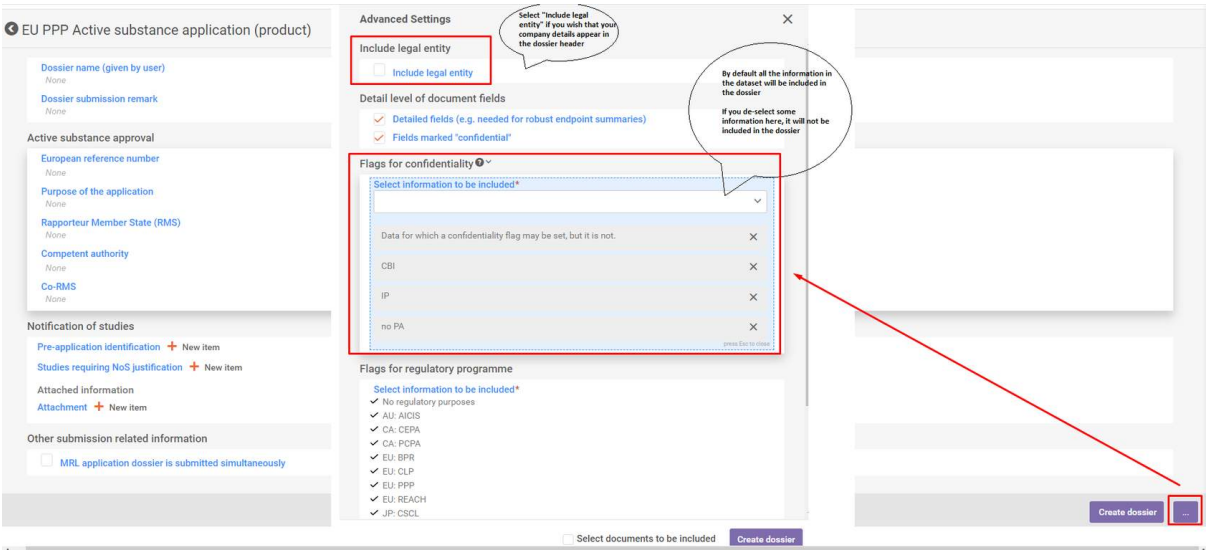


To create the dossier, search and open your **Mixture / Product dataset** for the active substance or biocidal product application or Substance dataset if you create a dossier for assessment of technical equivalence. Click **'Create dossier'** top right corner; this will launch the dossier creation wizard.

The page opened is the dossier header; if you didn't complete it in the previous steps, now you can add the requested information.

Step 2

Dossier creation wizard, open advanced settings



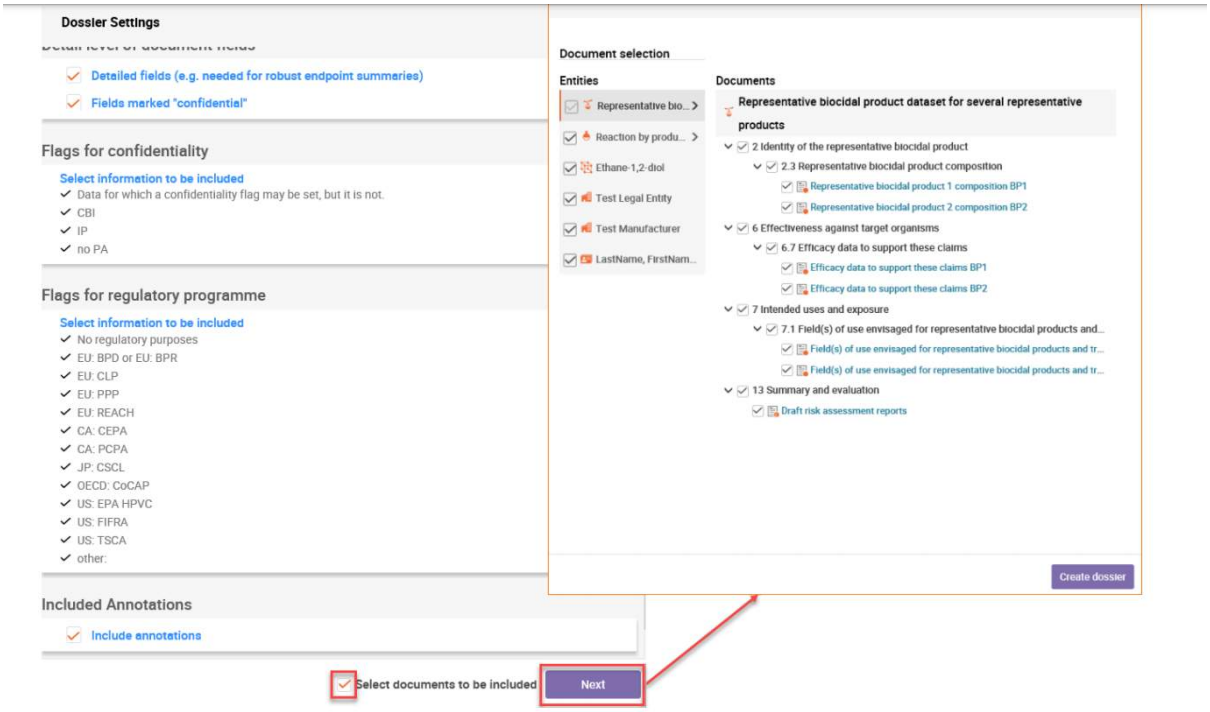
To access the **advanced settings**, click on the button labelled with three dots '...' near the "Create" button.

All the other information, except the **legal entity,** will be included in the dossier by default. To **exclude** records from the dossier, un-select the relevant section in advanced settings when creating a dossier.

For most cases, it is recommended not to un-select the checkboxes, making sure that all of the required elements of the 'Substance' or 'Mixture/Product' dataset are included in the dossier to be submitted.

