

Poison centre notifications

A GUIDE TO DOSSIER PREPARATION AND SUBMISSION

Version 1.0 April 2019



Table of contents

Getting access	3
ECHA Submission Portal for poison centre notifications	9
Guided dossier preparation for PCN submissions	17
Dossier preparation: 'Mixture information' section	27
Reporting mixture (in mixture) components	38
Reporting substance components	46
Dossier preparation: 'Product information' section	52
Validate information and create dossier	60
Updating dossier information	65



Getting access

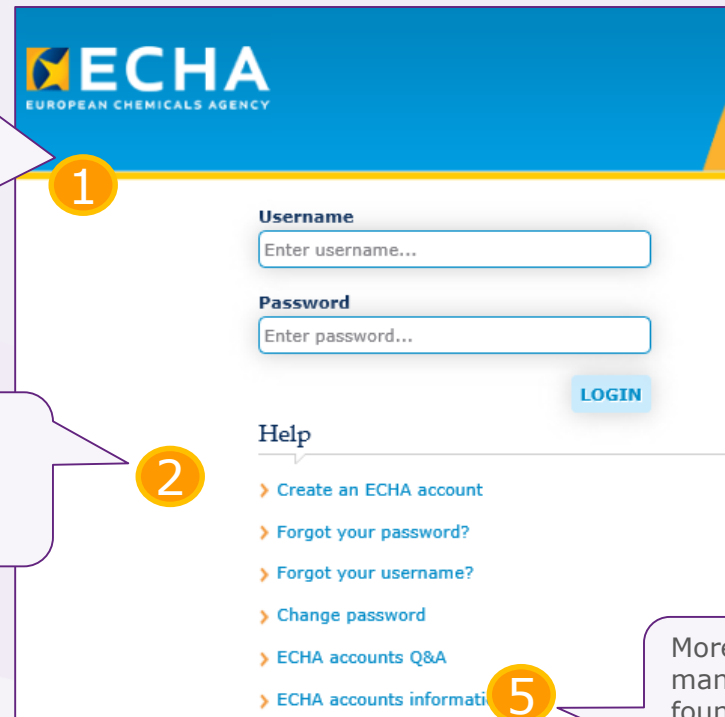
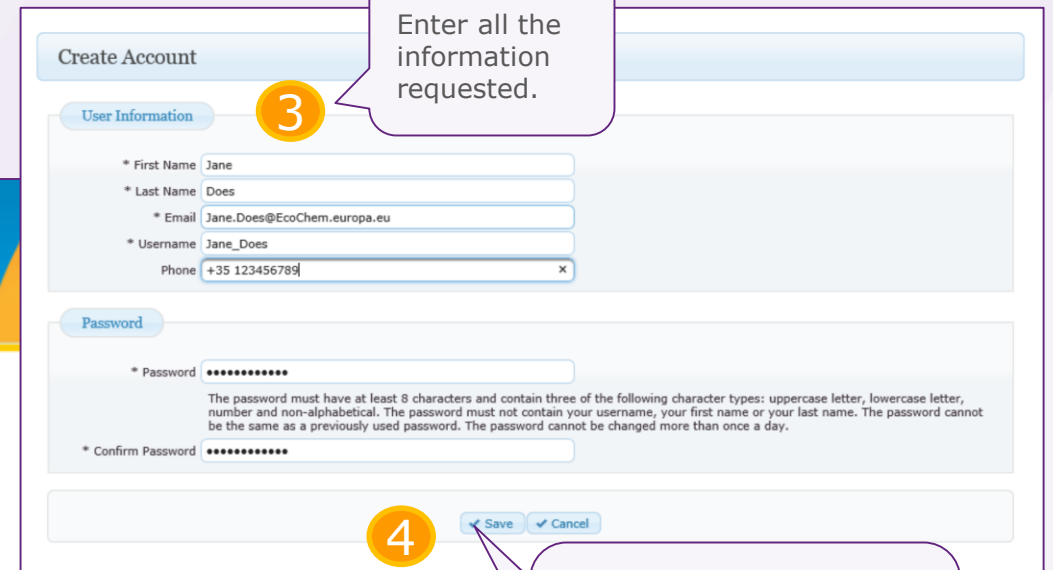
This chapter describes the process how to create an ECHA Account and detail and link the legal entity information in order to use the tools for the preparation and submission of notifications.

Creating an ECHA account

In order to use the ECHA Cloud Services for preparing your notifications, an ECHA Account must first be created.

The ECHA Accounts Login page is located at <https://idp-industry.echa.europa.eu/idp/>

If you do not have a valid username and password, then you will need to register a legal entity by creating an account.

More detailed information about managing your account can be found in the ECHA Accounts Manual.

Enter all the information requested.

Click Save. A message will appear prompting to verify the given email address before continuing.



Assign the Legal Entity

Once an ECHA Account has been created, it needs to have a legal entity (LE) assigned to it before the ECHA IT applications can be accessed.

A legal entity may represent anything between a complex business structure and a simple organised business, for example, a corporation, a company, or a single person.

A legal entity manager is the first user associated with a legal entity.

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ECHA Applications You are connected as [JaneDoez](#) | [Logout](#)

Create Legal Entity

In order to use ECHA's submission systems you need to provide your Legal Entity's details, contact information, D-U-N-S, VAT number, and website. You can either import an IUCLID format file or encode a legal entity.

Import IUCLID format file: If you already have a legal entity definition file in IUCLID exchange format (e.g. .leox), you should import your LE. If you have the same UUID for your legal entity definition as for your IUCLID LEOX, you should import your LE. If you do not have the same UUID, you will be redirected to the Legal Entity profile screens to review / update imported details as well as to enter additional details.

Encode Legal Entity: If you do not have any IUCLID format file or do not intend to import one, you can encode a legal entity manually.

1

Import IUCLID format file Encode Legal Entity

If you do not have an existing legal entity to import e.g. created in IUCLID, you can select Encode Legal Entity and enter the details.

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Create Legal Entity

Please provide the required details. Fields marked with an asterisk (*) are mandatory. Hovering over a (?) sign displays help information.

Account security

* Security Question
 * Security Answer
 Four characters or more. Make sure your answer is easy to remember for you, but hard for others to guess!

Security Alerts Receive e-mail alerts about signing-in activities and access to your ECHA account

General details

* Legal Entity name
 D-U-N-S ?
 VAT number ?
 Remarks ?

General Contact information

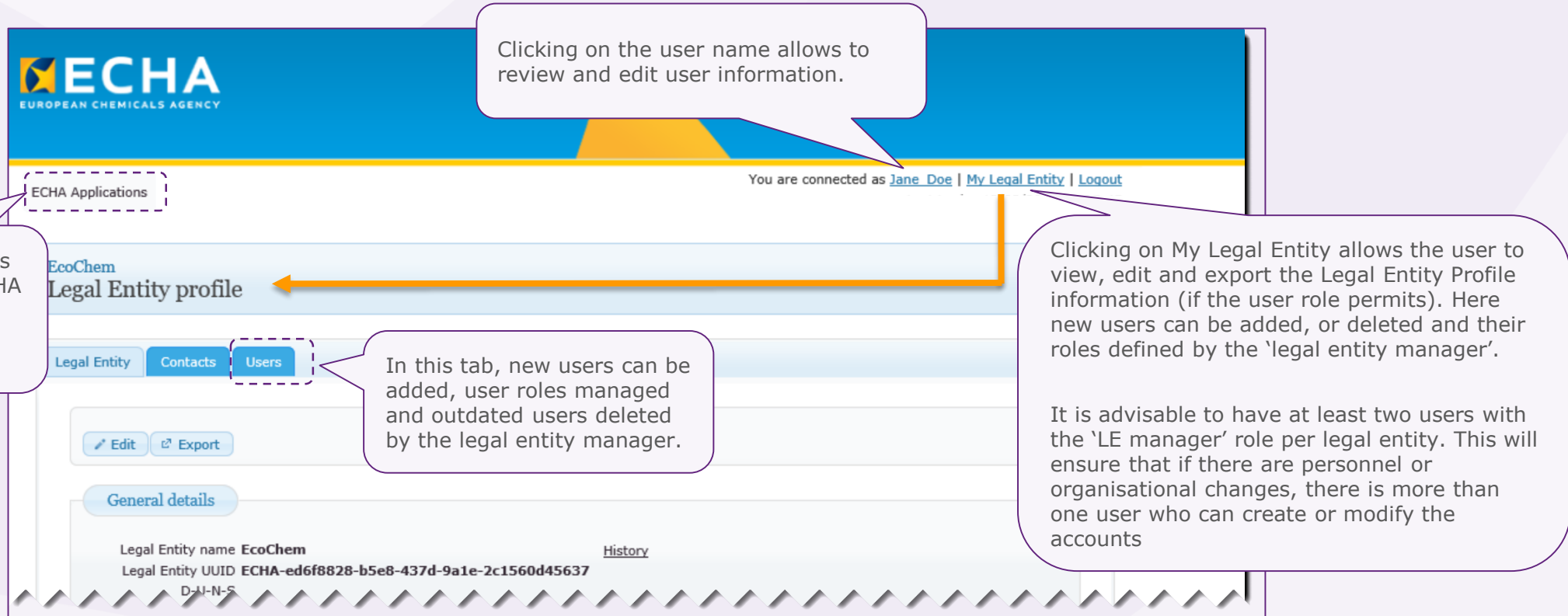
* Phone
 * Email Example: name@domain.com
 Website
 Fax

Address Information

2

Enter as much information as possible for the legal entity and press Save.

ECHA Accounts navigation



The screenshot shows the ECHA Accounts navigation interface. At the top left is the ECHA logo (EUROPEAN CHEMICALS AGENCY). Below it, a navigation bar contains 'ECHA Applications' (highlighted with a dashed box), 'Legal Entity', 'Contacts', and 'Users' (also highlighted with a dashed box). The main content area shows the 'Legal Entity profile' for 'EcoChem'. It includes 'Edit' and 'Export' buttons, and a 'General details' section with fields for 'Legal Entity name EcoChem' and 'Legal Entity UUID ECHA-ed6f8828-b5e8-437d-9a1e-2c1560d45637'. A 'History' link is also visible. A user status bar at the top right indicates 'You are connected as Jane Doe | My Legal Entity | Logout'. An orange arrow points from the 'My Legal Entity' link to the 'Legal Entity profile' section.

Clicking on the user name allows to review and edit user information.

Clicking ECHA Applications redirects to the list of ECHA IT applications, including the ECHA Submission Portal.

Clicking on My Legal Entity allows the user to view, edit and export the Legal Entity Profile information (if the user role permits). Here new users can be added, or deleted and their roles defined by the 'legal entity manager'.

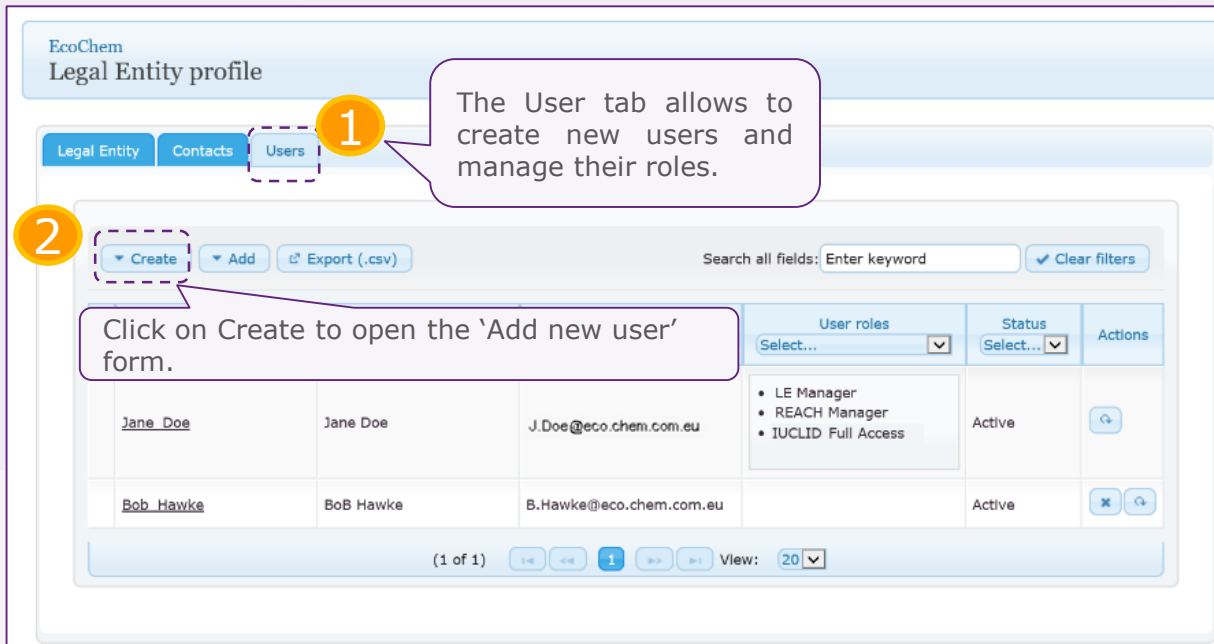
In this tab, new users can be added, user roles managed and outdated users deleted by the legal entity manager.

It is advisable to have at least two users with the 'LE manager' role per legal entity. This will ensure that if there are personnel or organisational changes, there is more than one user who can create or modify the accounts

Defining the user roles

The user roles define the user access level within the ECHA IT applications:

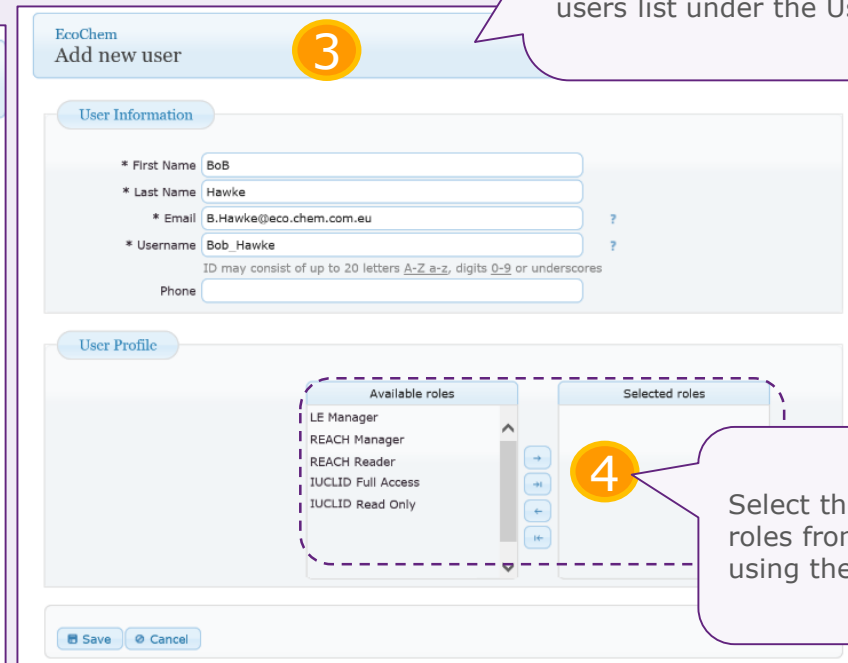
- **LE Manager** can view and edit the LE account and add, remove or edit user's data and contacts.
- **REACH manager** can make submissions through ECHA Submission portal
- **IUCLID full access** can prepare submissions online in IUCLID Cloud.
- **'Reader' and 'Read' roles** are entitled to read only access.



The User tab allows to create new users and manage their roles.

Click on Create to open the 'Add new user' form.

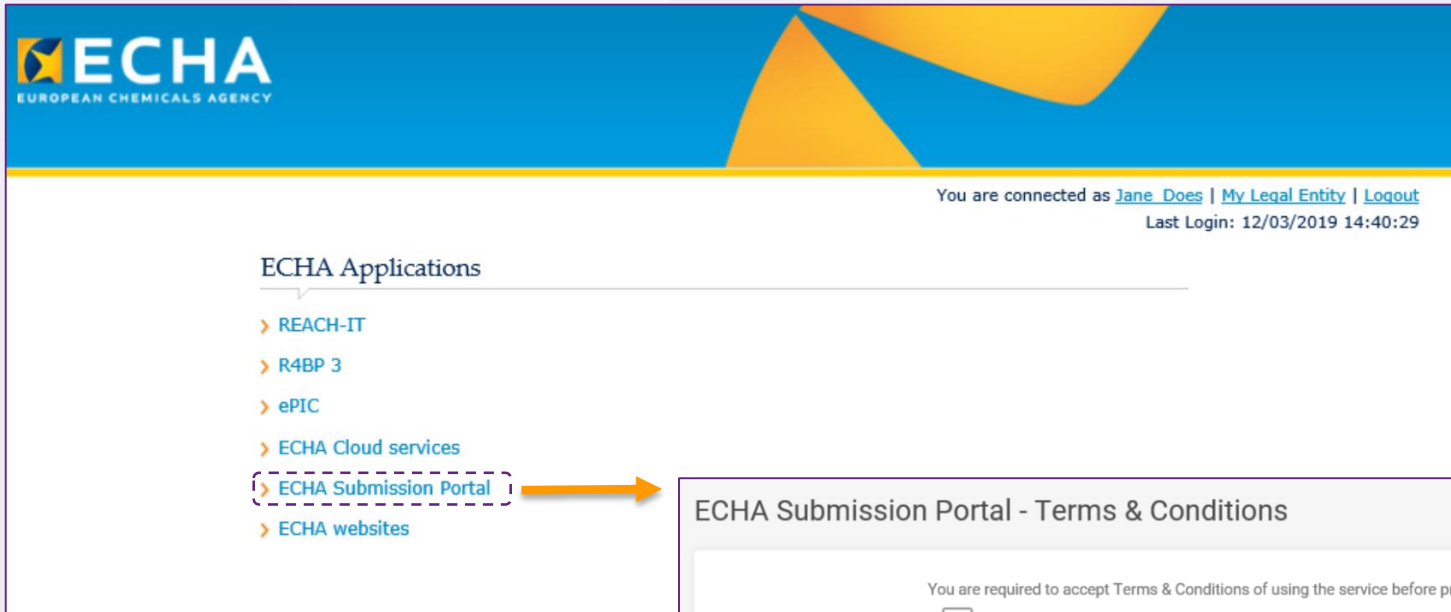
			User roles	Status	Actions
			Select...	Select...	
Jane Doe	Jane Doe	J.Doe@eco.chem.com.eu	<ul style="list-style-type: none"> LE Manager REACH Manager IUCLID Full Access 	Active	
Bob Hawke	BoB Hawke	B.Hawke@eco.chem.com.eu		Active	



Enter all the user information details for the new user and indicate the type or types of roles that the user should have. Press Save, and the user will appear in the users list under the User tab.

Select the relevant user roles from the available list using the arrow buttons.

Accessing ECHA applications for the first time



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You are connected as [Jane Does](#) | [My Legal Entity](#) | [Logout](#)
Last Login: 12/03/2019 14:40:29

ECHA Applications

- > REACH-IT
- > R4BP 3
- > ePIC
- > ECHA Cloud services
- > **ECHA Submission Portal**
- > ECHA websites

ECHA Submission Portal - Terms & Conditions

You are required to accept Terms & Conditions of using the service before proceeding.

I acknowledge that I have read and agreed to the linked [Terms & Conditions](#)

[Accept and Continue](#) [Decline](#)

First time users will be required to accept to terms and conditions of each application before being able to proceed.



ECHA Submission portal for poison centre notifications

A navigational guide around the ECHA Submission Portal; highlighting the three pillars of the notification process; dossier creation, dossier submission and searching for notifications.



ECHA Submission portal page

The ECHA Submission portal webpage is available from the ECHA Poison Centre website:

<https://poisoncentres.echa.europa.eu/echa-submission-portal>

Links to key documents and support can be found on the right hand side of the page, and additional related links at the bottom.

The screenshot shows the ECHA Submission portal interface. At the top, there is a navigation bar with 'About us', 'Steps for industry', 'Tools', and 'Support'. A search bar is located on the right. The main content area is titled 'ECHA Submission portal' and contains introductory text and a list of key documents. A callout box points to the 'ECHA Submission portal' link in the left sidebar. Another callout box points to a list of links including 'Signing in', 'How to prepare a PCN dossier', 'How to submit a PCN dossier', 'Languages required for notifications', and 'Submission acceptance - Member State overview'. A third callout box points to the 'Support' section on the right, which includes links for 'National helpdesks', 'List of national appointed bodies', and 'ECHA contact form'. At the bottom, there is a 'Related links' section with links to 'Terms and Conditions of use and service of the ECHA Submission portal', 'IUCLID Cloud', and 'IUCLID 6 website'.

Log in to the ECHA Submission portal here.



Click for more details and where to find more information on these topics.

ECHA Submission portal landing page

The portal navigation bar to the 'Upload and submit' page or go to 'Create dossier online' using IUCLID Cloud.

The bell icon will alert e.g. when new versions have been released.

