

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

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:

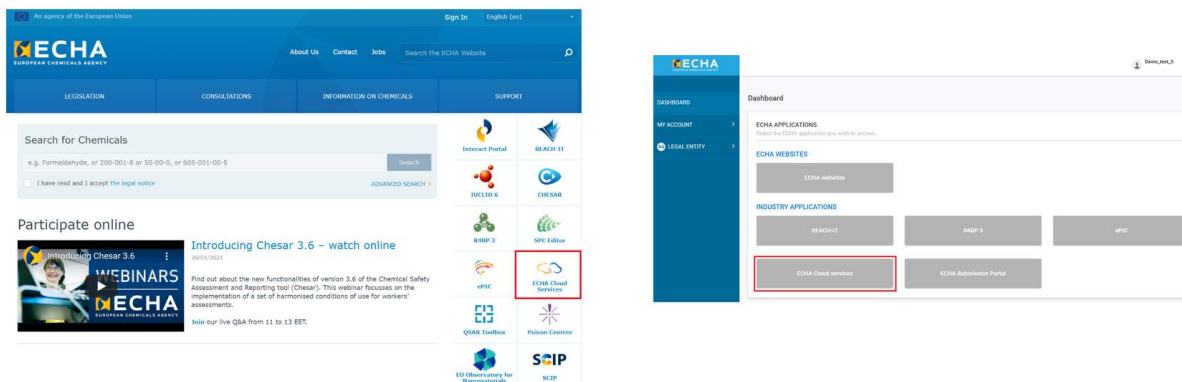
- Access from anywhere, anytime, to the latest release of the IUCLID application, maintained by ECHA;
- Regular and automated data backups by ECHA;
- Easy online collaboration. Companies can improve data security by reducing the number of local copies;
- Secure submission portal to submit EU_PPP applications 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 Cloud 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.

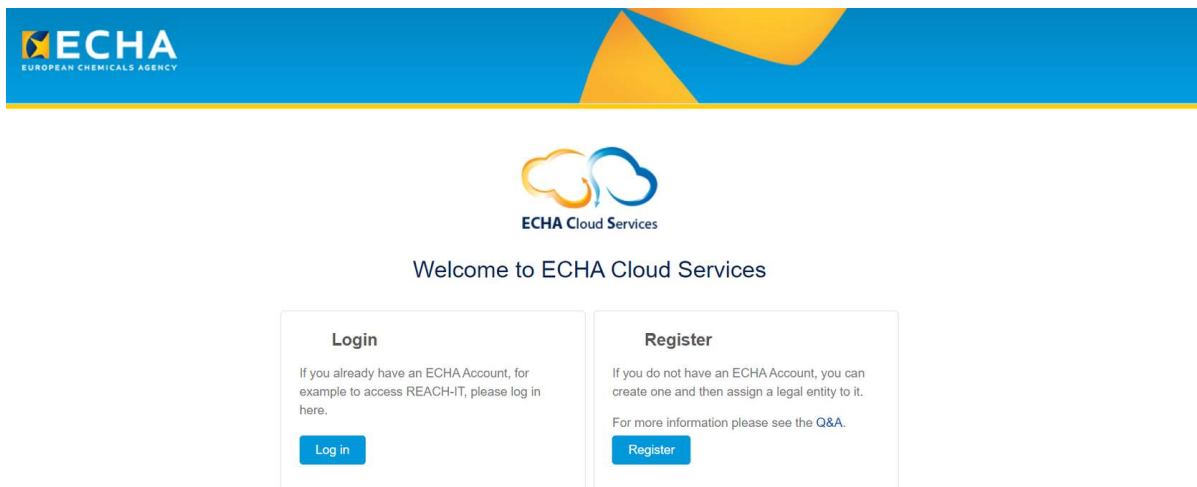
To access the cloud space, you need to **log in** using your ECHA Account credentials.

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 to **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

Create Account

USER INFORMATION AND PASSWORD

Enter your user information and password

First Name *

0/64

Last Name *

0/64

Email *

Please provide an email address used only by the user you are creating

Username *

A user id of your choice that will be used later by the user to login. It may consist of letters A-Z, a-z, digits 0-9 or underscores

0/20

Phone

0/50

Password *

The password must have at least 8 characters and contain three of the following character types: uppercase letter, lowercase letter, number and non-alphabetical. The password must not contain your username, your first name or your last name. The password cannot be the same as a previously used password. The password cannot be changed more than once a day.

Create User

Cancel

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

The image displays two screenshots of the ECHA user interface. The left screenshot shows the 'Dashboard' with a sidebar containing 'DASHBOARD' and 'MY ACCOUNT'. The 'MY ACCOUNT' section is expanded, showing 'ECHA APPLICATIONS', 'ECHA WEBSITES', and 'INDUSTRY LEGAL ENTITY CREATION'. The 'Create a New Legal Entity' button is highlighted with a red box. The right screenshot shows the 'Create Legal Entity' form, which includes sections for 'ACCOUNT SECURITY', 'ALERTS', 'CREATION METHOD', and 'GENERAL DETAILS'.

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

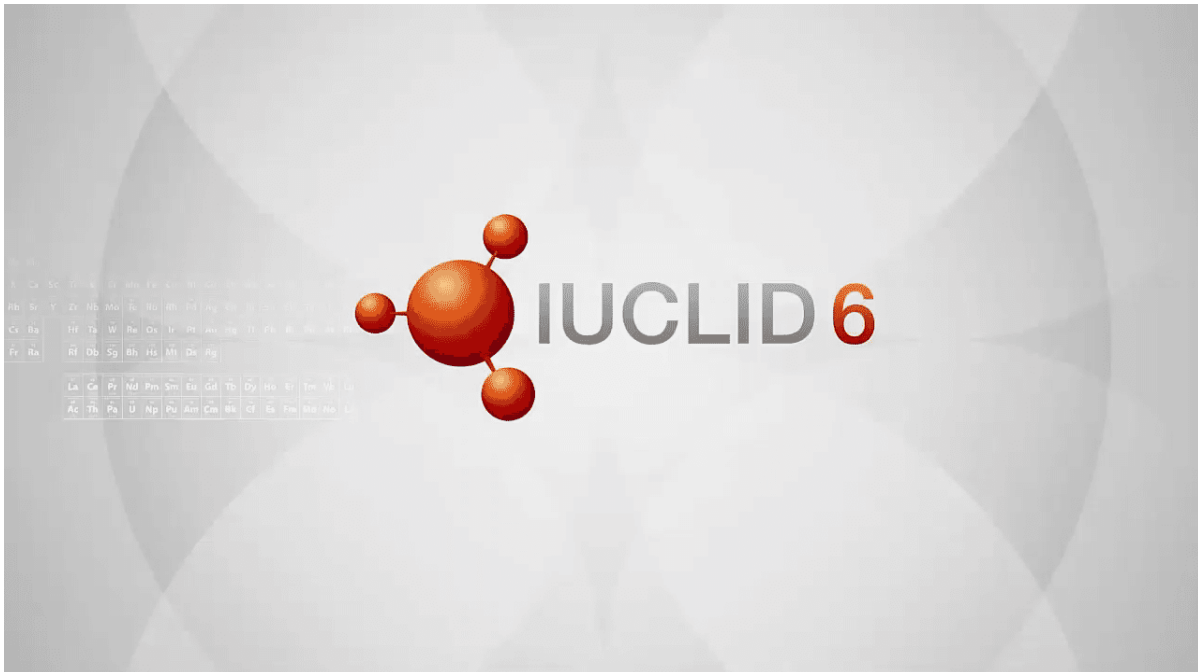
In case the company already has a legal entity, it can reuse it for EU_PPP submissions.

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

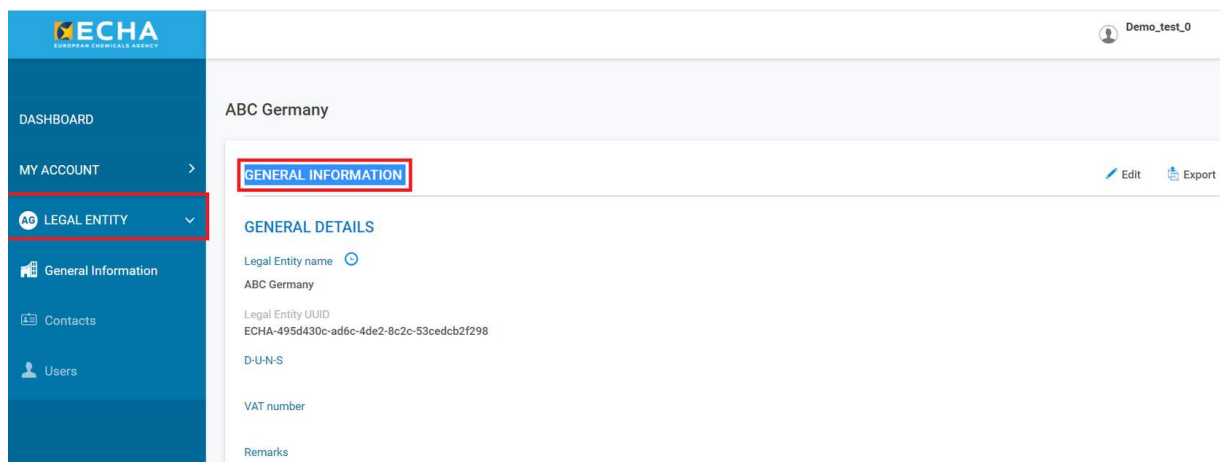


For guided journey please watch the video.

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**.