Step 3

Verify the sections to be included

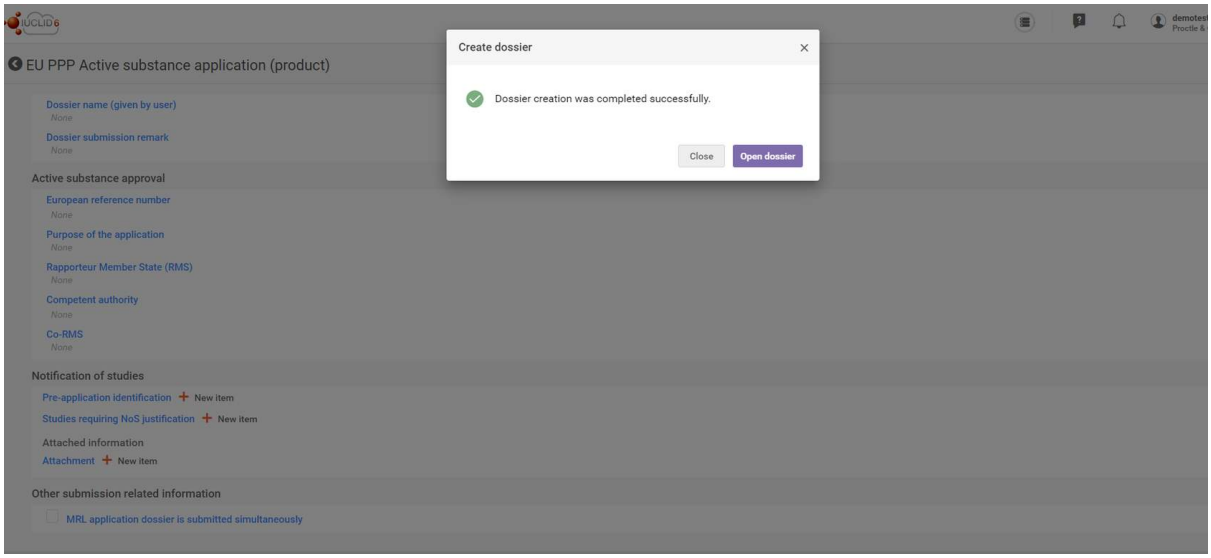


Verify the selected sections for **inclusion**. In this step, it will be displayed all the dossier entities. To view the sections of each entity, click the name of the entity, e.g. **dataset name**.

By default, all the **entities and sections are included** in the dossier. **To exclude** an entity or section, **deselect** it in the relevant dataset.

Step 4

Create dossier



Specify the **dossier name** in the free text field and include any additional remarks if relevant.

A prompt window will appear, giving an option to open the newly **created dossier**. Validation rules run the dossier to verify if basic information is compiled correctly in the dossier.

Once the button "Create dossier" is clicked, you will have accesses to read-only version.

Lesson 4 of 4

Submitting a dossier

Objectives

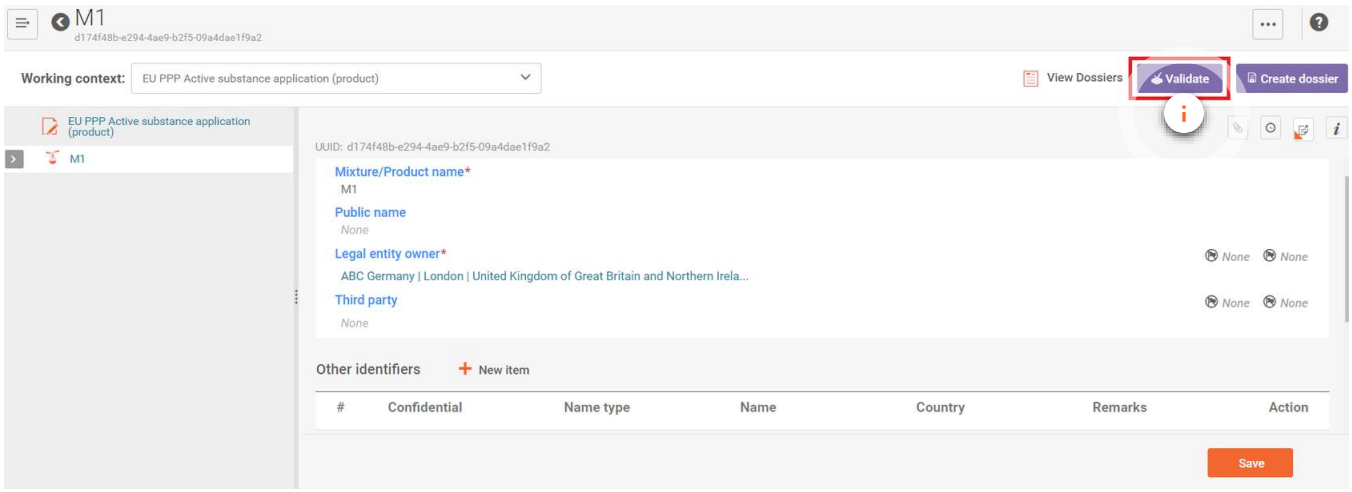
Once completed this module, you will have a clear understanding of:

