

The screenshot shows the IUCLID 6 dashboard interface. At the top left, the IUCLID 6 logo is visible. Below it, a navigation menu shows 'Dashboard'. On the right side of the dashboard, there is a search bar labeled 'Search dossier by UUID'. The main content area is divided into two columns. The left column contains three summary cards: 'Guided dossier preparation' with a count of 0, 'Substances' with a count of 2, and 'Mixtures' with a count of 0. The right column is titled 'Import IUCLID file(s)' and includes an 'Overwrite settings' dropdown menu set to 'If newer than existing'. Below this, there is a large dashed border area for file upload, with the text 'Drop file to upload or Browse' and a 'Browse' button.



1 hour training presentation



30-45 min Q&A session

Note: so that we have access to the training material later on, we kindly ask for your approval to record this session. Let us know in chat if you disagree.



Keep your microphone off while others are speaking



Possibly keep your camera on while speaking



Raise your hand if you wish to speak or use the chat if you have any questions



ECHA Cloud Services overview

How to access ECHA CS

Understanding the purpose of a Legal entity

How to subscribe to an ECHA CS



IUCLID Cloud overview

Key concepts of an IUCLID dossier

- Dataset
- Document
- Entities
- Dossier header


How to create a dossier

How to submit a dossier




Overview of ECHA Cloud Services

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](#)

- A secure online platform to host 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 cloud data is safe and cannot be accessed by anyone else.



A platform to host IUCLID installations



Reduces the technical burden and related costs of operating IUCLID locally



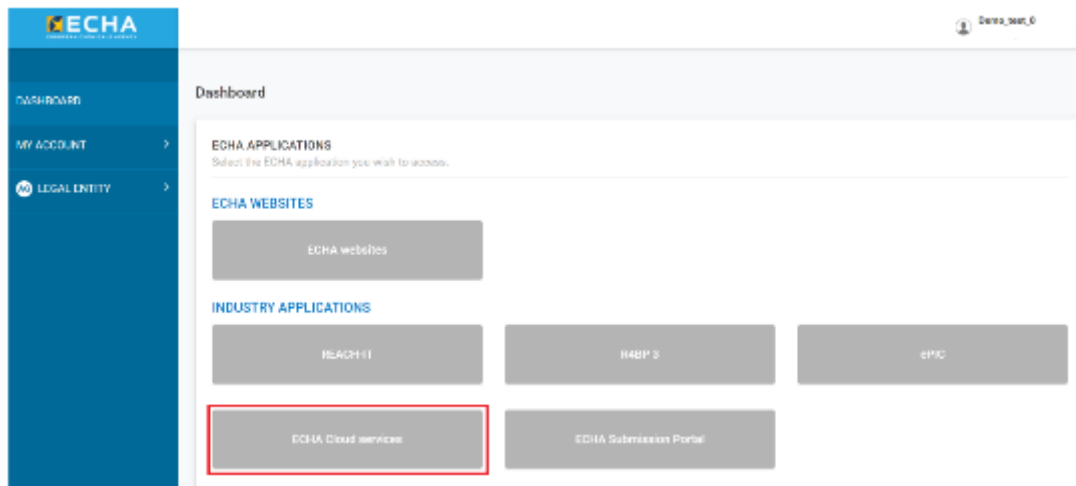
Data protection



Continuous availability



Dedicated support



- **ECHA Cloud Services** are available directly for the main page of the ECHA website - <https://echa.europa.eu/>
- **Login** using an “ECHA account”
or
- **Register**
 - Define Legal entity (LE)
 - Add users



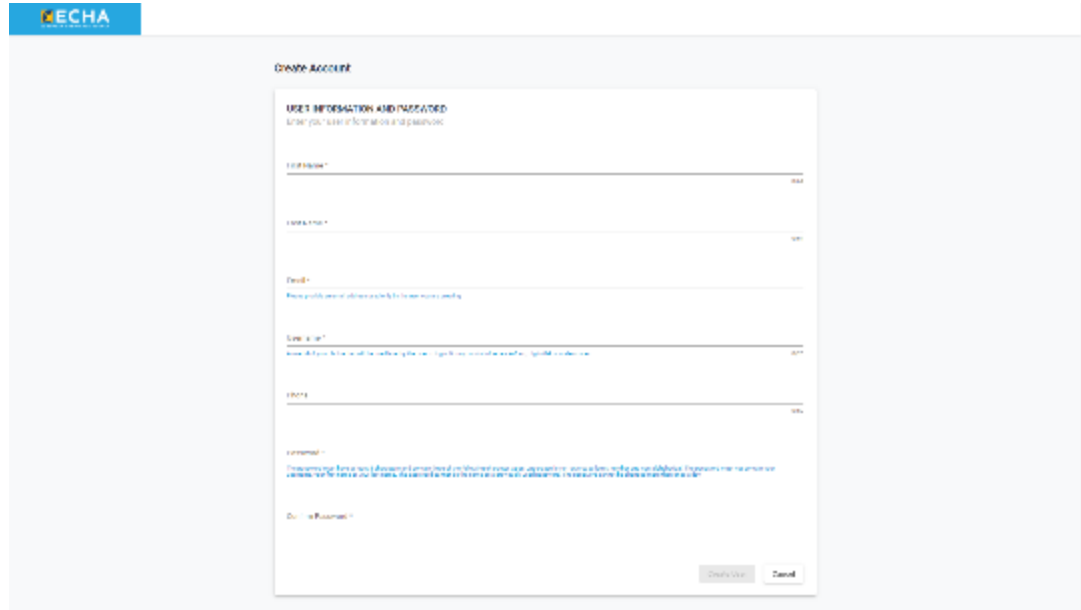
Welcome to ECHA Cloud Services

Login	Register
If you already have an ECHA Account, for example to access REACH-IT, please log in here.	If you do not have an ECHA Account, you can create one and then assign a legal entity to it. For more information, please visit the link.
Login	Register



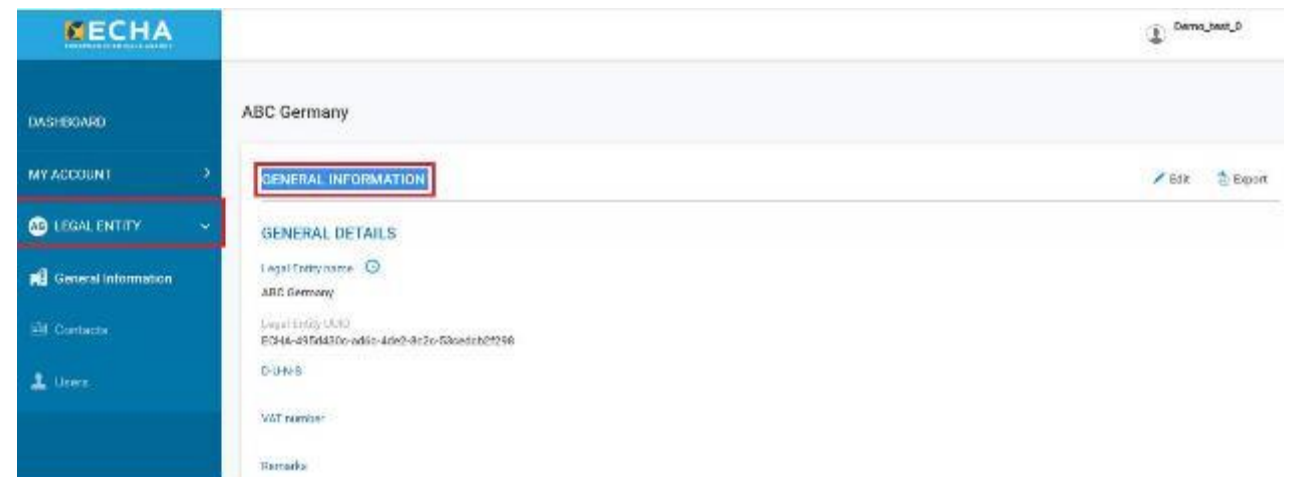
Understanding the purpose of a Legal entity

Understanding the purpose of a Legal entity

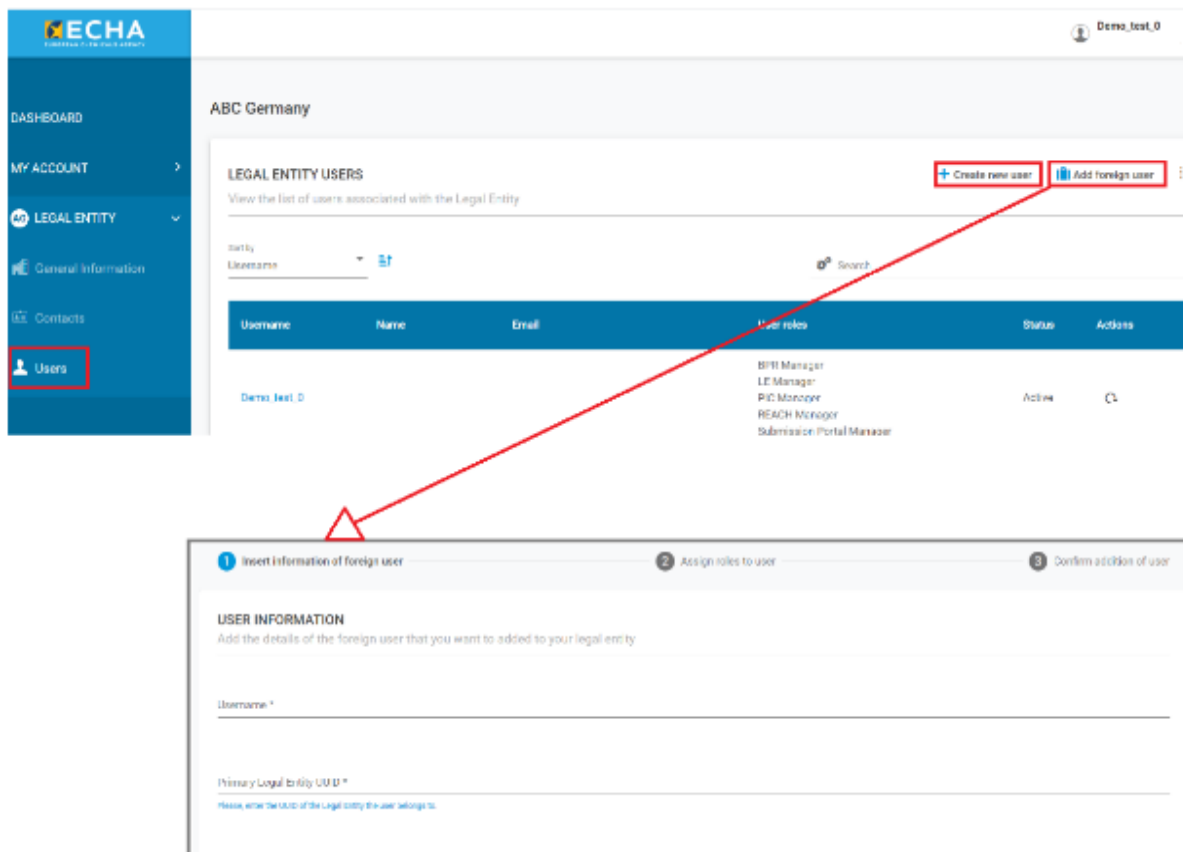


- A Legal entity (LE) is actually the organisation (**the submitting entity**) for which the user is working.
- It is the dossier owner or leads applicant.
- It is associated to each submission you make.

- 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 or a foreign entity



The screenshot shows the ECHA system interface. On the left is a navigation menu with 'Users' highlighted. The main content area is titled 'ABC Germany' and 'LEGAL ENTITY USERS'. It contains a table of users with columns for Username, Name, Email, User roles, Status, and Actions. A red box highlights the 'Add foreign user' button. Below the table is a modal form with three steps: 1. Insert information of foreign user, 2. Assign roles to user, and 3. Confirm addition of user. The form includes fields for Username and Primary Legal Entity UID.

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

- A Legal Entity manager can assign roles and give permissions to:
 - **New users**
 - **A foreign user from a 3rd party or a consultant** e.g. there is an ongoing joint submission or you need to provide access to a consultant etc.
- A foreign user can perform actions on behalf of the LE that has granted him access to its subscriptions.
- You can add users (internal or external) that have an “ECHA account” to your LE and assign them specific roles to use your Cloud subscriptions (i.e. your IUCLIDs).