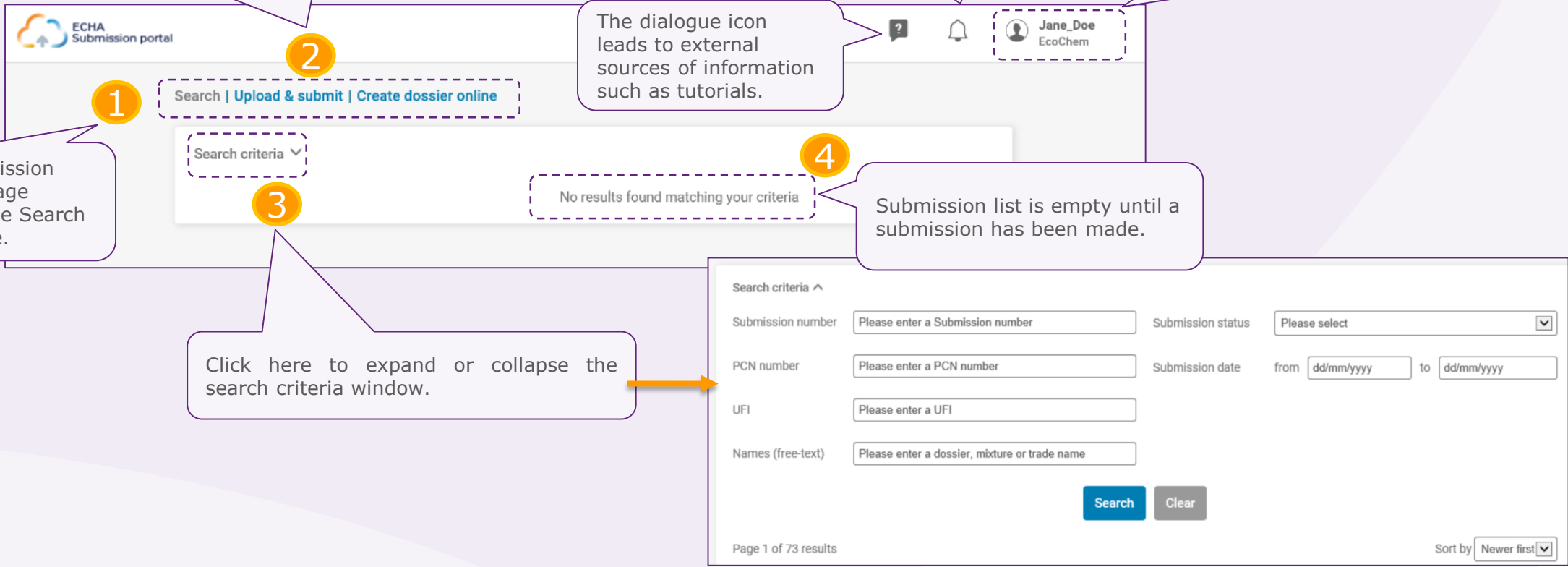
The user icon displays the name and legal entity of the user and, when clicked on, opens a new window for redirection to the ECHA Cloud dashboard, accounts management and the logout functionality.

The dialogue icon leads to external sources of information such as tutorials.

The ECHA Submission portal landing page directs you to the Search submission page.

Click here to expand or collapse the search criteria window.

Submission list is empty until a submission has been made.



1 Search | Upload & submit | Create dossier online

2 Search criteria v

3 No results found matching your criteria

4 Search criteria ^

Submission number Submission status

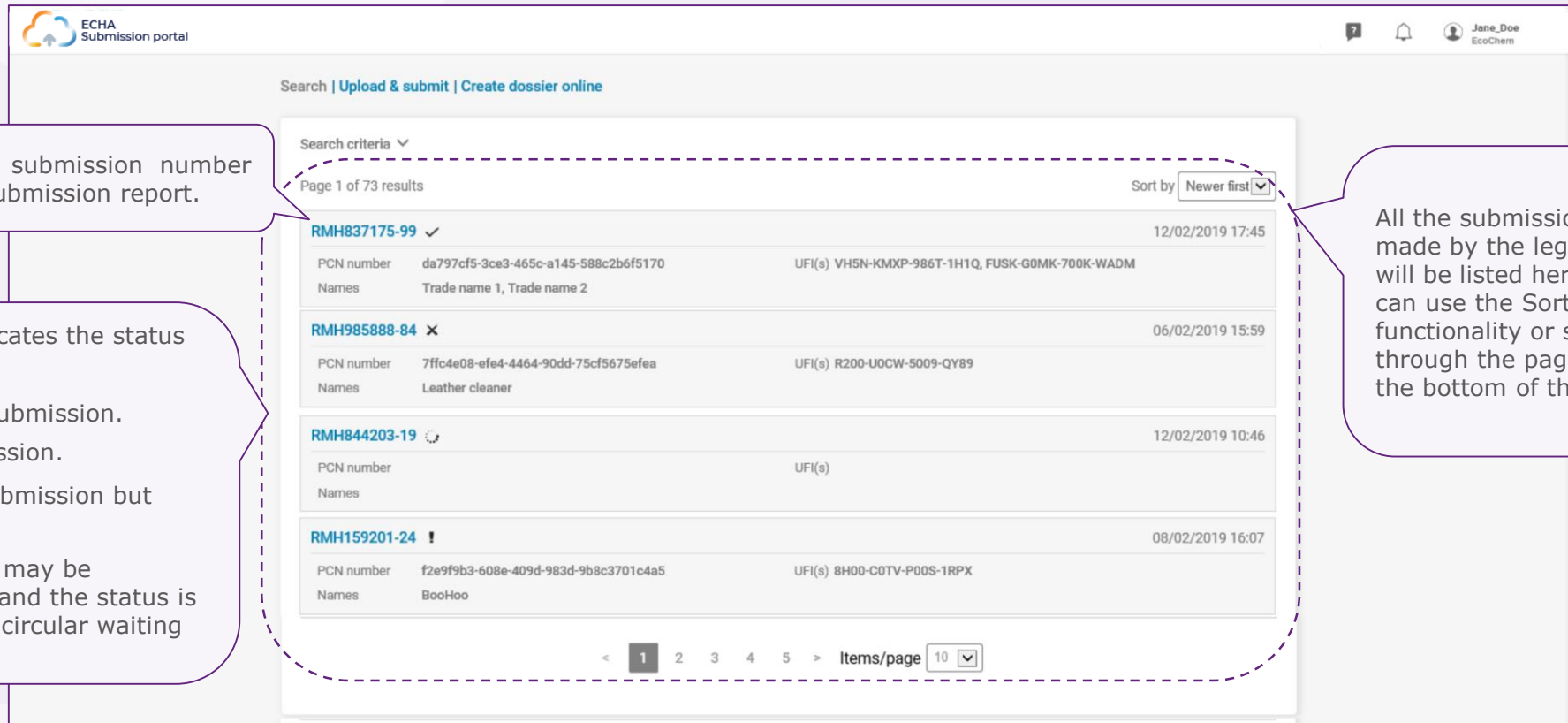
PCN number Submission date from to

UFI

Names (free-text)

Page 1 of 73 results Sort by

ECHA Submission portal Search page



Click on the submission number to view the submission report.

Each submission listed indicates the status of the submission:

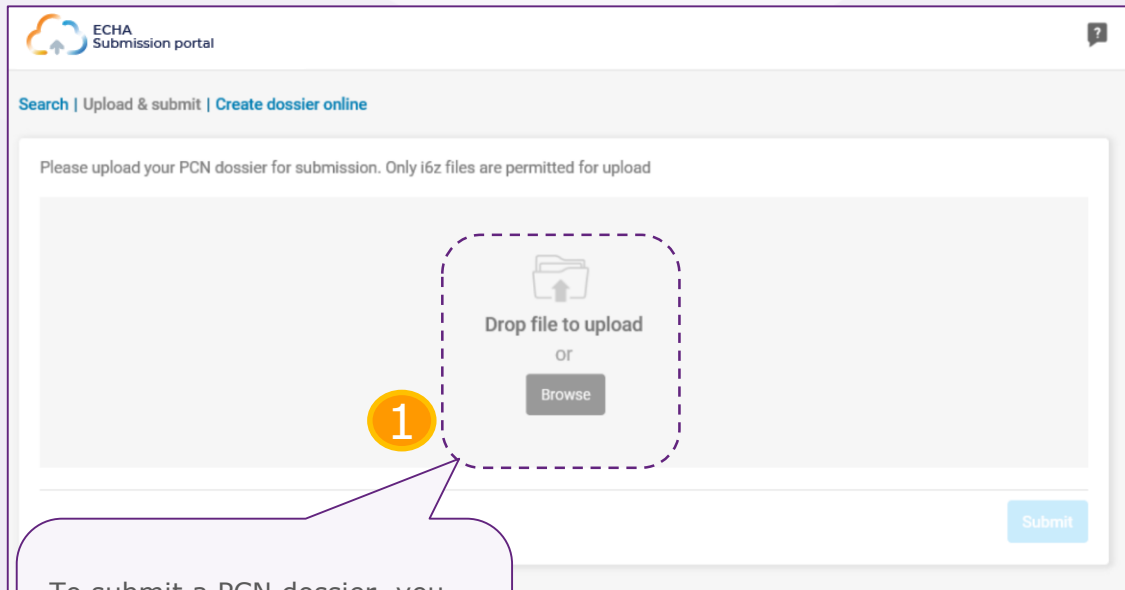
- ✓ indicates a successful submission.
- ✗ indicates a failed submission.
- ! indicates a successful submission but contains warnings.

In some cases, the system may be processing the submission and the status is pending – indicated by the circular waiting symbol.

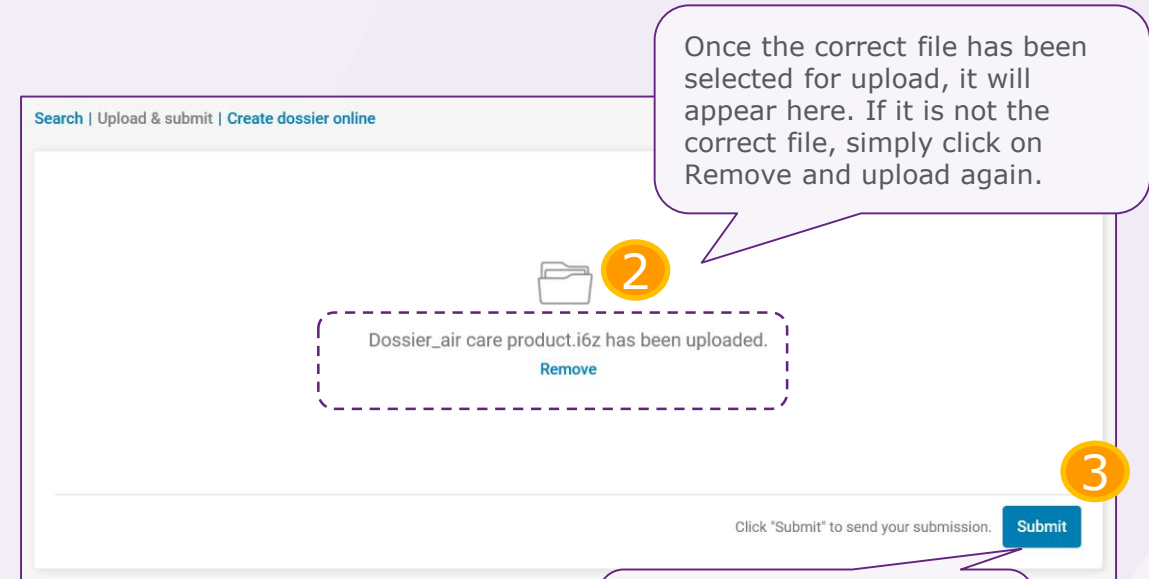
All the submissions made by the legal entity will be listed here. You can use the Sort by functionality or scroll through the pages on the bottom of the page.

Submission number	Status	PCN number	Names	UFI(s)	Date
RMH837175-99	✓	da797cf5-3ce3-465c-a145-588c2b6f5170	Trade name 1, Trade name 2	VH5N-KMXP-986T-1H1Q, FUSK-G0MK-700K-WADM	12/02/2019 17:45
RMH985888-84	✗	7ffc4e08-efe4-4464-90dd-75cf5675efea	Leather cleaner	R200-U0CW-5009-QY89	06/02/2019 15:59
RMH844203-19	⌛				12/02/2019 10:46
RMH159201-24	!	f2e9f9b3-608e-409d-983d-9b8c3701c4a5	BooHoo	8H00-C0TV-P00S-1RPX	08/02/2019 16:07

Upload and submit

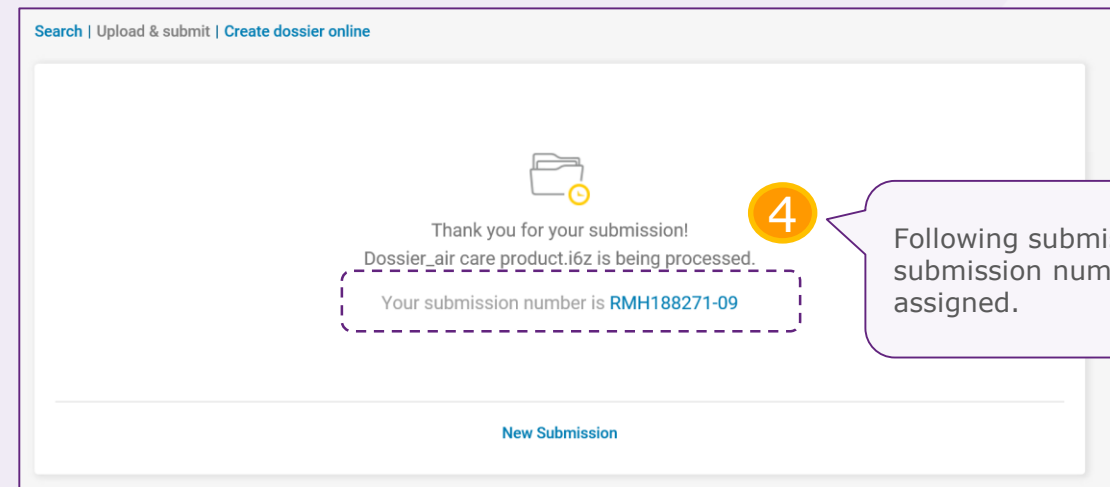


To submit a PCN dossier, you need to first upload it here by using either selecting the relevant file using the Browse or Drag and drop functionality.



Once the correct file has been selected for upload, it will appear here. If it is not the correct file, simply click on Remove and upload again.

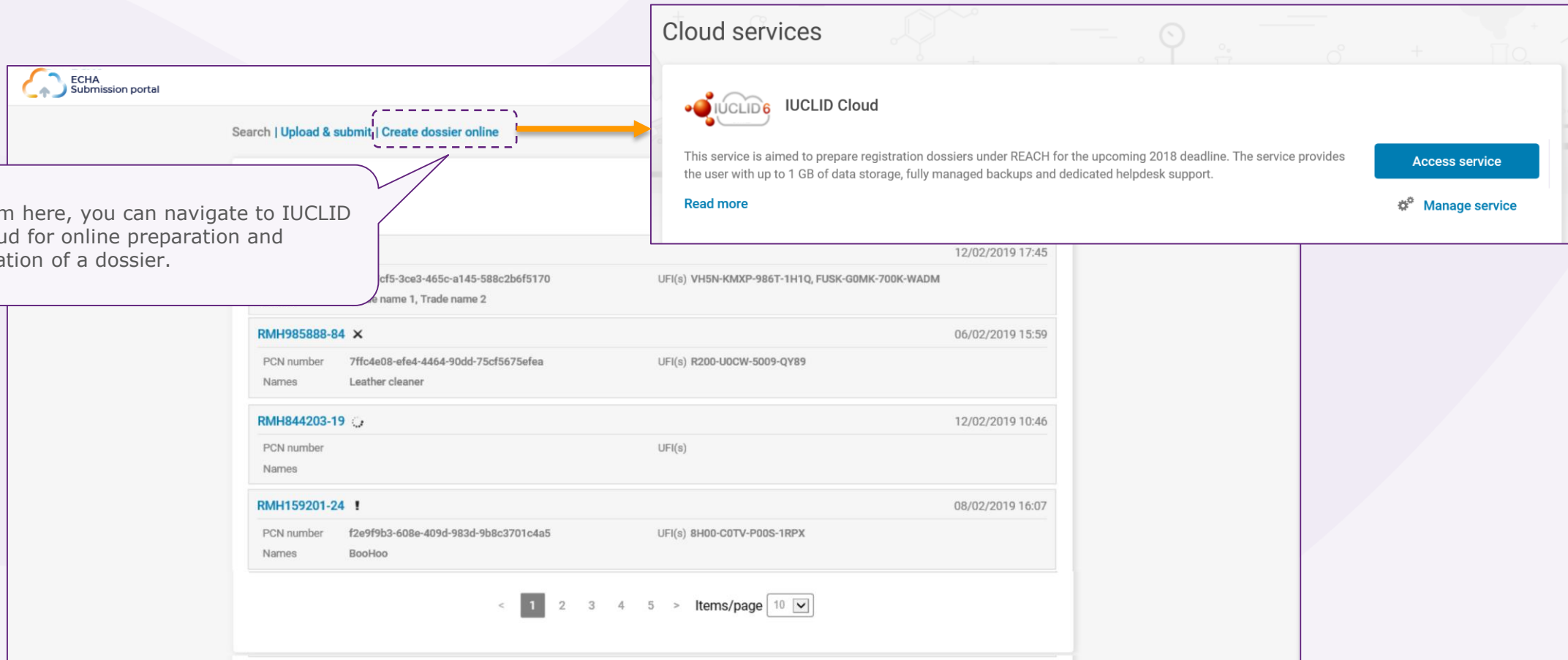
When everything is ready, Submit the dossier!



Following submission, a submission number is assigned.

Create dossier online

From here, you can navigate to IUCLID Cloud for online preparation and creation of a dossier.



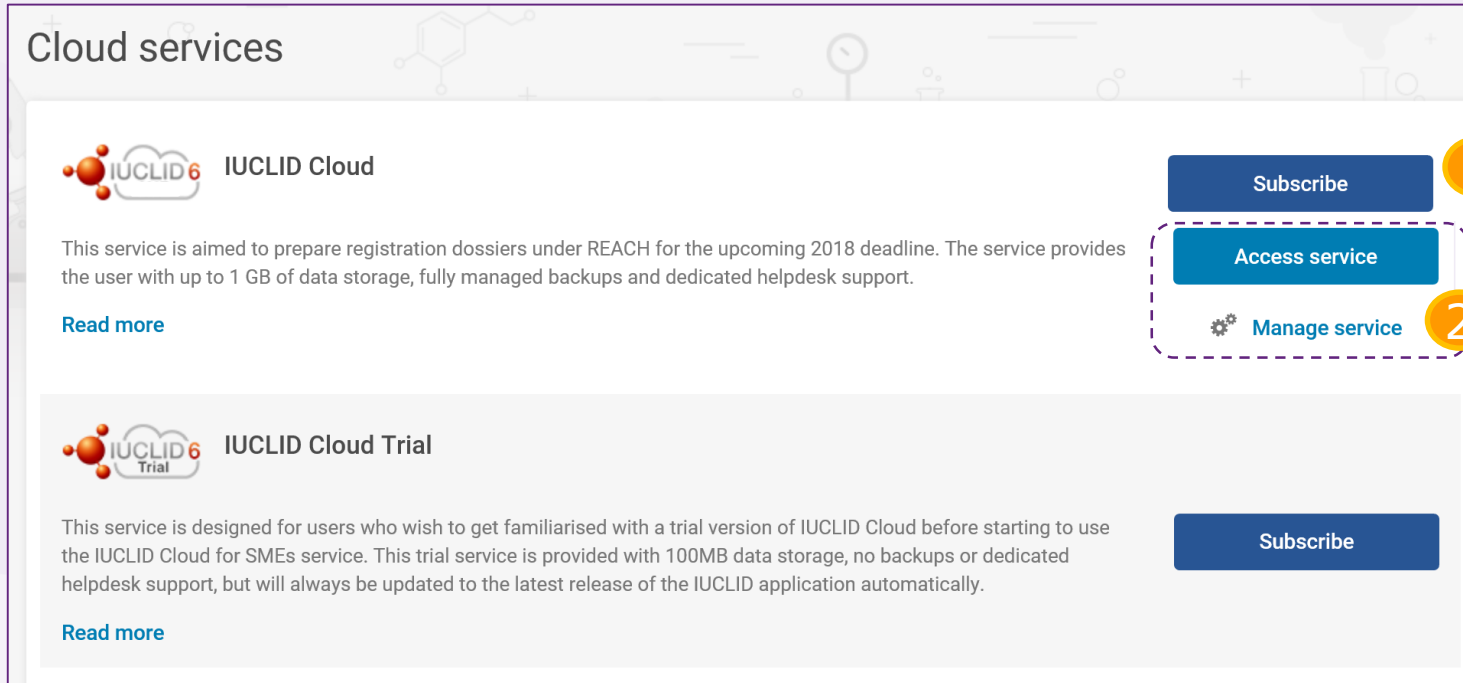
The screenshot shows the ECHA Submission portal interface. At the top left is the ECHA Submission portal logo. Below it is a navigation bar with links for 'Search', 'Upload & submit', and 'Create dossier online'. An orange arrow points from the 'Create dossier online' link to a 'Cloud services' panel on the right. This panel features the IUCLID Cloud logo and a description: 'This service is aimed to prepare registration dossiers under REACH for the upcoming 2018 deadline. The service provides the user with up to 1 GB of data storage, fully managed backups and dedicated helpdesk support.' There are two buttons: 'Access service' and 'Manage service'. Below the cloud services panel, a table lists existing dossiers with columns for PCN number, Names, UFI(s), and a date. The table contains three rows of data.