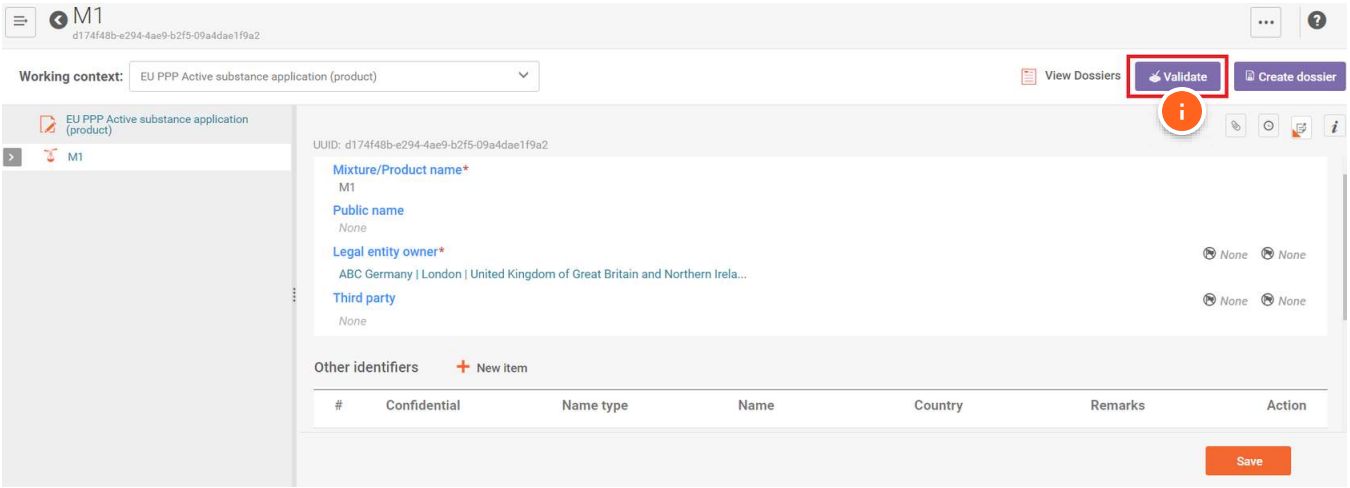
1. Role and purpose of validation assistant
2. Output of the dissemination preview
3. How can a dossier be exported
4. Submission of a dossier

1

Role and purpose of validation assistant

- Once all the data have been inserted and all needed documents have been added, the user can VALIDATE them.


M1
d174f48b-e294-4ae9-b2f5-09a4dae1f9a2
Working context:
EU PPP Active substance application (product)
View Dossiers
Validate
Create dossier
EU PPP Active substance application (product)
M1
UUID: d174f48b-e294-4ae9-b2f5-09a4dae1f9a2
Mixture/Product name*
M1
Public name
None
Legal entity owner*
ABC Germany | London | United Kingdom of Great Britain and Northern Irela...
None
None
Third party
None
None
None
Other identifiers
New item
Confidential Name type Name Country Remarks Action
Save



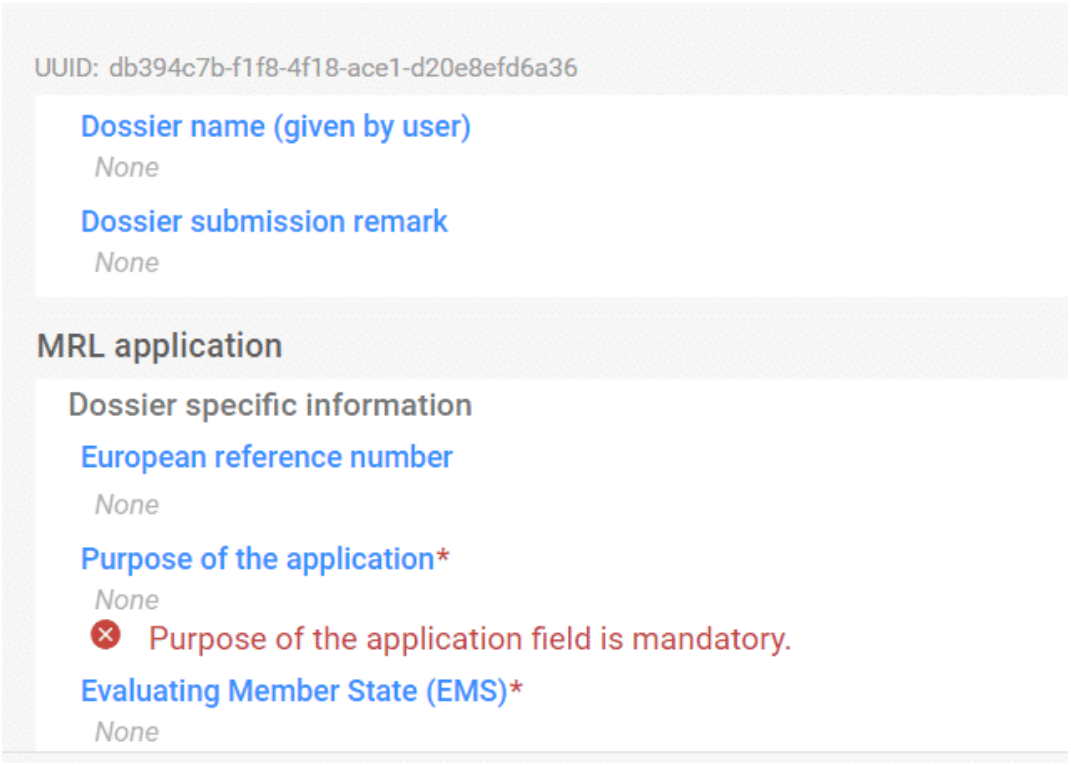
Validate

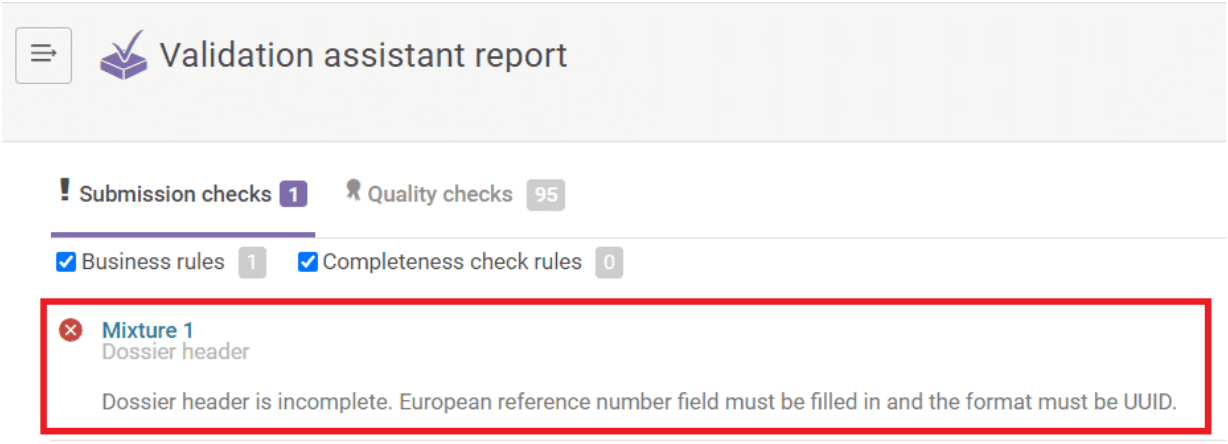
- The validation assistant helps you to prepare the dossier before submission to ECHA, by **validating the data** against the service technical completeness rules.
- You can run the validation assistance against your substance dataset or dossier and the results are detailed in the validation report