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



IUCLID Cloud overview

- **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** distributions:

IUCLID 6 Desktop

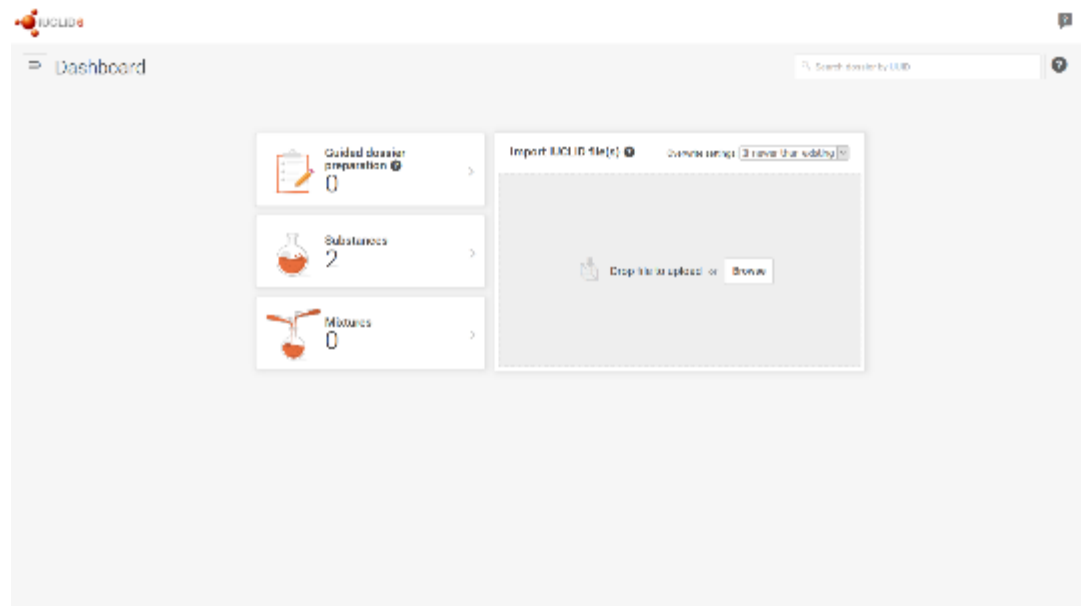
- Single machine
- One user a time
- Easy instalation

IUCLDI 6 Server

- Shared with multiple users
- Network installation

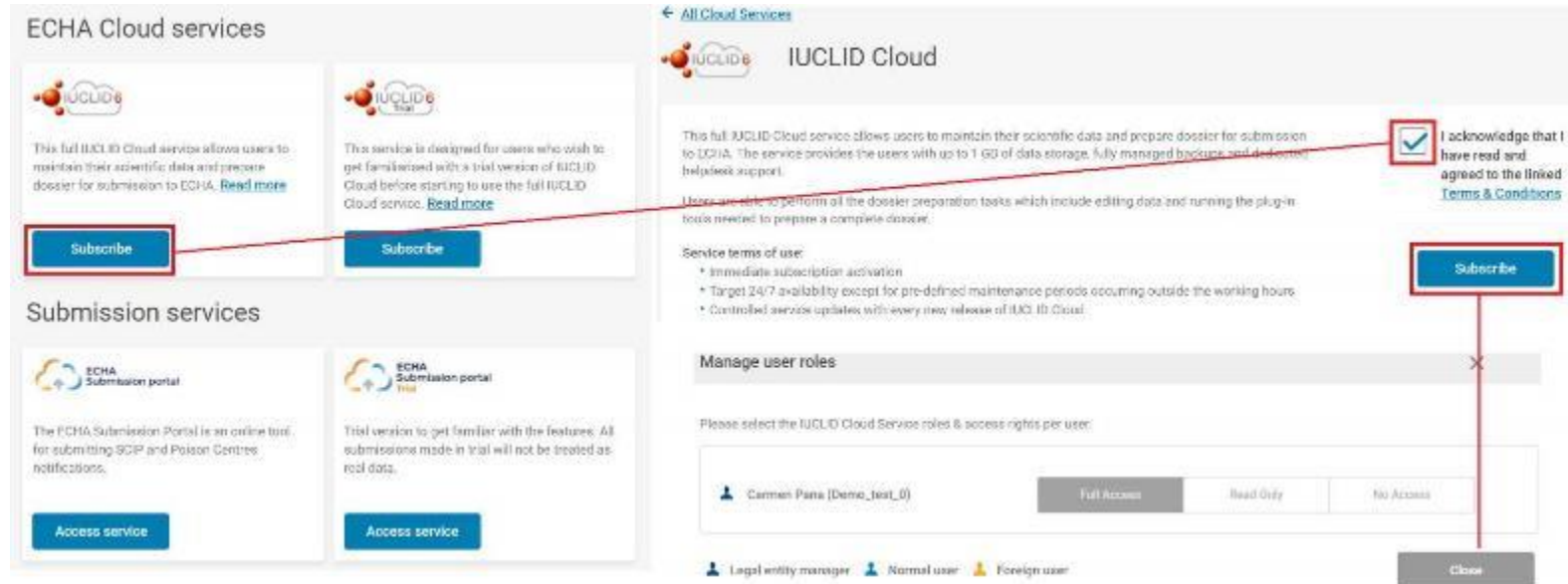
IUCLID Cloud

- Access from everywhere
- Aimed for SMEs
- Storage space per instance is of 5GB



- **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

Subscribe to IUCLID Cloud services



The screenshot shows the ECHA Cloud services interface. On the left, there are two columns of service cards. The top column, 'ECHA Cloud services', includes 'IUCLID Cloud' (with a 'Subscribe' button) and 'IUCLID Cloud Trial' (with a 'Subscribe' button). The bottom column, 'Submission services', includes 'ECHA Submission portal' (with an 'Access service' button) and 'ECHA Submission portal Trial' (with an 'Access service' button). On the right, the 'IUCLID Cloud' service details are shown, including a description, service terms of use, and a 'Manage user roles' section. A red box highlights the 'Subscribe' button in the 'Manage user roles' section, and a red line connects it to a 'Subscribe' button in the 'IUCLID Cloud' service details. A red box also highlights the 'I acknowledge that I have read and agreed to the linked Terms & Conditions' checkbox, which is checked.

- <https://ecs.echa.europa.eu/cloud/subscriptions>
- Subscribe to a IUCLID Cloud service:
 - Cloud
 - Cloud Trial – not recommended to be used for pesticide submission



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).

- A **dataset** is a **collection of documents**, in an **editable version**, related to a particular chemical substance or grouping of chemical substances. It can be of the following types: Substance, Mixture/Product, Template.
- All **EU PPP dossiers** start from a mixture of the dataset.
 - A **Mixture/Product** is a type of entity in IUCLID **used to store information on a chemical substance** considered to be in a regulatory context, either a mixture, a product, or both.
 - Can link the **active substance dataset** to the Mixture/Product dataset by completing the Mixture/Composition document, which describes the formulation.
It contains all the studies where the active substance was the **test material**. If the test material was a metabolite or impurity, create an 'other substance for assessment' **dataset**.

The four types of EU_PPP Dossiers

EU PPP Active substance application

EU PPP Active substance application

Active substance information

Other substance for assessment

Other mixture for assessment

EU PPP Microorganisms - active substance application

EU PPP Microorganisms - active substance application

Microorganisms - active substance information

Other substance for assessment

Microorganism mixture for assessment

EU PPP MRL application

Product (Formulation & GAP)

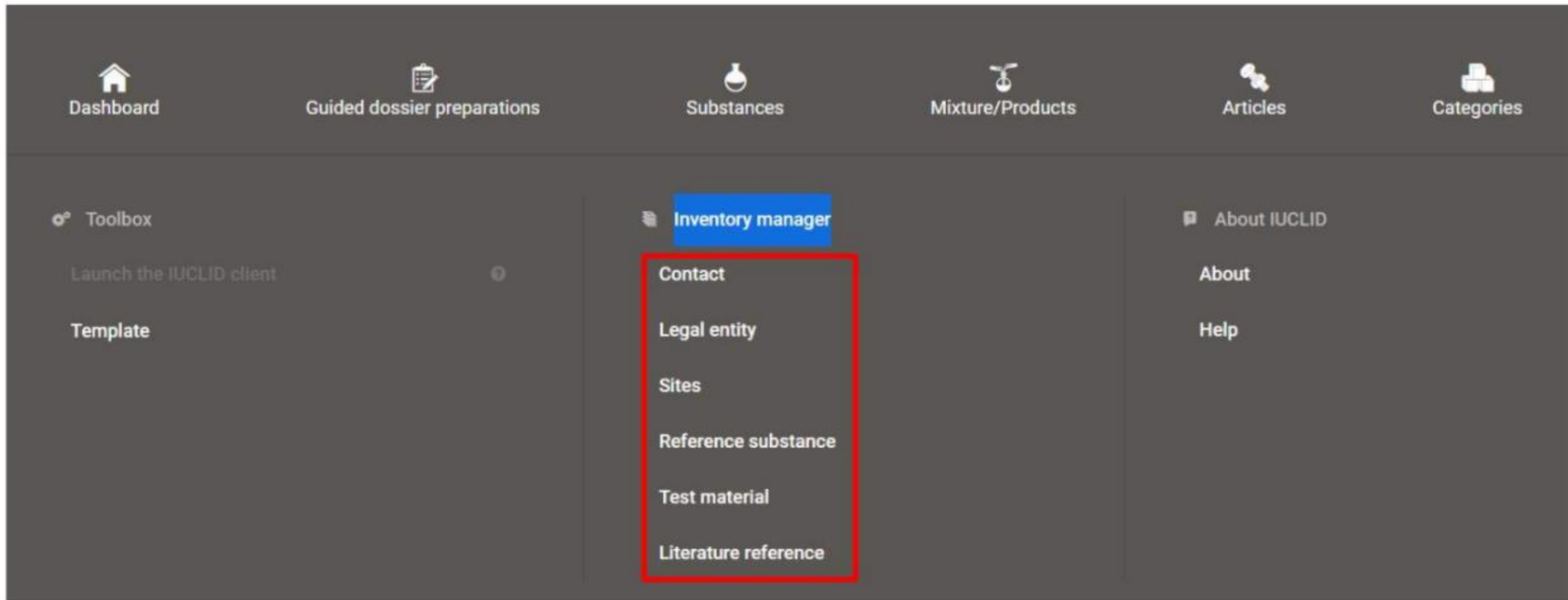
Active substance information

Other substance for assessment

EU PPP Basic substance application

EU PPP Basic substance application

- In IUCLID, an Entity is usually an inventory of information **linked to and reused** by any document
- Here is the list of **reusable IUCLID entities** that can be managed through the **Inventory Manager**:



The screenshot displays the IUCLID web interface. At the top, there is a navigation bar with icons and labels for Dashboard, Guided dossier preparations, Substances, Mixture/Products, Articles, and Categories. Below this, the main content area is divided into three sections. The left section is titled 'Toolbox' and contains a button for 'Launch the IUCLID client' and a 'Template' section. The middle section is titled 'Inventory manager' and contains a list of entities: Contact, Legal entity, Sites, Reference substance, Test material, and Literature reference. The right section is titled 'About IUCLID' and contains links for 'About' and 'Help'. A red rectangular box highlights the list of entities in the 'Inventory manager' section.

Entity Type
Contact
Legal entity
Sites
Reference substance
Test material
Literature reference

CONTACTS

- It is an entity that is used **to record the contact details of a particular person, or** 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.

LEGAL ENTITY

- It is used **to store information about a party or person** involved in a chemical substance, mixture, or product life-cycle
- 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

SITES

- It is an entity used to associate a Legal or a Foreign entity, and therefore its associated entities, with a **physical location**
- 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

REFERENCE SUBSTANCE

- It 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.**
- Reference substances **can be shared and exchanged among instances and users** of IUCLID.

TEST MATERIAL

- It is an entity used to **describe the material on which a physical test has been performed.**
- 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

LITERATURE REFERENCE

- It is an entity that **identifies a particular document** that contains information on a Substance or a Mixture/Product
- The creation and editing 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.

- A **Dossier header** is a set of fields used to store administrative information relevant to data submission under a particular regulation.
- Dossier header is dependent/defined by the working context.
- 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.
- During Dossier creation, the first step is to review and/or edit the Dossier header.

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

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

How to add a new mixture/product



Selecting the "Working context"



How to add an active substance dataset and metabolite dataset



How to access the table of content and edit it



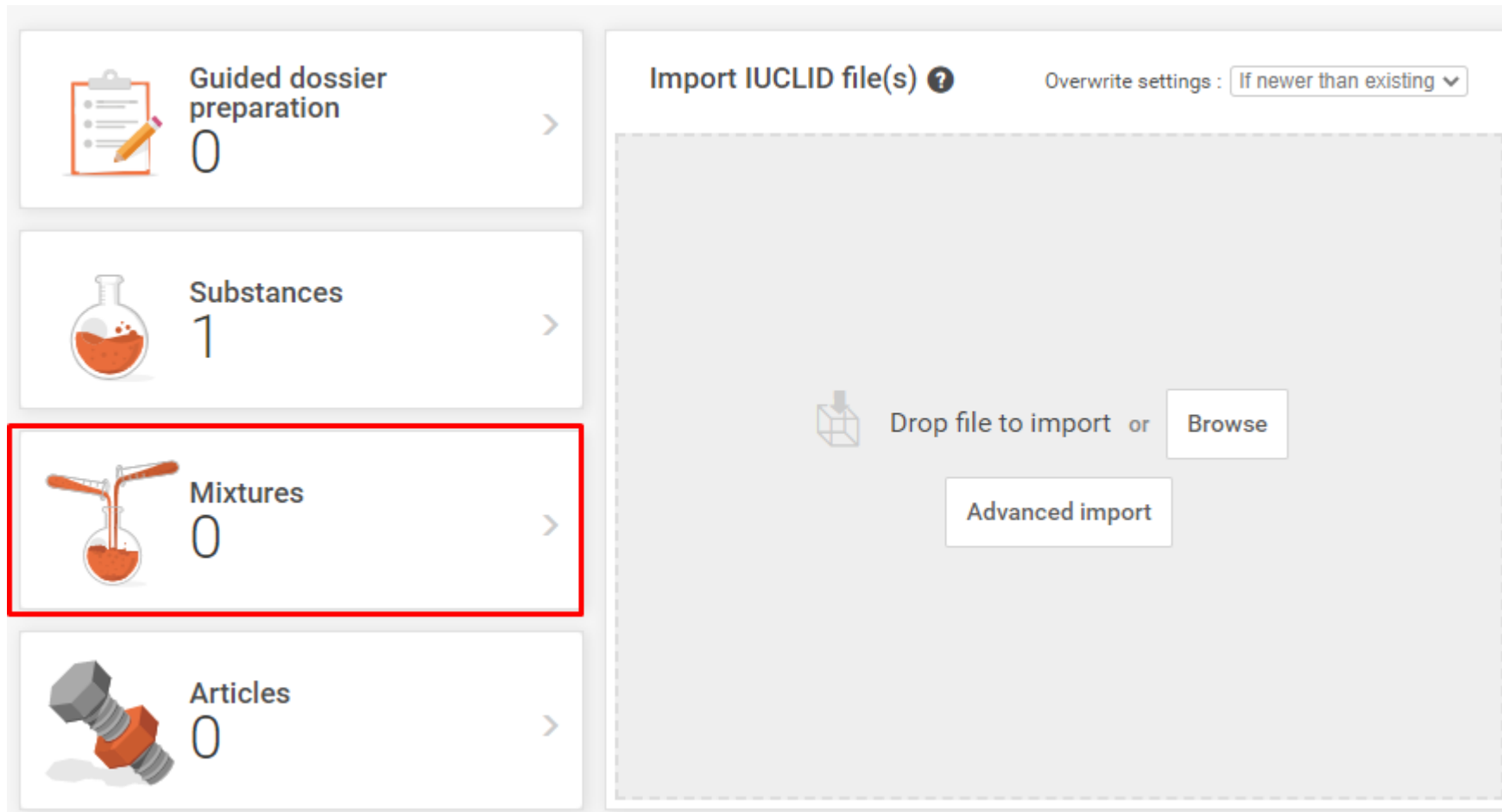
What is the dossier header and where you can find it