PCN number	Names	UFI(s)	Date
RMH985888-84	Leather cleaner	VH5N-KMXP-986T-1H1Q, FUSK-G0MK-700K-WADM	12/02/2019 17:45
RMH844203-19		R200-U0CW-5009-QYB9	06/02/2019 15:59
RMH159201-24	BooHoo	8H00-C0TV-P00S-1RPX	12/02/2019 10:46


At the bottom of the table, there is a pagination control showing 'Items/page' set to 10 and a list of page numbers (1, 2, 3, 4, 5).

ECHA Cloud Services Dashboard

Once you have successfully logged into the system, the ECHA Cloud Services Dashboard page opens. The **IUCLID Cloud** service allows for the online preparation of a dossier by way of the guided dossier preparation, while the **IUCLID Cloud Trial** service is used only for training purposes to get more familiar with the tool.




Cloud services

 **IUCLID Cloud**

This service is aimed to prepare registration dossiers under REACH for the upcoming 2018 deadline. The service provides the user with up to 1 GB of data storage, fully managed backups and dedicated helpdesk support.

[Read more](#)

 **IUCLID Cloud Trial**

This service is designed for users who wish to get familiarised with a trial version of IUCLID Cloud before starting to use the IUCLID Cloud for SMEs service. This trial service is provided with 100MB data storage, no backups or dedicated helpdesk support, but will always be updated to the latest release of the IUCLID application automatically.

[Read more](#)

Subscribe

Access service

Manage service

Subscribe

1 You will first need to perform a one-time subscription to use the particular service.

2 Once subscribed, you can access and manage the service.



Guided dossier preparation for PCN submissions

An overview of the features and functionalities in IUCLID Cloud to help you get started with the preparation, validation and creation of a PCN dossier.

The IUCLID Dashboard for dossier preparation

The IUCLID Dashboard page is displayed after logging in and accessing the service.

There is always a link to the main menu via the three bar icon at the left of the header.

A user can return to the Dashboard from anywhere in the interface by clicking on the Cloud icon.

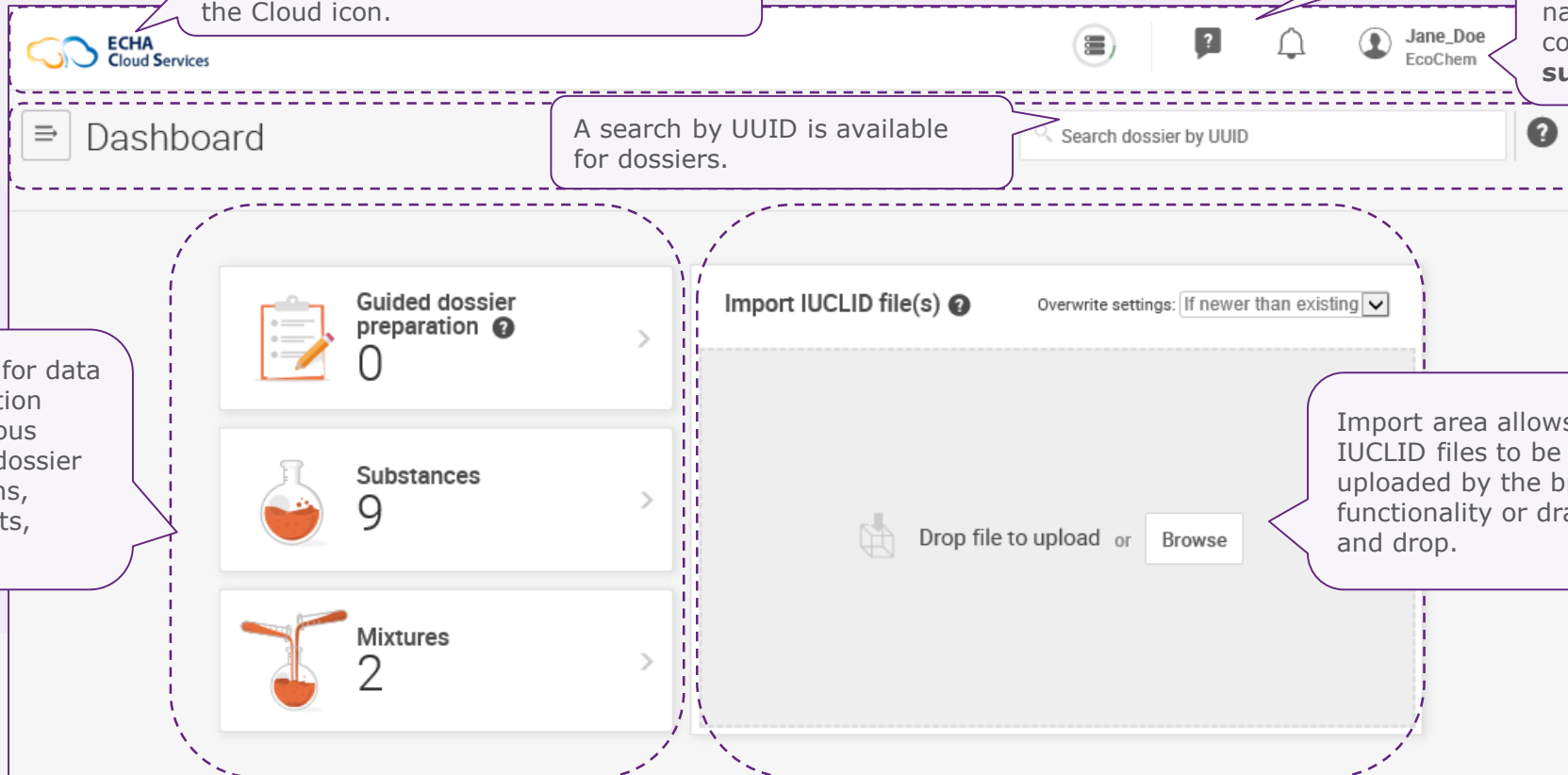
The top bar always contains the same options throughout the guided dossier preparation.

The user icon displays the name of the user and company name of the **submitting legal entity**.

A search by UUID is available for dossiers.

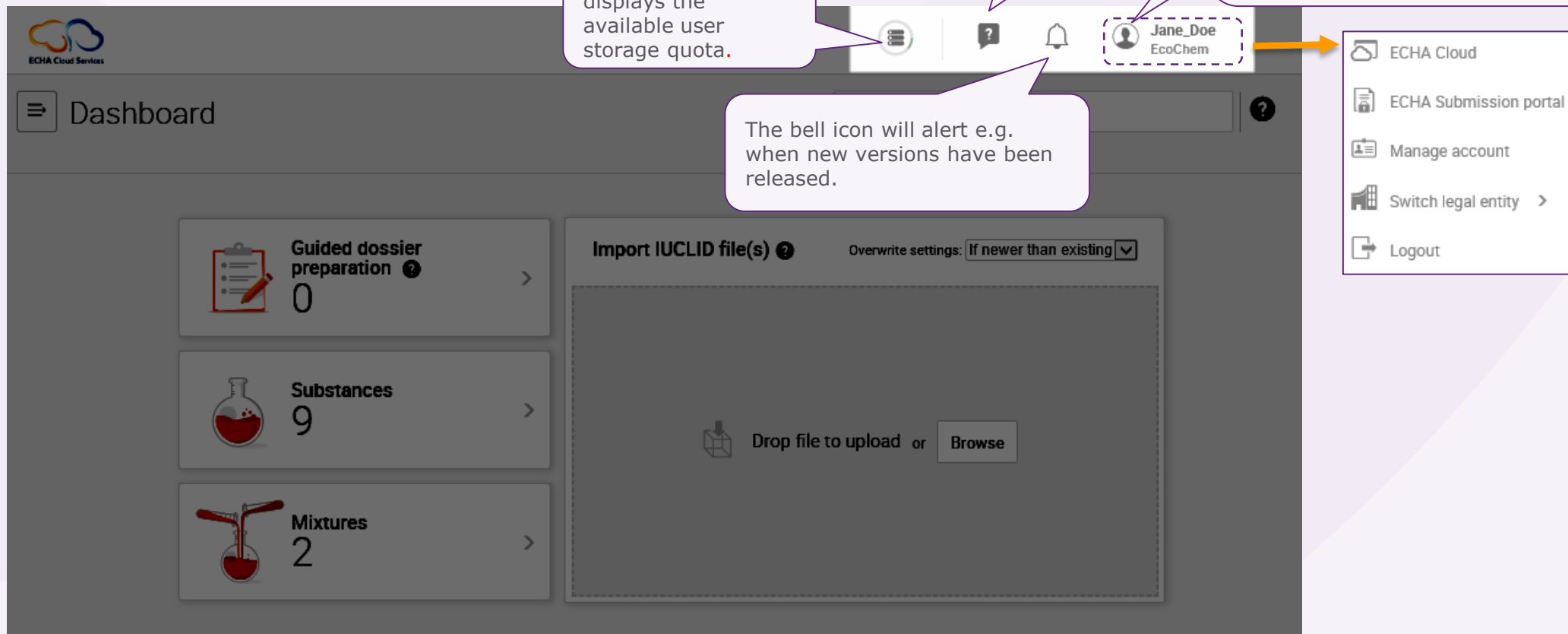
This area is used for data entry and navigation between the various IUCLID entities; dossier under preparations, substance datasets, mixture datasets.

Import area allows IUCLID files to be uploaded by the browse functionality or drag and drop.



The screenshot shows the IUCLID Dashboard interface. At the top left is the ECHA Cloud Services logo. The top navigation bar includes a three-bar menu icon, a search icon, a help icon, a notification bell, and a user profile icon for Jane_Doe EcoChem. Below the navigation bar is a 'Dashboard' header with a search bar for 'Search dossier by UUID'. The main content area is divided into two columns. The left column contains three cards: 'Guided dossier preparation' with a count of 0, 'Substances' with a count of 9, and 'Mixtures' with a count of 2. The right column features an 'Import IUCLID file(s)' section with an 'Overwrite settings' dropdown set to 'If newer than existing' and a file upload area with a 'Drop file to upload' instruction and a 'Browse' button.

The dashboard top user bar



The dialogue icon leads to external sources of information on using ECHA Cloud services, such as tutorials.

The quota icon displays the available user storage quota.

The bell icon will alert e.g. when new versions have been released.

The user icon displays the name and legal entity of the user and, when clicked on, opens a new window for redirection to the ECHA Cloud dashboard and to the search page of the submission portal, accounts management and the logout functionality.

- ECHA Cloud
- ECHA Submission portal
- Manage account
- Switch legal entity >
- Logout

The dashboard interface shows the ECHA Cloud Services logo, a 'Dashboard' menu, and three summary cards: 'Guided dossier preparation' (0), 'Substances' (9), and 'Mixtures' (2). The main content area is titled 'Import IUCLID file(s)' with an 'Overwrite settings' dropdown set to 'If newer than existing'. A file upload area contains the text 'Drop file to upload or Browse'.



Initiating a guided dossier preparation

This is the Guided dossier preparation page which contains a list of all the dossiers under preparation that have been initiated. To initiate the dossier preparation for a poison centre notification, click '+New' and select 'PCN submission'.

This is the name of the **mixture** to which the Guided dossier preparation refers to (this name is created when a new 'PCN submission' is selected).

Dashboard > Guided dossier preparations

Guided dossier preparations

2 results found

+ New ▾

REACH submission

PCN submission

Hazardous mixture 1 04/03/2019 07:34 ⋮

Legal Entity	EcoChem	Submission type	CLP Poison centres notification	Dossier Name	Update submission
					PCN

zinc oxide / 215-222-5 / oxozinc / 1314-13-2 21/02/2019 08:05 ⋮

Legal Entity	Placeholder substance LE	Submission type	REACH Registration member of a joint submission - general case	Dossier Name	
					REACH

Here, you can **resume preparation** of a dossier previously started, or, initiate an update by clicking anywhere in the bar of the relevant mixture.

By clicking on '+New', and selecting the relevant item, you can **initiate the preparation of a new dossier** for a PCN submission.

Dossier types are colour coded.



Establishing the dossier context for a new mixture – step 1

Once a dossier preparation for a PCN submission has been initiated, the submission context is defined in a two-step process – Specify your mixture, and Dossier information.

1

Specify your mixture by entering:

- a name for the mixture (mandatory)
- a name for the dossier (optional)

Here the name of the dossier may be optionally provided – this may assist you with the identifying the stage of the life cycle of the project e.g.
My hazardous mixture's name_initial submission

Guided dossier preparation for your Poison Centres Notification ×

1 Specify your mixture

2 Dossier information

Let's get started by providing a name for your mixture and dossier!

Specify the mixture and the name of the dossier to be used for your Poison Centres Notification

Create a new mixture

Hazardous mixture 1

Specify the dossier name of your

My hazardous mixture's name _ initial submission ^

3 Next

Click on Next to go to step 2.

Define the dossier – step 2

This page is called the **Dossier Header** page and collects the information required to define the dossier so as to configure the relevant dossier fields e.g. for multilingual support, as well as determine the specific validation rules, e.g. if limited submission is selected, then an emergency contact(s) must be provided.

Please consult the Guidance for Annex VIII to the CLP for full details on information requirements and submission types: <https://echa.europa.eu/guidance-documents/guidance-on-clp>

2

Define the dossier by:

- Indicating the countries/languages
- Flagging alternatives to the standard information requirements e.g. limited
- Verifying the submission type e.g. initial
- Declaring, when relevant, the reason for updating.

You can view and edit the submitter information in ECHA Accounts by clicking on the name of the legal entity.

The **language** selection is required and is used to determine the multilingual fields where you need to provide information as free text.

Dossier flags to indicate that differences to the standard information requirements are being notified. Note that here, a submission for a non-hazardous mixture refers to a **'voluntary'** submission and may be used for mixtures classified for environmental hazards only.

If 'The submission is an update' was selected, then a **reason/justification for updating** needs to be provided – see [Updating the dossier header](#). Select +New item and make a selection from the picklist.

Guided dossier preparation for your Poison Centres Notification

The information you provide in this step will determine what fields will be visible during the preparation of your dossier.

Specify your mixture


2 Dossier information

Check the submitter information

Submitter information

Undefined Company Name

Define the dossier information

PCN number* 

PCN number field is mandatory.

Country (market placement)

Language

Limited submission (industrial use only)

Non hazardous mixture

The submission is an initial notification

The submission is a new notification after a significant change of composition

The submission is an update

Reason for updating

Justification + New item

No items added + New item

? Finish

Generate and assign a **PCN number** to the initial notification by clicking on the circular arrows. This number will be used by poison centres to track all related notification updates.

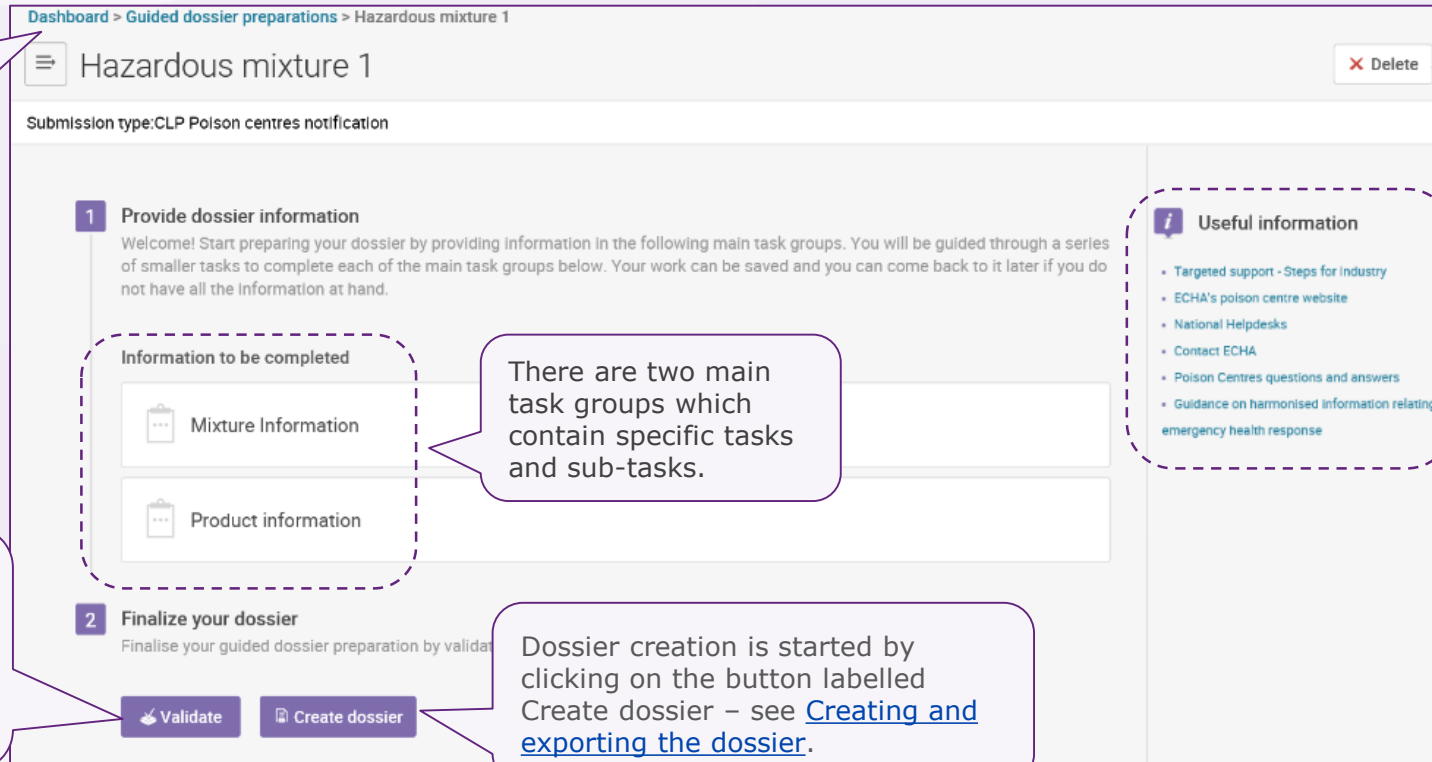
Make a selection in the drop down list for every **country (market placement)** you intend to place the mixture on the market.

A **submission type** must be selected.

Guided dossier preparation 'navigation page'

The navigation page for the mixture allows easy movement from the main functionalities i.e. data entry, validation and dossier creation. Data entry needs to be provided in two main sections, one for the mixture and one for the product. Each section is comprised of a series of tasks and sub-tasks.

Breadcrumbs refers to the path to a page in the interface that is shown in the application bar. The links provide a convenient way to navigate to previous pages in the interface.



Dashboard > Guided dossier preparations > Hazardous mixture 1

Hazardous mixture 1

Submission type: CLP Poison centres notification

1 Provide dossier information
Welcome! Start preparing your dossier by providing information in the following main task groups. You will be guided through a series of smaller tasks to complete each of the main task groups below. Your work can be saved and you can come back to it later if you do not have all the information at hand.

Information to be completed

- Mixture Information
- Product information

Useful information

- Targeted support - Steps for industry
- ECHA's poison centre website
- National Helpdesks
- Contact ECHA
- Poison Centres questions and answers
- Guidance on harmonised information relating to emergency health response

2 Finalize your dossier
Finalise your guided dossier preparation by validating your information.

Validate Create dossier

The Delete button will delete the dossier preparation for the mixture.

There are two main task groups which contain specific tasks and sub-tasks.

The Validation assistant carries out checks according to a set of pre-defined rules to verify that the information was provided as expected – see [The validation assistant](#).

Dossier creation is started by clicking on the button labelled Create dossier – see [Creating and exporting the dossier](#).

Here is a list of links to support the poison centre notification process.



The task page

A specific task page exists for the Mixture information and the Product information. Here in the Mixture information task page the six tasks that are required to be completed for this section are listed.

Each task requires to first [create a new record](#) (in some cases, multiple records are allowed) which acts as a page where information can be entered in specific fields. Records can also [created from existing information](#), where it is copied from another dossier.

The information contained in a record can be viewed and updated. Records can be deleted if needed.

Mixture Information

Here are the group of tasks that need to be completed to collect information about the identification of the mixture, its composition and other characteristics.

- Contact person(s) 2
- pH
- Toxicological information
- Mixture composition
- Unique formula identifiers (UFI) and other identifiers
- Classification and labelling information

Help for this task

Open the file to access tailored help for how to complete this task.

Useful information

- If you have not yet created your UFI, you can use the UFI Generator

Help and support text will be available and updated regularly.

The number indicates how many records have been created. In some cases, e.g. pH, classification and labelling, and toxicological information only allow the creation of a single document.



Creating a new record

Mixture Information

Here are the group of tasks that need to be completed to collect information about the identification of the mixture, its composition and other characteristics.

- Contact person(s)
- pH
- Toxicological information**
 - Provide information**
 - Use existing information
- Mixture composition
- Unique formula identifiers (UFI) and other identifiers
- Classification and labelling information

Hover the mouse over the relevant task, e.g. Toxicological information, and click on Provide information. The dedicated page for entering the information will open.

Toxicological information

1 SDS information (mixtures)

Information on mixtures

Toxicological information (section 11 of SDS)

Edit Format Table

B I U S x² x₂

Paragraph A A

The record has now been created and you can now enter the information. Click on Finish at the bottom of the page to ensure the entered information is saved.