VALIDATION ASSISTANT

Before running the validation assistant on a dataset, one **must select a working context.**

- The dossier header provides the information that allows the checks applied to fit the regulatory context, submitting the data to an authority.
- You must fill in the Dossier specific information before running the validation assistant.

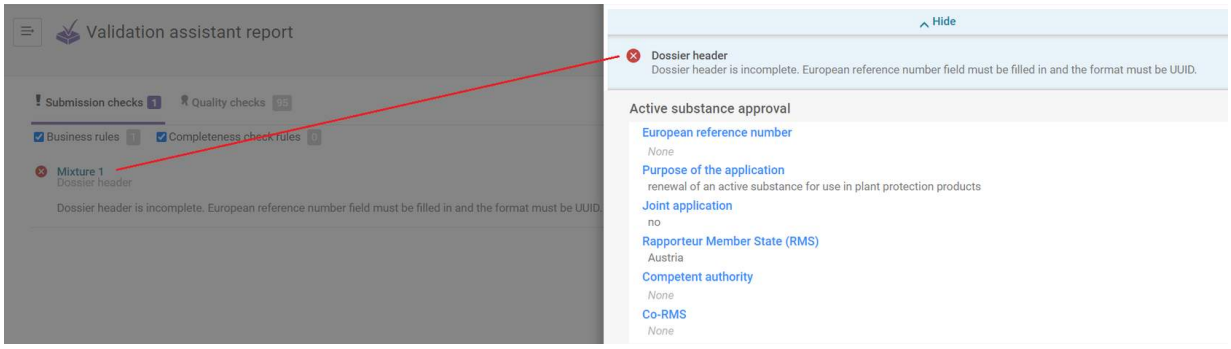




Validation assistant applies Quality checks, Business rules and Completeness checks.

The report lists all the **errors** found in the substance or dossier.

These checks do not apply only to single documents but also check values across documents/datasets.



If the data is incomplete the user can directly fix validation assistant errors by clicking on the link.

For each section where an issue is found, if no link for the record is provided, this means that the record is missing.

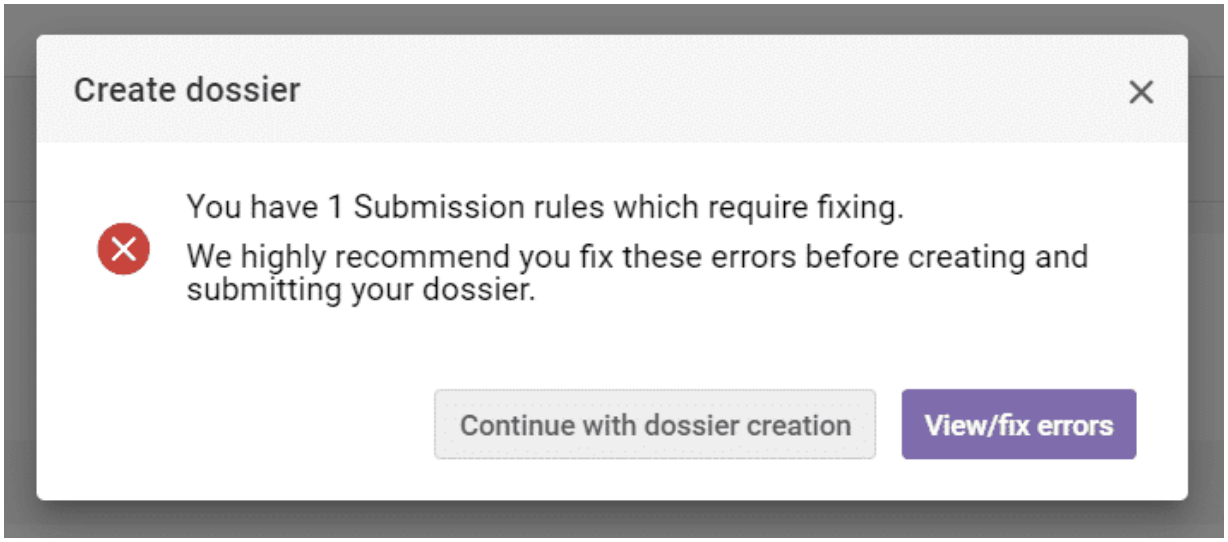
The results of validation assistance can be **downloaded in Excel format**.

VALIDATION DURING DOSSIER CRE...

During the creation of a dossier, the user may opt to run the validation assistant.

This is an option provided by the validation assistant to start fixing the dataset's problems before creating a dossier.