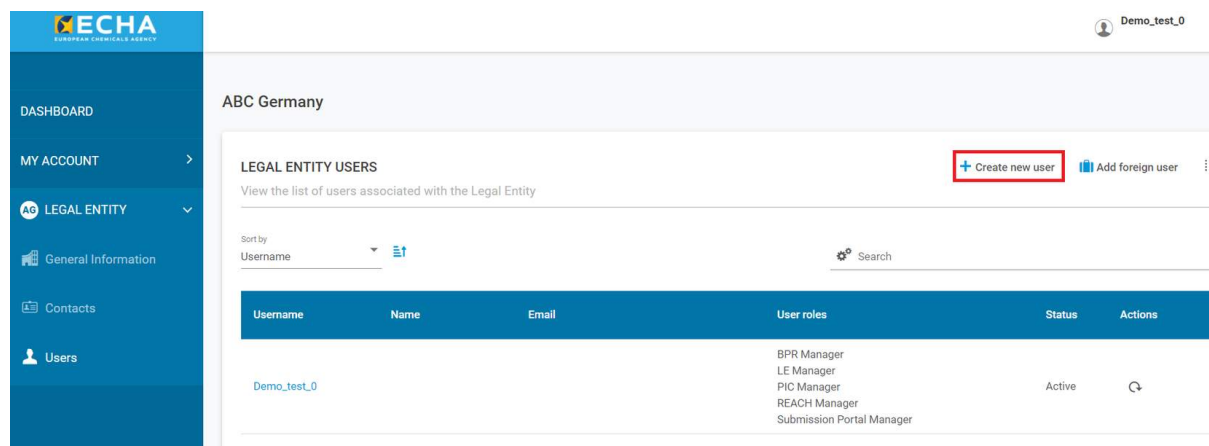
How to add new users

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.



The screenshot shows the ECHA Legal Entity Users management interface. On the left is a blue sidebar with the ECHA logo and a menu including DASHBOARD, MY ACCOUNT, LEGAL ENTITY (selected), General Information, Contacts, and Users. The main content area is titled 'ABC Germany' and 'LEGAL ENTITY USERS'. It includes a '+ Create new user' button (highlighted with a red box), an 'Add foreign user' button, and a search bar. Below is a table with columns: Username, Name, Email, User roles, Status, and Actions. One user, 'Demo_test_0', is listed with roles: BPR Manager, LE Manager, PIC Manager, REACH Manager, and Submission Portal Manager. The status is 'Active'.

Username	Name	Email	User roles	Status	Actions
Demo_test_0			BPR Manager LE Manager PIC Manager REACH Manager Submission Portal Manager	Active	

Click the link below to access the guided tutorial.

[How to create users in a Legal Entity \(company\) as a Legal Entity Manager](#)

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.

ECHA
EUROPEAN CHEMICALS AGENCY

DASHBOARD
MY ACCOUNT
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	

1 Insert information of foreign user **2** Assign roles to user **3** Confirm addition of user

USER INFORMATION
Add the details of the foreign user that you want to added to your legal entity

Username *

Primary Legal Entity UUID *

Please, enter the UUID of the Legal Entity the user belongs to.

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.

ABC Germany

LEGAL ENTITY USERS

+ Create new user

Add foreign user

View the list of users associated with the Legal Entity

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	<div></div>
<div><div></div>DemoTest1</div>			IUCLID Full Access	Active	<div></div>

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 Cloud 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>

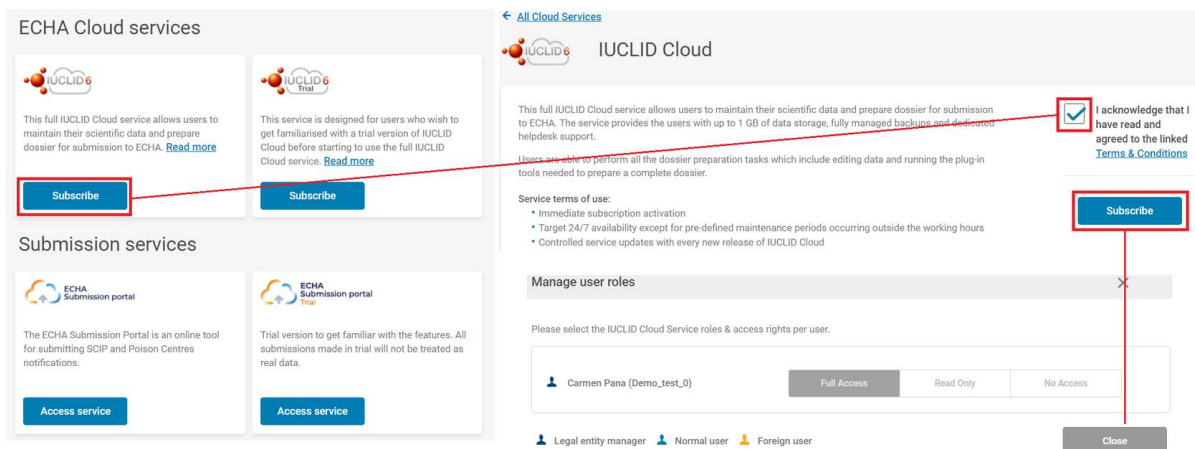
 **CLOUD:** ECHA Cloud Services, hosted by ECHA. The current storage allocation for IUCLID cloud services is 5GB per instance.

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



ECHA Cloud services

This full IUCLID Cloud service allows users to maintain their scientific data and prepare dossier for submission to ECHA. [Read more](#)

[Access service](#) [Manage service](#)

This service is designed for users who wish to get familiarised with a trial version of IUCLID Cloud before starting to use the full IUCLID Cloud service. [Read more](#)

[Subscribe](#)

Submission services

The ECHA Submission Portal is an online tool for submitting SCIP and Poison Centres notifications.

[Access service](#)

Trial version to get familiar with the features. All submissions made in trial will not be treated as real data.

[Access service](#)

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

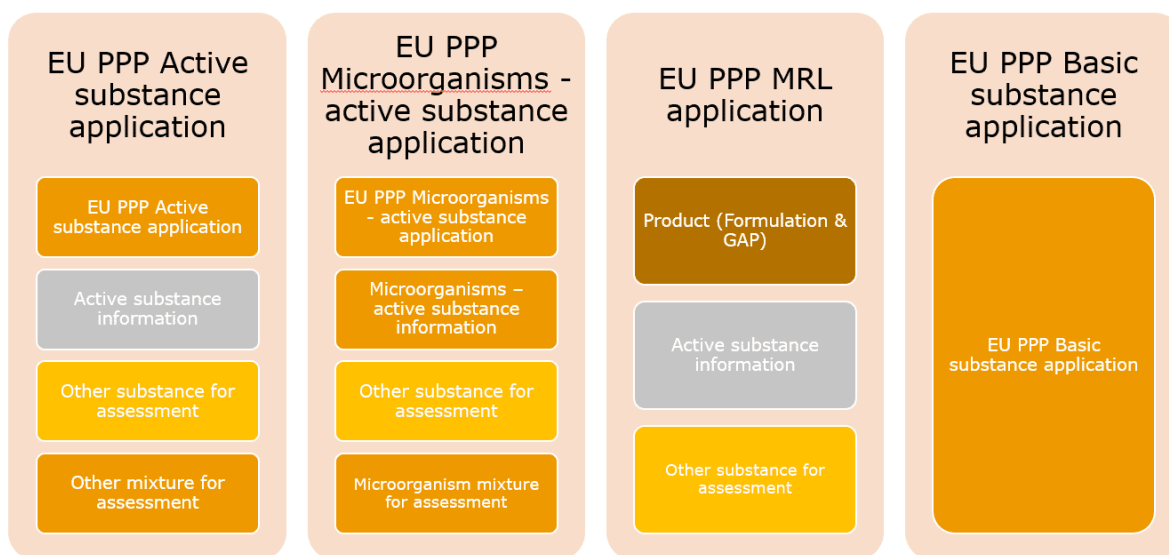
Key concepts of an IUCLID dossier

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 or 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.

The screenshot displays the OECD EHS interface. On the left, a sidebar lists nine categories of endpoint study records, each with a count in a grey circle: 1 Identity of the plant protection product and applicant (6), 2 Physical, chemical and technical properties of the plant protection product (4), 3 Data on application (12), 4 Further information on the plant protection product (1), 5 Analytical methods (2), 6 Efficacy data (3), 7 Toxicological studies on the plant protection product (8), 8 Residues in or on treated products, food and feed, and 9 Fate and behaviour in the environment. Two records are expanded under category 5: '2001_Monitoring purposes_Cereal' and '2005_Method_Risk_Assessment_Cereal'. The right panel shows the details for '2001_Monitoring purposes_Cereal', including its UUID (6f6e25ca-02c7-4d38-abcd-d69119181637) and administrative data (None). The main content area lists predefined fields: Endpoint (methods for post-approval control and monitoring purposes), Type of information (experimental study), Adequacy of study (key study), Robust study summary (checked), Used for classification (unchecked), Used for SDS (unchecked), Study period (2001), and Reliability (1 (reliable without restriction)).

Category	Count
1 Identity of the plant protection product and applicant	6
2 Physical, chemical and technical properties of the plant protection product	4
3 Data on application	12
4 Further information on the plant protection product	1
5 Analytical methods	2
6 Efficacy data	3
7 Toxicological studies on the plant protection product	8
8 Residues in or on treated products, food and feed	
9 Fate and behaviour in the environment	

2001_Monitoring purposes_Cereal
UUID: 6f6e25ca-02c7-4d38-abcd-d69119181637
Administrative data: 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**

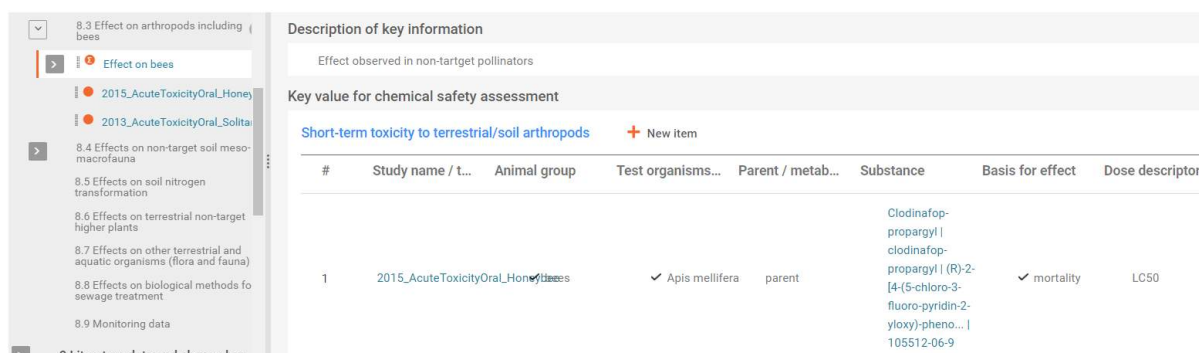
Study period
2001

Reliability
1 (reliable without restriction)

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).