How to create a dossier



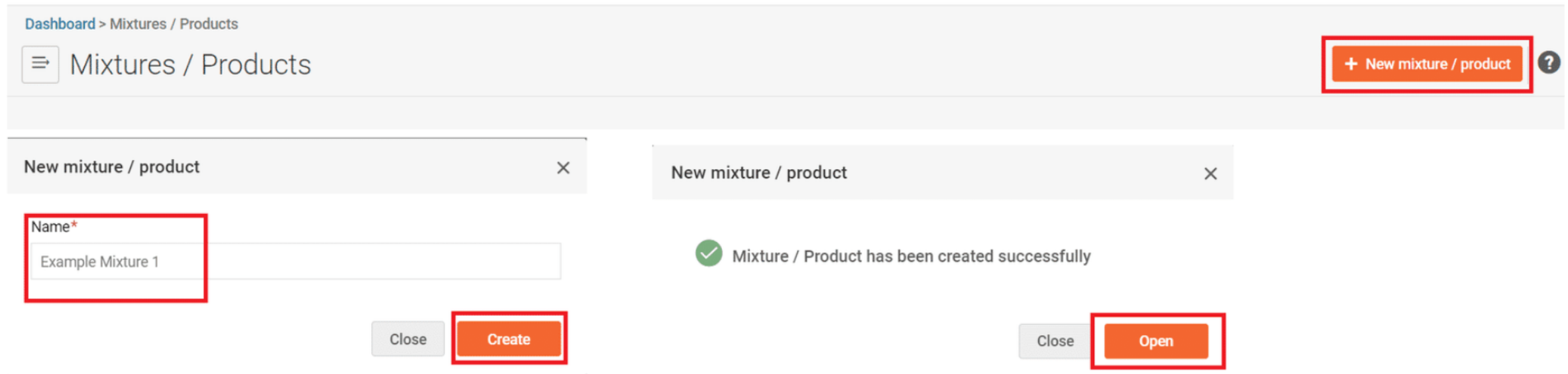
How to add a new mixture/product



The screenshot displays a dashboard with a left-hand navigation menu and a main content area. The navigation menu includes four items: 'Guided dossier preparation' (0), 'Substances' (1), 'Mixtures' (0), and 'Articles' (0). The 'Mixtures' item is highlighted with a red border. The main content area is titled 'Import IUCLID file(s)' and features an 'Overwrite settings' dropdown menu set to 'If newer than existing'. Below this is a large dashed box containing a file upload area with a 'Drop file to import' prompt, a 'Browse' button, and an 'Advanced import' button.

- The **mixture product** can be accessed from the dashboard

How to add your mixture/product in IUCLID



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

- 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.

How to complete the mixture

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

Mixture/Product name*
Example Mixture 1

Public name
None

Legal entity owner* None None
ELL | Bucuresti | Romania

Third party None None
None

Role in the supply chain None None

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.

- **Mandatory** fields:

- Name
- Legal entity – for which you are submitting the dossier and is synchronized with the login

- **Optional** fields:

- Public name
- Third party - if the organisation appoints a third party representative to create the dataset.
- Legal entity – for which you are submitting the dossier and is synchronized with the login

Note! You can click on the "support" button to better understand



How to add the working context

Select working context

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.**"

New working context ×

Select working context

BPR Active substance application (representative product) ▼

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

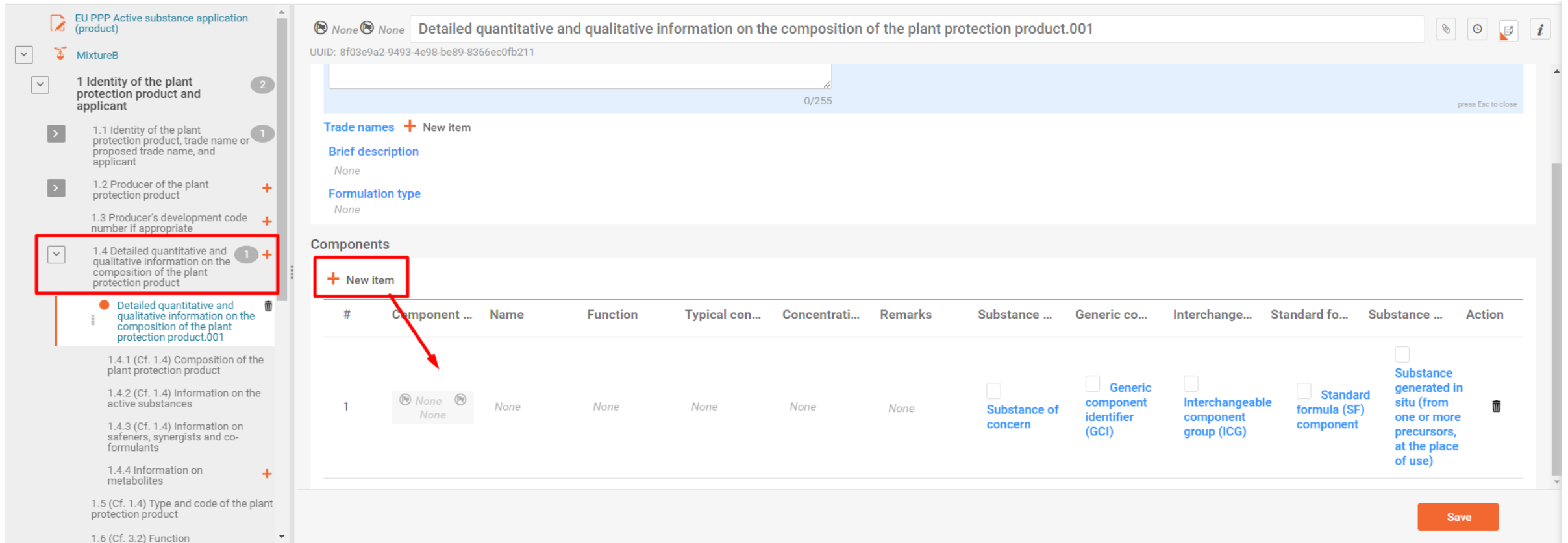
OECD harmonised templates - mixture

- The working context includes the Table of Contents and the IUCLID documents needed to meet the regulatory data requirements
- The working contexts that EFSA accepts are the ones highlighted - **EU PPP**



How to add an active substance dataset and a metabolite dataset

Add mixture composition

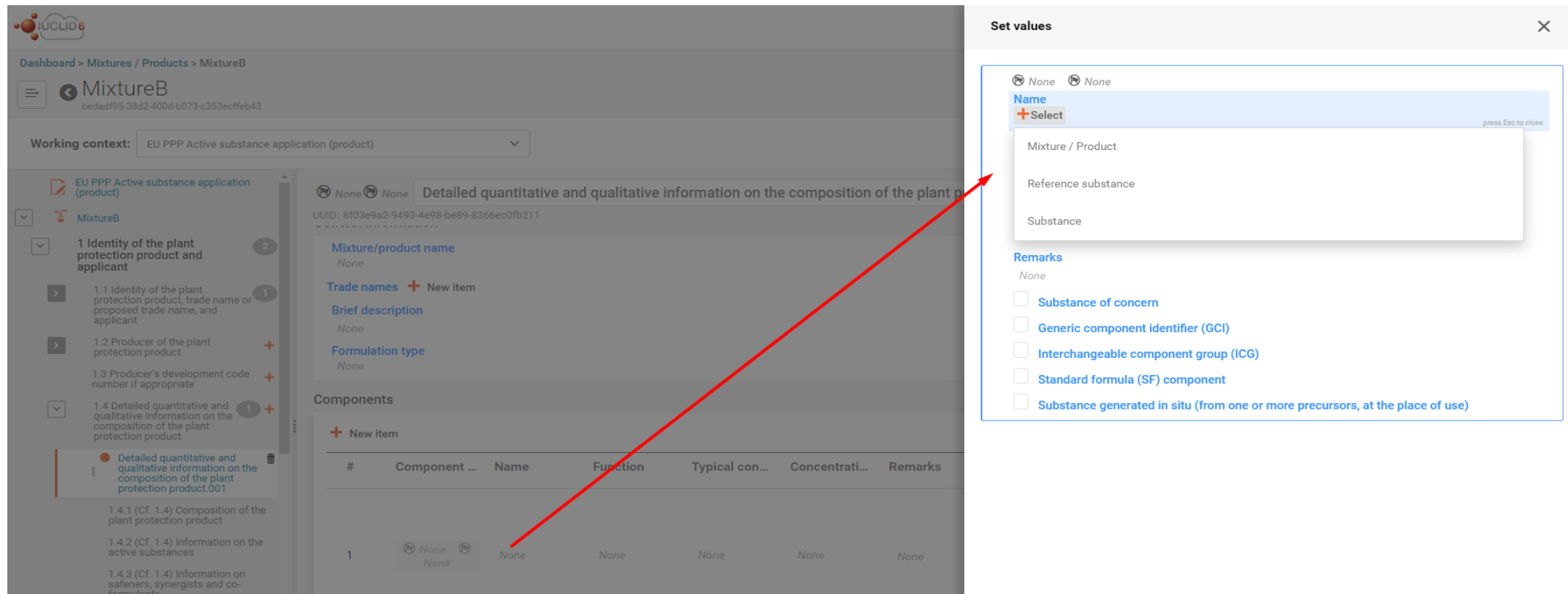


The screenshot displays the 'EU PPP Active substance application (product)' interface. The left sidebar shows a navigation menu with 'MixtureB' selected and '1.4 Detailed quantitative and qualitative information on the composition of the plant protection product' highlighted with a red box. The main content area is titled 'Detailed quantitative and qualitative information on the composition of the plant protection product.001' and includes a text input field (0/255), 'Trade names', 'Brief description', and 'Formulation type' sections. Below these is a 'Components' table with a '+ New item' button highlighted by a red box and an arrow. The table has columns for '#', 'Component ...', 'Name', 'Function', 'Typical con...', 'Concentrati...', 'Remarks', 'Substance ...', 'Generic co...', 'Interchange...', 'Standard fo...', 'Substance ...', and 'Action'. A single row is visible with values '1', 'None', 'None', 'None', 'None', 'None', 'None', and several checkboxes. A 'Save' button is located at the bottom right.

#	Component ...	Name	Function	Typical con...	Concentrati...	Remarks	Substance ...	Generic co...	Interchange...	Standard fo...	Substance ...	Action
1	None	None	None	None	None	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)	

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

Set values



The screenshot shows the IUCLID 6 interface with a 'Set values' dialog box open. The dialog box has a 'Name' section with a dropdown menu showing 'Mixture / Product', 'Reference substance', and 'Substance'. Below this is a 'Remarks' section with several checkboxes: 'Substance of concern', 'Generic component identifier (GCI)', 'Interchangeable component group (ICG)', 'Standard formula (SF) component', and 'Substance generated in situ (from one or more precursors, at the place of use)'. A red arrow points from the 'Substance' option in the Name dropdown to the 'Substance' checkbox in the Remarks section.

- 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**.

Create/Add new substance

Select Substance + Create X

Type at least 3 characters 8 results found

▶ Advanced search

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

Water			
Inventory number	CAS number		
Legal Entity	Chemical123		UUIT

Create new Substance X

Substance name*
None
❌ Substance name field is mandatory.

Public name
None

Legal entity* None None

None
❌ Legal entity field is mandatory.

Third party None None

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**.

Set confidentiality flag




CBI EU: PPP FormulationHyper100
UUID: 6a40965f-8ac0-4ccf-80a9-9267cedea00c
+ New item

#	Component flag	Name	Function	Typical conce...	Concentration ...	Remarks
1	None None	Hypercare safener Hypercare 345-65-5	safener	<= 5 % (w/w)	> 4 <= 5 % (w/w)	None
2	None None	Water Water 7732-18-5	solvent	ca. 10 % (w/w)	> 8 <= 10 % (w/w)	None
3	CBI EU: PPP	Aqueous extract from the germinated seeds of sweet... hypercare substance hypy 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.