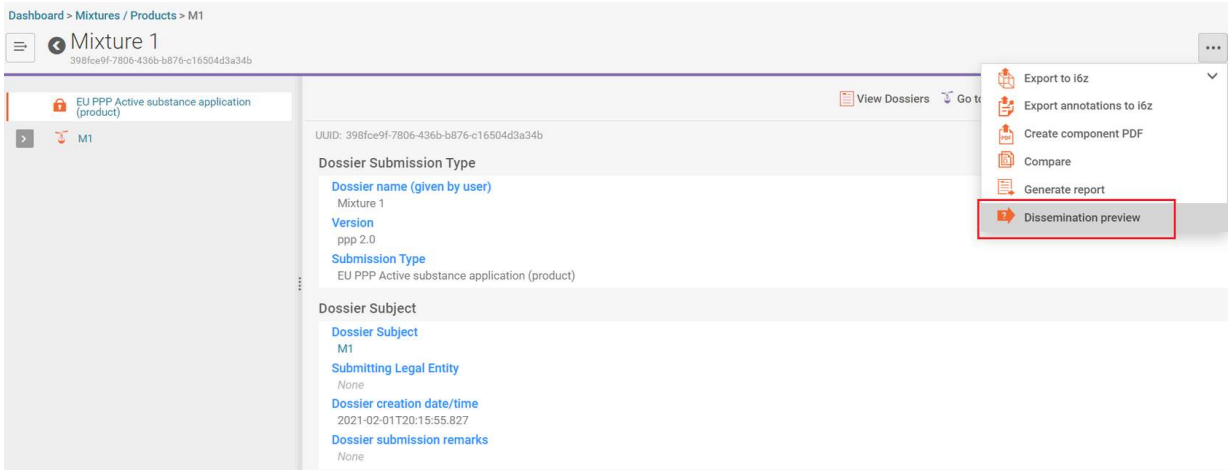
It is also possible to ignore the warning and create a dossier, but bear in mind it will not be possible to submit the dossier as long as the errors exist.



2

Output of the dissemination preview

The dissemination preview allows you to simulate which information from your dossier is likely to be made publicly available by EFSA in the process known as dissemination.

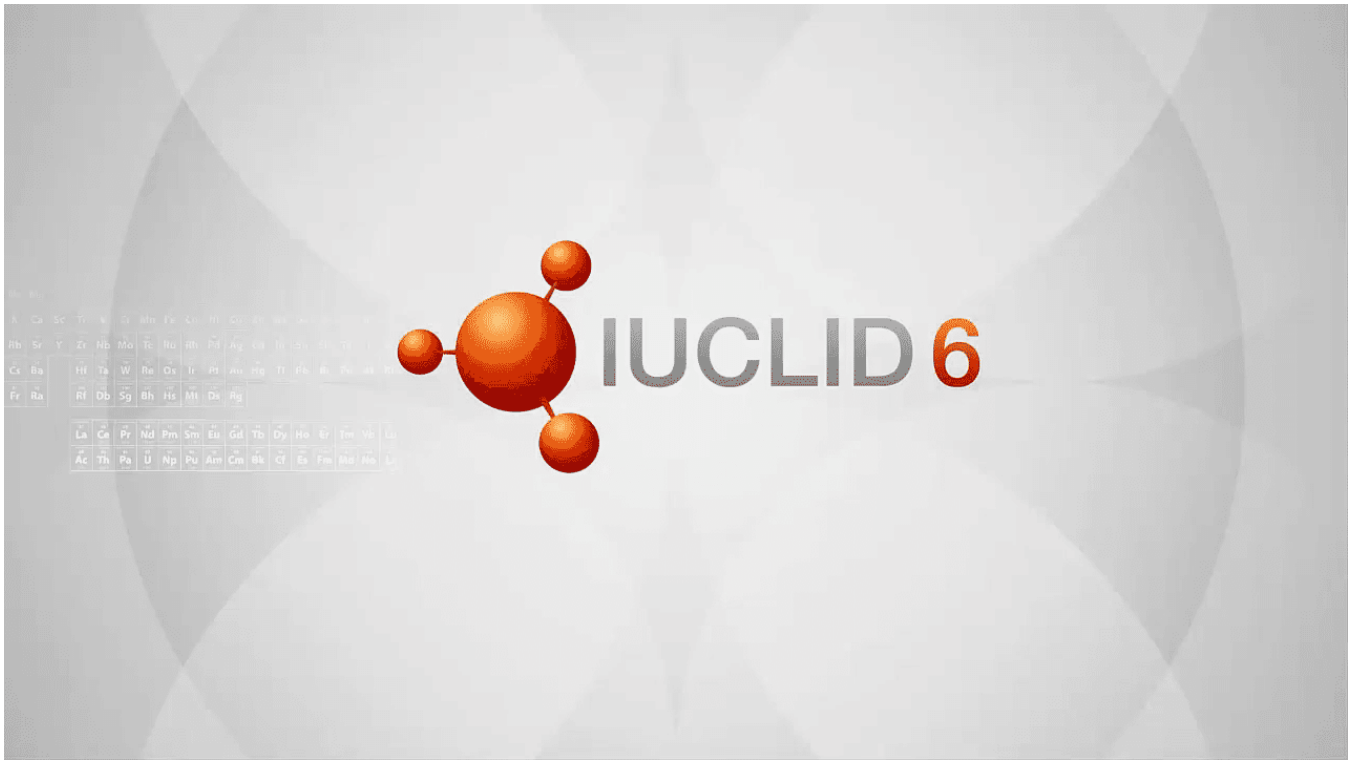


The **dissemination preview** is run from the top level of the record for a dossier.

The **output** of the dissemination preview is a file in the format of Microsoft Excel (XLSX).

The output contains an indication of the publicly available information over the internet when a link to the dossier is available from the OpenEFSA portal.