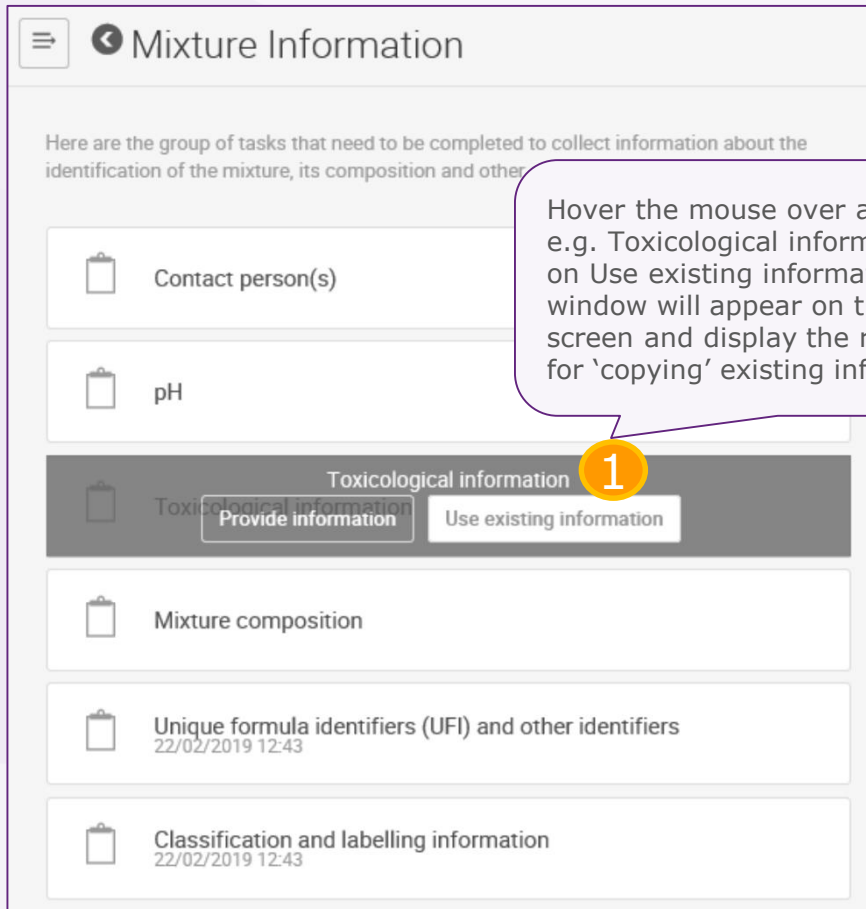
Toxicological information

Record + Record

- Toxicological Information(only) 22/02/2019 13:01

Once the record has been saved, it is possible to remove it by clicking on the X. Note that the +Record button is disabled as this task can refer to only one document, i.e. is 'fixed'.

Creating a record from existing information



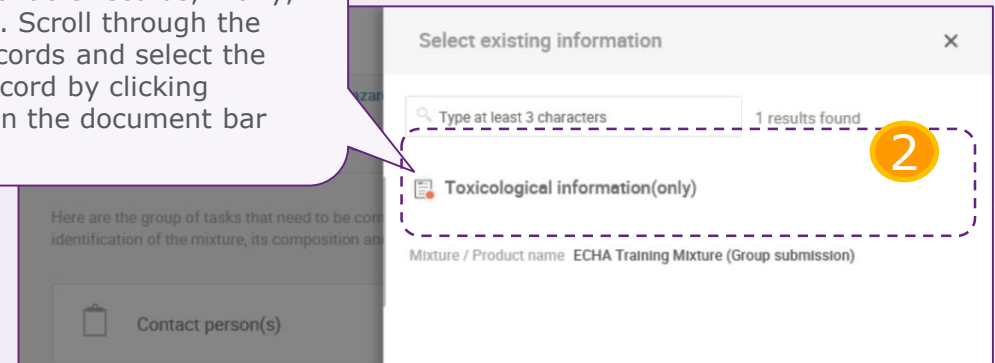
Mixture Information

Here are the group of tasks that need to be completed to collect information about the identification of the mixture, its composition and other

- Contact person(s)
- pH
- Toxicological information** 1
Provide information Use existing information
- Mixture composition
- Unique formula identifiers (UFI) and other identifiers
22/02/2019 12:43
- Classification and labelling information
22/02/2019 12:43

Hover the mouse over a specific task, e.g. Toxicological information, and click on Use existing information, a sliding window will appear on the left of the screen and display the records available for 'copying' existing information from.

A list of available records, if any, will appear. Scroll through the existing records and select the relevant record by clicking anywhere in the document bar area.

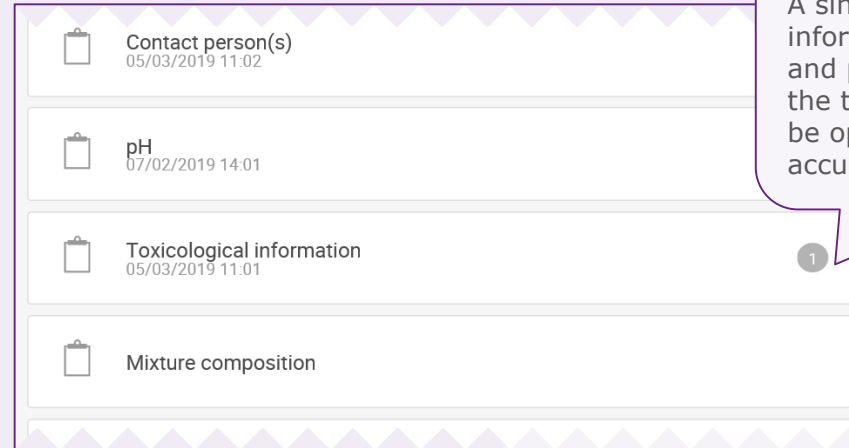


Select existing information

Type at least 3 characters 1 results found

- Toxicological information(only)** 2

Mixture / Product name ECHA Training Mixture (Group submission)



- Contact person(s)
05/03/2019 11:02
- pH
07/02/2019 14:01
- Toxicological information** 3
05/03/2019 11:01
- Mixture composition

A single Toxicological information record, now created and prepopulated, is visible in the task list. The record should be opened and checked for accuracy and completeness.



Dossier preparation: 'Mixture information' section

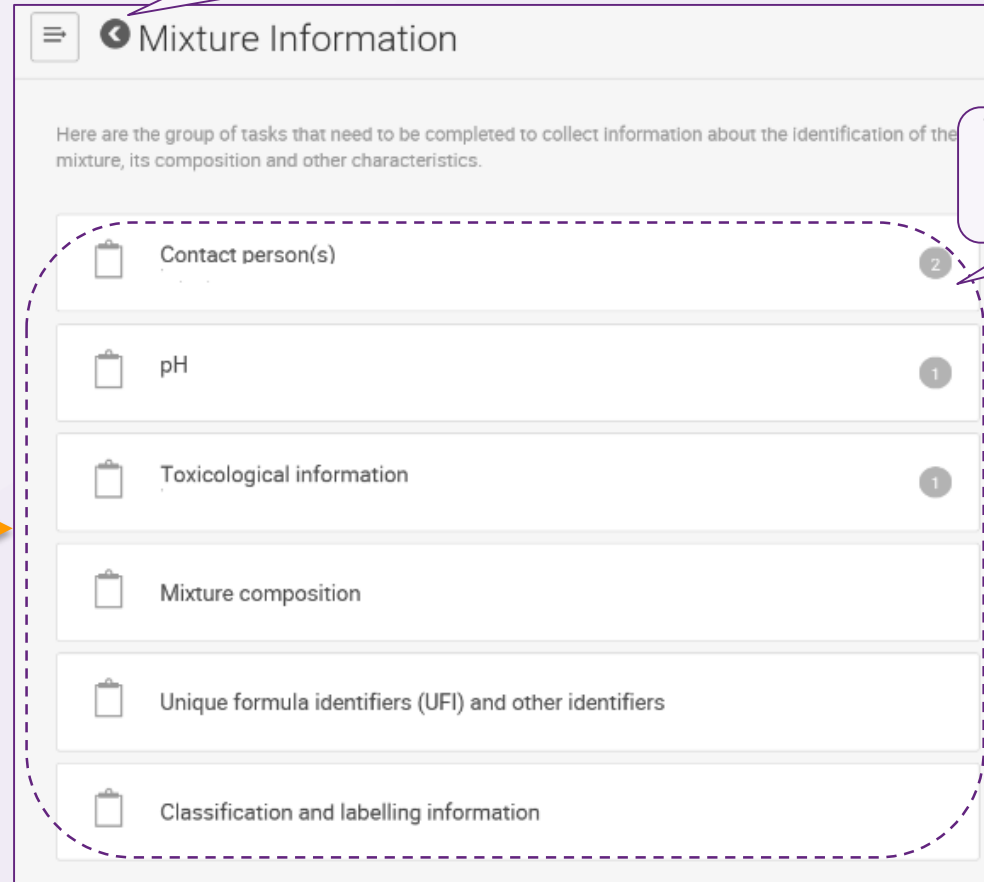
An overview of how to use IUCLID to complete the tasks in the Mixture information section for the preparation of a PCN dossier.

Mixture information task page

The back button is useful to navigate back from sub-tasks and tasks.

Clicking on 'Mixture information' from the dossier preparation navigation page, redirects to the Mixture information task page, listing the six tasks (some tasks contain additional sub-tasks) that are required to be completed for this section

The number here indicates how many records have been created.



The screenshot shows a mobile application interface for 'Mixture Information'. At the top, there is a back arrow and a hamburger menu icon. Below the title, a descriptive text reads: 'Here are the group of tasks that need to be completed to collect information about the identification of the mixture, its composition and other characteristics.' The main content is a list of six tasks, each with a clipboard icon and a record count in a grey circle:

- Contact person(s) (2 records)
- pH (1 record)
- Toxicological information (1 record)
- Mixture composition
- Unique formula identifiers (UFI) and other identifiers
- Classification and labelling information

A dashed purple box highlights the entire list of tasks. An orange arrow points from the 'Mixture Information' task in the navigation menu to this list.

1 Information to be completed

Mixture Information

Product information

The 'Contact person(s)' task

A Contact person record is used to record the a person's role and contact, for example, an emergency contact in the case of a limited submission.

Here are the group of tasks that need to be completed to collect information about the identification of the mixture, its composition and other characteristics.

Contact person(s)	
Contact person(s)	1
pH 05/02/2019 14:01	1
Toxicological information 05/02/2019 14:02	1
Mixture composition 05/02/2019 14:52	6
Unique formula Identifiers (UFI) and other Identifiers 05/02/2019 13:59	1
Classification and labelling information 05/02/2019 14:04	1

1 To create a contact person record, select Provide information

Note: Separate the groups of digits in accordance to national convention, to ensure the number is easy to read i.e. +CountryCode AreaCode LocalNumber

3 For limited submissions to multiple Member States, the 'Country' field is used to identify the relevant market area for each emergency contact – see [Providing emergency contacts](#).

Contact person(s)

1 Contact person

Contact person

Contact type: emergency contact 2

Title: Mr

First name: John

Last name*: Howard

Organisation*: EcoChem ACT.

Phone: e.g. +358 09 123456789

Email: name@domain.com

Country: Finland 3

Finish 4

Select the contact person type from the picklist by clicking on Please select, then enter the information in as many fields as possible for completeness.

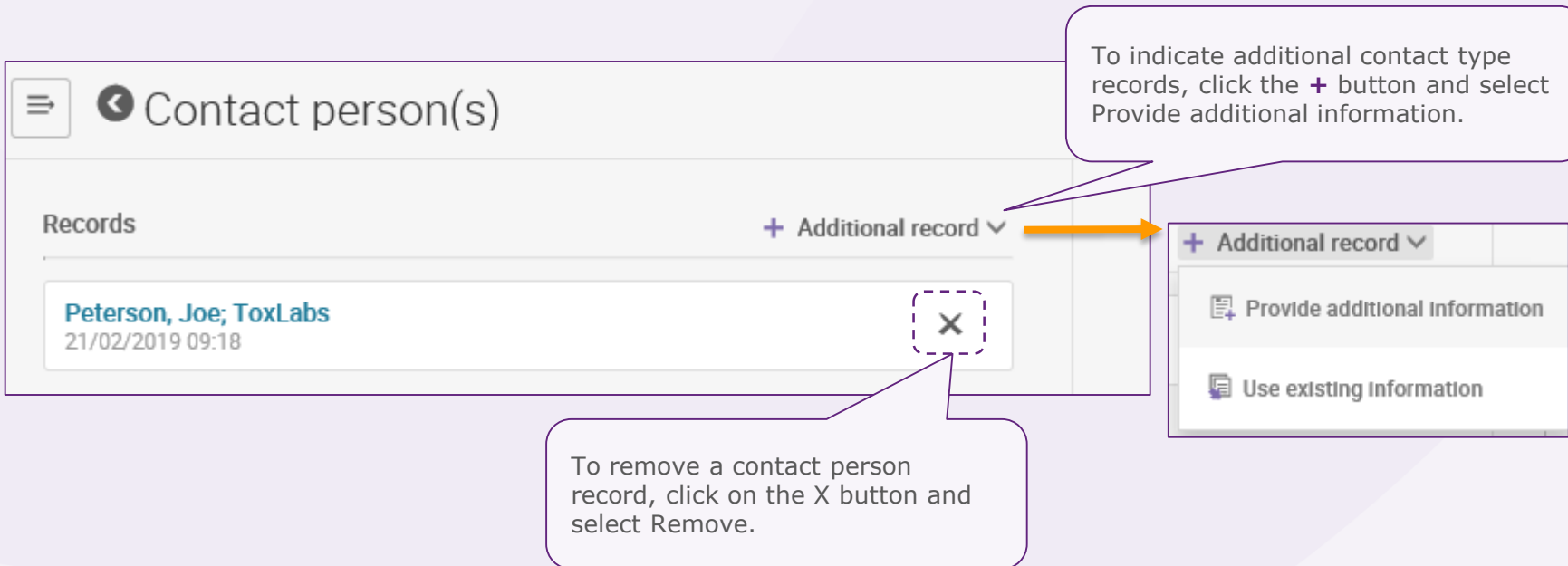
If the picklist does not contain the contact person you wish to specify, you can select 'Other' and enter the information.

- competent person responsible for the SDS
- emergency contact
- substance manager
- toxicologist
- other.

Click on Finish at the bottom of the page and the information will be saved in a single record. You will be given the opportunity to create additional records to indicate more contact persons.

Providing emergency contacts

! An 'Emergency contact' person is always required for limited submissions. If the mixture is placed on the market in a single market area, then only one emergency contact record containing this information must be provided. If the submission is for multiple market areas, then multiple Contact person(s) records, each containing 'Emergency contact' person information, must be provided for each country using the 'Country' field, even if the same details are applicable for all the countries. See below for how to add additional contact person records.



The screenshot shows the 'Contact person(s)' interface. It features a header with a menu icon and a back arrow. Below the header is a 'Records' section containing one record: 'Peterson, Joe; ToxLabs' with a timestamp '21/02/2019 09:18'. To the right of the records is a '+ Additional record' button with a dropdown arrow. A callout box points to this button, stating: 'To indicate additional contact type records, click the + button and select Provide additional information.' A second callout box points to an 'X' button on the record, stating: 'To remove a contact person record, click on the X button and select Remove.' A third callout box points to the dropdown menu of the '+ Additional record' button, which shows two options: 'Provide additional information' and 'Use existing information'.

The 'pH' task

Once you have clicked on the pH task from the task list, you are directed to the data entry page.

To indicate the exact pH value, only a single entry is required e.g.:

pH value

▼	7.6	▼	
---	-----	---	--

← pH

1 pH

Key value for chemical safety assessment

pH is not relevant **3**

pH value

1 > ▼ 7.6 < ▼ 8.5

Solution concentration (%)

100 **2**

4 Finish

A pH value (and operators) must be provided. You can provide an exact value or a range.

When the pH value is provided, the solution concentration must be given in any case.

If the pH is not able to be measured, the tick box pH is not relevant must be checked and no pH value (or solution concentration) should be indicated.

Click on Finish to save your entries and move to the next task

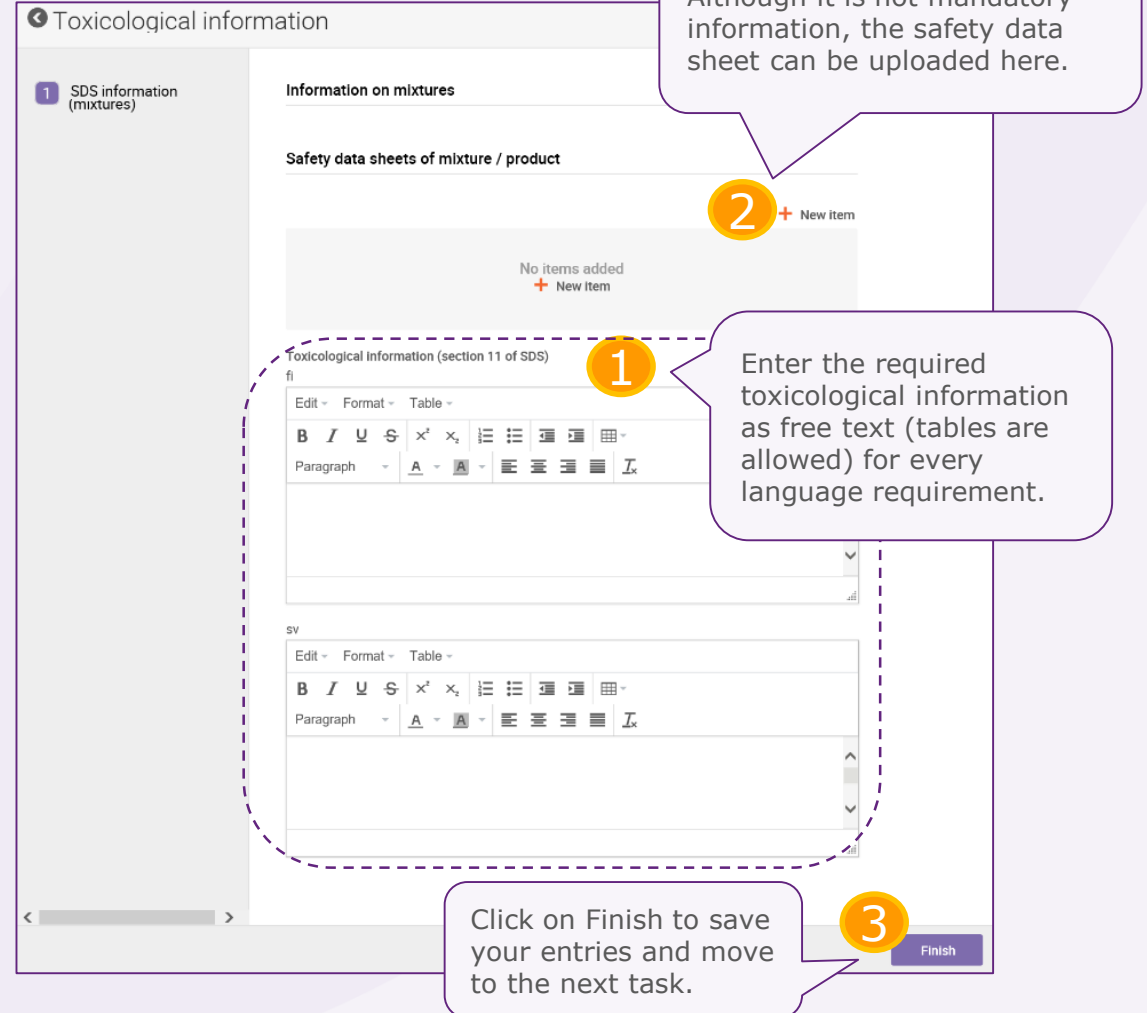
The 'Toxicological information' task

Only one toxicological record can be created from the mixture information task, but if the submission is for multiple markets or it is a submission that requires more than one national language, then this information must be given **for each language requirement**.

In all cases, this section must include the information on the toxicological effects of the mixture or its components such as is required in **Section 11 of the safety data sheet** for the mixture.

It must be ensured that the information entered here is 'stand alone' information and does not e.g. contain cross-references to other sections of the SDS.

! If your mixture/product is related to a **multi-component** product, then all relevant information should be included in the toxicological information field.



The screenshot shows the 'Toxicological information' task interface. It includes a sidebar with '1 SDS information (mixtures)', a main content area with 'Information on mixtures' and 'Safety data sheets of mixture / product' (with a '+ New Item' button), and two text editors for 'fi' and 'sv' languages. A 'Finish' button is at the bottom right.

1 Enter the required toxicological information as free text (tables are allowed) for every language requirement.

2 Although it is not mandatory information, the safety data sheet can be uploaded here.

3 Click on Finish to save your entries and move to the next task.

The 'Mixture composition' task

The Mixture composition task contains additional sub-tasks to define the components of the mixture. Mixture components can be either substances or other mixtures. The mixture components are referred to as mixture in mixtures or MiMs.

☰
⬅
Mixture composition

Mixture components
+Mixture component

No components have been added yet.

Substance components
+Substance component

No components have been added yet.

☰
Function and concentration
15/02/2019 15:59
1

☰ Unique formula identifiers (UFI)

☰ Mixture-in-mixture composition

☰ Classification and labelling information of the mixture-in-mixture

☰ Supplier

☰ Mixture safety data sheets

The sub-tasks for mixture components are further explained - see [Mixture \(in mixture\) components](#).