The screenshot shows the IUCLID interface. On the left is a sidebar with a tree view of categories: 8.3 Effect on arthropods including bees, 8.4 Effects on non-target soil meso-macrofauna, 8.5 Effects on soil nitrogen transformation, 8.6 Effects on terrestrial non-target higher plants, 8.7 Effects on other terrestrial and aquatic organisms (flora and fauna), 8.8 Effects on biological methods for sewage treatment, 8.9 Monitoring data, and 9 Literature data and change log. The main panel is titled 'Description of key information' and contains a section 'Key value for chemical safety assessment' with a sub-section 'Short-term toxicity to terrestrial/soil arthropods'. Below this is a table with the following data:

#	Study name / t...	Animal group	Test organisms...	Parent / metab...	Substance	Basis for effect	Dose descriptor
1	2015_AcuteToxicityOral_Honeybees	bees	✓ Apis mellifera	parent	Clodinafop-propargyl clodinafop-propargyl (R)-2-[4-(5-chloro-3-fluoro-pyridin-2-yloxy)-pheno... 105512-06-9	✓ mortality	LC50

Which are IUCLID entities?

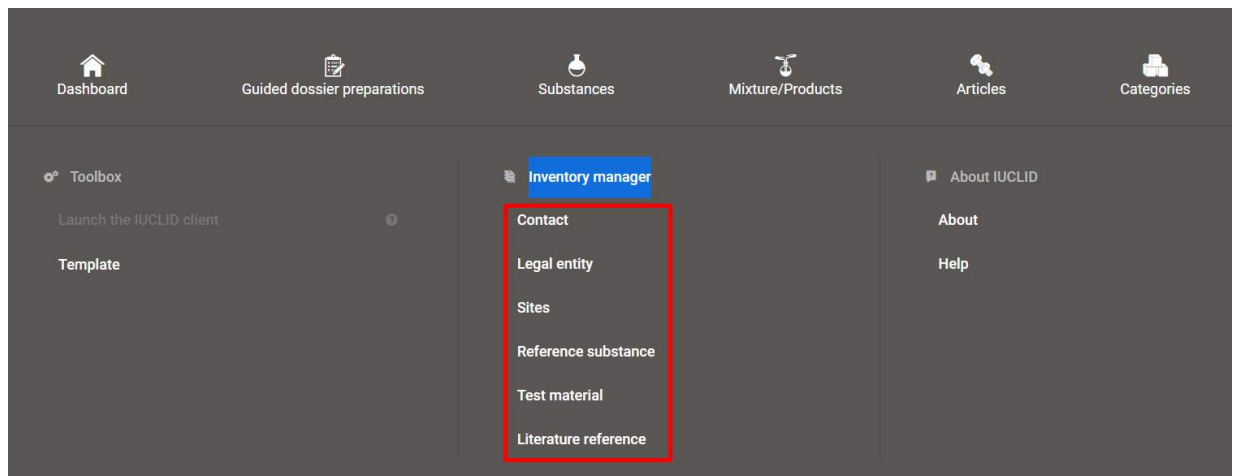
In IUCLID, an Entity is usually an inventory of information **linked to and reused** by any document.

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	TEST MATERIAL
<p>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).</p> <p>Using Contacts removes the need to re-enter details where a particular person is involved across multiple processes and Substances.</p> <p>A Contact can be either edited or created from the place within a document or entity that links to it.</p>				

Dashboard > Contacts

Contacts

+ New contact ?

Advanced search

1 result found | Export Delete

Sort by Newest first

☐ Jones, Mike
 25/01/2021 21:49

Last Name	Jones	First Name	Mike
UUID	53aee216-6689-4607-84fb-6f160c4e059c		

CONTACTS

LEGAL ENTITY

SITES

REFERENCE
SUBSTANCE

TESTS

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.

Dashboard > Legal entities

Legal entities

+ New legal entity ?

Advanced search

1 result found | Export Delete

Sort by Newest first

☐ ABC Germany
 21/01/2021 16:19

Legal entity town	London	Legal entity country	United Kingdom of Great Britain and Northern Ireland (the)	UUID	ECHA-495d430c-ad6c-4de2-8c2c-53cedcb2f298
-------------------	--------	----------------------	--	------	---

CONTACTS	LEGAL ENTITY	SITES	REFERENCE SUBSTANCE	TEST
<p>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.</p>				

CONTACTS	LEGAL ENTITY	SITES	REFERENCE SUBSTANCE	TEST
<p>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.</p> <p><i>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 mass</i> <i>Microorganisms: Identity of the microorganism – Name, taxonomy, species description and strain characterisation.</i></p> <p>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.</p>				

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

CONTACTS	LEGAL ENTITY	SITES	REFERENCE SUBSTANCE	TEST MATERIAL
<p>Test materials is an entity used to describe the material on which a physical test has been performed.</p> <p>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.</p> <p>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.'</p>				

UUID: ed59bdaf-644e-4384-ae0d-2a074855e1f4

Name*

Batch 12345

Composition

Composition

+ New item

#	Type	Reference substance	Concentration
1	impurity	Impurity A 2-(trichloromethylsulfanyl)isoindole-1,3-dione 133-07-3	ca. 1 mg/kg
2	Constituent	Cloquintocet-mexyl Cloquintocet-mexyl 99607-70-2	31 % (v/v)

Composition / purity: other information

technical grade

Other characteristics

Test material form

None

Details on test material

Expiry date 23/05/2020

CONTACTS

LEGAL ENTITY

SITES

REFERENCE
SUBSTANCE

TEST

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 report** should be uploaded in the literature reference with a **sanitised version**.

UUID: 383bf5fd-2bc5-4bd7-9f1a-5cb3e592b780

General information

Reference Type

study report

Title*

New study with NoSID

Author

Smith, et al

Year

2020

Bibliographic source

None

Testing facility

My lab

Report no.

12345

Study sponsor

None

Study no.

None

Report date

None

Remarks

None

Attached documents

StudyWithNoSID.pdf

Attached (sanitised) documents for publication

SutdyWithNoSID(Sanitised).pdf

Other study identifier(s)

+ New item

#	Study ID
1	EFSA_2020_123456778

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 **read-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.

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

	Guided dossier preparation 0	>
	Substances 1	>
	Mixtures 1	>
	Articles 0	>

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

Step 2

How to add your mixture/ product in IUCLID

The screenshot shows the IUCLID interface for adding a new mixture or product. At the top, the breadcrumb 'Dashboard > Mixtures / Products' is visible. Below it, a navigation bar contains a hamburger menu icon, the text 'Mixtures / Products', and a red-bordered button labeled '+ New mixture / product' with a help icon. Below the navigation bar, there are two panels. The left panel, titled 'New mixture / product', contains a text input field labeled 'Name*' with the placeholder text 'Example Mixture 1'. Below the input field are two buttons: 'Close' and 'Create'. The 'Create' button is highlighted with a red border. The right panel, also titled 'New mixture / product', displays a green checkmark icon and the text 'Mixture / Product has been created successfully'. Below this message are two buttons: 'Close' and 'Open'. The 'Open' button is highlighted with a red border.

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

UUID: ddd3565f-ce1a-45a5-861b-4c883a5f4489

Mixture/Product name*
Example Mixture 1

Public name
None

Legal entity owner*
ELL | Bucuresti | Romania

Third party
None

Role in the supply chain ☐ None ☐ None

Manufacturer
☐ **Manufacturer**
☐ **Importer**
☐ **Only representative**
☐ **Downstream user**

Manufacturer
The manufacturer is any natural or legal person who manufactures the mixture.

Importer
Any natural or legal person who is responsible for import.

Only representative
For example, any EU-based representative of a non EU-manufacturer. The 'only representative' needs to have sufficient background in the practical handling of substances and information related to them. The only representative has to be designated by the non-EU manufacturer. The official assignment documentation from a non EU manufacturer may be indicated in the section Suppliers. The other importers of the same mixture from the same non-EU manufacturer are considered to be downstream users for the only representative, and if necessary, they can be specified the section Suppliers.

To complete your mixture product dataset, you need to **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

The screenshot shows the 'Example Mixture 1' page with the breadcrumb 'Dashboard > Mixtures / Products > Example Mixture 1'. The 'Working context' dropdown is open, showing 'Please select' and 'No results found'. A red box highlights the '+ New working context' button. Below it, the 'New working context' dialog box is open, showing a list of working contexts. The first item, 'BPR Active substance application (representative product)', is highlighted in blue. A red box highlights the dropdown arrow in the dialog box.