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



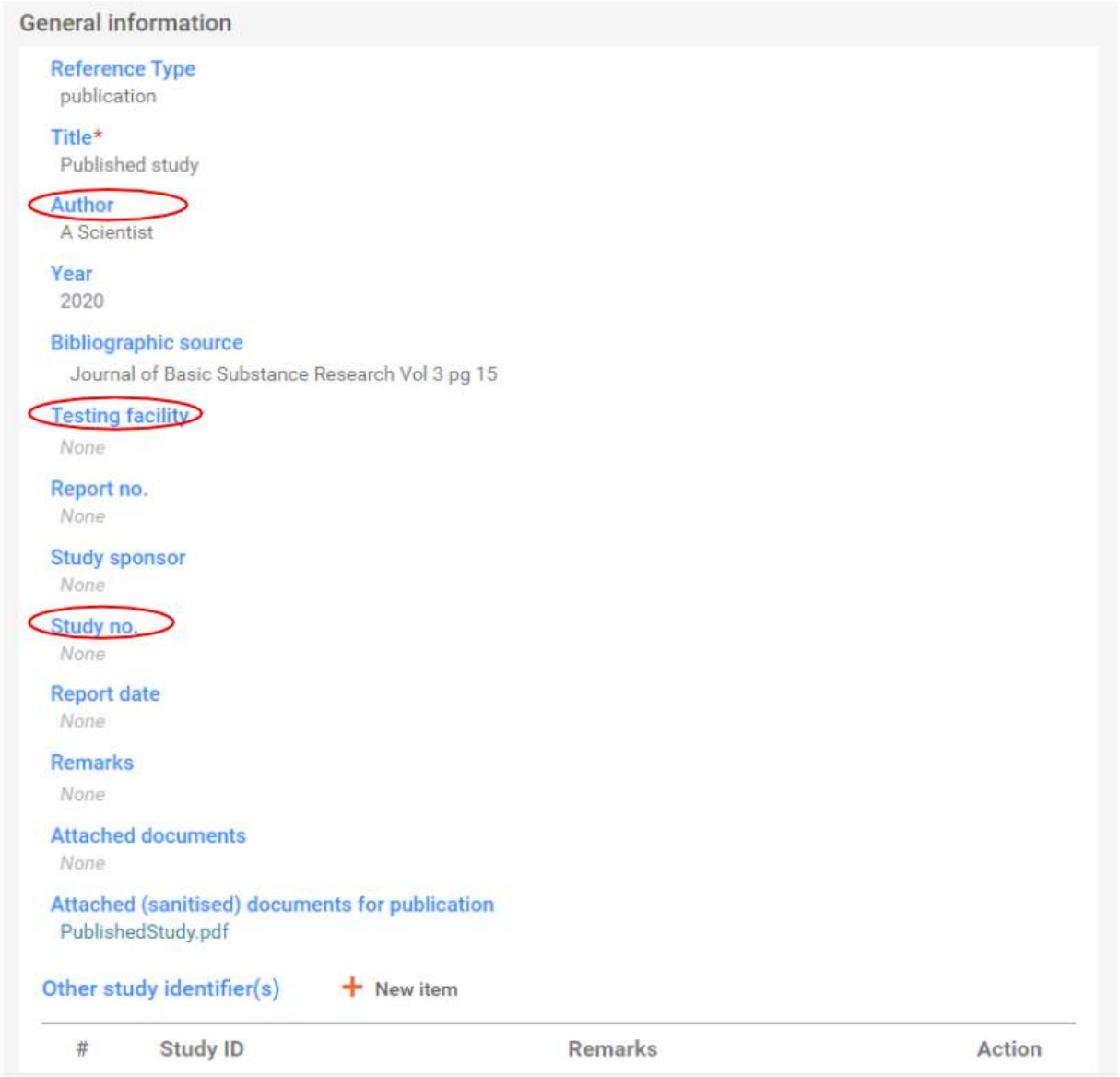
IUCLID 6.5 paths	DRAFT filter rule
LITERATURE.GeneralInfo.LiteratureType	PUBLISHED
LITERATURE.GeneralInfo.Name	PUBLISHED
LITERATURE.GeneralInfo.Author	STUDY_REF_PPP
LITERATURE.GeneralInfo.ReferenceYear	PUBLISHED
LITERATURE.GeneralInfo.Source	PUBLISHED
LITERATURE.GeneralInfo.TestLab	STUDY_REF_PPP
LITERATURE.GeneralInfo.ReportNo	STUDY_REF_PPP
LITERATURE.GeneralInfo.CompanyOwner	PUBLISHED
LITERATURE.GeneralInfo.CompanyOwnerStudyNo	PUBLISHED
LITERATURE.GeneralInfo.ReportDate	PUBLISHED
LITERATURE.GeneralInfo.Remarks	PUBLISHED
LITERATURE.GeneralInfo.AttachedDocuments	PUBLISHED
LITERATURE.GeneralInfo.AttachedSanitisedDocsForPublication	PUBLISHED
LITERATURE.GeneralInfo.StudyIdentifiers	PUBLISHED
LITERATURE.GeneralInfo.StudyIdentifiers.StudyID	PUBLISHED
LITERATURE.GeneralInfo.StudyIdentifiers.Remarks	PUBLISHED

You can format the report as a table keeping the headers row. You can **search** and **sort** based on outcome type review all the information per field **removed** or **published** in the filtered

dossier.