Save the formulation

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

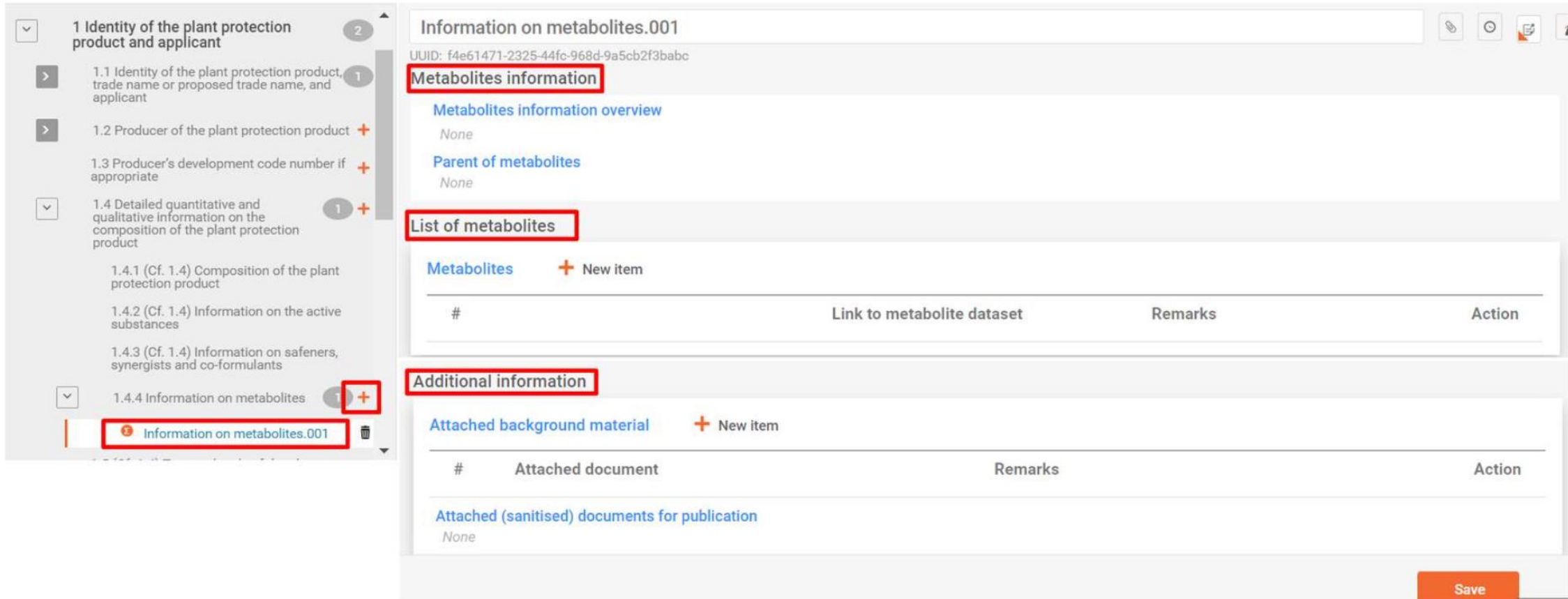
#	Component ...	Name	Function	Typical con...	Concentrati...	Remarks	Substance ...	Generic co...	Interchange...	Standard fo...	Substance ...	Action
1	None None	Hypercare safener	safener	<= 5 % (w/w)	> 4 <= 5 % (w/w)	None	<input type="checkbox"/> Substance of concern	<input type="checkbox"/> Generic component 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,	

Save

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



Information on metabolites (Section 1.4.4)



The screenshot shows a web interface for reporting metabolite information. On the left is a navigation menu with sections for product identity, producer information, and detailed quantitative/qualitative information. The 'Information on metabolites.001' section is selected and highlighted. The main content area is titled 'Information on metabolites.001' and includes a UUID. It contains three main sections: 'Metabolites information' (with sub-sections for overview and parent of metabolites), 'List of metabolites' (a table with columns for #, Link to metabolite dataset, Remarks, and Action), and 'Additional information' (with sub-sections for attached background material and attached documents for publication). A 'Save' button is located at the bottom right.

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: f4e61471-2325-44fc-968d-9a5cb2f3babcb

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

- 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

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

1 Cour
✓ Ne
Trad
HYF

Brief desc
The mix

Formulati
✓ WP Wet

Component

+ New ite

#

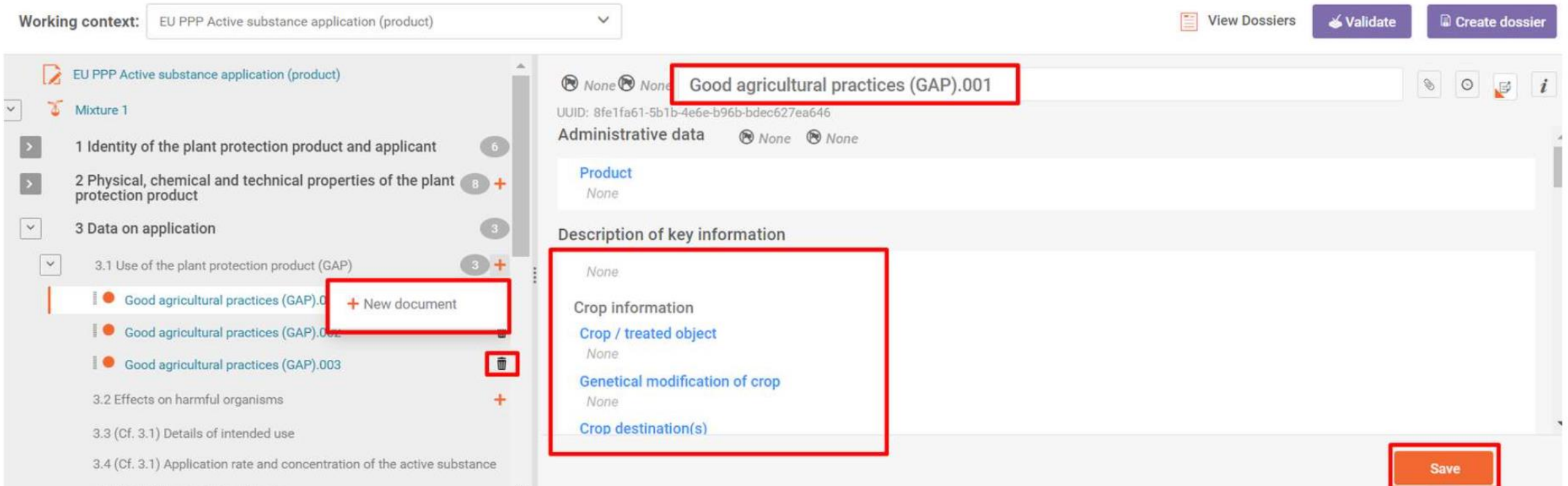
i 1

i 2

i 3

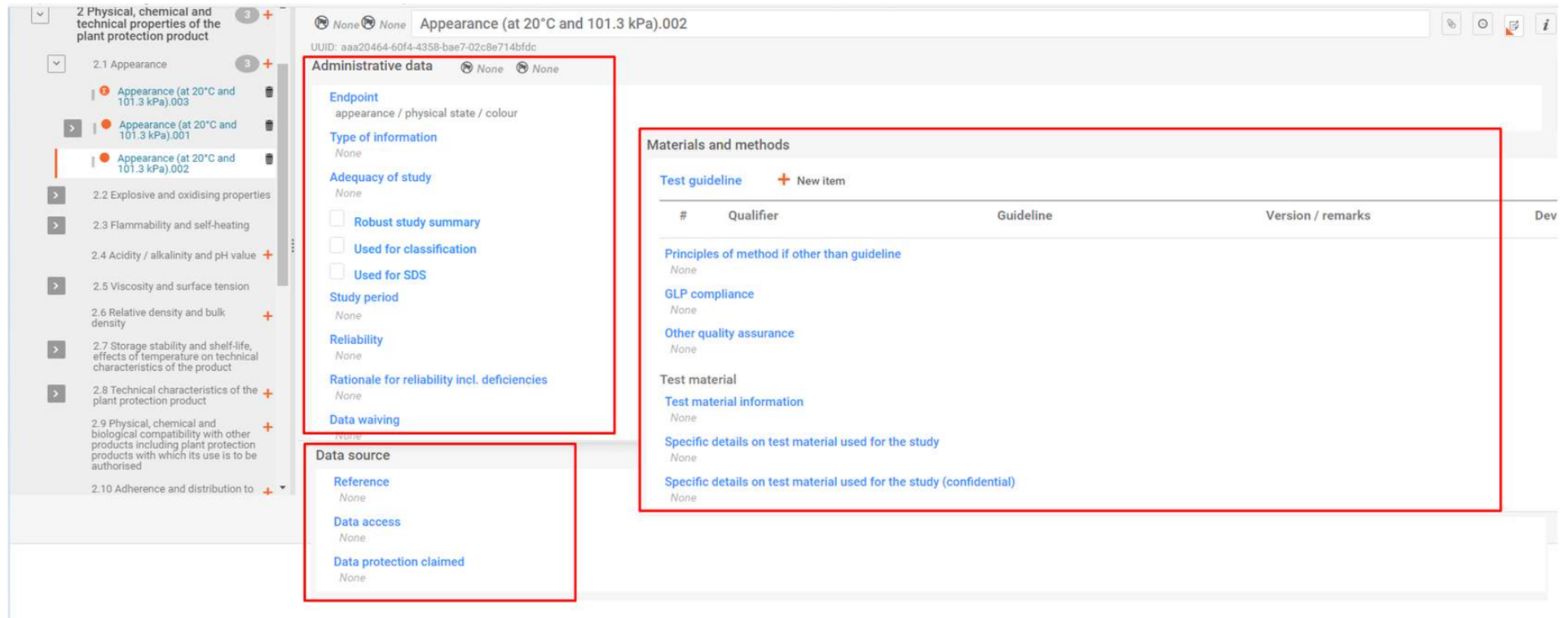
- For **each working context**, you will have a **specific table of content**.
- You'll need to create your documents for the defined TOC (Table of Contents).
- If you want to **reuse the information in a different working context** (e.g. to use information from a new active substance application in 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.

Complete the table of content (TOC)



The screenshot shows the EFSA application interface. At the top, the 'Working context' is set to 'EU PPP Active substance application (product)'. On the right, there are buttons for 'View Dossiers', 'Validate', and 'Create dossier'. The left sidebar shows a tree view of the application structure, with '3.1 Use of the plant protection product (GAP)' expanded. A '+ New document' button is highlighted in red. The main content area shows the 'Good agricultural practices (GAP).001' document being created. The 'Administrative data' section is visible, and the 'Description of key information' section is highlighted in red, showing fields for 'Crop information', 'Crop / treated object', 'Genetical modification of crop', and 'Crop destination(s)'. A 'Save' button is highlighted in red 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.
- Complete all relevant fields.
- By clicking the "**Save**" button, your information is saved in the document.



The screenshot shows a web-based interface for creating an endpoint study record. The main title is "Appearance (at 20°C and 101.3 kPa).002". The interface is divided into several sections:

- Administrative data:** Includes fields for Endpoint (appearance / physical state / colour), Type of information (None), Adequacy of study (None), Robust study summary (checkbox), Used for classification (checkbox), Used for SDS (checkbox), Study period (None), Reliability (None), Rationale for reliability incl. deficiencies (None), and Data waiving (None).
- Data source:** Includes fields for Reference (None), Data access (None), and Data protection claimed (None).
- Materials and methods:** Includes a Test guideline section with a table, Principles of method if other than guideline (None), GLP compliance (None), Other quality assurance (None), Test material section, Test material information (None), Specific details on test material used for the study (None), and Specific details on test material used for the study (confidential) (None).

#	Qualifier	Guideline	Version / remarks	Dev
---	-----------	-----------	-------------------	-----

- 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.

Working context: EU PPP Active substance application (product)

View Dossiers Validate Create dossier

use

4 Further information on the plant protection product

4.1 (Cf. 3.1) Safety intervals and other precautions to protect humans, animals and the environment

4.2 Recommended methods and precautions

Recommended methods and precautions.001

4.3 (Cf. 4.2) Emergency measures in the case of an accident

4.4 Packaging, compatibility of the plant protection product with proposed packaging materials

4.5 (Cf. 4.2) Procedures for destruction or decontamination of the plant protection product and its packaging

5 Analytical methods

2001_Monitoring purposes_Cereal

Analytical methods.002

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

None None Analytical methods.002

UUID: 54dbd87b-f4fe-44a2-afdb-b10ecea4b260

Endpoint

None

Type of information

experimental study

Adequacy of study

key study

Robust study summary

Used for classification

Used for SDS

Study period

None

Reliability

Please select

1 (reliable without restriction)

2 (reliable with restrictions)

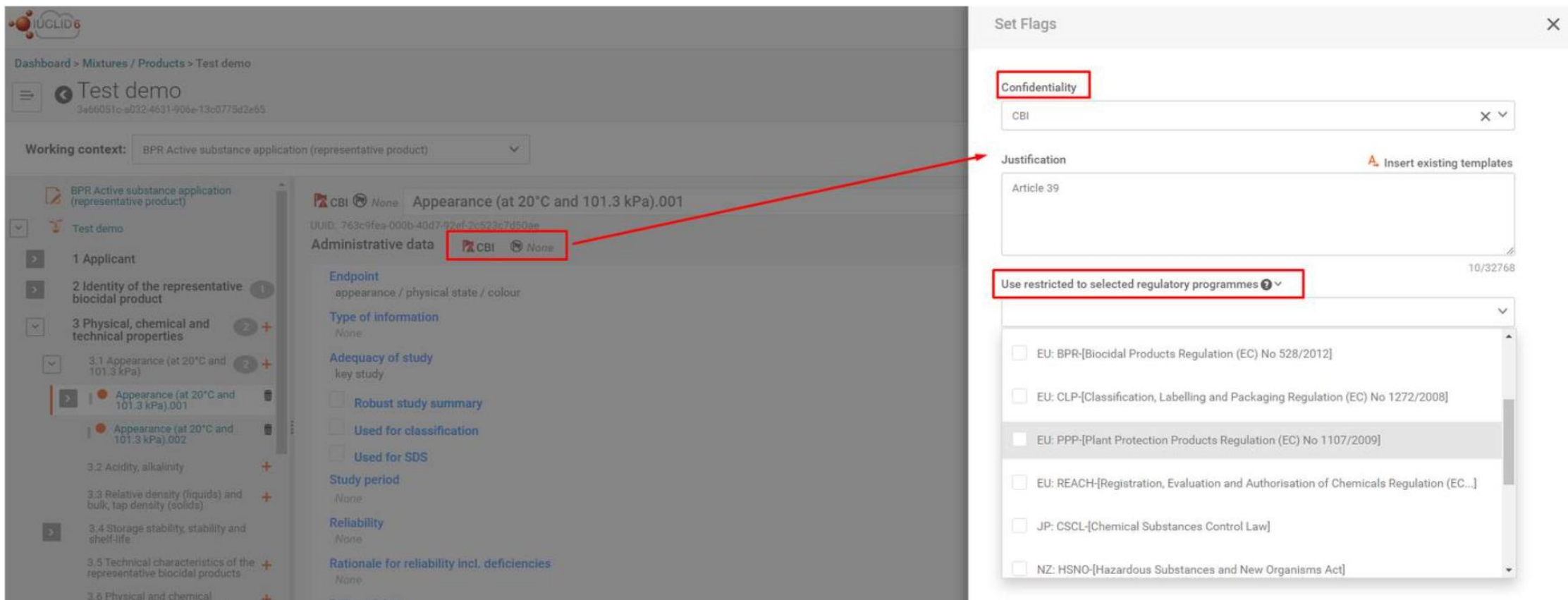
3 (not reliable)

press Esc to close

Save

- 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.