☰
Function and concentration
15/02/2019 16:00
1

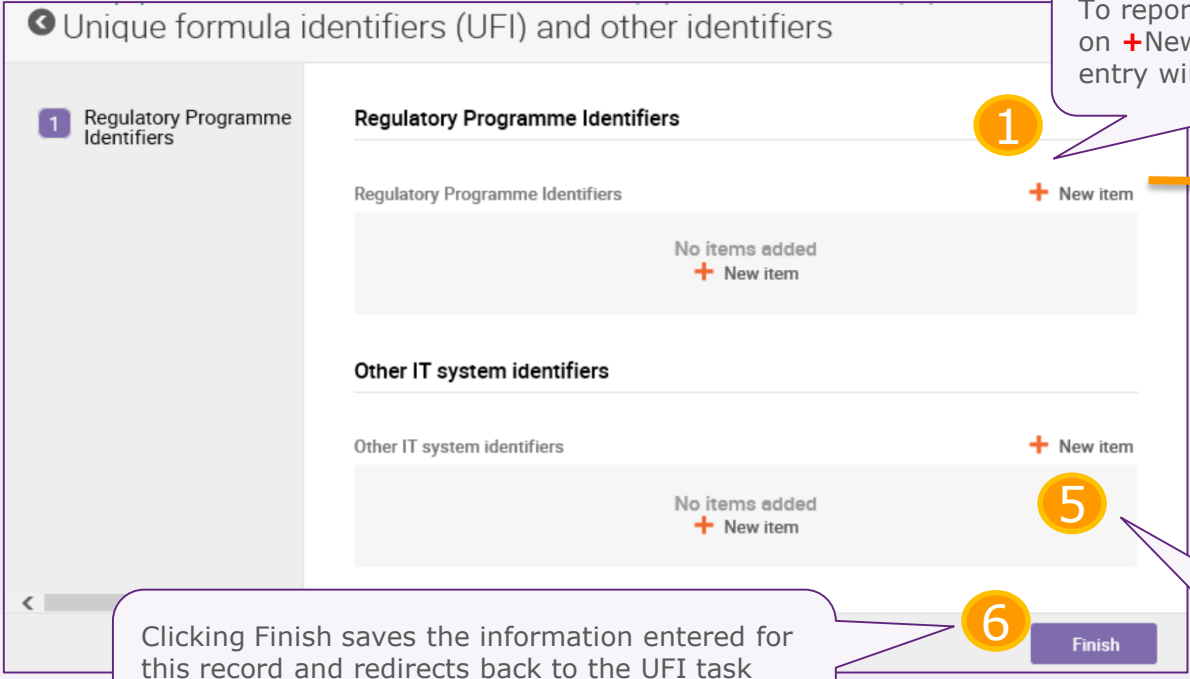
☰ Substance identification
15/02/2019 16:00

☰ Classification and labelling information of the substance

The sub-tasks for substance components are further explained - see [Substance components](#).

The 'UFI and other identifiers' task

The UFI task is the repository of all the UFIs associated to a single mixture composition in the notification. The relevant UFIs can be entered here but note that they must be referenced or 'linked' to a product(s) in the [Product information](#) section. It is also possible to enter the UFIs in the Product information section - in any case, they will be visibly stored in the UFI task here.



1 Regulatory Programme Identifiers

2 Regulatory Programme

3 CLP unique formula identifier (UFI)

4 Close

5 Other IT system identifiers

6 Finish

To report a single UFI, click on +New to open the data entry window.

Select CLP Unique Formula Identifier (UFI).

The UFI assigned to the mixture must be reported in the Id field in the correct format e.g. E200-U0CW-500A-Q27E

Other IT system identifiers is a non-mandatory field to specify other identifiers you wish to include e.g. national notification number.

Clicking Close, saves the information and redirects back to the UFI record where the item will now be listed.

Clicking Finish saves the information entered for this record and redirects back to the UFI task page where the record is displayed. Additional records can be created.



Reporting multiple UFIs for the mixture

Multiple UFIs can be included in a notification in a flexible way, depending on your business needs. There are two ways to report them, either

- a) Multiple UFI records exist each containing one UFI item
- b) A single UFI record exists which contains multiple UFIs items

The way in which multiple UFIs are recorded depends on the preferred method of assigning each UFI to a specific product.

Information on assigning UFIs to individual products is covered in the [Product information](#) section of this document.

Multiple records exist; each record consists of one UFI item. Additional records are created and listed together on the UFI task page.

Unique formula identifiers (UFI) and other identifiers

Records **a** + Additional record ▾

Unique formula identifiers (UFI) and other identifiers.003 22/02/2019 15:01	✕
Unique formula identifiers (UFI) and other identifiers.002 22/02/2019 15:01	✕
Unique formula identifiers (UFI) and other identifiers.001 22/02/2019 14:43	

Multiple UFI items exist in a single record; Additional items are created and listed together from within the record itself.

Unique formula identifiers (UFI) and other identifiers

1 Regulatory Programme Identifiers

Regulatory Programme Identifiers **b** + New item

Regulatory Programme Identifiers 01	✕
Regulatory Programme Identifiers 02	✕
Regulatory Programme Identifiers 03	✕

The 'Classification and labelling' task – step 1

Only a single classification and labelling record can exist for a mixture for a standard submission. Environmental hazards may be included, but are not mandatory to indicate.

The classification and labelling task is divided into two steps, classification and labelling.

1 Classify your mixture by providing:

- Hazard category
- Hazard statements
- Any relevant additional information

Classification and labelling information

1 Classification

2 Labelling

1 Not classified

2

Next

In case your mixture is not classified for any physical, health or environmental hazards, select Not classified.

Select the hazard category and the hazard statement for each of the hazard classes your mixture falls under, by clicking on the 'v'.

Some health hazards contain free text fields to include information e.g. about the effected organs or specific effects. This information should be provided in all the relevant languages.

Reproductive toxicity

Hazard category

Repr. 2 X v

Hazard statement

H361: Suspected of damaging fertility or the unborn child <state specific effect if known> <state X v

3

Specific effect

fi

sv

Route of exposure

Oral X v

Add remark

The 'Classification and labelling' task - step 2

Some hazard and precautionary statements may require further information in the additional remarks field. In such cases, all free text information must be provided in all relevant languages.

2

Labelling of your mixture:

- Signal word
- Hazard pictograms
- Hazard statements
- Precautionary statements

Clicking Back redirects to Step 1 Classification

Classification and labelling information

1 Classification

2 Labelling

Labelling

Signal word
Danger

Hazard pictogram

1 + New item

No items added
+ New item

Hazard statements

+ New item

H302: Harmful if swallowed. 2

Precautionary statements

+ New item

01

3 Finish

Back

Selecting +New item displays the pick lists with the relevant selections. Multiple items are allowed.

Selecting the pencil icon allows you to edit the information contained the record, the X will delete the record.

Clicking Finish saves the information entered for this record and redirects back to the C&L record listing.



Reporting mixture (in mixture) components

An overview of how to use IUCLID to complete the sub-tasks for mixture (in mixture) components.



Mixture (in mixture) components

Ideally, if all the substances in the mixture component are known, they need to be reported individually, as for all other substances.

Reporting multiple mixture components is allowed and should be declared in descending order of concentration.

☰ Mixture composition

Mixture components

No components have been added yet.

+Mixture component

Substance components

No components have been added yet.

+Substance component

1 From the Mixture composition task, Click on **+Mixture component** to begin the process of declaring each mixture (in mixture) component i.e. MiM, present in the mixture.

Specify your mixture-in-mixture component

Select an existing mixture

+ Select

OR

Provide a mixture name

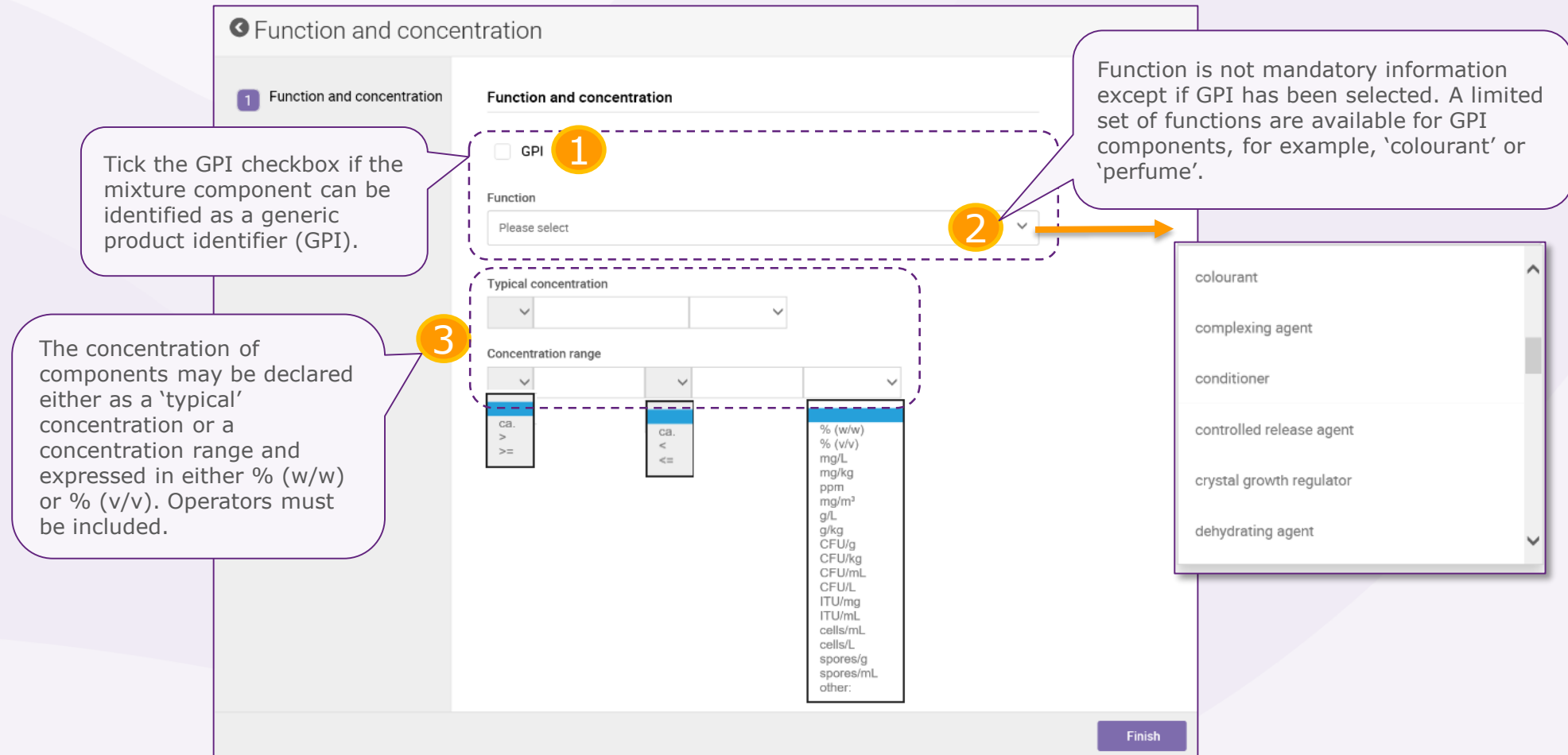
Continue

2 Specify your mixture component (MiM) by either selecting an existing mixture dataset, or begin the creation of a new dataset, by giving the MiM a name, then press Continue.

- ☑ Function and concentration
15/02/2019 15:59
- ☑ Unique formula identifiers (UFI)
- ☑ Mixture-in-mixture composition
- ☑ Classification and labelling information of the mixture-in-mixture
- ☑ Supplier
- ☑ Mixture safety data sheets

3 Once the mixture component (MiM) has been specified, the relevant sub-tasks will be displayed.

Sub-task 'Function and concentration' for the mixture (in mixture)



1 Function and concentration

1 GPI

Function
Please select

Typical concentration

Concentration range

ca. > >=

< ca. <=

- % (w/w)
- % (v/v)
- mg/L
- mg/kg
- ppm
- mg/m³
- g/L
- g/kg
- CFU/g
- CFU/kg
- CFU/mL
- CFU/L
- ITU/mg
- ITU/mL
- cells/mL
- cells/L
- spores/g
- spores/mL
- other:

colourant

complexing agent

conditioner

controlled release agent

crystal growth regulator

dehydrating agent

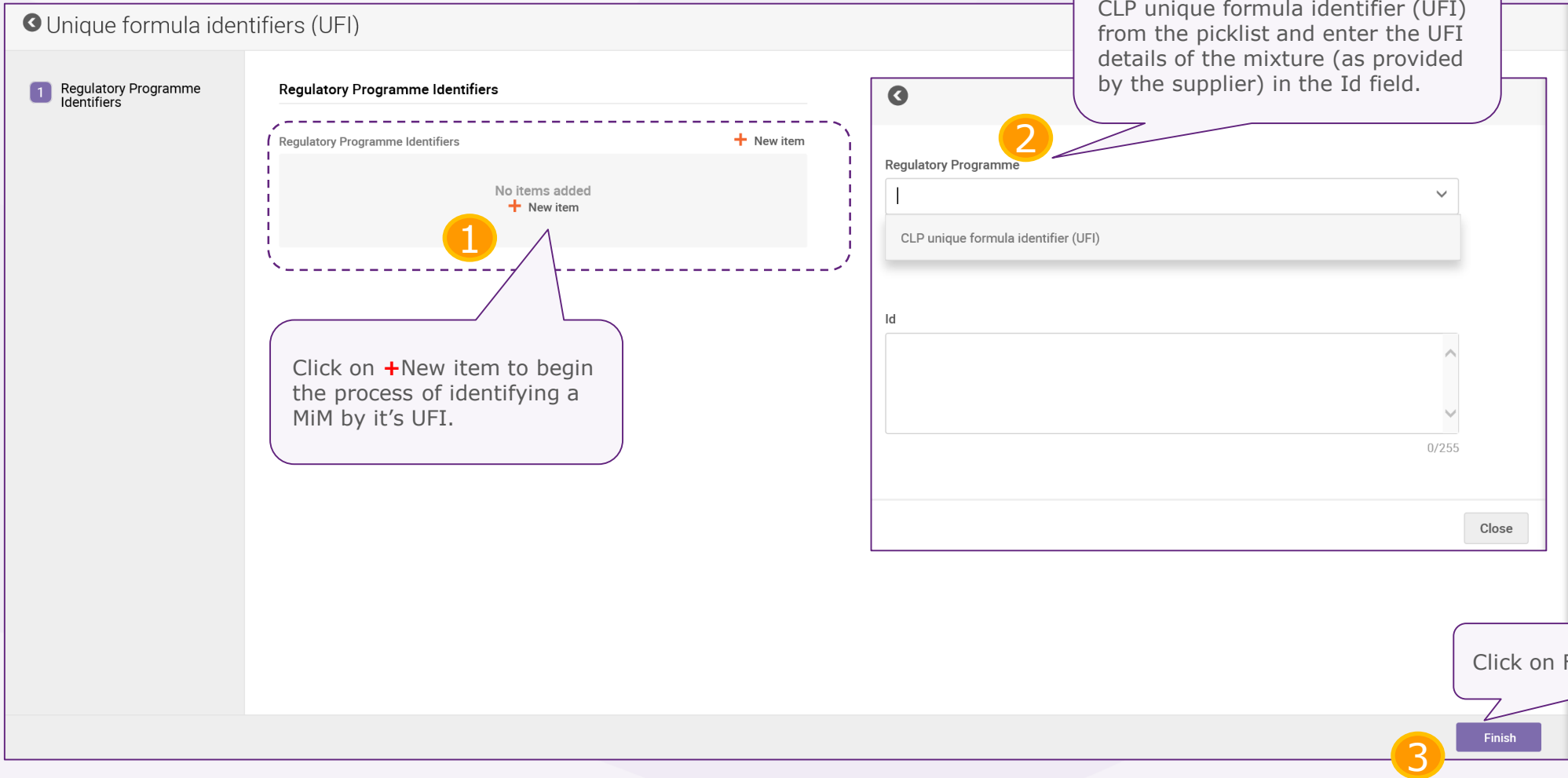
Finish

Tick the GPI checkbox if the mixture component can be identified as a generic product identifier (GPI).

Function is not mandatory information except if GPI has been selected. A limited set of functions are available for GPI components, for example, 'colourant' or 'perfume'.

The concentration of components may be declared either as a 'typical' concentration or a concentration range and expressed in either % (w/w) or % (v/v). Operators must be included.

Sub-task 'UFI' for the mixture (in mixture)



1 Regulatory Programme Identifiers

Regulatory Programme Identifiers + New item

No items added + New item

1

2

Regulatory Programme

CLP unique formula identifier (UFI)

Id

0/255

Close

3

Finish

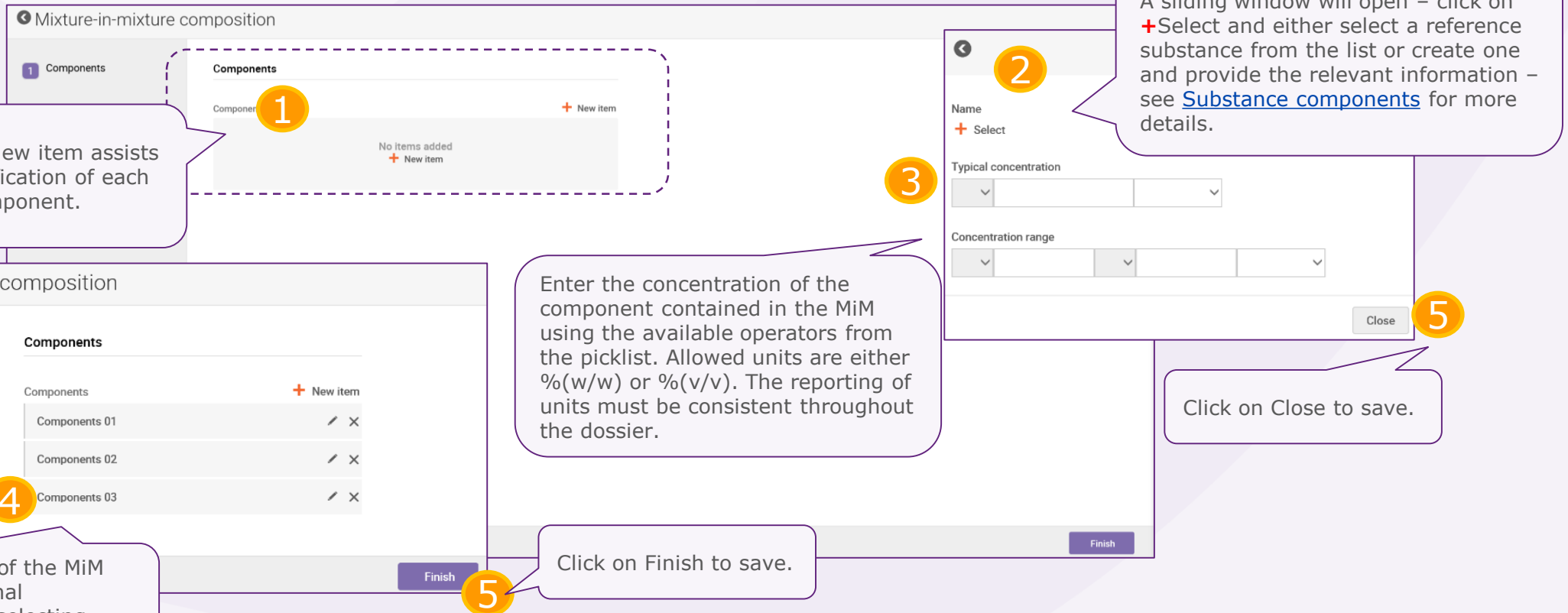
Click on +New item to begin the process of identifying a MiM by it's UFI.

A sliding window will open – select CLP unique formula identifier (UFI) from the picklist and enter the UFI details of the mixture (as provided by the supplier) in the Id field.

Click on Finish to save.

Sub-task 'Mixture in mixture composition'

This sub-task allows to declare the components of mixture in mixture (MiM). Note, only substance components can be indicated in a MiM composition.



1 Clicking on **+New item** assists with the specification of each substance component.

2 A sliding window will open – click on **+Select** and either select a reference substance from the list or create one and provide the relevant information – see [Substance components](#) for more details.

3 Enter the concentration of the component contained in the MiM using the available operators from the picklist. Allowed units are either $\%(w/w)$ or $\%(v/v)$. The reporting of units must be consistent throughout the dossier.

4 All substance components of the MiM are listed here and additional components are added by selecting **+New item**.

5 Click on **Close** to save.

5 Click on **Finish** to save.

Sub-task 'Classification of the mixture in mixture'

This sub-task is based on the same record structure as for the mixture information – note though, that the Labelling information is not required for the mixture in mixture, though can be included if available.

Classification and labelling information of the mixture-in-mixture

1 Classification
2 Labelling

General Information

Not classified **1**

In case the mixture in mixture is not classified for any physical, health or environmental hazards, select Not classified.

Classification

Physical Hazards

Explosives

Hazard category **2**

Please select

Hazard statement

Please select

Some health hazards contain free text fields to include information e.g. about the effected organs or specific effects. This information should be provided in all the relevant languages.