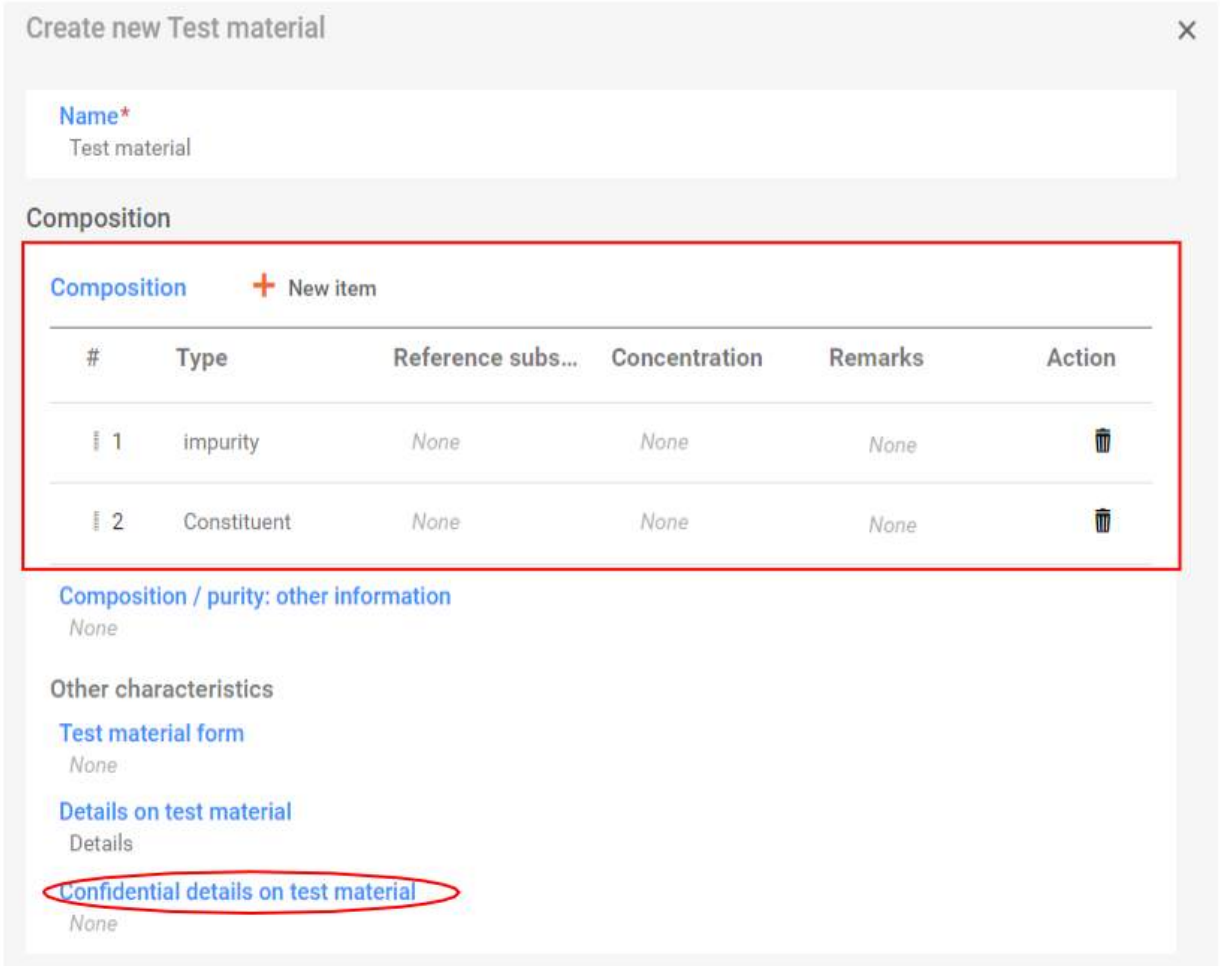
You can either search for a given section of the dossier or copy the path for a specific field from the IUCLID manual.

- Every field used in pesticide submissions in IUCLID has been assigned a preliminary **filter rule**, which determines whether the underlying information will be published or not.
- **Currently,** the following rules are used:
    - **PUBLISHED** – default rule implies publication
    - **UNLESS_CONF**
        - The information is published unless claimed confidential.
        - If **claimed confidential,** the information **will not be published** pending the outcome of the confidentiality assessment.
        - If the claim is **rejected**, will subsequently **publish** the underlying data.



- The following **rules** are currently being implemented and will be available by March 2021:
    - **STUDY_REF_PPP,** which impacts certain data in the Literature Entity:
    - Will apply it to **TOX/ECOTOX** studies or, in general, studies involving tests on vertebrate animals (i.e. including Metabolism in livestock & Residues in livestock)
    - No action if the Reference Type is set to “publication” or “review article or handbook” publication of the data

- If the study is **unpublished**, the following data will be **removed**:
    a. Author
    b. Testing facility
    c. Study no.



- **TEST_MATERIAL_PPP,** which impacts certain data in the **Test Material Entity**:

- It will read the confidentiality flag in an endpoint study record and remove the following associated information:

    a. Composition repeatable block

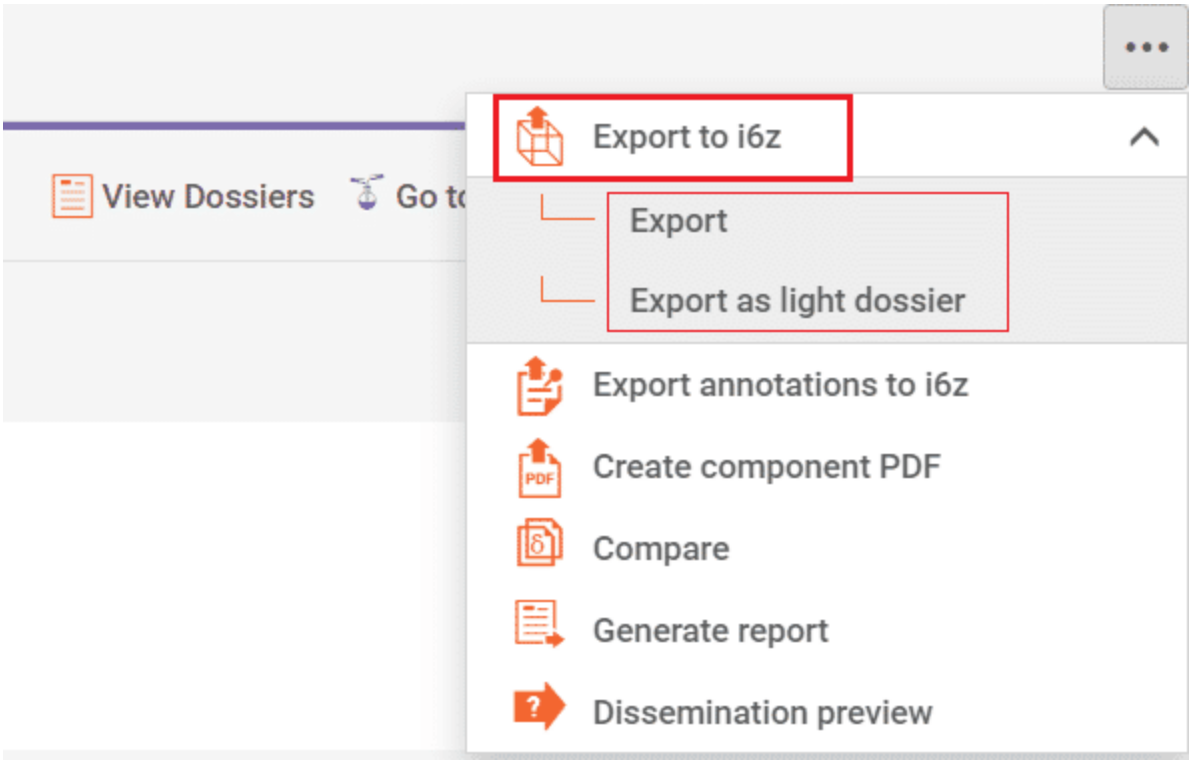
    b. Confidential details on test material

3

How to export a dossier

To share/submit the completed dossier, it is necessary to export the dossier.