Dashboard > Mixtures / Products > Example Mixture 1

Example Mixture 1
ddd3565f-ce1a-45a5-861b-4c883a5f4489

Working context: Please select

No results found

+ New working context

New working context

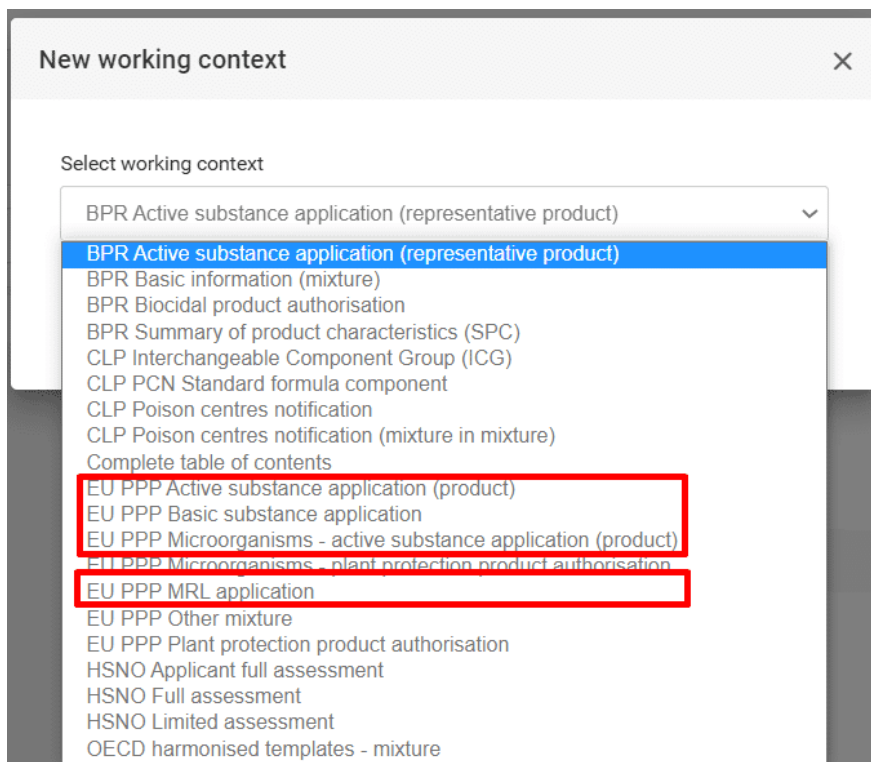
Select working context

- BPR Active substance application (representative product)
- BPR Basic information (mixture)
- BPR Biocidal product authorisation
- BPR Summary of product characteristics (SPC)
- CLP Interchangeable Component Group (ICG)
- CLP PCN Standard formula component
- CLP Poison centres notification
- CLP Poison centres notification (mixture in mixture)
- Complete table of contents
- EU PPP Active substance application (product)
- EU PPP Basic substance application
- EU PPP Microorganisms - active substance application (product)
- EU PPP Microorganisms - plant protection product authorisation
- EU PPP MRL application
- EU PPP Other mixture
- EU PPP Plant protection product authorisation
- HSNO Applicant full assessment
- HSNO Full assessment
- HSNO Limited assessment
- OECD harmonised templates - mixture

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

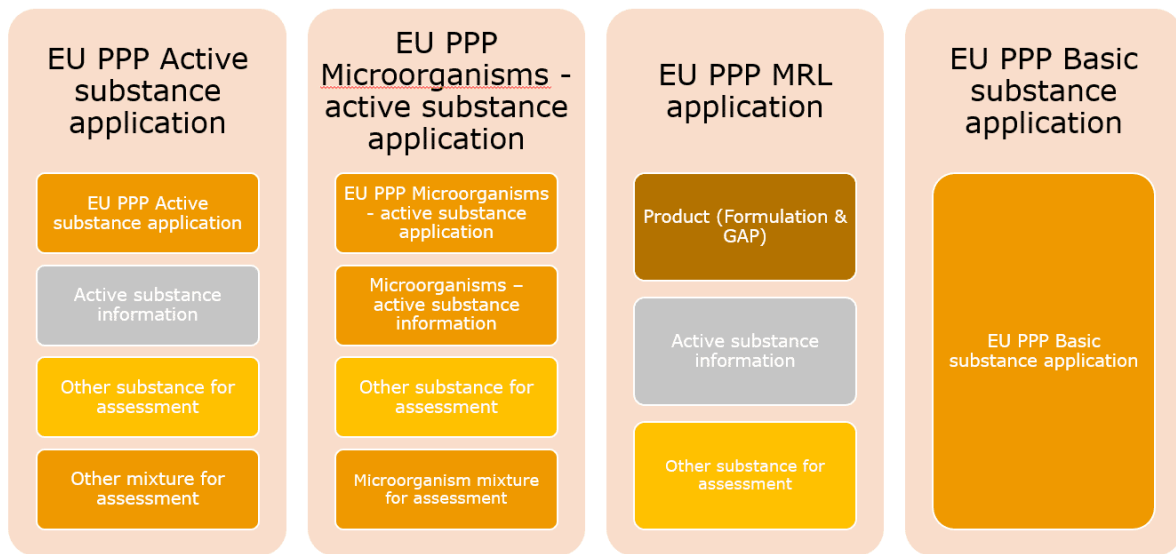


The working context includes the Table of Contents and the IUCLID documents needed to meet the regulatory data requirements (see links below).

<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.'



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**

Working context: EU PPP Active substance application (product)

View Dossiers Validate Create dossier

protection product and applicant

1.1 Identity of the plant protection product, trade name or proposed trade name, and applicant

1.2 Producer of the plant protection product

1.3 Producer's development code number if appropriate

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

1.4.1 (Cf. 1.4) Composition of the plant protection product

1.4.2 (Cf. 1.4) Information on the active substances

1.4.3 (Cf. 1.4) Information on adjuvants, synergists and co-formulants

1.4.4 Information on metabolites

1.5 (Cf. 1.4) Type and code of the plant protection product

1.6 (Cf. 3.2) Function

2 Physical, chemical and technical properties of the plant protection product

Administrative data

General information

Mixture/product name

Trade names

Brief description

Formulation type

Components

New item

#	Component ...	Name	Function	Typical con...	Concentrati...	Remarks	Substance o...	Generic co...	Interchange...	Standard for...	Substance g...	Action
---	---------------	------	----------	----------------	----------------	---------	----------------	---------------	----------------	-----------------	----------------	--------

Save

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

Set values

✕

None None

Name

+ Select

Mixture / Product

Reference substance

Substance

Remarks

None

☐ Substance of concern

☐ Generic component identifier (GCI)

☐ Interchangeable component group (ICG)

☐ Standard formula (SF) component

☐ Substance generated in situ (from one or more precursors, at the place of use)

press Esc to close

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**.

Select Substance

Type at least 3 characters 8 results found

► Advanced search

Aqueous extract from germinated seeds of sweet		
Inventory number	CAS number	
Legal Entity	Chemical123	UUIC

Water		
Inventory number	CAS number	
Legal Entity	Chemical123	UUIC

Create new Substance

Substance name*
None
✗ Substance name field is mandatory.

Public name
None

Legal entity*
None
✗ Legal entity field is mandatory.

Third party
None

Other substance identifiers + New item

#	Flags	Identifier	Identity	Country	Relation	Remarks	Action
---	-------	------------	----------	---------	----------	---------	--------

Contact persons + New item

Identification of substance None None

Reference substance
None










Type of substance

Type of substance
None

Origin
None

Role in the supply chain None None

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

<div>  CBI  EU: PPP FormulationHyper100 </div>						
UUID: 6a40965f-8ac0-4ccf-80a9-9267cedea00c						
<div>  New item </div>						
#	Component flag	Name	Function	Typical conce...	Concentration ...	Remarks
1	<div>  None  None </div>	Hypercare safener Hypercare 345-65-5	safener	<= 5 % (w/w)	> 4 <= 5 % (w/w)	None
2	<div>  None  None </div>	Water Water 7732-18-5	solvent	ca. 10 % (w/w)	> 8 <= 10 % (w/w)	None
3	<div>  CBI  EU: PPP </div>	Aqueous extract from the germinated seeds of sweet... hypercare substance hyppy 000-00-0	active substance	82 % (w/w)	> 80 < 85 % (w/w)	None

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**

CBI EU: PPP FormulationHyper100
 UUID: 190164e4-8c37-45bb-b638-0af7afd80c5d

#	Component ...	Name	Function	Typical con...	Concentrati...	Remarks	Substance ...	Generic co...	Interchange...	Standard fo...	Substance ...	Action
1	None None	Hypercare safener	safener	<= 5 % (w/w)	> 4 <= 5 % (w/w)	None	<input type="checkbox"/> Substance of concern	<input type="checkbox"/> Generic component identifier (GCI)	<input type="checkbox"/> Interchangeable component group (ICG)	<input type="checkbox"/> Standard formula (SF) component	<input type="checkbox"/> Substance generated in situ (from one or more precursors, at the place of use)	
2	None None	Water	solvent	ca. 10 % (w/w)	> 8 <= 10 % (w/w)	None	<input type="checkbox"/> Substance of concern	<input type="checkbox"/> Generic component identifier (GCI)	<input type="checkbox"/> Interchangeable component group (ICG)	<input type="checkbox"/> Standard formula (SF) component	<input type="checkbox"/> Substance generated in situ (from one or more precursors, at the place of use)	
3	CBI EU: PPP	Aqueous extract from germinated seeds of	active substance	82 % (w/w)	> 80 <= 85 % (w/w)	None	<input type="checkbox"/> Substance of concern	<input type="checkbox"/> Generic component identifier (GCI)	<input type="checkbox"/> Interchangeable component group (ICG)	<input type="checkbox"/> Standard formula (SF) component	<input type="checkbox"/> Substance generated in situ (from one or more precursors, at the place of use)	

Save

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

Information on metabolites (Section 1.4.4)

1 Identity of the plant protection product and applicant

1.1 Identity of the plant protection product, trade name or proposed trade name, and applicant

1.2 Producer of the plant protection product

1.3 Producer's development code number if appropriate

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

1.4.1 (Cf. 1.4) Composition of the plant protection product

1.4.2 (Cf. 1.4) Information on the active substances

1.4.3 (Cf. 1.4) Information on safeners, synergists and co-formulants

1.4.4 Information on metabolites

Information on metabolites.001

Information on metabolites.001
 UUID: f4e61471-2325-44f6-968d-9a5cb2f3babc

Metabolites information

Metabolites information overview
 None

Parent of metabolites
 None

List of metabolites

Metabolites + New Item

#	Link to metabolite dataset	Remarks	Action
---	----------------------------	---------	--------

Additional information

Attached background material + New Item

#	Attached document	Remarks	Action
---	-------------------	---------	--------

Attached (sanitised) documents for publication
 None

Save

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.