3

Specific target organ toxicity - single

Hazard category

STOT Single Exp. 3 X v

Hazard statement

H371: May cause damage to organs <or state all organs affected, if known> <state route of exposure> X v

Affected organs

fi

sv

Route of exposure

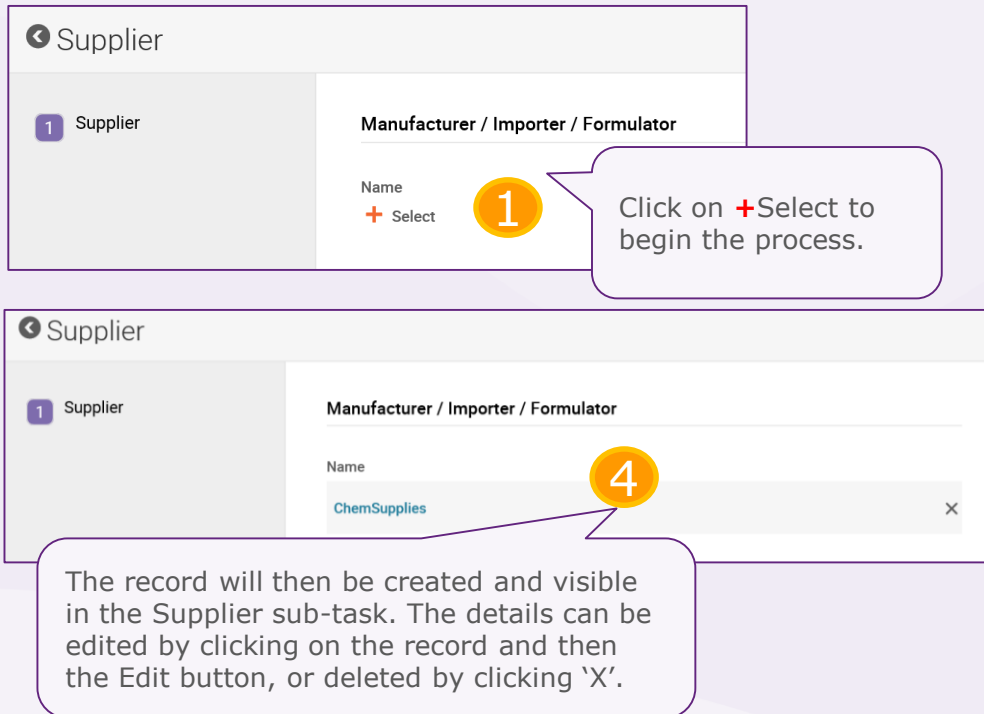
Oral X v

Add remark

Select the hazard category and the hazard statement for each of the hazard classes your mixture in mixture falls under, by clicking on the 'v'.

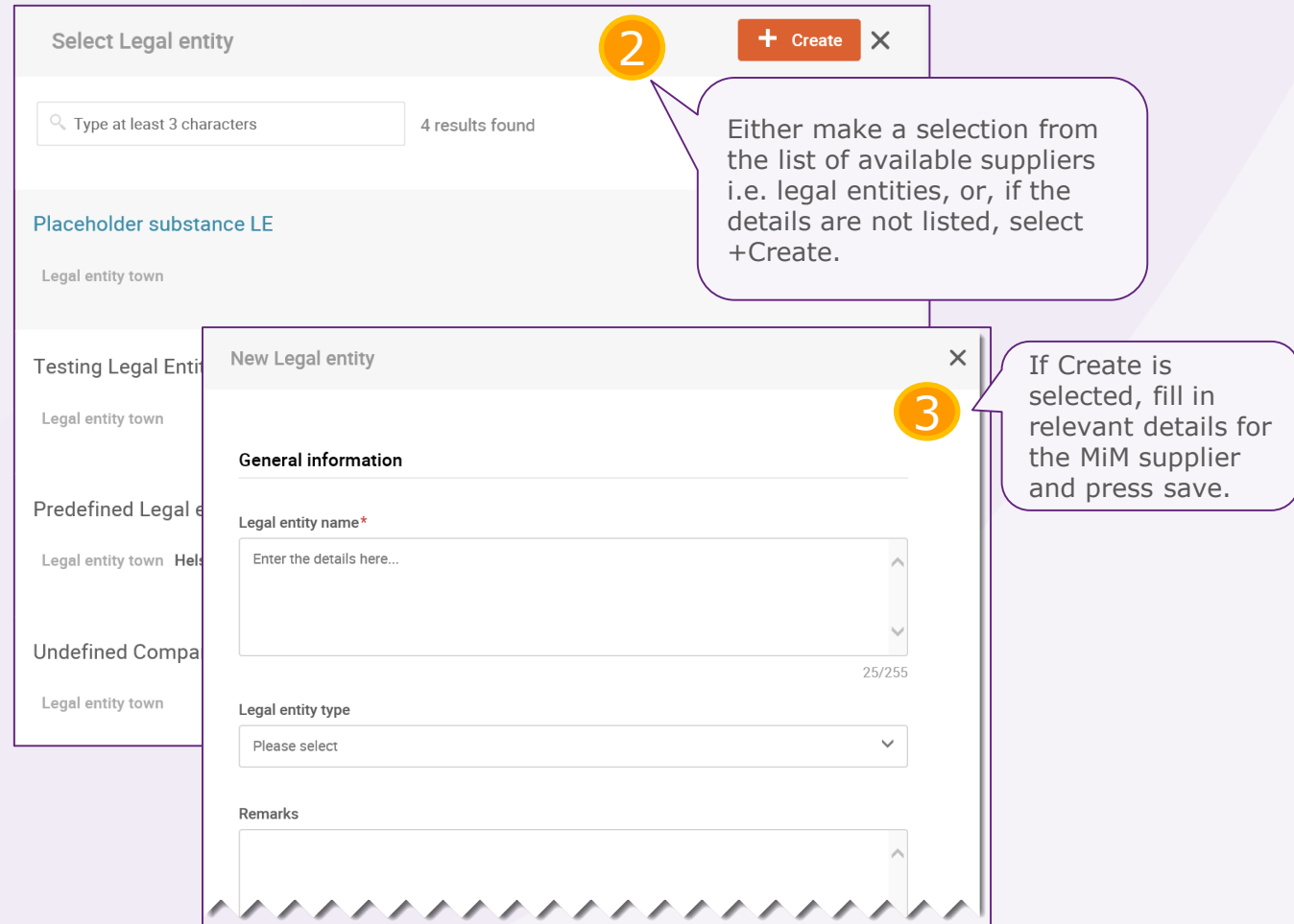
Sub-task 'Supplier' for the mixture (in mixture)

It is possible to include the details of the supplier of the mixture in mixture (MiM) i.e. at least the name, email address and telephone number. Note that only one Supplier record per MiM is foreseen.



1 Click on **+ Select** to begin the process.

4 The record will then be created and visible in the Supplier sub-task. The details can be edited by clicking on the record and then the Edit button, or deleted by clicking 'X'.



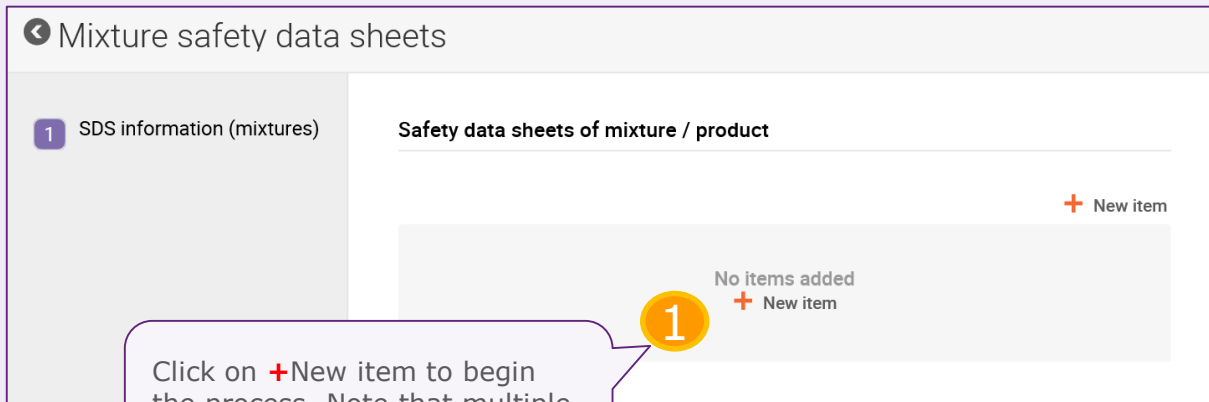
2 Either make a selection from the list of available suppliers i.e. legal entities, or, if the details are not listed, select **+ Create**.

3 If Create is selected, fill in relevant details for the MiM supplier and press save.

Sub-task 'Mixture safety data sheet' for the mixture (in mixture)

It is possible to include the safety data sheet for the mixture in mixture (MiM) in this sub-task.

Note that multiple records per MiM can be created e.g. if several files exist as in the case of multimarket submissions.



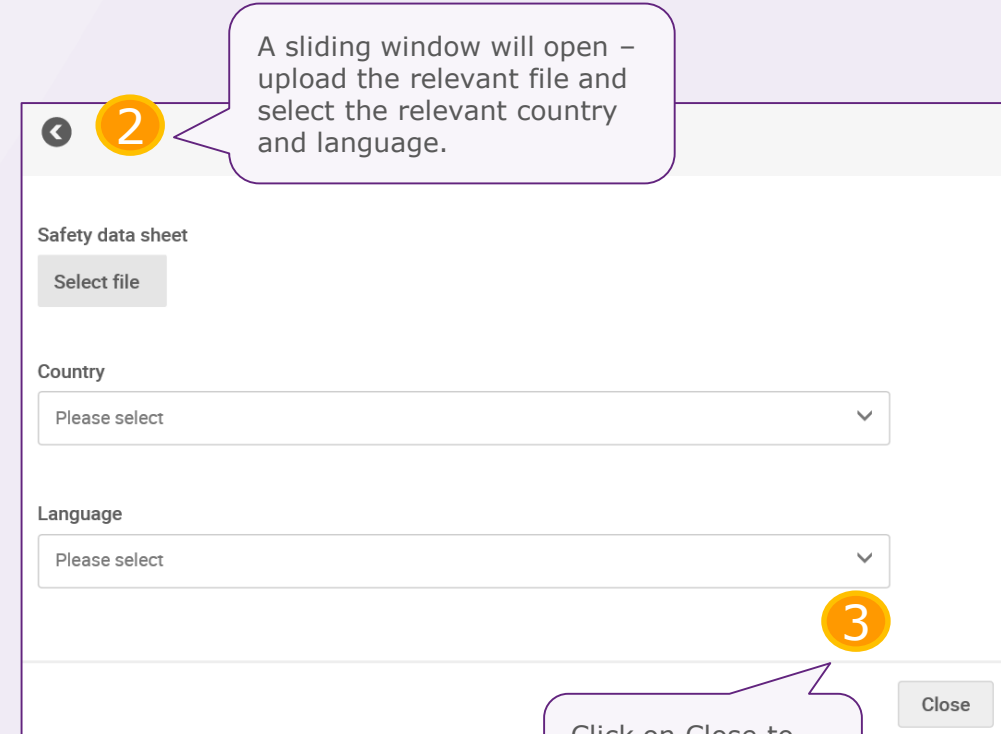
1 SDS information (mixtures)

Safety data sheets of mixture / product

+ New item

No items added
+ New item

Click on +New item to begin the process. Note that multiple items can be added here



2

A sliding window will open – upload the relevant file and select the relevant country and language.

Safety data sheet

Select file

Country

Please select

Language

Please select

3

Close

Click on Close to save the entries, then Finish.



Reporting substance components

An overview of how to use IUCLID to complete the sub-tasks for substance components.

Substance components

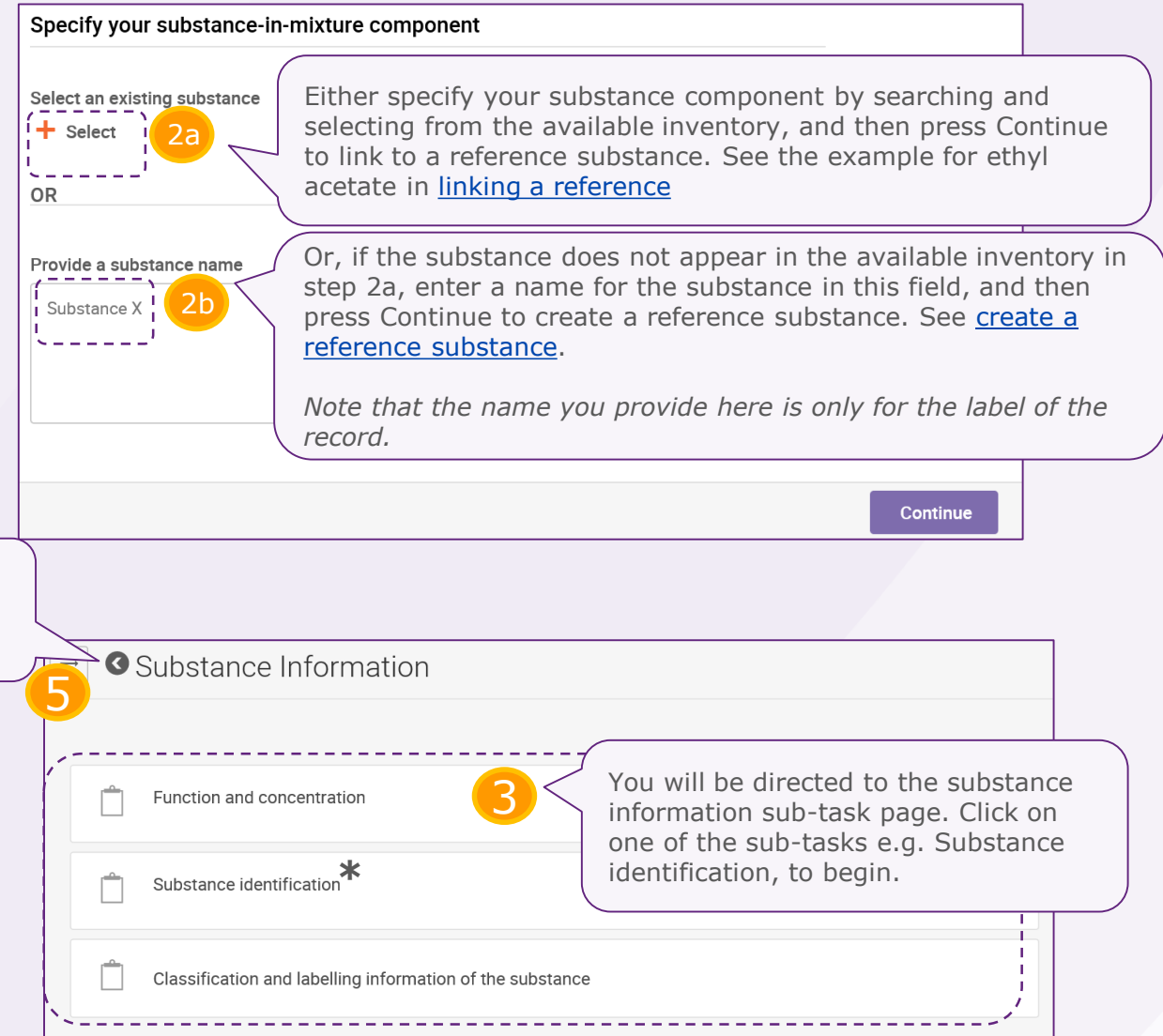
A substance component requires a record that contains information about function and concentration, its identity and its classification. Each substance component is linked to a **Reference Substance**.

A reference substance is used to define the identity of a substance, in such a way that the definition may be re-used in more than one dossier if needed. Reference substance documents can be created during dossier preparation, however, it is also possible and more efficient to import and re-use them as a ready-made set from the IUCLID web site - <https://iuclid6.echa.europa.eu/get-iuclid-data>



Click on the back button `<` to return to the mixture composition task to add more substances.

From the Mixture composition task, Click on **+ Substance component** to begin the process of declaring and identifying each substance present in the mixture.



Either specify your substance component by searching and selecting from the available inventory, and then press Continue to link to a reference substance. See the example for ethyl acetate in [linking a reference](#)

Or, if the substance does not appear in the available inventory in step 2a, enter a name for the substance in this field, and then press Continue to create a reference substance. See [create a reference substance](#).

Note that the name you provide here is only for the label of the record.

You will be directed to the substance information sub-task page. Click on one of the sub-tasks e.g. Substance identification, to begin.

Sub-task 'Substance identification' – linking a reference substance

1

Select Substance

Eth 1 results found

Ethyl acetate 05/11/2018 14:45

Inventory number 205-500-4 CAS number 141-78-6 IUPAC name ethyl acetate

Legal Entity Placeholder substance LE

In step 2a 'Select an existing substance' in the [Substance components](#), a substance can be specified by searching and selecting from the inventory. This example here uses 'Ethyl acetate'. When the substance is found, click on its name

2

Specify your substance-in-mixture component

Select an existing substance

Ethyl acetate

OR

Provide a substance name

Continue

The substance has now been specified and linked to a reference substance. Press Continue to go to the Substance information page to view the the substance identification (or complete the other sub-tasks).

3

Substance identification

1 Reference substance

ReferenceSubstance

Reference substance

ethyl acetate

Finish

Clicking on the name of the component opens the pre-populated document to review the contents.

Reference substance Edit

General information

Reference substance name ethyl acetate

Inventory

Inventory number EC 205-500-4
Name Number
CAS Number
Molecular formula

Inventory information available

Group / category information Description: organics... IUPAC Category: Esters... (Acute toxicity)

Molecular and structural information

Molecular formula C4H8O2

Molecular weight 88.105

SMILES notation CCOC(=O)C

InChI InChI=1/C4H8O2/c1-3-6-4(2)5/h3H2,1-2H3

Structural formula

Et-O-Ac

Sub-task 'Substance identification' – create a reference substance

Substance components + Substance component

Substance X
15/03/2019 10:22

✕

In step 2b in the [Substance components](#), 'Substance X' was used as an example to create and specify a substance component record – note that Substance X is the name of the record label only.

Substance identification

ReferenceSubstance

Reference substance
+ Select

The record must adequately identify the substance. For this record, the process of identifying the substance by linking it to a Reference substance is shown. Click on +Select to begin.

Select Reference substance + Create ✕

🔍 Type at least 3 characters 12 results found

ethyl acetate		16/05/2018 13:06
CAS number	141-78-6	IUPAC name ethyl acetate
Inventory number	205-500-4	

Click on +Create. This will open an empty document in which information about the substance identity can be entered.

New Reference substance

General information

Reference substance name*

Inventory

Inventory number
Select by typing inventory name, EC number, or CAS number

No inventory information available

Justification
Please select

Reference substance information

IUPAC name

Description + Add

Synonyms + New Item

Synonyms 01 ✕

Molecular and structural information

Molecular formula

Molecular weight

SMILES notation

InChI

Structural formula
Select file

Save

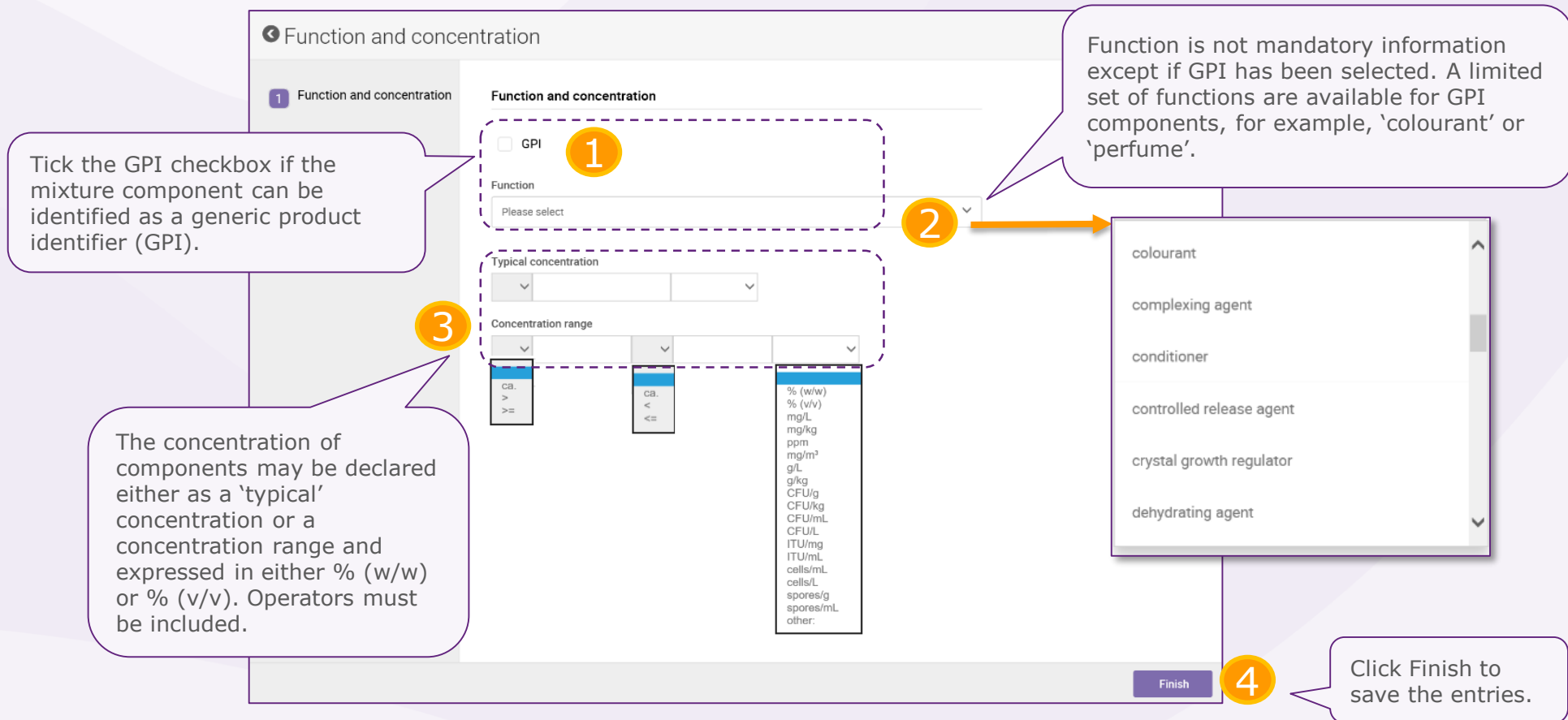
The reference substance name is mandatory – it may be the same as the record label but does not need to be.