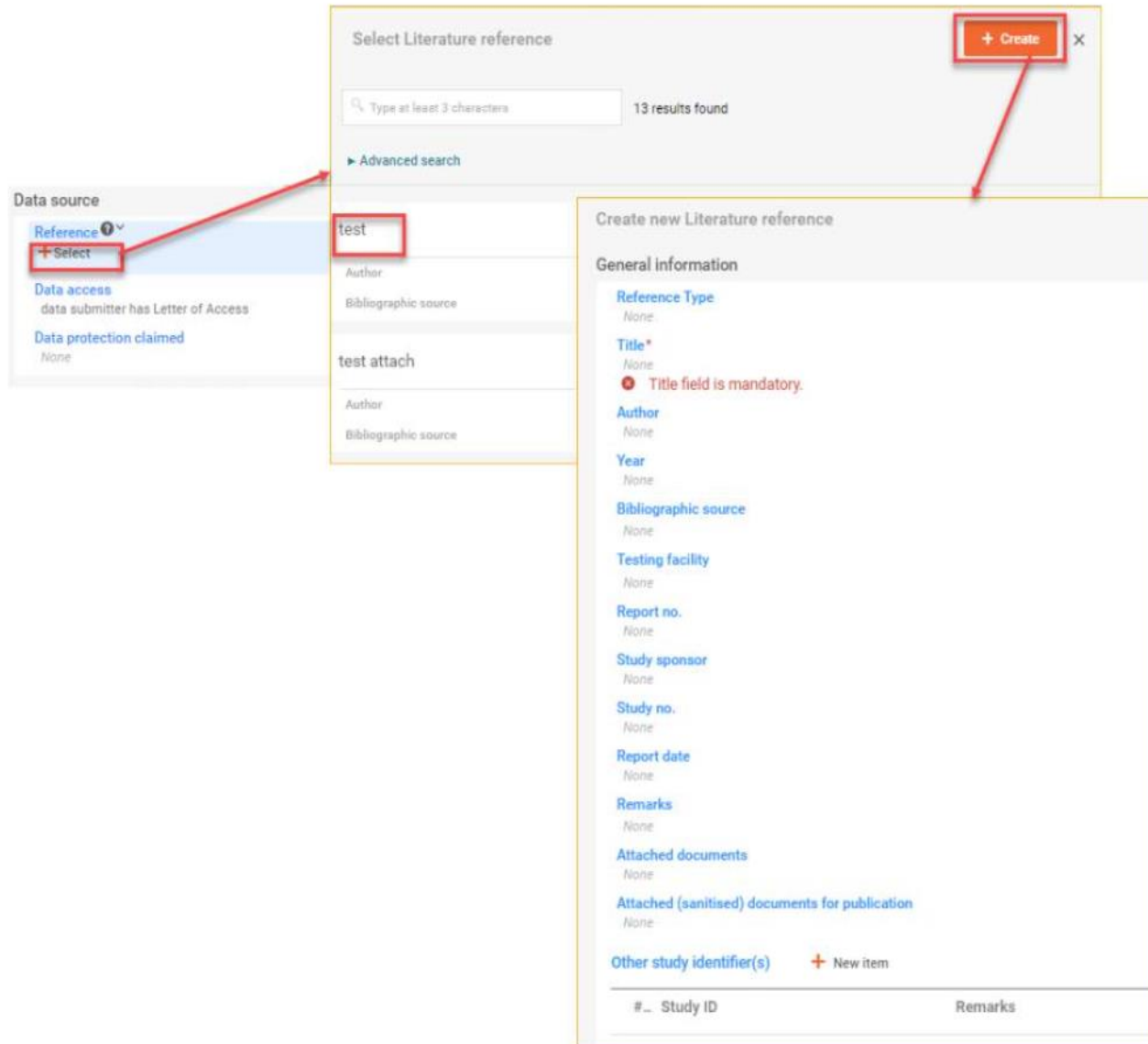
Endpoint study records – Set a confidentiality flag



The screenshot displays the UGLID 6 interface for editing an endpoint study record. The main window shows the 'Administrative data' section for the endpoint 'Appearance (at 20°C and 101.3 kPa).001'. A red box highlights the 'CBI' flag icon in the 'Administrative data' section. A red arrow points from this icon to the 'Set Flags' dialog box on the right. The dialog box has a 'Confidentiality' dropdown menu set to 'CBI' and a 'Justification' text area containing 'Article 39'. Below these, there is a dropdown menu 'Use restricted to selected regulatory programmes' with a list of regulatory programmes, including 'EU: BPR-[Biocidal Products Regulation (EC) No 528/2012]', 'EU: CLP-[Classification, Labelling and Packaging Regulation (EC) No 1272/2008]', 'EU: PPP-[Plant Protection Products Regulation (EC) No 1107/2009]', 'EU: REACH-[Registration, Evaluation and Authorisation of Chemicals Regulation (EC...)]', 'JP: CSCL-[Chemical Substances Control Law]', and 'NZ: HSNO-[Hazardous Substances and New Organisms Act]'. The 'EU: PPP' option is currently selected.

- 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.
- If the flag is set as confidential then a justification must be provided

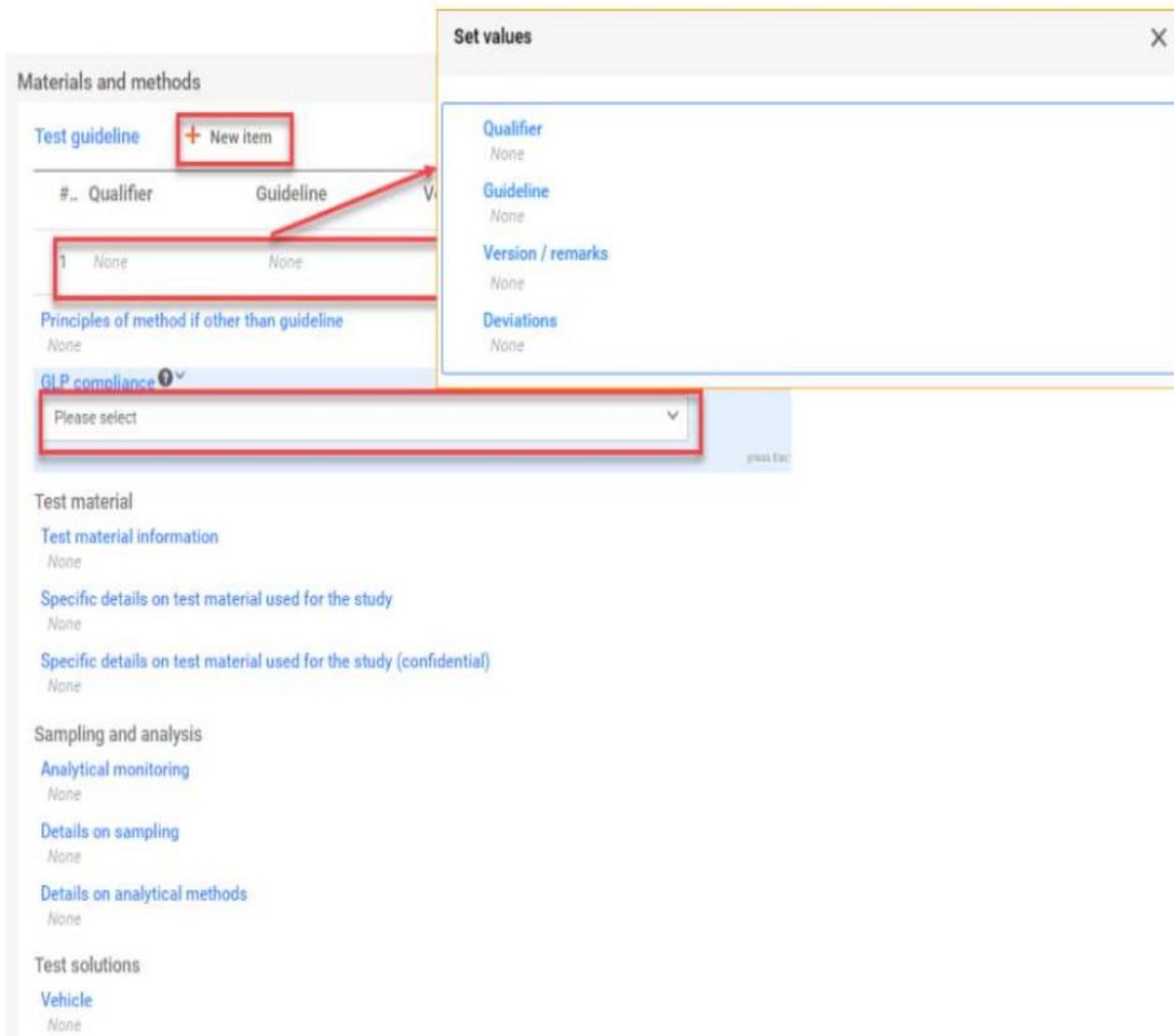
Endpoint study records – Data source



The screenshot displays the 'Data source' management interface. On the left, the 'Data source' panel shows a dropdown menu for 'Reference' with a '+ Select' button highlighted. A red arrow points from this button to the 'Select Literature reference' dialog box. The dialog box contains a search bar with the text 'test' and a '+ Create' button. Another red arrow points from the '+ Create' button to the 'Create new Literature reference' form. This form includes fields for 'Reference Type', 'Title*', 'Author', 'Year', 'Bibliographic source', 'Testing facility', 'Report no.', 'Study sponsor', 'Study no.', 'Report date', 'Remarks', 'Attached documents', and 'Attached (sanitised) documents for publication'. A table at the bottom of the form has columns for '#', 'Study ID', and 'Remarks'.

- 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.