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 applicant2

2 Physical and chemical properties of the active substance4+

3 Further information on the active substance1+

4 Analytical methods+

5 Toxicological and metabolism studies on the active substance2+

6 Residues in or on treated products, food and feed1+

7 Fate and behaviour in the environment+

8 Ecotoxicological studies on the active substance3+

9 Literature data and change log

10 Classification and labelling of the active substance

11 Summary and evaluation1

Inherited templates

CBI EU

UUID: 6a40965

1 Cour
✓ Ne
Trad
HYF

Brief desc
The mix
Formulati
✓ WP Wet

Component

+ New ite

#

1

2

3

Step 1

How can you complete the TOC (table of content)

The screenshot shows the 'EU PPP Active substance application (product)' interface. On the left, a sidebar lists sections: 1 Identity of the plant protection product and applicant, 2 Physical, chemical and technical properties of the plant protection product, and 3 Data on application. Under section 3.1 Use of the plant protection product (GAP), there are three entries: 'Good agricultural practices (GAP).001', 'Good agricultural practices (GAP).002', and 'Good agricultural practices (GAP).003'. A red box highlights the '+ New document' button next to the first entry. The main area on the right shows the details for 'Good agricultural practices (GAP).001'. It includes a field for 'Product' (None), a 'Description of key information' section with fields for 'Crop information' (Crop / treated object), 'Genetical modification of crop' (None), and 'Crop destination(s)'. A red box highlights the 'Save' button at the bottom right.

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.

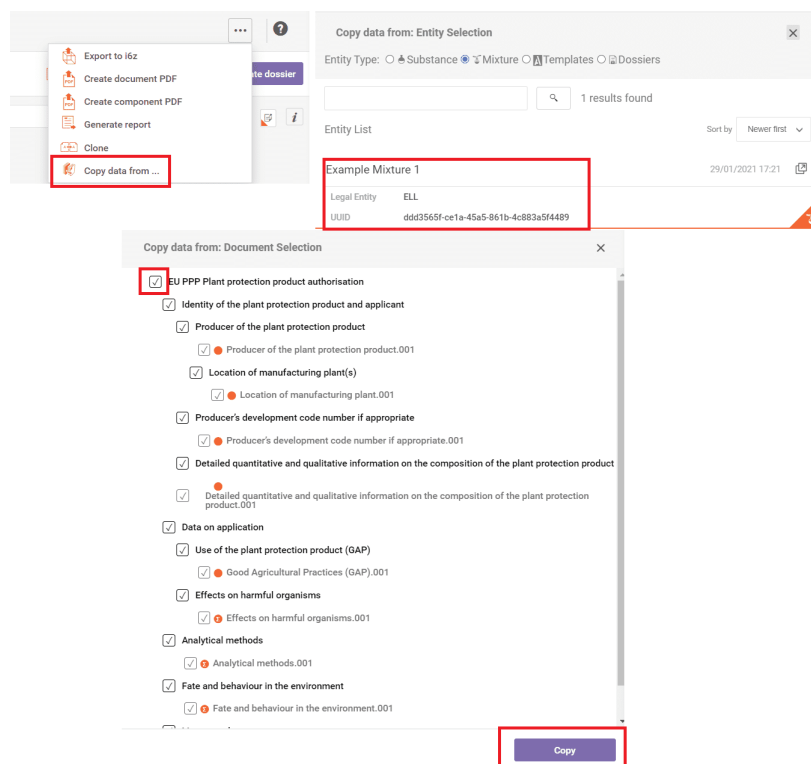
Complete all relevant fields. See EU_PPP manuals for more information on completing IUCLID documents.

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.

The screenshot shows the OECD endpoint study record interface. On the left is a sidebar with a tree view of study categories. The main area is titled 'Appearance (at 20°C and 101.3 kPa).002' and contains several data entry blocks. Three blocks are highlighted with red rectangles: 'Administrative data', 'Data source', and 'Materials and methods'. The 'Administrative data' block includes fields for 'Endpoint', 'Type of information', 'Adequacy of study', 'Study period', 'Reliability', 'Rationale for reliability incl. deficiencies', and 'Data waiving'. The 'Data source' block includes 'Reference', 'Data access', and 'Data protection claimed'. The 'Materials and methods' block includes a table for 'Test guideline' and sections for 'Principles of method if other than guideline', 'GLP compliance', 'Other quality assurance', 'Test material', and 'Specific details on test material used for the study'.

General information

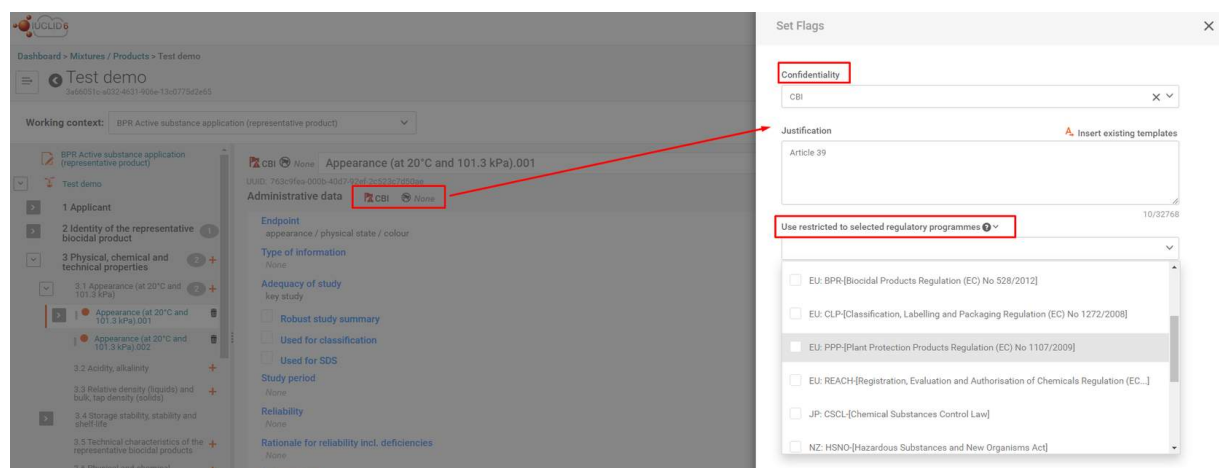
Endpoint study records usually consist of the data entry blocks: ‘Administrative data’, ‘Data source’, ‘Materials and methods’, ‘Test material’.

The screenshot shows the OECD endpoint study record interface for 'Analytical methods.002'. The 'Working context' is set to 'EU PPP Active substance application (product)'. The main area contains several data entry blocks. One block, 'Reliability', is highlighted with a red rectangle. It includes a dropdown menu with options: '1 (reliable without restriction)', '2 (reliable with restrictions)', and '3 (not reliable)'. The 'Save' button is visible at the bottom right.

'Administrative data' block

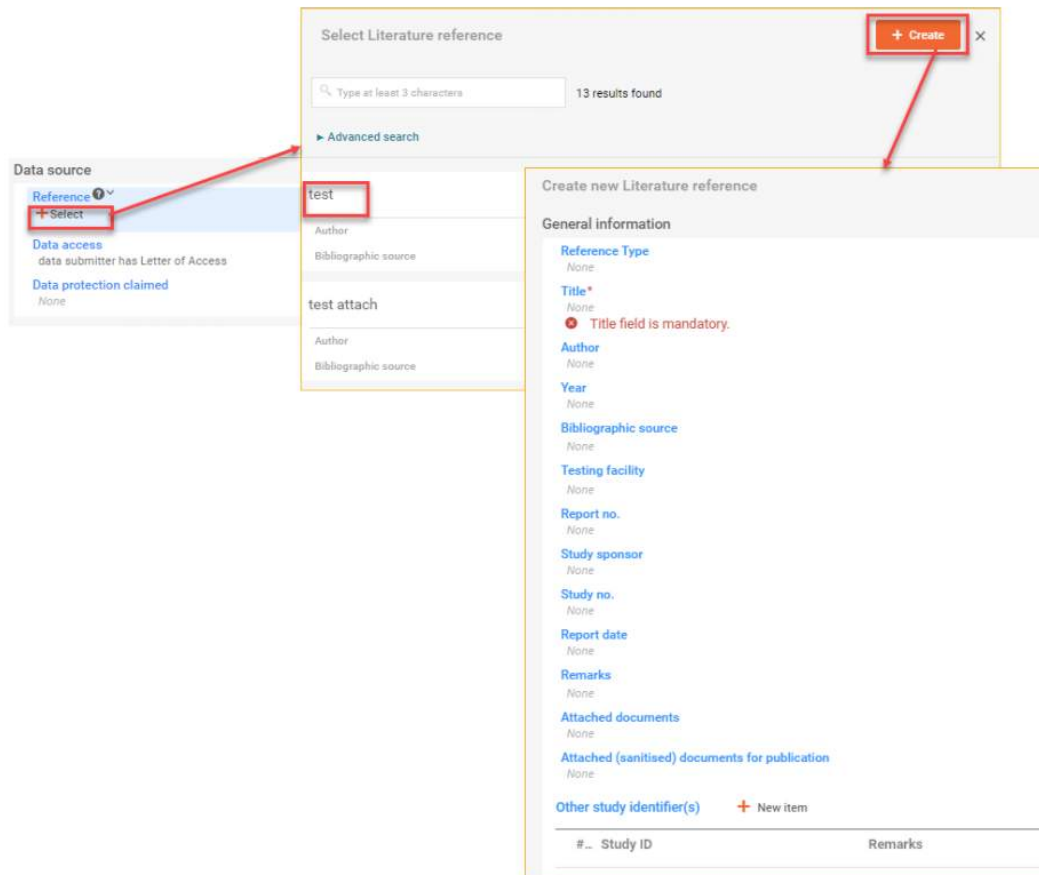
Make a selection (e.g. 'key study') in the field '**Adequacy of study**' using the drop-down list by clicking in the field.