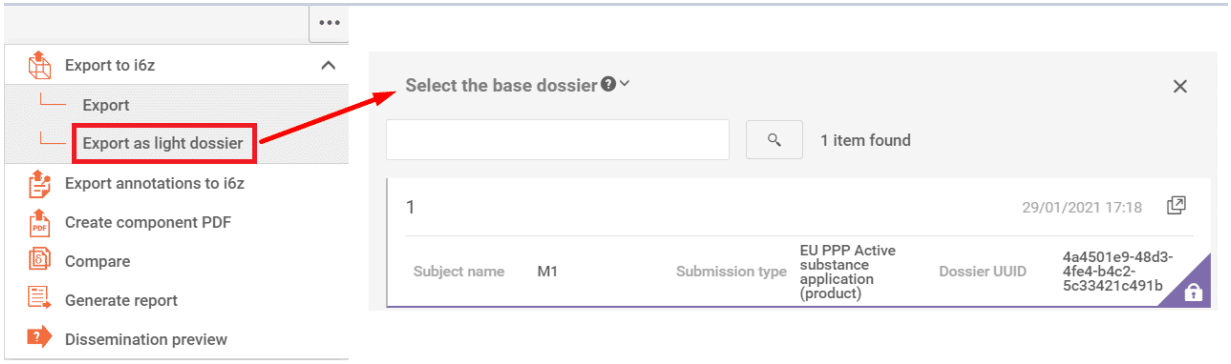
The **export** is accessed from the top level of the application window.



i6z is the ZIP format for IUCLID.

Can submit the exported document to EFSA via the submission portal.

There are two options for exporting a dossier, and the selection is dependent on the size of the dossier and the number of attachments.



Export as a light dossier

A light dossier will include only those attachment files that have been changed compared to another version of the dossier (the base dossier).

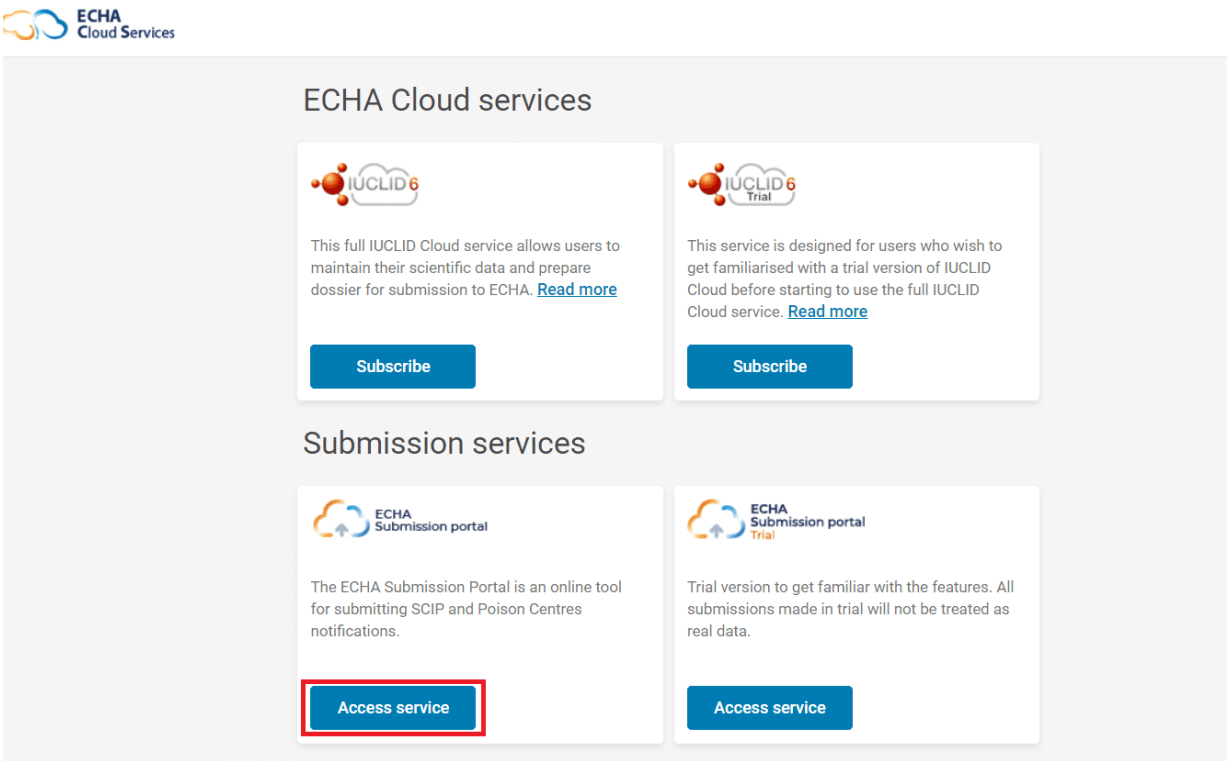
4

Submission of a dossier

Once you are satisfied with the data in your IUCLID dossier, you can submit it to EFSA.

You can submit a dossier via IUCLID Cloud. Still, if you already have all the needed documents/ files, you can upload them directly to ECHA Submission Portal.

In case you already have the documents..... you can access the **ECHA Submission portal** and upload the documents.



ECHA Submission Portal

- is used to submit and follow-up EU PPP, PCN and SCIP dossiers
- is scalable, and there can be submitted higher volume dossiers

- allows dossiers also to be submitted from other systems