Endpoint study records – Materials & Methods



Materials and methods

Test guideline + New item

#.	Qualifier	Guideline	V
1	None	None	

Principles of method if other than guideline
None

GLP compliance i
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

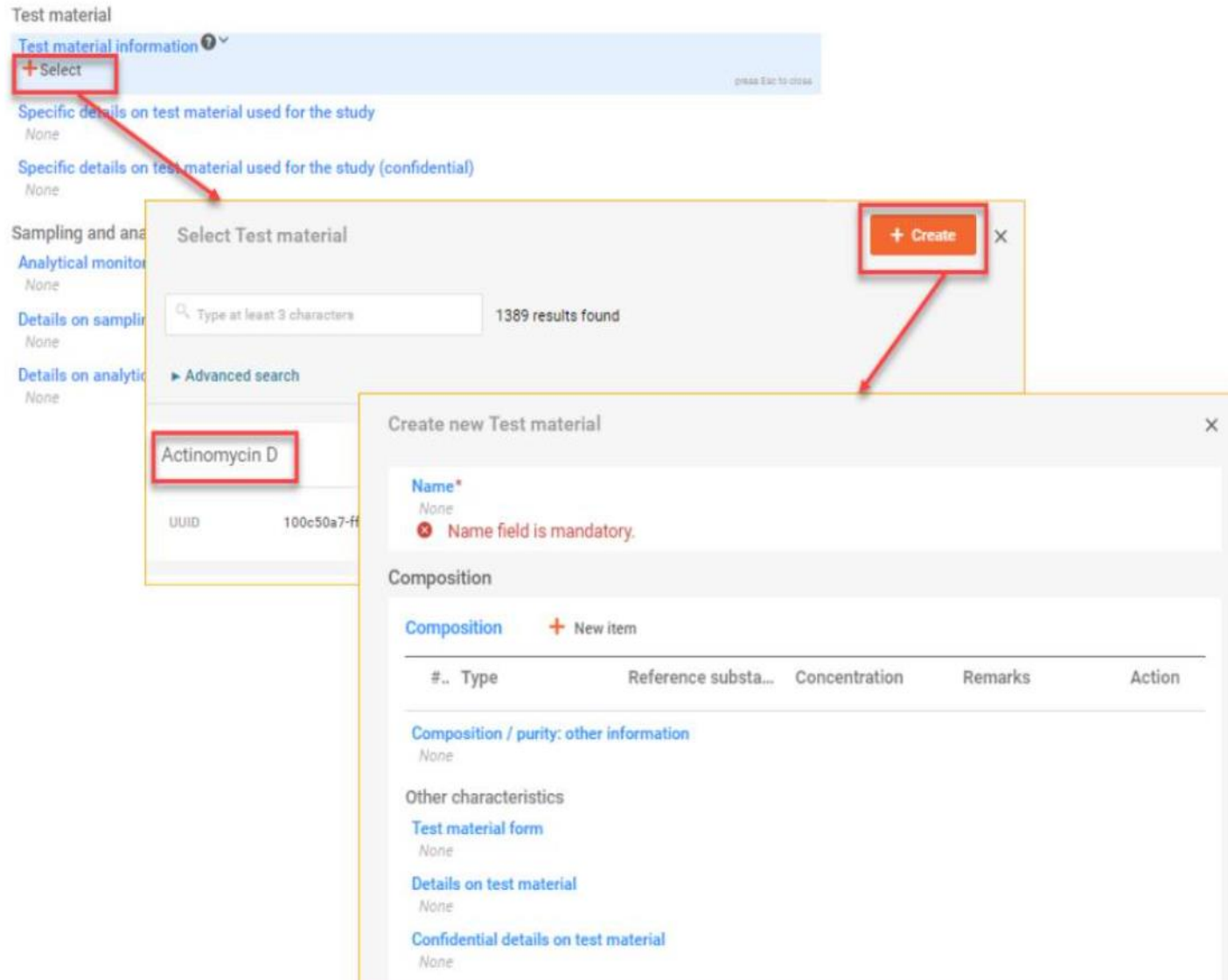
Details on analytical methods
None

Test solutions

Vehicle
None

- 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

Endpoint study records – Add details on the test material



Test material information

+ Select

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 method
None

Select Test material

+ Create

Type at least 3 characters 1389 results found

Advanced search

Actinomycin D

UUID 100c50a7-f...

Create new Test material

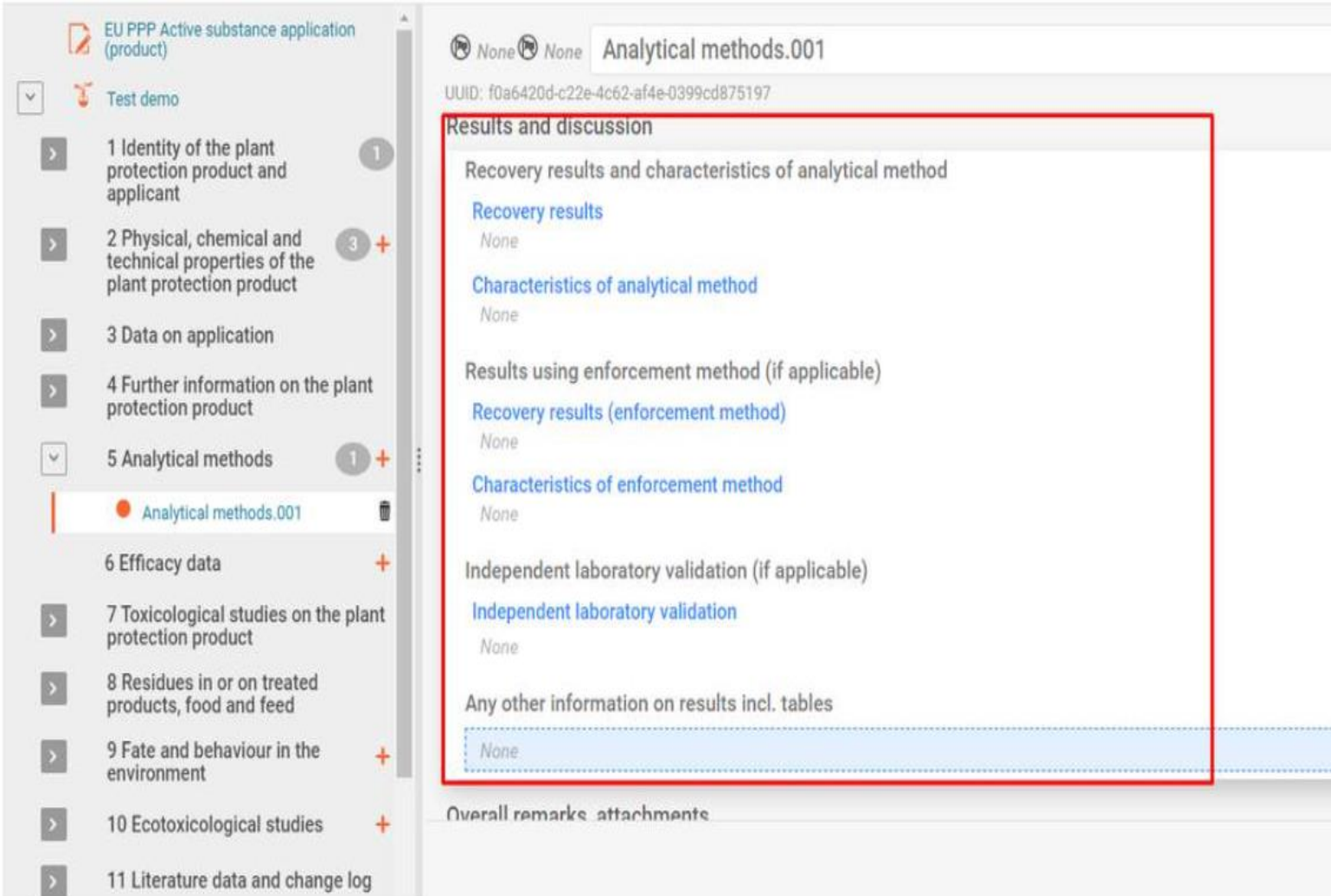
Name*
None
Name field is mandatory.

Composition

Composition + New item

#..	Type	Reference substa...	Concentration	Remarks	Action
Composition / purity: other information None					
Other characteristics					
Test material form None					
Details on test material None					
Confidential details on test material None					

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



The screenshot displays the EFSA application interface. On the left is a navigation menu with 11 items, including '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', and '11 Literature data and change log'. The '5 Analytical methods' item is selected, showing a sub-entry 'Analytical methods.001'. The main content area shows the details for 'Analytical methods.001' with a UUID of 'f0a6420d-c22e-4c62-af4e-0399cd875197'. A red box highlights the 'Results and discussion' section, which contains the following fields: 'Recovery results and characteristics of analytical method' (with sub-fields 'Recovery results' and 'Characteristics of analytical method', both set to 'None'), 'Results using enforcement method (if applicable)' (with sub-fields 'Recovery results (enforcement method)' and 'Characteristics of enforcement method', both set to 'None'), 'Independent laboratory validation (if applicable)' (with sub-field 'Independent laboratory validation' set to 'None'), and 'Any other information on results incl. tables' (set to 'None'). Below this section is the 'Overall remarks attachments' field.

- 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**'.

Working context: EU PPP Active substance application (product)

View Dossiers Validate Create dossier

EU PPP Active substance application (product)

Test demo

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

None None Appearance (at 20°C and 101.3 kPa).003

UUID: 3bc69274-8a28-43d1-b380-deda98b9cc32

Administrative data None None

Link to relevant study record(s)

Study name / type

+ Select

Select existing document

+ Create

Appearance (at 20°C and 101.3 kPa).001 02/03/2021 14:13

Mixture / Product Test demo UUID 763c9fea-000b-40d7-92ef-2c523c7d50ae

Appearance (at 20°C and 101.3 kPa).002 02/03/2021 13:39

Mixture / Product Test demo UUID aaa20464-60f4-4358-bae7-02c8e714bfdc

Save

#	Attached document	Remarks	Action
	Attached (sanitised) documents for publication		
	None		

- 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.

Key value for chemical safety assessment

Acute toxicity: via oral route

Link to relevant study records

Study name / type

experimental study | 1 (reliable without restriction) | standard acute method | rat | oral: gavage

Endpoint conclusion

Endpoint conclusion

adverse effect observed

Dose descriptor

LD50

Value

1829 mg/kg bw

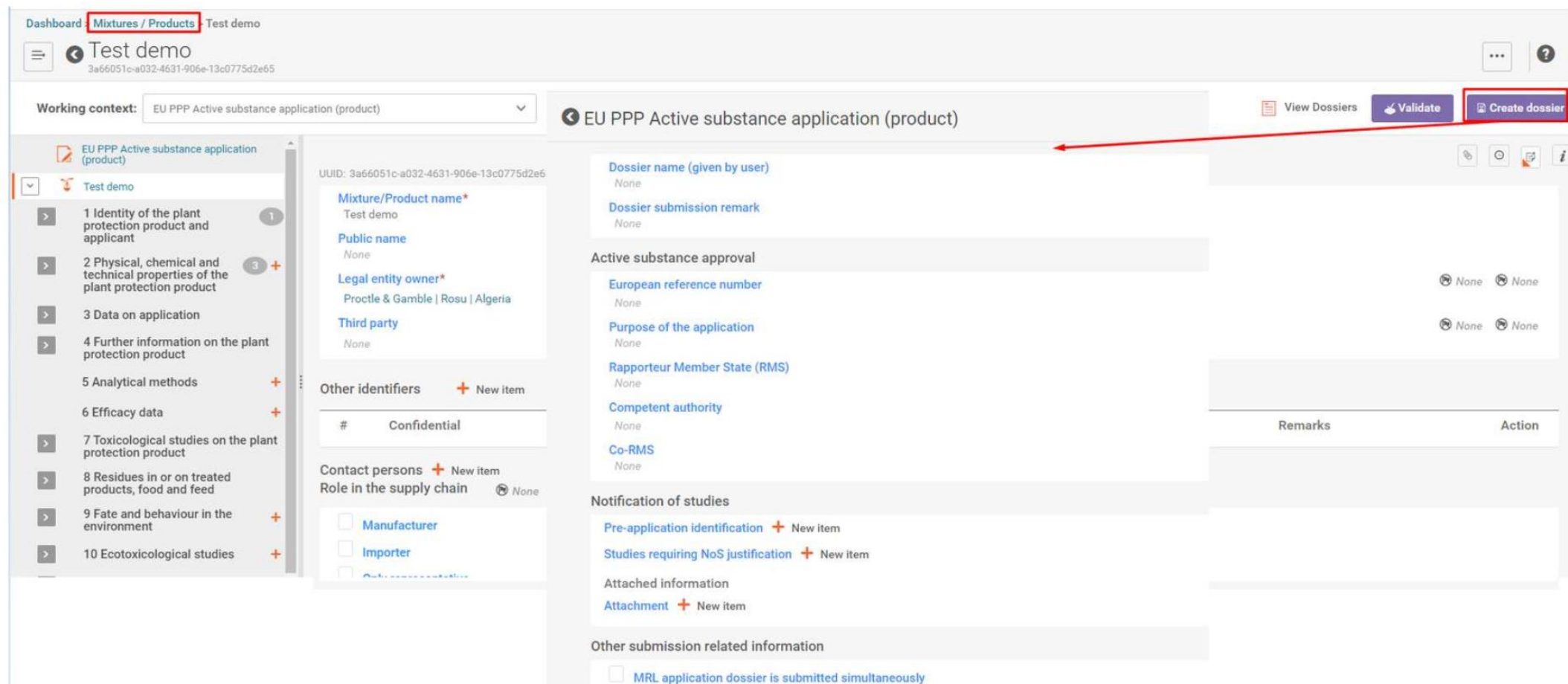
- The key value for safety assessment is the **endpoint** defined from the studies provided in the dossier

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

Rat LD 50 oral	>2000 mg/kg bw
Rat LD 50 dermal	>2000 mg/kg bw
Rat LC 50 oral inhalation	>5.5 mg/L air/4h (state way, e.g. nose only)