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

[Test guideline](#) + New item

#..	Qualifier	Guideline
1	None	None

[Principles of method if other than guideline](#)
None

[GLP compliance](#) Please select

Set values ✕

[Qualifier](#)
None

[Guideline](#)
None

[Version / remarks](#)
None

[Deviations](#)
None

Test material

[Test material information](#)
None

[Specific details on test material used for the study](#)
None

[Specific details on test material used for the study \(confidential\)](#)
None

Sampling and analysis

[Analytical monitoring](#)
None

[Details on sampling](#)
None

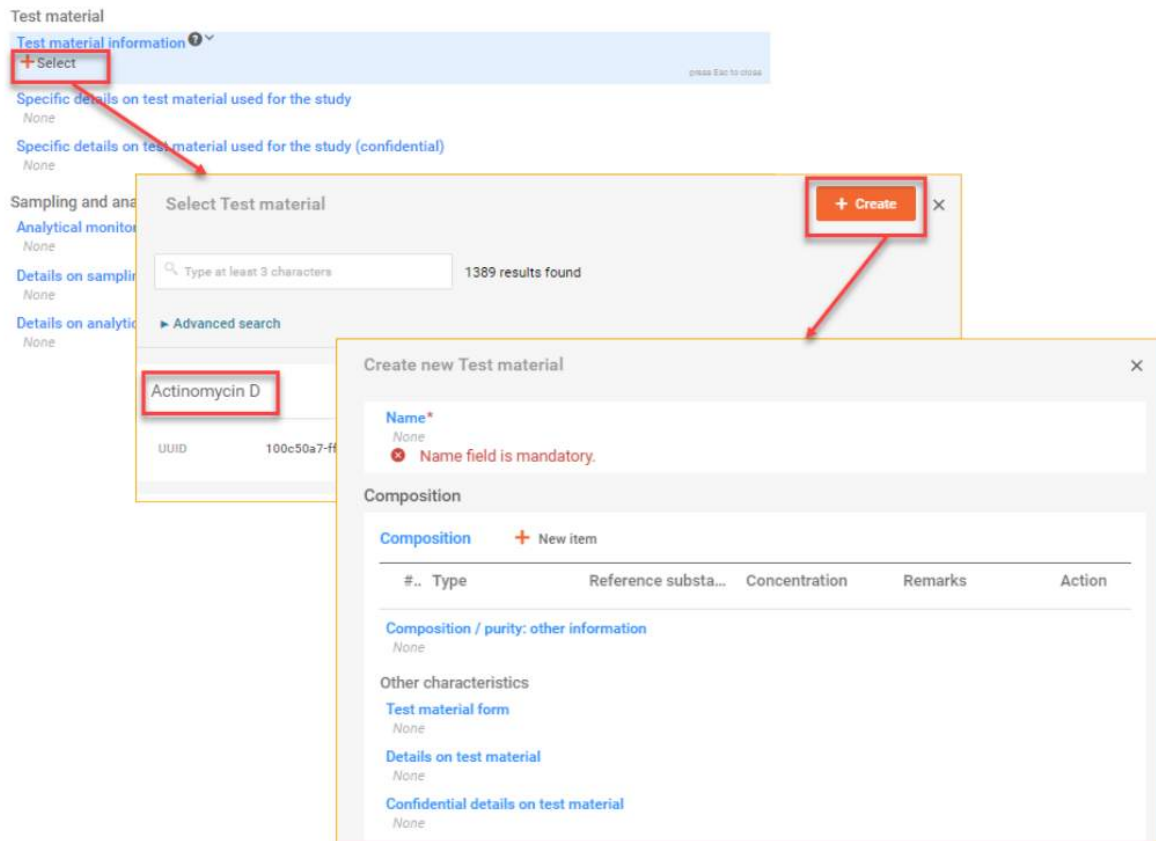
[Details on analytical methods](#)
None

Test solutions

[Vehicle](#)
None

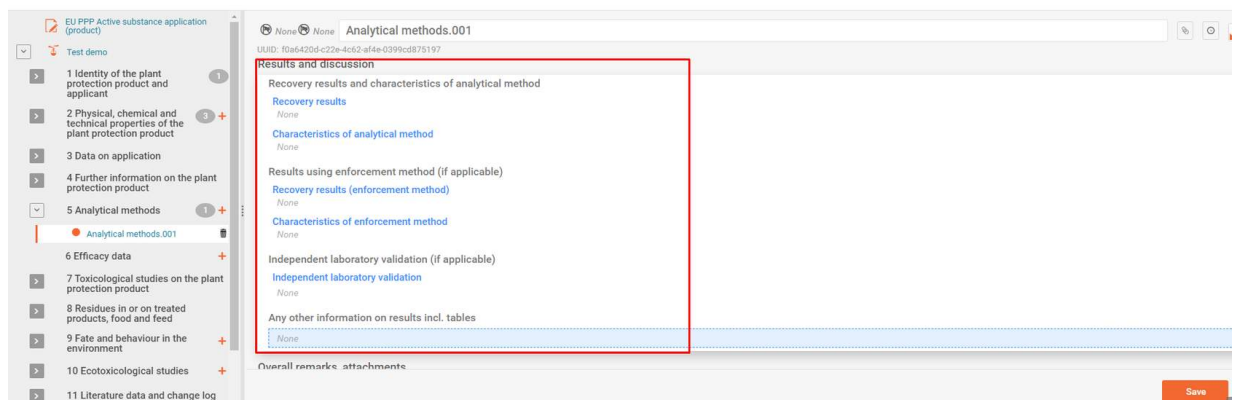
‘Materials and Methods’ block

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.

The screenshot displays the 'EU PPP Active substance application (product)' interface. The 'Working context' is set to 'EU PPP Active substance application (product)'. The left sidebar shows a tree view with the following items:

- 1 Identity of the plant protection product and applicant
- 2 Physical, chemical and technical properties of the plant protection product
 - 2.1 Appearance
 - Appearance (at 20°C and 101.3 kPa).003
 - Appearance (at 20°C and 101.3 kPa).001
 - Appearance (at 20°C and 101.3 kPa).002
 - 2.2 Explosive and oxidising properties
 - 2.3 Flammability and self-heating
 - 2.4 Acidity / alkalinity and pH value
 - 2.5 Viscosity and surface tension
 - 2.6 Relative density and bulk density
 - 2.7 Storage stability and shelf-life, effects of temperature on technical characteristics of the product

The main content area shows the 'Appearance (at 20°C and 101.3 kPa).003' endpoint summary. The summary is divided into several sections, each with a red box highlighting the title:

- Administrative data**: None
- Link to relevant study record(s)**: Study name / type: None
- Description of key information**: None
- Key value for chemical safety assessment**: Physical state at 20°C and 101.3 hPa: None
- Additional information**: None

Below the summary sections, there is a table for 'Attached background material' with a 'New Item' button. The table has columns for '#', 'Attached document', 'Remarks', and 'Action'. The table is currently empty.

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.

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 product applicant

1.1 Identity of the plant protection product proposed trade name, and applicant

▼ 1.2 Producer of the plant protection product

1.2.1 Location of manufacturing plant

▼ Location of manufacturing plant

▼ 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

The screenshot displays the 'EU PPP Active substance application (product)' dossier creation wizard. The top navigation bar includes 'View Dossiers', 'Validate', and 'Create dossier' buttons. A red arrow points to the 'Create dossier' button. The main form area is divided into several sections:

- Dossier name (given by user):** None
- Dossier submission remark:** None
- Active substance approval:**
 - European reference number: None
 - Purpose of the application: None
 - Rapporteur Member State (RMS): None
 - Competent authority: None
 - Co-RMS: None
- Notification of studies:**
 - Pre-application identification: New item
 - Studies requiring NoS justification: New item
 - Attached information: Attachment + New item
- Other submission related information:**
 - MRL application dossier is submitted simultaneously: ☐

The sidebar on the left lists 10 steps for the dossier creation process:

- 1 Identity of the plant protection product and applicant
- 2 Physical, chemical and technical properties of the plant protection product
- 3 Data on application
- 4 Further information on the plant protection product
- 5 Analytical methods
- 6 Efficacy data
- 7 Toxicological studies on the plant protection product
- 8 Residues in or on treated products, food and feed
- 9 Fate and behaviour in the environment
- 10 Ecotoxicological studies

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

EU PPP Active substance application (product)

Dossier name (given by user)
None

Dossier submission remark
None

Active substance approval

European reference number
None

Purpose of the application
None

Rapporteur Member State (RMS)
None

Competent authority
None

Co-RMS
None

Notification of studies

Pre-application identification + New item

Studies requiring NoS justification + New item

Attached information

Attachment + New item

Other submission related information

☐ MRL application dossier is submitted simultaneously

Advanced Settings

Include legal entity

☐ Include legal entity

Select "Include legal entity" if you wish that your company details appear in the dossier header

Detail level of document fields

☒ Detailed fields (e.g. needed for robust endpoint summaries)

☒ Fields marked "confidential"

Flags for confidentiality

Select information to be included*

Data for which a confidentiality flag may be set, but it is not.

CBI

JP

no PA

By default all the information in the dataset will be included in the dossier

If you de-select some information here, it will not be included in the dossier

Flags for regulatory programme

Select information to be included*

☒ No regulatory purposes

☒ AU: AUCIS

☒ CA: CEPA

☒ CA: PCPA

☒ EU: BPR

☒ EU: CLP

☒ EU: PPP

☒ EU: REACH

☒ JP: CSCL

Create dossier

Select documents to be included

Create dossier

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

The screenshot displays the 'Dossier Settings' interface, which is divided into several sections for configuring a dossier. On the left, under 'Dossier Settings', there are checkboxes for 'Detailed fields (e.g. needed for robust endpoint summaries)' and 'Fields marked "confidential"'. Below this, 'Flags for confidentiality' includes a link 'Select information to be included' and checkboxes for 'Data for which a confidentiality flag may be set, but it is not.', 'CBI', 'IP', and 'no PA'. The 'Flags for regulatory programme' section also has a link 'Select information to be included' and a list of regulatory programmes with checkboxes: 'No regulatory purposes', 'EU: BPD or EU: BPR', 'EU: CLP', 'EU: PPP', 'EU: REACH', 'CA: CEPA', 'CA: PCPA', 'JP: CSCL', 'OECD: CoCAP', 'US: EPA HPVC', 'US: FIFRA', 'US: TSCA', and 'other:'. At the bottom left, 'Included Annotations' has a checkbox for 'Include annotations'. On the right, the 'Document selection' panel is active, showing a list of 'Entities' with checkboxes: 'Representative bio...', 'Reaction by produ...', 'Ethane-1,2-diol', 'Test Legal Entity', 'Test Manufacturer', and 'LastName, FirstNam...'. To the right of the entities is a 'Documents' section for the 'Representative biocidal product dataset for several representative products', which includes a list of sections with checkboxes: '2 Identity of the representative biocidal product', '2.3 Representative biocidal product composition' (with sub-items 'Representative biocidal product 1 composition BP1' and 'Representative biocidal product 2 composition BP2'), '6 Effectiveness against target organisms', '6.7 Efficacy data to support these claims' (with sub-items 'Efficacy data to support these claims BP1' and 'Efficacy data to support these claims BP2'), '7 Intended uses and exposure', '7.1 Field(s) of use envisaged for representative biocidal products and tr...' (with sub-items 'Field(s) of use envisaged for representative biocidal products and tr...' and 'Field(s) of use envisaged for representative biocidal products and tr...'), and '13 Summary and evaluation' (with sub-item 'Draft risk assessment reports'). A 'Create dossier' button is at the bottom right of the document selection panel. A red arrow points from the 'Next' button at the bottom of the 'Included Annotations' section to the 'Next' button at the bottom of the 'Document selection' panel.