It is possible to link the reference substance to the EC inventory by entering the name, EC number or CAS number.

The IUPAC name field is also available for substances which are identified by an alternative international chemical name.

Note that the Synonyms field can be used to indicate if the substance is identified by colour index or INCI name.

Sub-task 'Function and concentration' for the substance



1 Function and concentration

1 Tick the GPI checkbox if the mixture component can be identified as a generic product identifier (GPI).

2 Function is not mandatory information except if GPI has been selected. A limited set of functions are available for GPI components, for example, 'colourant' or 'perfume'.

3 The concentration of components may be declared either as a 'typical' concentration or a concentration range and expressed in either % (w/w) or % (v/v). Operators must be included.

4 Click Finish to save the entries.

Function and concentration

GPI

Function
Please select

Typical concentration

Concentration range

ca. > >= ca. < <=

- % (w/w)
- % (v/v)
- mg/L
- mg/kg
- ppm
- mg/m³
- g/L
- g/kg
- CFU/g
- CFU/kg
- CFU/mL
- CFU/L
- ITU/mg
- ITU/mL
- cells/mL
- cells/L
- spores/g
- spores/mL
- other.

colourant

complexing agent

conditioner

controlled release agent

crystal growth regulator

dehydrating agent

Finish



Sub-task 'Classification of the substance'

This sub-task is based on the same record structure as for the mixture (and mixture in mixture) information – note though, that step 2 Labelling information is not required for the substance, though can be included if available.

Classification and labelling information of the substance

- 1 Classification
- 2 Labelling

General Information

Not classified

Classification

Physical Hazards

Explosives

Hazard category

Please select

Hazard statement

Please select

1 In case the substance is not classified for any physical, health or environmental hazards, select Not classified.

2 Select the hazard category and the hazard statement for each of the hazard classes your mixture falls under, by clicking on the 'v'.

3 Some health hazards contain free text fields to include information e.g. about the effected organs or specific effects. This information should be provided in all the relevant languages.

Specific target organ toxicity - single

Hazard category

STOT Single Exp. 2

Hazard statement

H371 May cause damage to organs <or state all organs affected, if known> <state route of exposure>

Affected organs

fi

sv

Route of exposure

Oral

Add remark

Close



Dossier preparation: 'Product information' section

An overview of how to use IUCLID to complete the tasks and sub-tasks in the Product information section for the preparation of a PCN dossier.



Navigating to the Product details page

At least one Product details record must be present in the final dossier.

1 Provide dossier information
Welcome! Start preparing your dossier by providing information in the following main task groups. You will be guided through a series of smaller tasks to complete each of the main task groups below. Your work can be saved and you can come back to it later if you do not have all the information at hand.

Information to be completed

- Mixture Information
- Product information**

2 Finalize your dossier
Finalise your guided dossier preparation by validating and submitting your dossier.

[Validate](#) [Create dossier](#)

Useful information

- Targeted support - Steps for Industry
- ECHA's poison centre website
- National Helpdesks
- Contact ECHA
- Poison Centres questions and answers
- Guidance on harmonised information relating to emergency health response

Product information

Here is where you can enter the product details. You will need to provide information on the product identifiers and other product characteristics such as the colour, uses, and packaging.

Product details
21/02/2019 10:24

Useful information

- The European product categorisation system (EuPCS): a practical guide.
- Using the UFI for your mixtures and products: webinar

Product details

- Product identifiers
- Market placement
- Additional information

Once you have clicked on Product information section from the dossier preparation navigation page, the Product details task appears.

The Product details task. The number here represents the number of product 'records' created.

Provide information in the Product details task - the task is further divided into three steps, each explained further.



Reporting multiple products

Reporting a single product with a single trade name is the most straightforward way to include product information in a notification i.e. a single Product details record referring to one product under one trade name, and one UFI.

For business reasons however, the Product details record allows a very flexible configuration where multiple products are concerned. In such cases, there is the possibility to manage these notifications in two different ways, where either:

- a) numerous '**Product records**' can be created to distinguish between several 'products' with the same chemical composition i.e. products with different trade names or UFIs or packaging types for instance
- b) numerous products or '**items**' are reported in a single Product details record.

Product details

Records + Additional record ▾

Product details.003 26/02/2019 14:42	✕
Product details.002 26/02/2019 14:42	✕
Product details.001 21/02/2019 10:24	✕

Product details

1 Product identifiers

2 Market placement

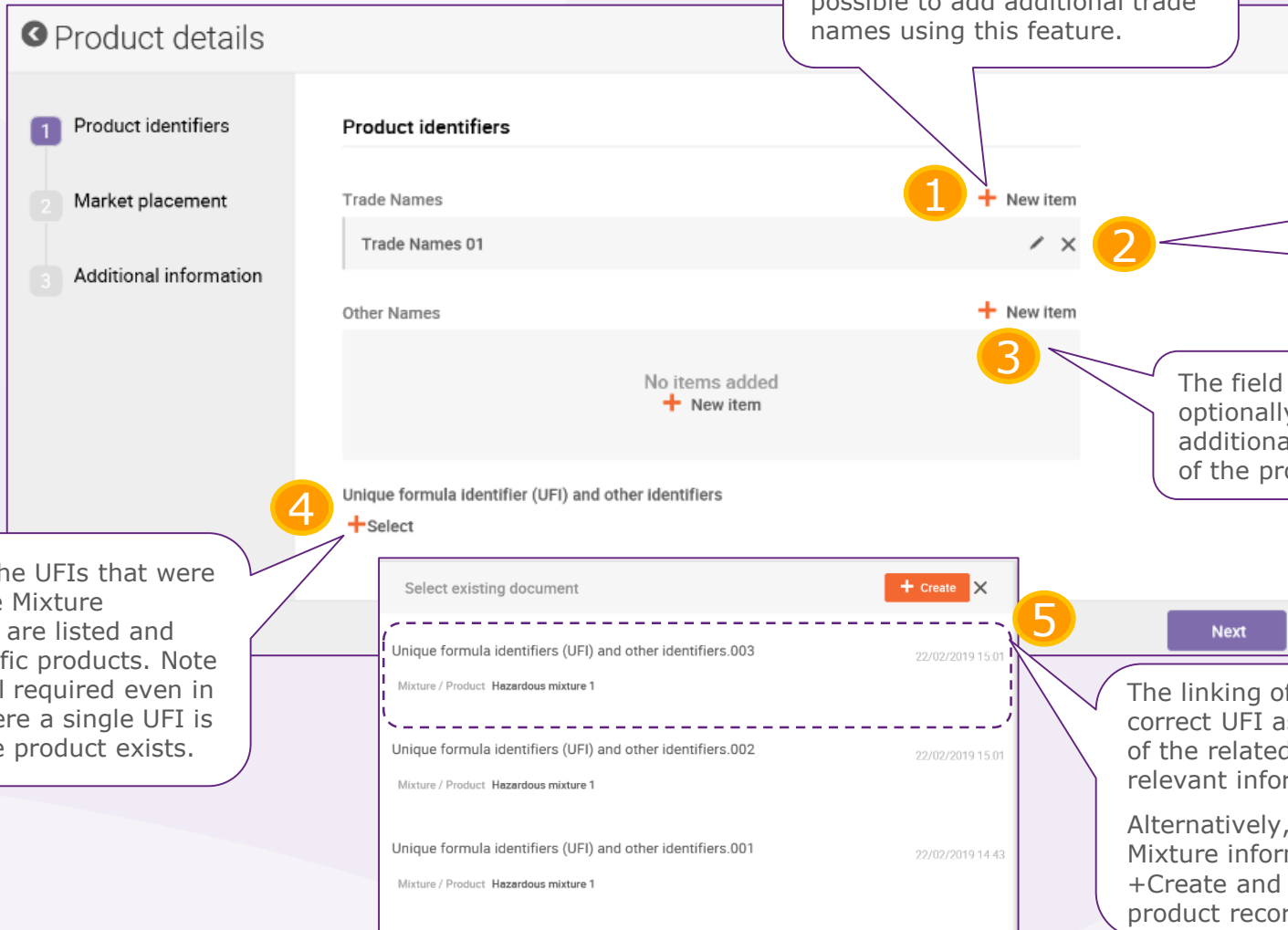
3 Additional information

Product identifiers + New Item

Trade Names

Trade Names 01	✎ ✕
Trade Names 02	✎ ✕
Trade Names 03	✎ ✕

'Product identifiers'



Product details

1 Product identifiers
2 Market placement
3 Additional information

Product identifiers

Trade Names

Trade Names 01

Other Names

No items added
+ New item

4 Unique formula identifier (UFI) and other identifiers
+ Select

Select existing document

Document Name	Date
Unique formula identifiers (UFI) and other identifiers.003 Mixture / Product Hazardous mixture 1	22/02/2019 15:01
Unique formula identifiers (UFI) and other identifiers.002 Mixture / Product Hazardous mixture 1	22/02/2019 15:01
Unique formula identifiers (UFI) and other identifiers.001 Mixture / Product Hazardous mixture 1	22/02/2019 14:43

Clicking **+New item**, opens a sliding window where the trade name can be entered. It is possible to add additional trade names using this feature.

Clicking on the pencil icon allows you to view or edit the entry, while the X button, allows you to delete the item.

The field Other Names may optionally be used if there are additional names on the label of the product.

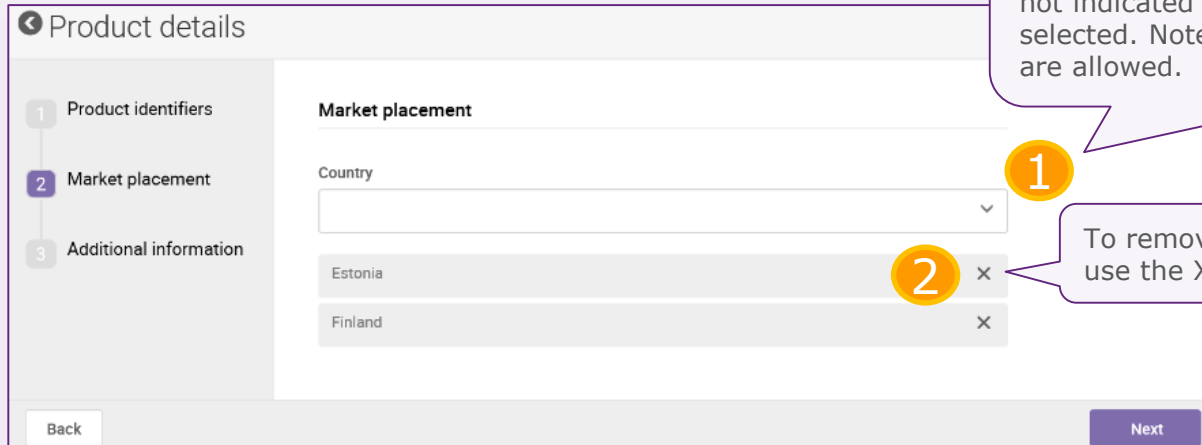
By clicking **+Select**, the UFIs that were declared earlier in the Mixture information 'UFI task' are listed and can be linked to specific products. Note that this linking is still required even in the simplest case where a single UFI is declared and only one product exists.

The linking of UFIs is done through selecting the correct UFI assigned to the mixture and on the label of the related product, by clicking anywhere in the relevant information bar.

Alternatively, if you did not indicate any UFIs in the Mixture information UFI task, then you can click **+Create** and enter the UFI details directly in the product record.

'Market placement'

This step requires that the product, as defined in the previous step 'Product identifiers', is linked to the relevant country(ies) where it will be placed on the market.



Product details

1 Product identifiers

2 Market placement

3 Additional information

Market placement

Country

Estonia X

Finland X

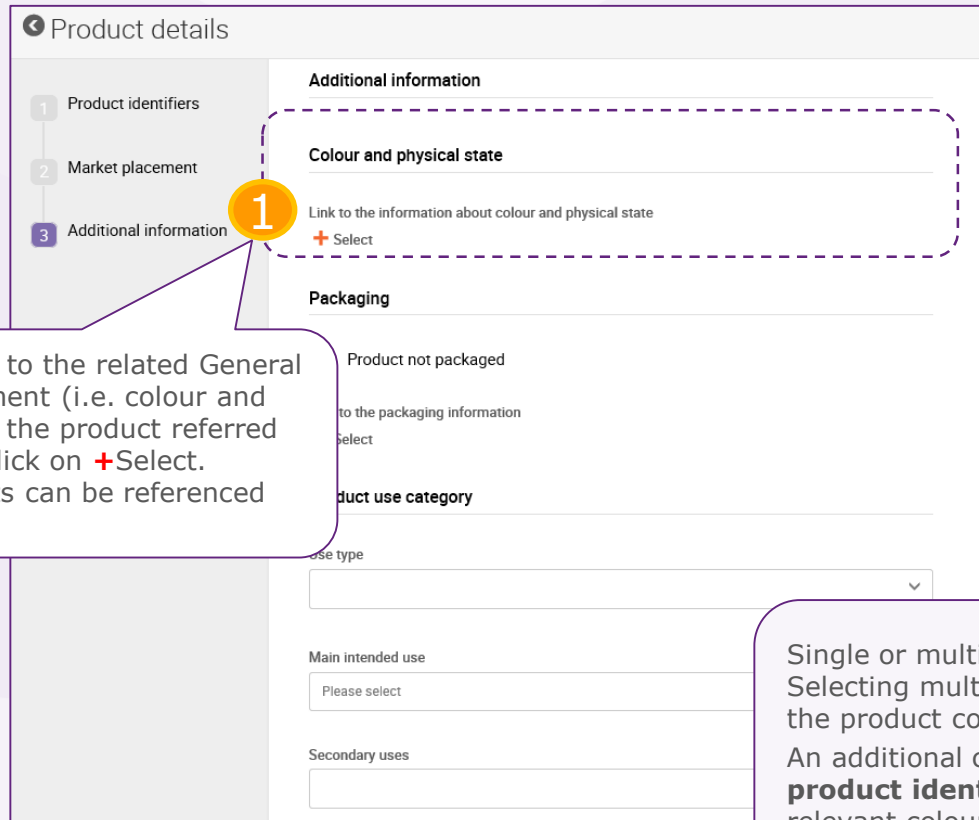
Back Next

1 Select the countries where the product is intended to be placed on the market – countries not indicated in the dossier header should not be selected. Note that multiple selections per record are allowed.

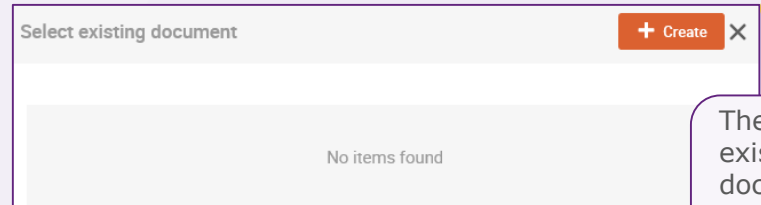
2 To remove an entry, simply use the X functionality.

3 Click on Next to save your entries and move to the next sub-task.

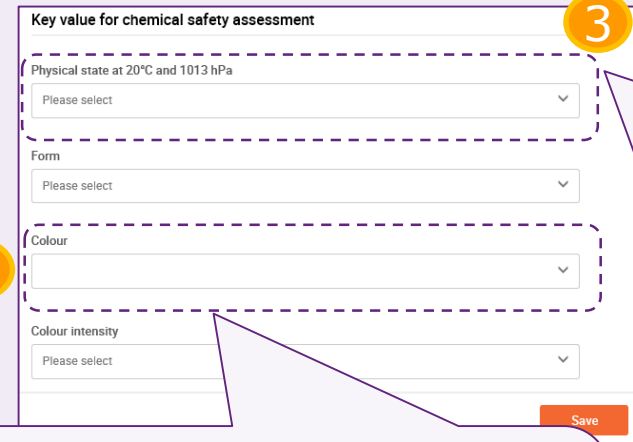
Additional information (1/3) – Colour and physical state



To establish a link to the related General information document (i.e. colour and physical state) for the product referred to in the record, click on **+Select**. Multiple documents can be referenced here.



The option to select an existing General information document (if one exists) or create a new document is offered.

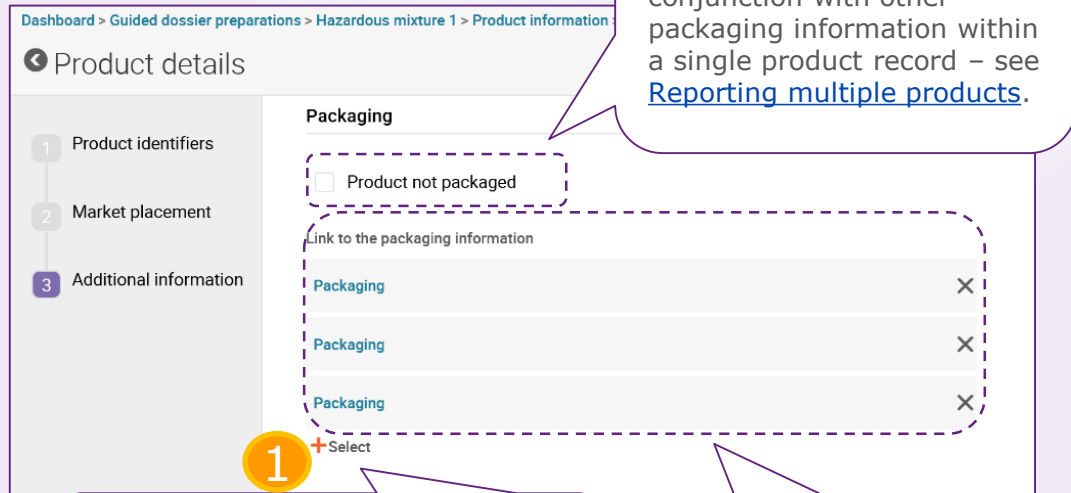


If you selected **+Create** in the previous step, a new General information document is created. Here, the physical state and colour are mandatory fields, while form and colour intensity are optional. If you selected an existing document, check the information carried over to this document is available and correct.

Single or multiple colour selections (x 15 total) are available. Selecting multiple colours, e.g. white and yellow, means that the product comes in white or yellow variations. An additional colour selection '**Mixtures containing generic product identifiers 'colouring agents'**' is available, and all relevant colours must be additionally selected.

Additional information (2/3) – Packaging

If a mixture is supplied in different types and sizes of packaging, information on all the relevant types and sizes placed has to be included. Note that mixtures for industrial use are not required to have packaging indicated.



Dashboard > Guided dossier preparations > Hazardous mixture 1 > Product information

Product details

- 1 Product identifiers
- 2 Market placement
- 3 Additional information

Packaging

Product not packaged

Link to the packaging information

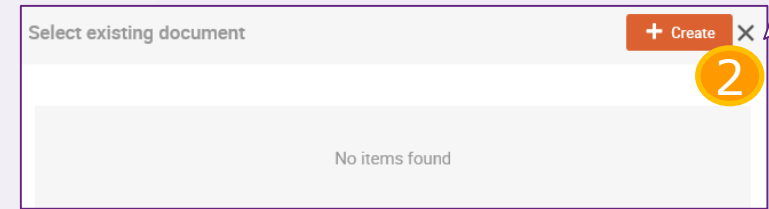
- Packaging
- Packaging
- Packaging

+ Select

Selecting the check box Not packaged can not be used in conjunction with other packaging information within a single product record – see [Reporting multiple products](#).

To establish a link to the related packaging information for the product referred to in the record, click on +Select.

Multiple packaging documents for a product are displayed here.