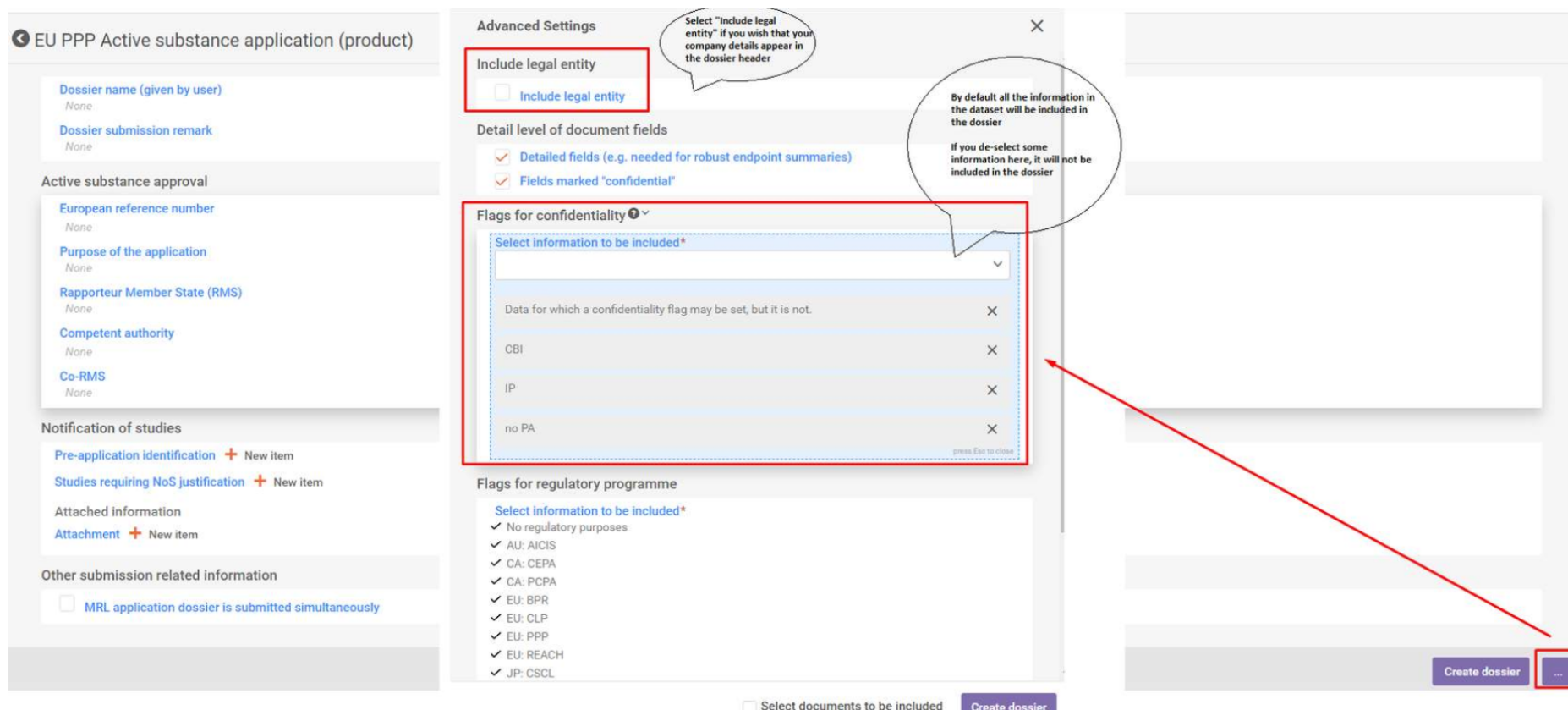
How to create a dossier



The screenshot shows the EFSA dossier creation interface. At the top, the breadcrumb navigation is 'Dashboard > Mixtures / Products > Test demo'. The main header displays 'Test demo' with a UUID '3a66051c-a032-4631-906e-13c0775d2e65'. Below this, the 'Working context' is set to 'EU PPP Active substance application (product)'. A red box highlights the 'Create dossier' button in the top right corner. The interface is divided into several sections: a left sidebar with a tree view of application steps (1-10), a central panel for 'EU PPP Active substance application (product)' with a 'Test demo' sub-section, and a right panel for 'EU PPP Active substance application (product)' containing various fields and sections. The right panel includes sections for 'Dossier name (given by user)', 'Dossier submission remark', 'Active substance approval' (with fields for European reference number, Purpose of the application, Rapporteur Member State (RMS), and Competent authority), 'Notification of studies' (with fields for Pre-application identification and Studies requiring NoS justification), and 'Attached information' (with an Attachment field). A table with 'Remarks' and 'Action' columns is also visible. At the bottom, there is a checkbox for 'MRL application dossier is submitted simultaneously'.

- 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.

Dossier creation wizard – 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

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"

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 confidentiality

Select information to be included*

Data for which a confidentiality flag may be set, but it is not.	X
CBI	X
IP	X
no PA	X

press Esc to close

Flags for regulatory programme

Select information to be included*

- No regulatory purposes
- AU: AICIS
- CA: CEPA
- CA: PCPA
- EU: BPR
- EU: CLP
- EU: PPP
- EU: REACH
- JP: CSCL

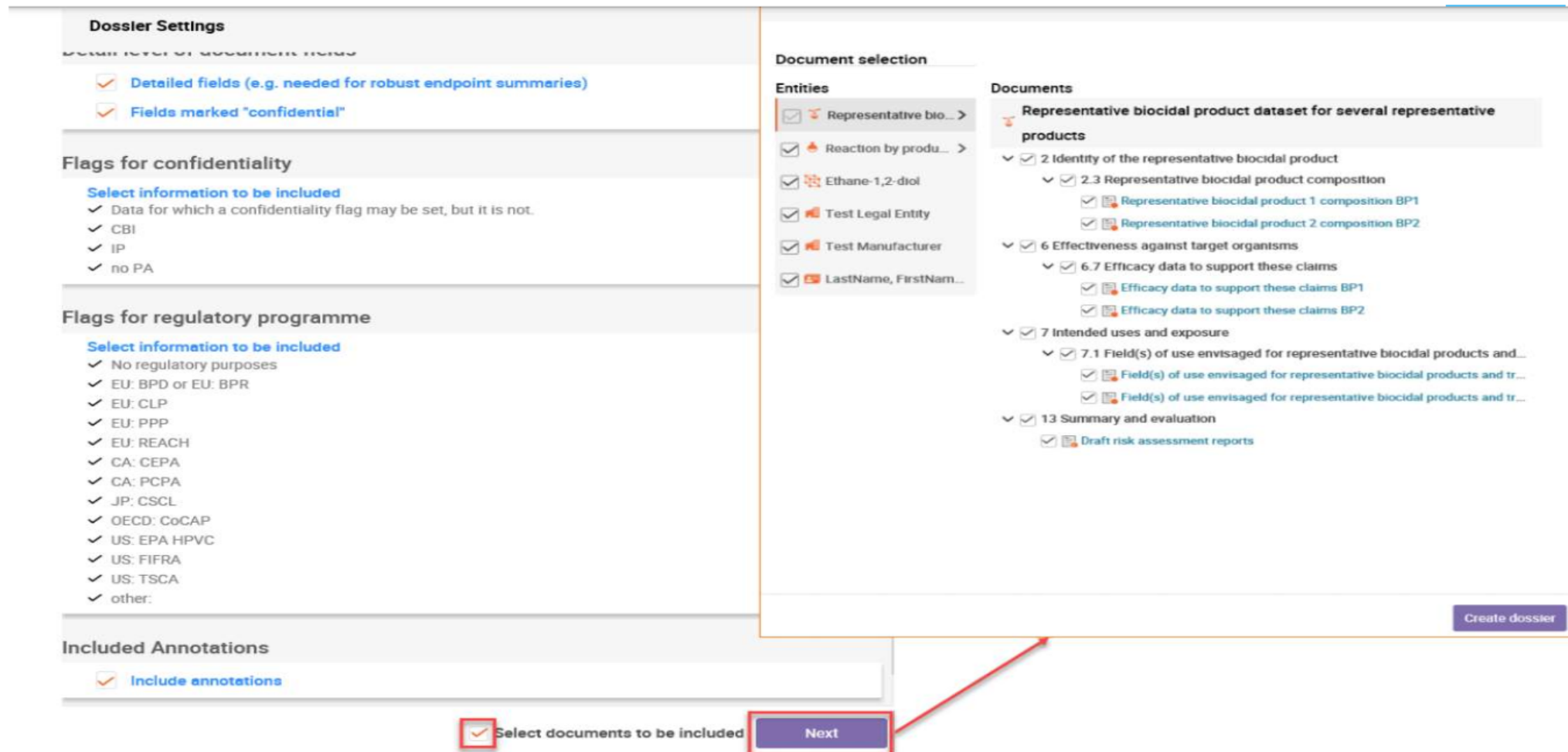
Select documents to be included

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, deselect the relevant section in advanced settings when creating a dossier.

Verify the sections to be included

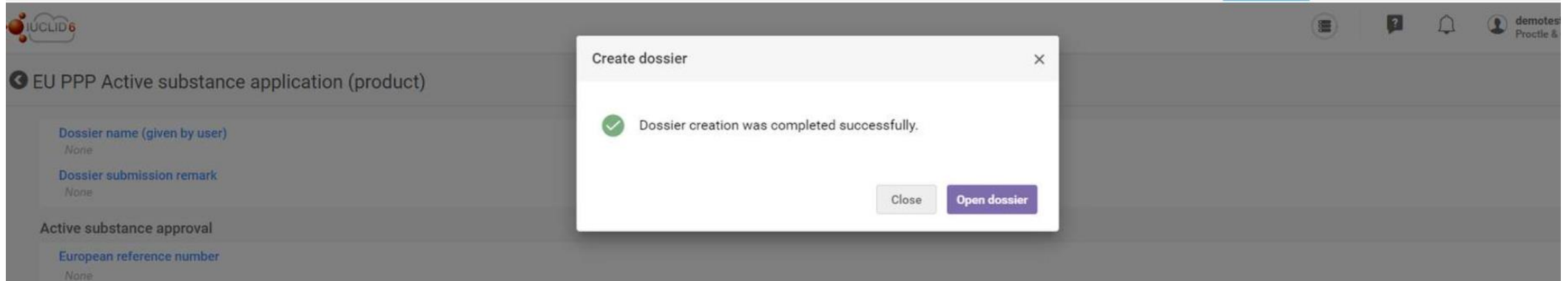


The screenshot displays the 'Dossier Settings' interface, which is divided into several sections:

- Dossier Settings**
 - 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
 - IP
 - no PA
 - Flags for regulatory programme**
 - Select information to be included
 - 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
 - other:
 - Included Annotations**
 - Include annotations
- 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...
 - 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

- Next** button

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



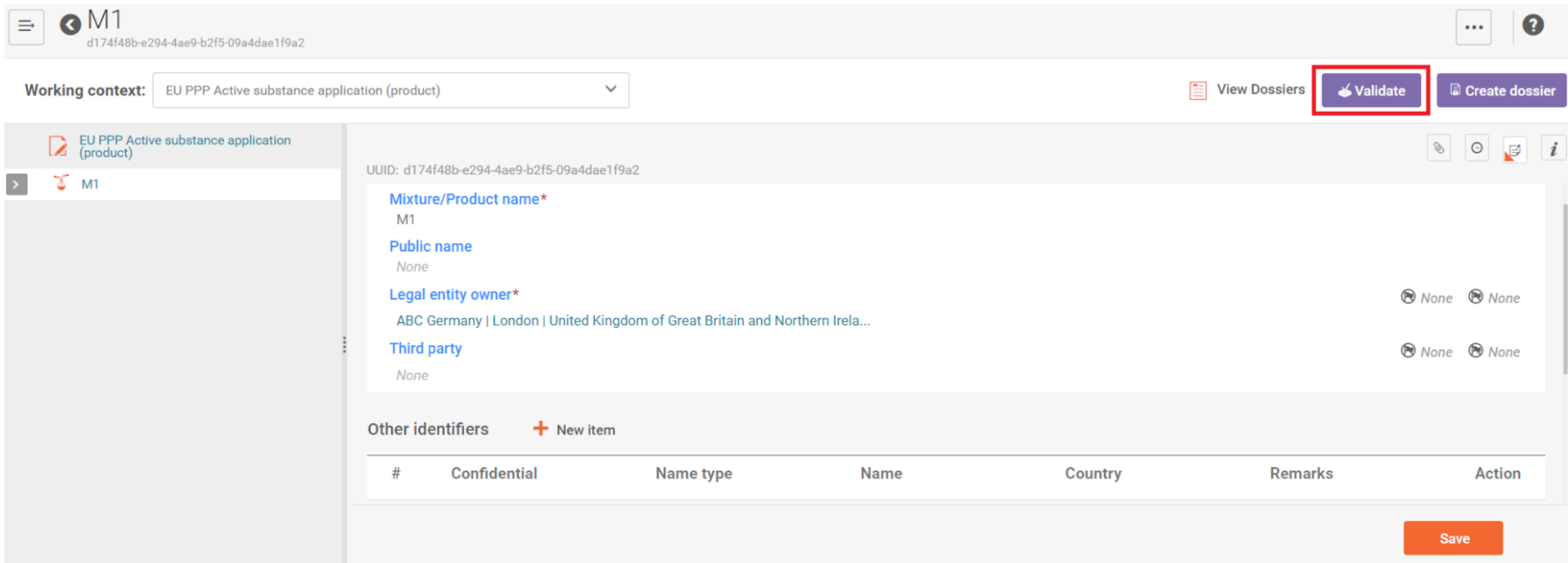
- Specify the **dossier name** in the free text field and include any additional remarks if relevant.
- A prompt window will appear, giving an option to open the newly **created dossier**. Validation rules run the dossier to verify if basic information is compiled correctly in the dossier.
- **Once the button "Create dossier" is clicked, you have accessed just in read-only version.**



Role and purpose of validation assistant

Validation assistant

- The validation assistant helps you to prepare the dossier before submission, 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



The screenshot shows the EFSA validation assistant interface. At the top, there is a breadcrumb trail: "M1" with a UUID "d174f48b-e294-4ae9-b2f5-09a4dae1f9a2". Below this, the "Working context" is set to "EU PPP Active substance application (product)". On the right, there are three buttons: "View Dossiers", "Validate" (highlighted with a red box), and "Create dossier".

The main content area displays the details for the dossier "M1". The UUID is "d174f48b-e294-4ae9-b2f5-09a4dae1f9a2". The fields are as follows:

- Mixture/Product name***: M1
- Public name**: None
- Legal entity owner***: ABC Germany | London | United Kingdom of Great Britain and Northern Irel... (with "None" selection buttons)
- Third party**: None (with "None" selection buttons)

Below the details, there is a section for "Other identifiers" with a "+ New item" button. A table is shown with the following columns: #, Confidential, Name type, Name, Country, Remarks, and Action.

At the bottom right, there is a "Save" button.