Dossier Settings

Document selection

Entities

- ☒ Representative bio...
- ☒ Reaction by produ...
- ☒ Ethane-1,2-diol
- ☒ Test Legal Entity
- ☒ Test Manufacturer
- ☒ LastName, FirstNam...

Documents

Representative biocidal product dataset for several representative products

- ☒ 2 Identity of the representative biocidal product
 - ☒ 2.3 Representative biocidal product composition
 - ☒ Representative biocidal product 1 composition BP1
 - ☒ Representative biocidal product 2 composition BP2
- ☒ 6 Effectiveness against target organisms
 - ☒ 6.7 Efficacy data to support these claims
 - ☒ Efficacy data to support these claims BP1
 - ☒ Efficacy data to support these claims BP2
- ☒ 7 Intended uses and exposure
 - ☒ 7.1 Field(s) of use envisaged for representative biocidal products and tr...
 - ☒ Field(s) of use envisaged for representative biocidal products and tr...
 - ☒ Field(s) of use envisaged for representative biocidal products and tr...
- ☒ 13 Summary and evaluation
 - ☒ Draft risk assessment reports

Create dossier

Included Annotations

- ☒ Include annotations

Select documents to be included

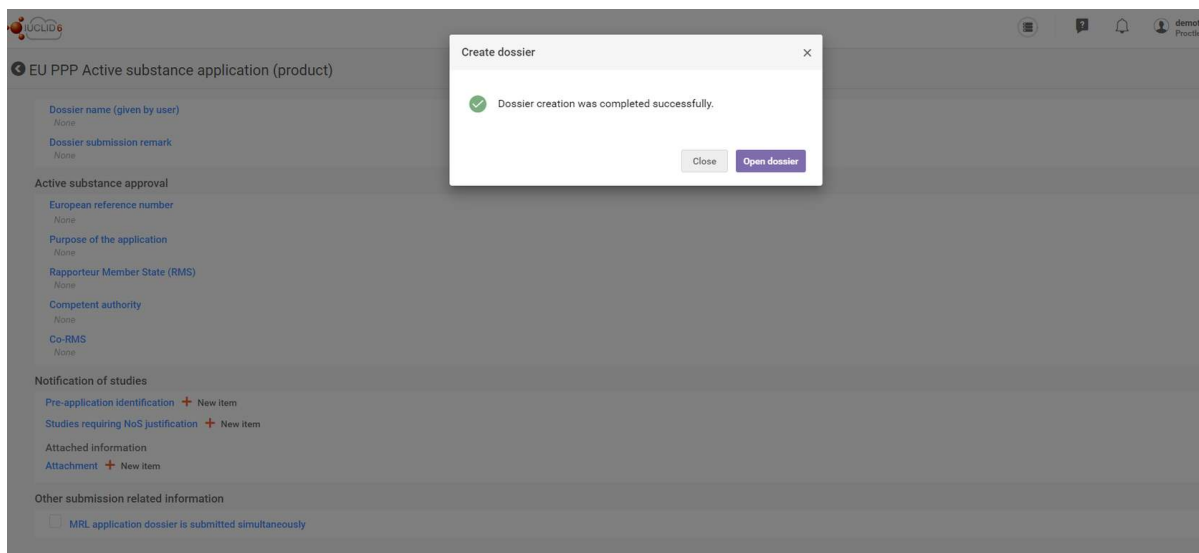
Next

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.

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...

NoneNone

Third party

None

NoneNone

Other identifiers

New item

#	Confidential	Name type	Name	Country	Remarks	Action
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Save

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.

UUID: db394c7b-f1f8-4f18-ace1-d20e8efd6a36

Dossier name (given by user)

None

Dossier submission remark

None

MRL application

Dossier specific information

European reference number

None

Purpose of the application*

None

✖ Purpose of the application field is mandatory.

Evaluating Member State (EMS)*

None



Validation assistant report

! Submission checks 1

👤 Quality checks 95

✓ Business rules 1

✓ Completeness check rules 0

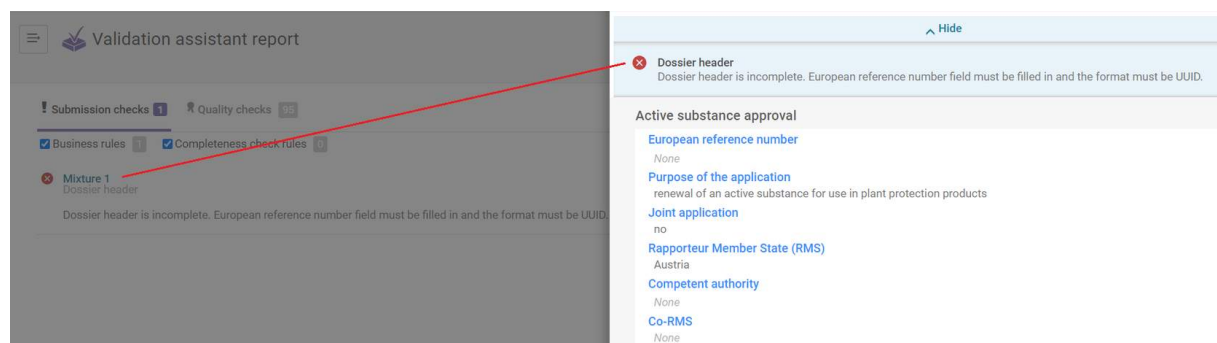
✖ Mixture 1
Dossier header

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

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.



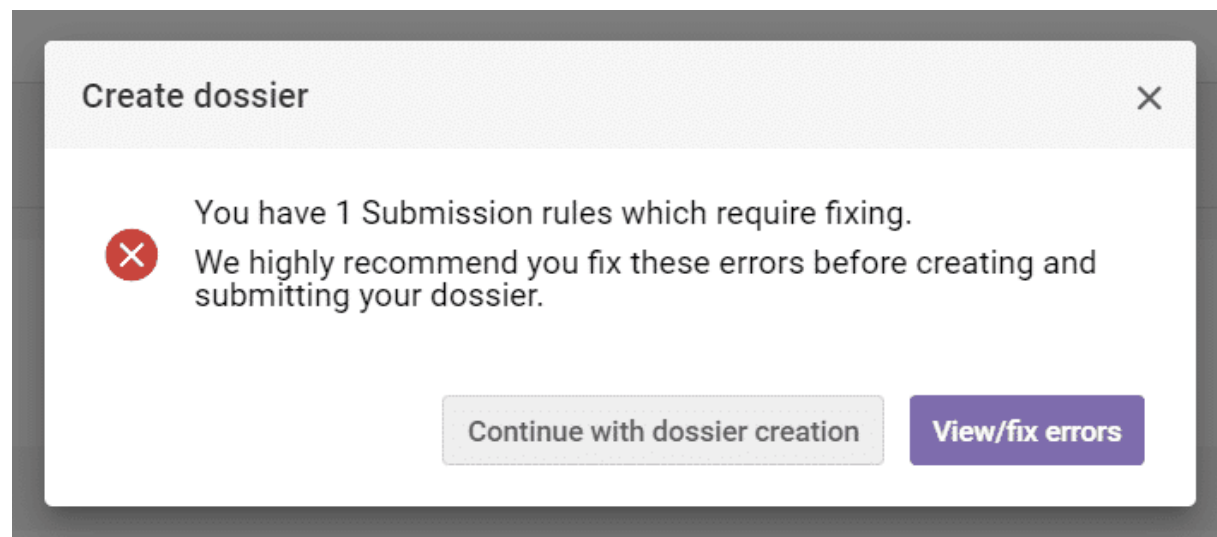
The results of validation assistance can be **downloaded in Excel format**.

VALIDATION DURING DOSSIER CRE...

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

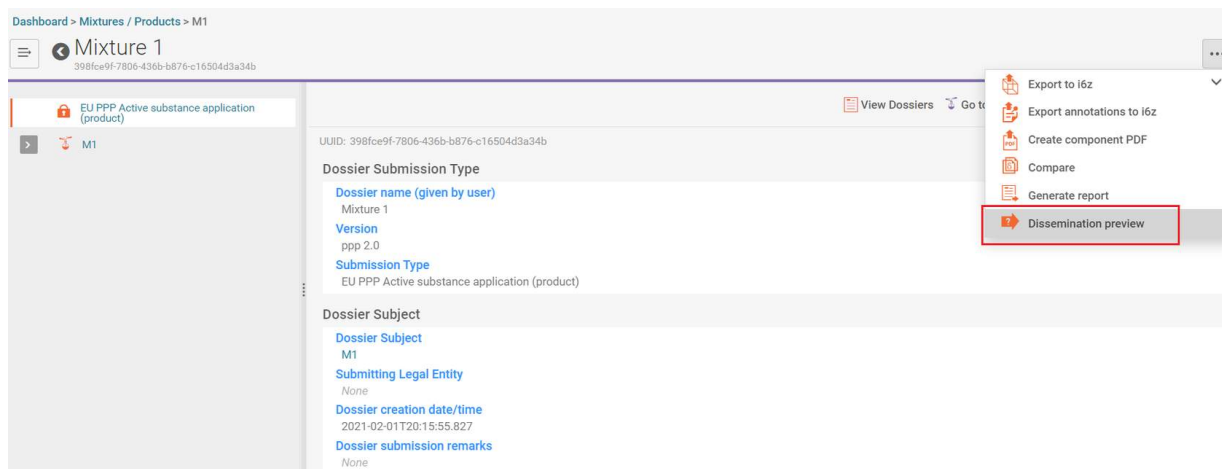
This is an option provided by the validation assistant to start fixing the dataset's problems before creating a dossier.