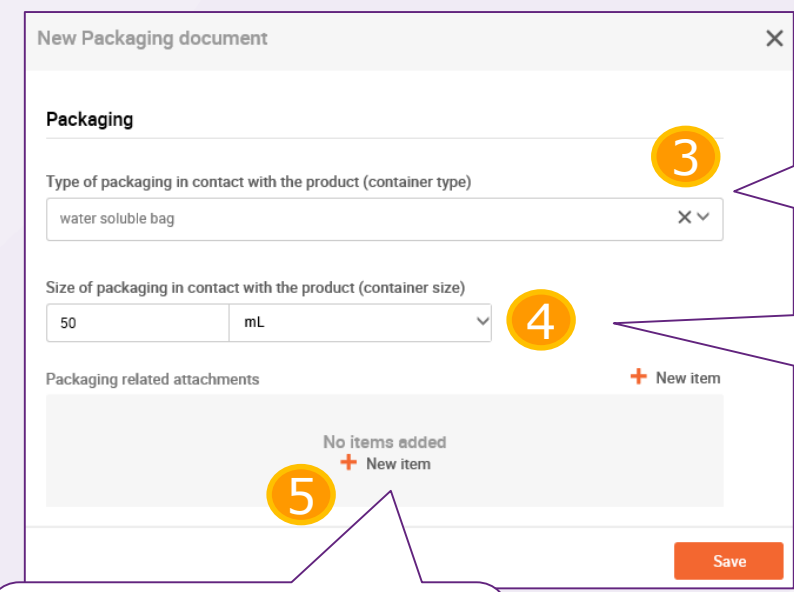


Select existing document

+ Create X

No items found

Select +Create to open a new document.



New Packaging document

Packaging

Type of packaging in contact with the product (container type)

water soluble bag

Size of packaging in contact with the product (container size)

50 mL

Packaging related attachments

+ New item

No items added

+ New item

Save

From here, a selection can be made from one of 33 different packaging types e.g. aerosol can, aerospray, atomizer, bag/sack...

The size of the packaging and the units are indicated here. Ranges e.g. 50–100mL are not permitted, meaning that multiple packaging documents will need to be created.

Any packaging related documents e.g. an example label, may be included here. Files accepted include, but are not limited to pdf, word, jpeg.

Additional information (3/3) – Product use category

The selection of the **use type** should reflect both the mixture as placed on the market as well as for other mixtures if it is incorporated for use further down the supply chain. For example, the use type of a mixture for industrial use will also need to reflect other use types if it is used as a mixture for further formulation in professional or consumer use products.

Dashboard > Guided dossier preparations > Hazardous mixture 1 > Product information > Product details

Product details

- Product identifiers
- Market placement
- Additional information

Product use category

Use type

Main intended use

Secondary uses

Back Finish

Use type

Consumer

Professional

Industrial

Selection of multiple use types for the mixture is possible.

Main intended use

Please select

PC-ADH-1 Adhesives and sealants - household, office or school use

PC-ADH-2 Adhesives and sealants - building and construction works (except cement based adhesives)

PC-ADH-3 Adhesives and sealants - footwear and leather goods

PC-ADH-4 Adhesives and sealants - paper and board related processes

PC-ADH-5 Adhesives and sealants - transportation industry

PC-ADH-6 Adhesives and sealants - woodworking and joinery (includes putty)

Secondary uses are not a mandatory requirement and they should not be provided in the notification if they are not intended to be used as such. The main intended use categories are however, available to make secondary use selections if needed – the maximum number recommended is three.

A single main intended use category per Product details record is allowed.

Note if the product may fit multiple categories and is subject to authorisation according to the **Biocidal Product Regulation (BPR)** or to the **Plant Protection Product Regulation (PPPR)**, the product category reflecting the intended use as a biocide or plant protection product must be selected.

More detailed information can be found at:
<https://poisoncentres.echa.europa.eu/eu-product-categorisation-system>

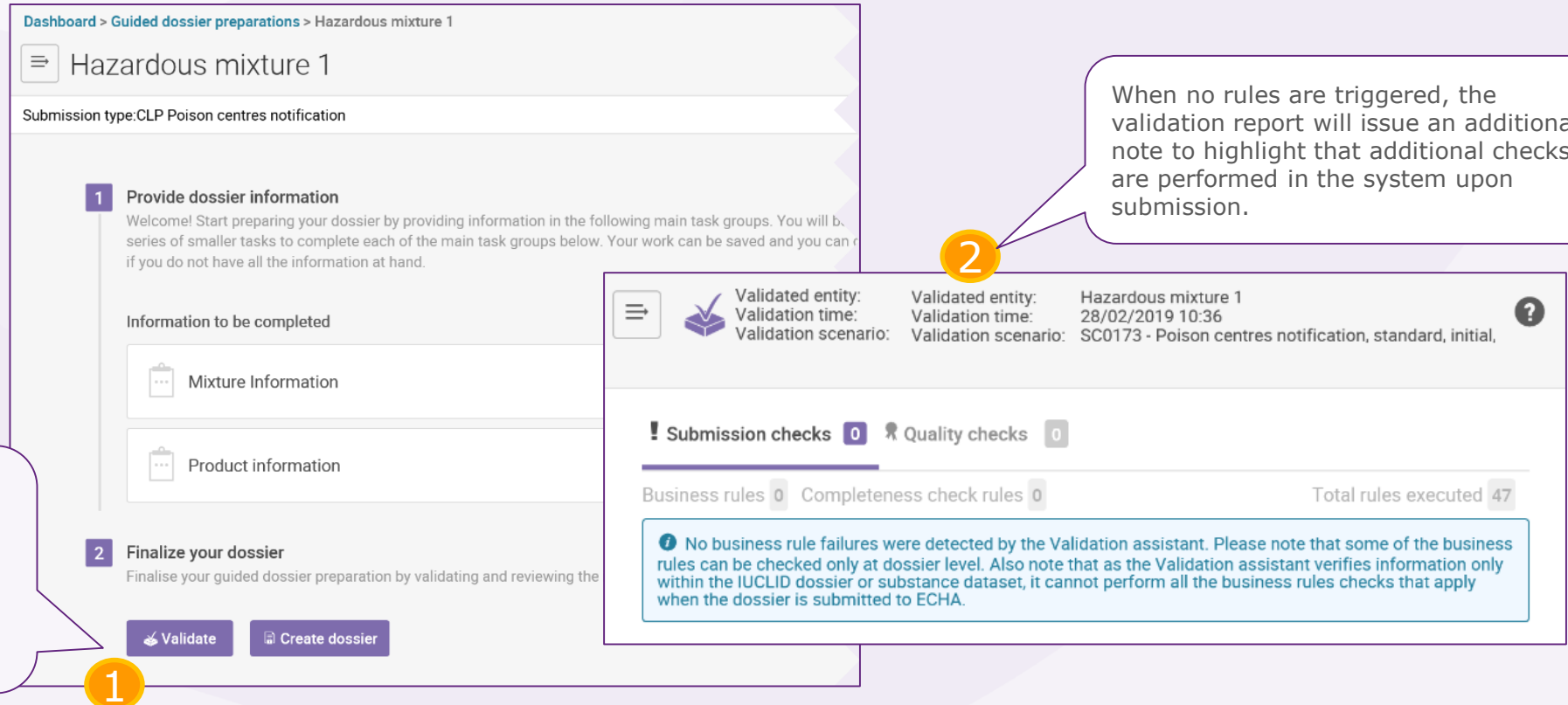


Validate information & create dossier

An explanation of the functionalities to validate and create a dossier.

The validation assistant

The validation assistant carries out checks according to a set of pre-defined rules to verify that the information was provided as expected. The outcome of the validation is a report, which lists the rules (if any) for which the validation failed.



The screenshot shows the 'Hazardous mixture 1' dossier preparation page. It includes a breadcrumb trail: Dashboard > Guided dossier preparations > Hazardous mixture 1. The submission type is 'CLP Poison centres notification'. The interface is divided into two main steps:

- 1 Provide dossier information**: This step is currently active. It contains a welcome message and a list of 'Information to be completed' tasks: 'Mixture Information' and 'Product information'.
- 2 Finalize your dossier**: This step involves finalizing the preparation by validating and reviewing the dossier. It features a 'Validate' button and a 'Create dossier' button.

At the bottom of the page, there are two callout boxes:

- Callout 1** (pointing to the 'Validate' button): Clicking Validate will display the Dossier header page for final review. Click on Validate again from the dossier header page and the Validation report will be displayed.
- Callout 2** (pointing to the validation summary): When no rules are triggered, the validation report will issue an additional note to highlight that additional checks are performed in the system upon submission.

The validation summary section shows the following details:

- Validated entity: Hazardous mixture 1
- Validation time: 28/02/2019 10:36
- Validation scenario: SC0173 - Poison centres notification, standard, initial
- Submission checks: 0
- Quality checks: 0
- Business rules: 0
- Completeness check rules: 0
- Total rules executed: 47

A message box at the bottom of the summary states: "No business rule failures were detected by the Validation assistant. Please note that some of the business rules can be checked only at dossier level. Also note that as the Validation assistant verifies information only within the IUCLID dossier or substance dataset, it cannot perform all the business rules checks that apply when the dossier is submitted to ECHA."

The validation report

When rules are triggered, the validation report will listing the submission checks as failures or warnings.

Validation assistant report

Validated entity: Hazardous mixture 1
 Validation time: 28/02/2019 10:17
 Validation scenario: SC0173 - Poison centres notification, standard, initial, not 'Limit...'

[Re-validate](#) [Edit dossier settings](#)

Submission checks 2 **Quality checks** 0

Business rules 2 **Completeness check rules** 0 Total rules executed 47

- Initial submission**
Dossier header
Market placement (country) indicated in product information record is not mentioned in dossier header as market placement countries indicated in Product information record(s) are also indicated in the dossier header.
- Product details.001**
Product information Trade names, (1)
1 Product information is incomplete. At least one 'Trade name' must be provided under Product details > Product identifiers.

Use the link, where available, to be redirected to the area that requires additional review or input.

Dashboard > Mixture / Products > Hazardous mixture 1 > Product details.001 > edit

Product details.001

Group submission

Product identifiers >

Market placement

Safety data sheet (SDS)

Additional information

Product information Trade names, (1) [Validation report](#)

Product information is incomplete. At least one 'Trade name' must be provided under Product details > Product identifiers.

Product identifiers

Trade names + New item

Trade names 01 ✎ ✕

[Save](#)

Make the changes where relevant and save before re-validating again.

Creating and exporting the dossier

Dashboard > Guided dossier preparations > Hazardous mixture 1

Hazardous mixture 1

Submission type: CLP Poison centres notification

1 Provide dossier information
 Welcome! Start preparing your dossier by providing information in the following main task groups. You will be guided through a series of smaller tasks to complete each of the main task groups below. Your work can be saved and you can return to it if you do not have all the information at hand.

Information to be completed

- Mixture Information
- Product information

2 Finalize your dossier
 Finalise your guided dossier preparation by validating and reviewing the information before you create your dossier.

Validate Create dossier **1**

Clicking Create dossier will display the Dossier header page for final review. Click on Create dossier again from the dossier header page.

Create dossier

✓ Dossier creation was completed successfully. Do you want to open the created dossier?

Close Open **2**

If the dossier did not trigger any warnings or errors, and the creation was successful, you can view the dossier contents by clicking Open.

- Export to i6z
- Create PDF
- Generate report
- Compare
- Dissemination preview

Dashboard > Mixture / Products > Hazardous mixture 1

Initial submission
 93a6c06a-9512-450b-a65e-49353d2c45b1

Table of contents

- Mixture information and product identity 4
- Classification of the mixture and label elements 1
- Mixture safety data sheets and toxicological information 1
- Additional information 9

Dossier information

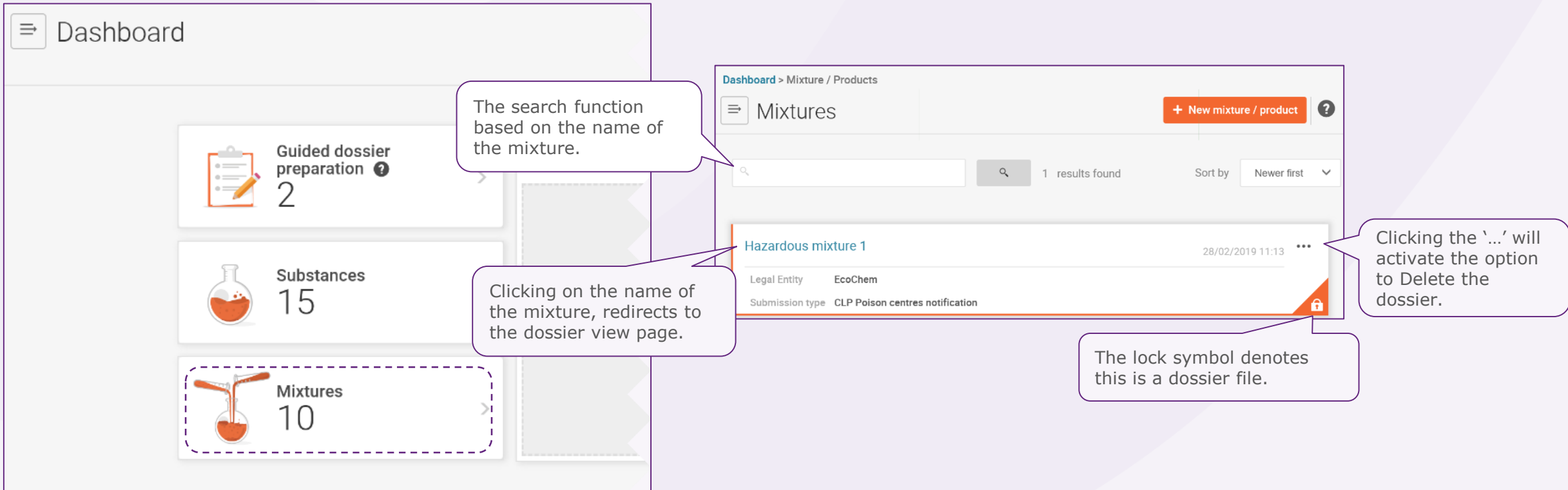
- Submission type: CLP Poison centres notification
- Dossier name: Initial submission
- Subject: Hazardous mixture
- Submitting legal entity: EcoChem
- Created on: 28/02/2019 11:13

Validate **3**

Export the dossier locally by Clicking '...' and selecting Export to i6z. Give the dossier a meaningful name to assist with the upload and submit process – see [Upload and submit](#).

Locating the dossier

Clicking on Mixtures from the IUCLID Dashboard will display all the mixture datasets and dossiers created. Mixtures that are associated with dossiers will have a lock symbol.



The screenshot shows the IUCLID Dashboard interface. On the left, the 'Dashboard' menu is visible. The main content area displays three cards: 'Guided dossier preparation' with a count of 2, 'Substances' with a count of 15, and 'Mixtures' with a count of 10. The 'Mixtures' card is highlighted with a dashed border. A callout points to the search bar in the 'Mixture / Products' view, stating: 'The search function based on the name of the mixture.' Another callout points to the 'Hazardous mixture 1' entry, stating: 'Clicking on the name of the mixture, redirects to the dossier view page.' A third callout points to the three-dot menu icon next to the entry, stating: 'Clicking the `...` will activate the option to Delete the dossier.' A fourth callout points to the lock icon in the bottom right corner of the entry, stating: 'The lock symbol denotes this is a dossier file.'

Dashboard

Guided dossier preparation 2

Substances 15

Mixtures 10

Dashboard > Mixture / Products

Mixtures

+ New mixture / product ?

1 results found

Sort by Newer first

Hazardous mixture 1 28/02/2019 11:13

Legal Entity EcoChem

Submission type CLP Poison centres notification

The search function based on the name of the mixture.

Clicking on the name of the mixture, redirects to the dossier view page.

Clicking the `...` will activate the option to Delete the dossier.

The lock symbol denotes this is a dossier file.



Updating dossier information

An explanation on how to prepare for a dossier update.

Updating dossier information

Dashboard > Guided dossier preparations

Guided dossier preparations

2 results found

1 Hazardous mixture 1

Legal Entity	EcoChem	Submission type	CLP Poison centres notification	Dossier Name
				314-13-2
		REACH Registration joint submission -		

Click on the name of the mixture for which you wish to modify information in the notification.

1 Provide dossier information
Welcome! Start preparing your dossier by providing information in the following main task groups. You will be guided through a series of smaller tasks to complete each of the main task groups below. Your work can be saved and you can come back to it later if you do not have all the information at hand.

Information to be completed

- Mixture Information
- Product information

2 Finalize your dossier
Finalise your guided dossier preparation by validating and reviewing the information before you create your dossier.

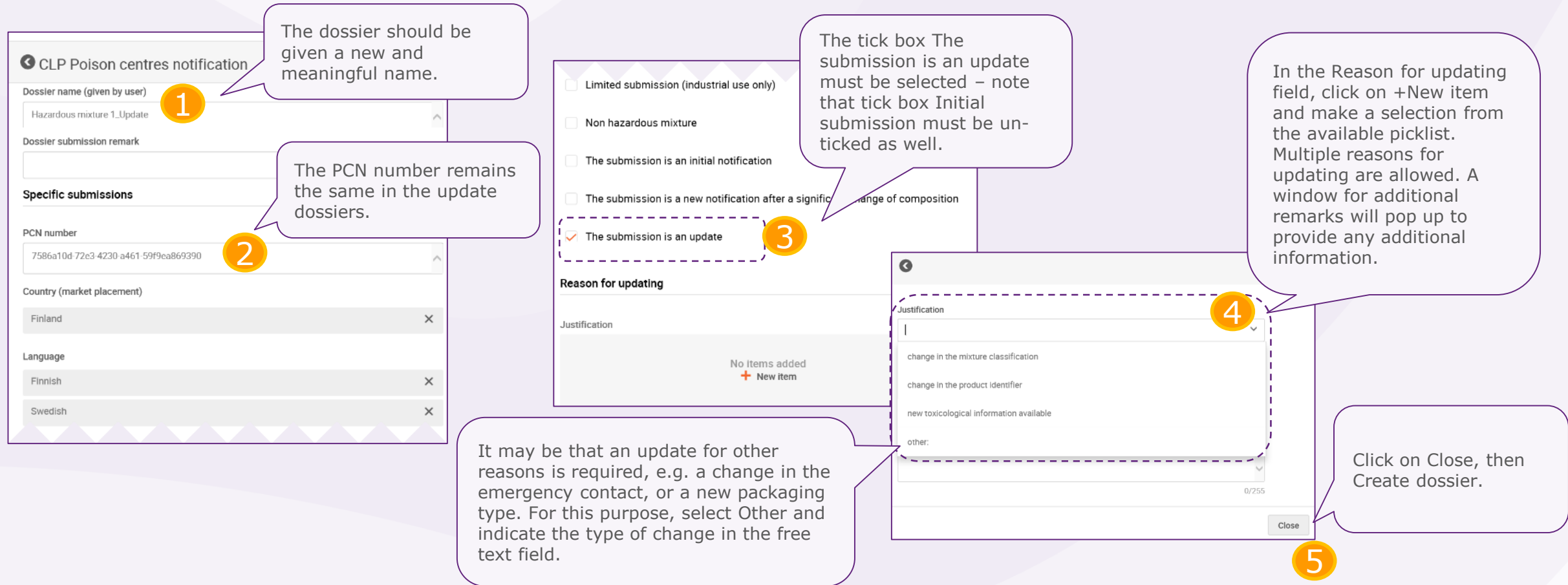
3 Validate **4** Create dossier

Navigate to the section where you need to make the change in the Mixture or Product Information task, and make the changes.

When you have made all the necessary changes to the notification, click on Validate - note that some validation checks can only be performed following the submission process, particularly in the case of updates.

When you click on Create dossier, the dossier header page will be displayed and will need to be edited - see [Updating the dossier header for submission update](#).

Updating the dossier header for a submission update



1 The dossier should be given a new and meaningful name.

2 The PCN number remains the same in the update dossiers.

3 The tick box The submission is an update must be selected – note that tick box Initial submission must be un-ticked as well.

4 In the Reason for updating field, click on +New item and make a selection from the available picklist. Multiple reasons for updating are allowed. A window for additional remarks will pop up to provide any additional information.

5 Click on Close, then Create dossier.

It may be that an update for other reasons is required, e.g. a change in the emergency contact, or a new packaging type. For this purpose, select Other and indicate the type of change in the free text field.

Form Fields:

- CLP Poison centres notification
- Dossier name (given by user): Hazardous mixture 1_Update
- Dossier submission remark
- Specific submissions
- PCN number: 7586a10d-72e3-4230-a461-59f9ea869390
- Country (market placement): Finland
- Language: Finnish, Swedish
- Reason for updating:
 - Limited submission (industrial use only)
 - Non hazardous mixture
 - The submission is an initial notification
 - The submission is a new notification after a significant change of composition
 - The submission is an update
- Justification:
 - change in the mixture classification
 - change in the product identifier
 - new toxicological information available
 - other:



Updating the dossier header when the mixture significantly changes in composition

When the mixture composition changes beyond the allowable limits defined in Annex VIII to the Classification and Labelling Regulation, by default, this will lead to two different 'products' on the market. In this case, a notification for the new composition must be made (containing a new PCN number) i.e. a new notification after a significant change in composition.

In addition to this, the notification must refer to the previous PCN number as the 'related PCN number', and a new UFI must be assigned, declared in the notification and included on the product.

CLP Poison centres notification

Specific submissions

PCN number 1

c3a5d43b-ab21-4a95-898e-62000e016348

Country (market placement)

Finland ×

Language

Finnish ×

Swedish ×

Limited submission (industrial use only)

Non hazardous mixture

The submission is an initial notification

The submission is a new notification after a significant change of composition

The submission is an update

A new PCN number must be provided for the notification. The previous PCN number will be referred to as the 'Related PCN number' – see [UFI and other identifiers task](#).

The submission type '...new notification...' must be selected.