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

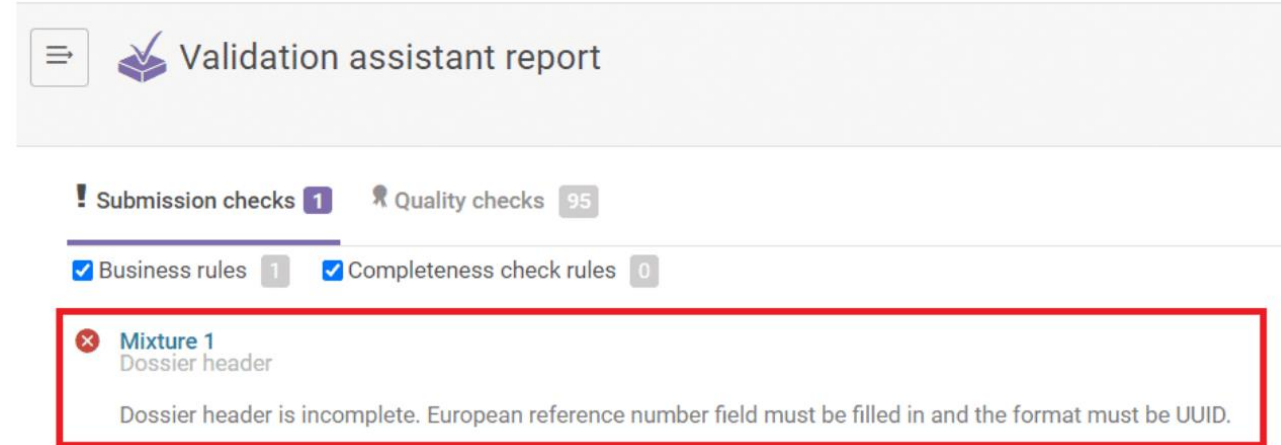
European reference number
None

Purpose of the application*
None
✘ Purpose of the application field is mandatory.

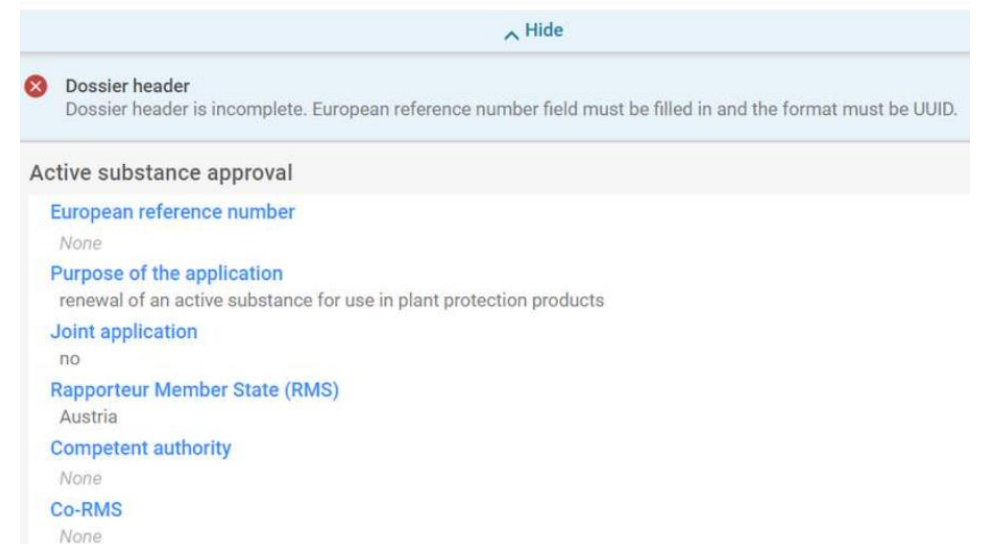
Evaluating Member State (EMS)*
None

Validation assistant 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, it can be accessed via the link provided - the user can directly fix validation assistant errors by clicking on the link.
- 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.



The screenshot shows the 'Validation assistant report' interface. At the top, there is a navigation menu with a hamburger icon and a checkmark icon. Below the title, there are two summary items: 'Submission checks 1' and 'Quality checks 95'. Underneath, there are two checked items: 'Business rules 1' and 'Completeness check rules 0'. A red box highlights an error entry for 'Mixture 1' under the 'Dossier header' category. The error message states: 'Dossier header is incomplete. European reference number field must be filled in and the format must be UUID.'

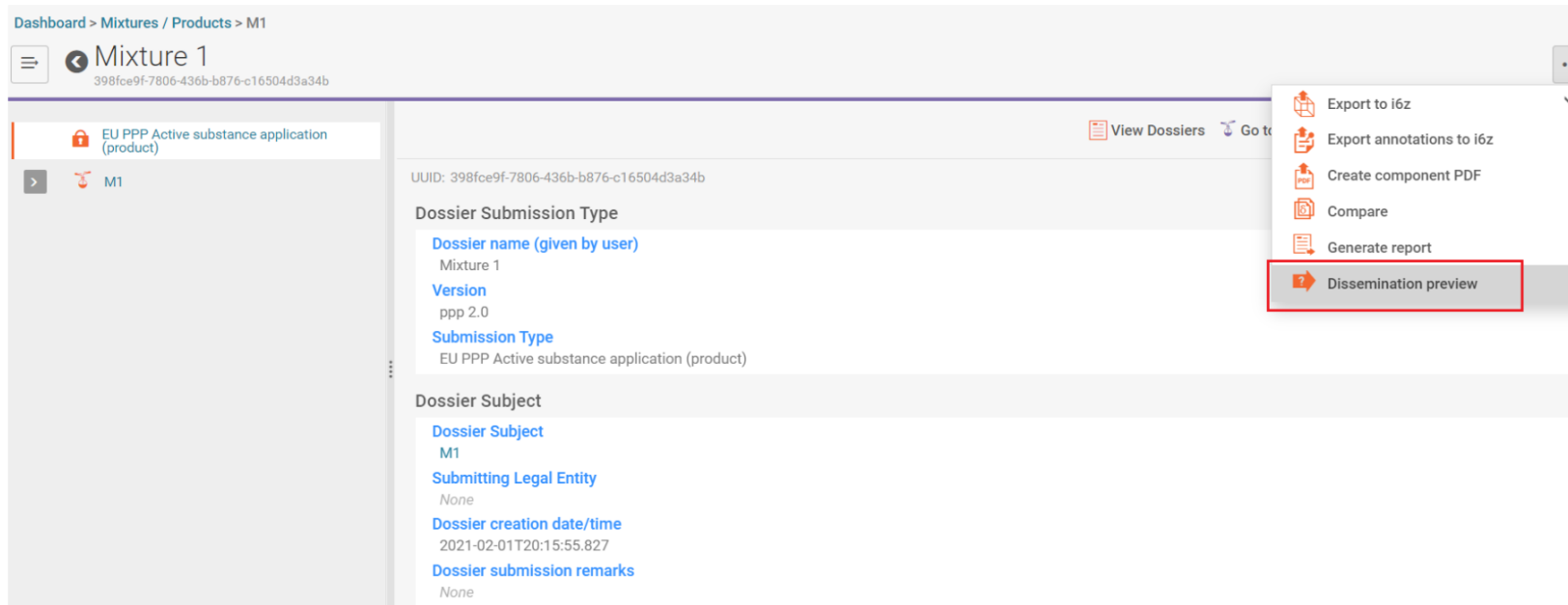


The screenshot shows a detailed view of the dossier. At the top, there is a 'Hide' button. Below it, there is an error entry for 'Dossier header' with the same message as in the previous screenshot. Underneath, there is a section for 'Active substance approval' with several fields: 'European reference number' (None), 'Purpose of the application' (renewal of an active substance for use in plant protection products), 'Joint application' (no), 'Rapporteur Member State (RMS)' (Austria), 'Competent authority' (None), and 'Co-RMS' (None).



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 and the **output** of it is a file in the format of Microsoft Excel (XLSX).
- It 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	Filtering outcome
LITERATURE.GeneralInfo.LiteratureType	PUBLISHED
LITERATURE.GeneralInfo.Name	PUBLISHED
LITERATURE.GeneralInfo.Author	STUDY_REF_AUTH_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	NOT_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 mainly 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
 - A small number of more sophisticated filter rules is used in specific cases

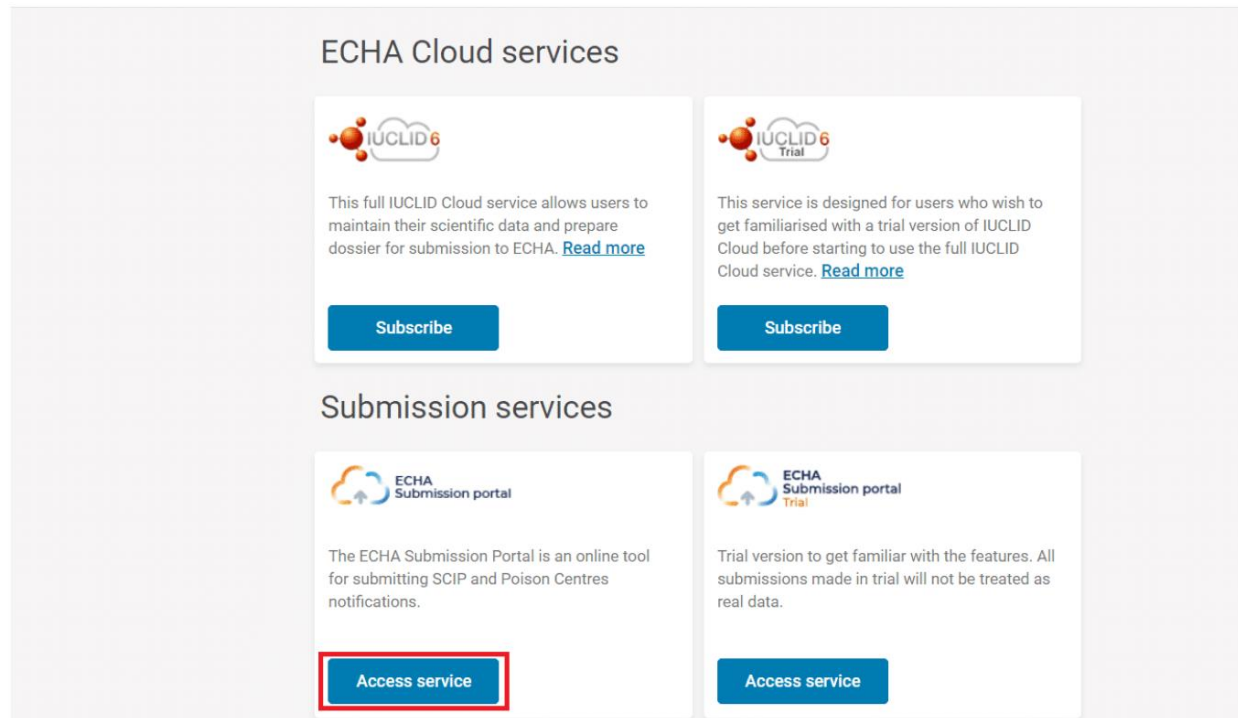


How to submit a dossier

How to submit 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.



The screenshot shows a webpage with two main sections: 'ECHA Cloud services' and 'Submission services'. Under 'ECHA Cloud services', there are two cards for 'IUCLID 6'. The first card is for the full service, allowing users to maintain scientific data and prepare dossiers for submission to ECHA, with a 'Subscribe' button. The second card is for a trial version, designed for users to get familiarised with the service before starting to use the full version, also with a 'Subscribe' button. Under 'Submission services', there are two cards for the 'ECHA Submission portal'. The first card is for the full service, an online tool for submitting SCIP and Poison Centres notifications, with an 'Access service' button highlighted by a red box. The second card is for a trial version, allowing users to get familiar with the features, with a note that trial submissions will not be treated as real data, and an 'Access service' button.

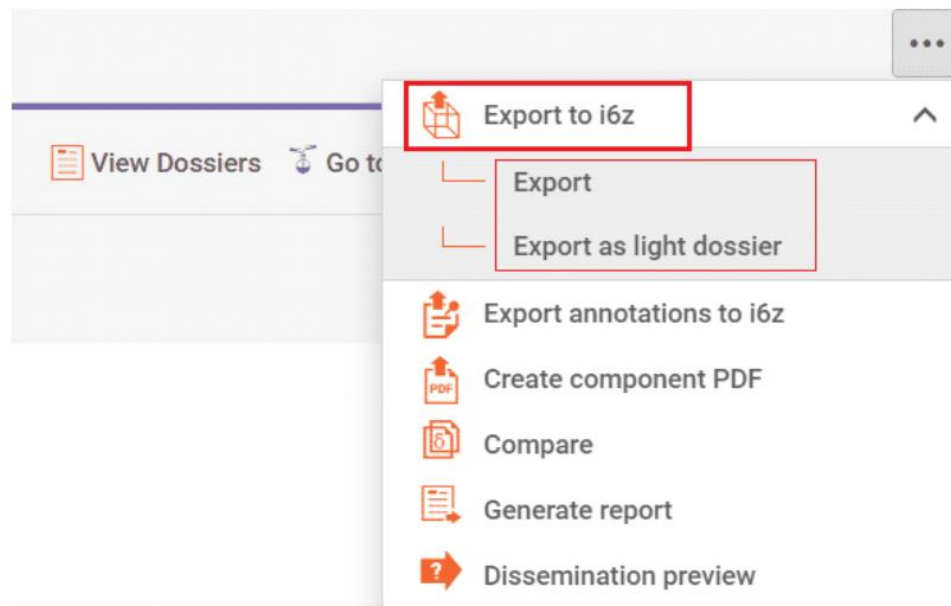
ECHA Submission Portal

- 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

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