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.



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.

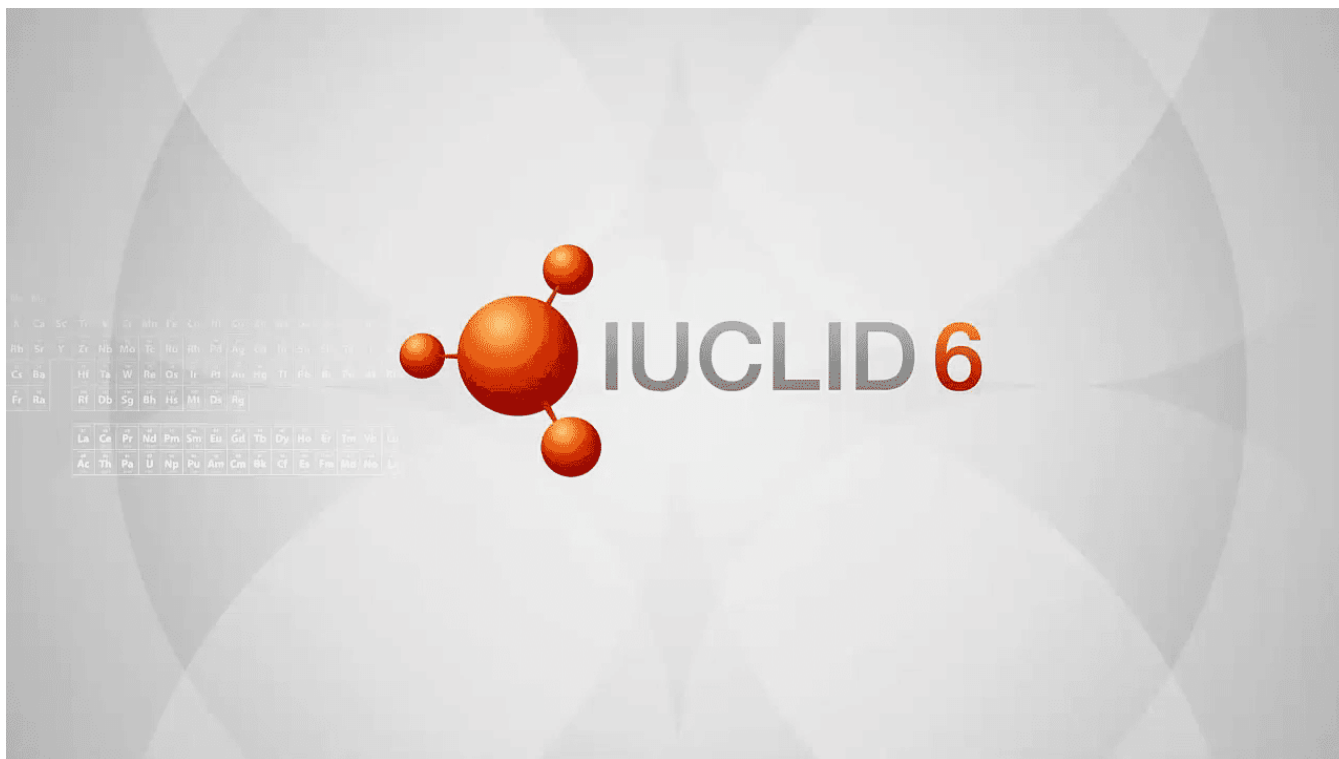


The **dissemination preview** is run from the top level of the record for a dossier.

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.

General information

Reference Type
publication

Title*
Published study

Author
A Scientist

Year
2020

Bibliographic source
Journal of Basic Substance Research Vol 3 pg 15

Testing facility
None

Report no.
None

Study sponsor
None

Study no.
None

Report date
None

Remarks
None

Attached documents
None


Attached (sanitised) documents for publication
PublishedStudy.pdf

Other study identifier(s) + New item

#	Study ID	Remarks	Action
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- 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.

 None  EU: PPP Baumann, W. (1993) - Ready biodegradability (summary)
 UUID: d5dca3cc-85a6-4374-b4c4-8dbbf65a4d4b
 Administrative data  None  EU: PPP

Create new Test material



Name*

Test material

Composition

Composition

+ New item

#	Type	Reference subs...	Concentration	Remarks	Action
1	impurity	None	None	None	
2	Constituent	None	None	None	

Composition / purity: other information

None

Other characteristics

Test material form

None

Details on test material

Details

Confidential details on test material

None

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

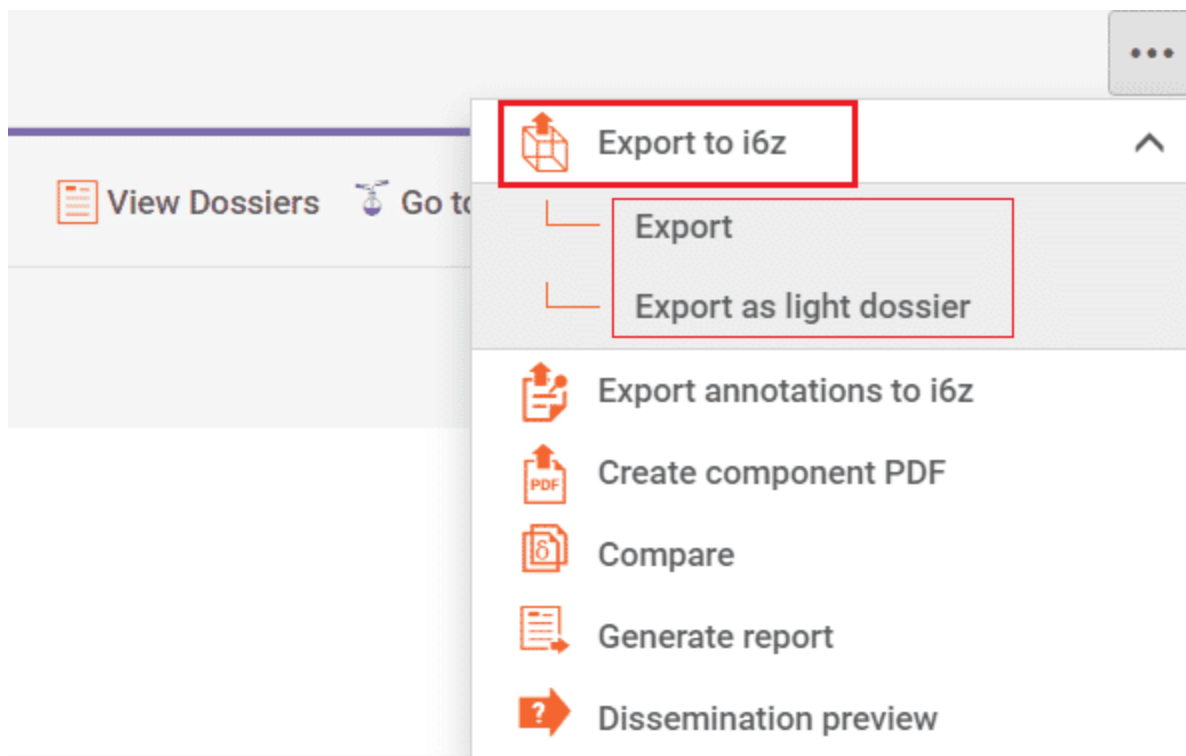
- It will read the confidentiality flag in an endpoint study record and remove the following associated information:
 - a. Composition repeatable block
 - b. Confidential details on test material

3

How to export a dossier

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

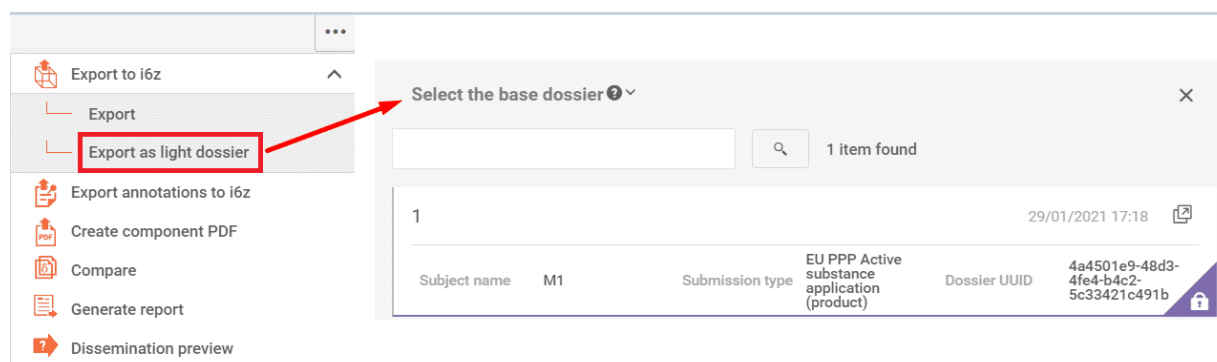
The **export** is accessed from the top level of the application window.



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).

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 Cloud services

 <p>This full IUCLID Cloud service allows users to maintain their scientific data and prepare dossier for submission to ECHA. Read more</p> <p>Subscribe</p>	 <p>This service is designed for users who wish to get familiarised with a trial version of IUCLID Cloud before starting to use the full IUCLID Cloud service. Read more</p> <p>Subscribe</p>
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Submission services

 <p>The ECHA Submission Portal is an online tool for submitting SCIP and Poison Centres notifications.</p> <p>Access service</p>	 <p>Trial version to get familiar with the features. All submissions made in trial will not be treated as real data.</p> <p>Access service</p>
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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