

# Poison centre notifications

A GUIDE TO DOSSIER PREPARATION AND SUBMISSION

Version 1.3 October 2019



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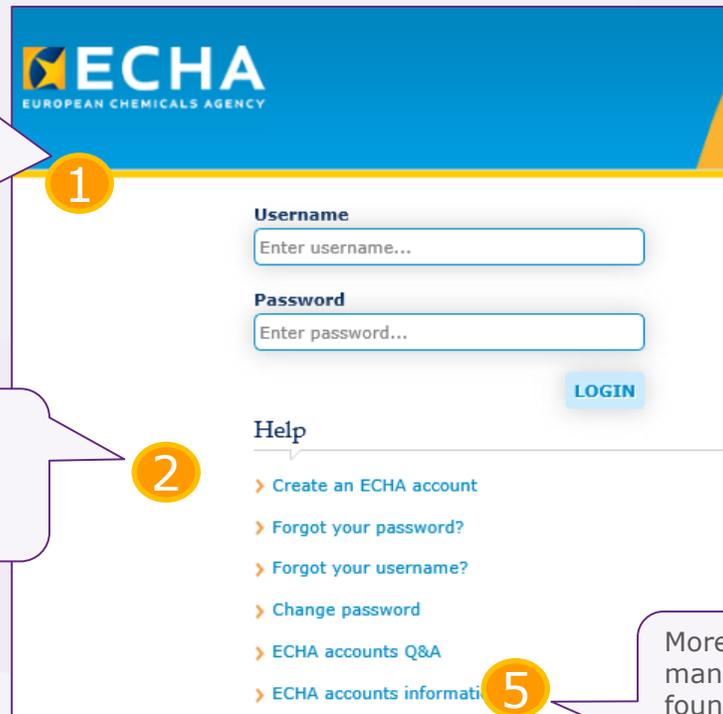
## Getting access

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/>

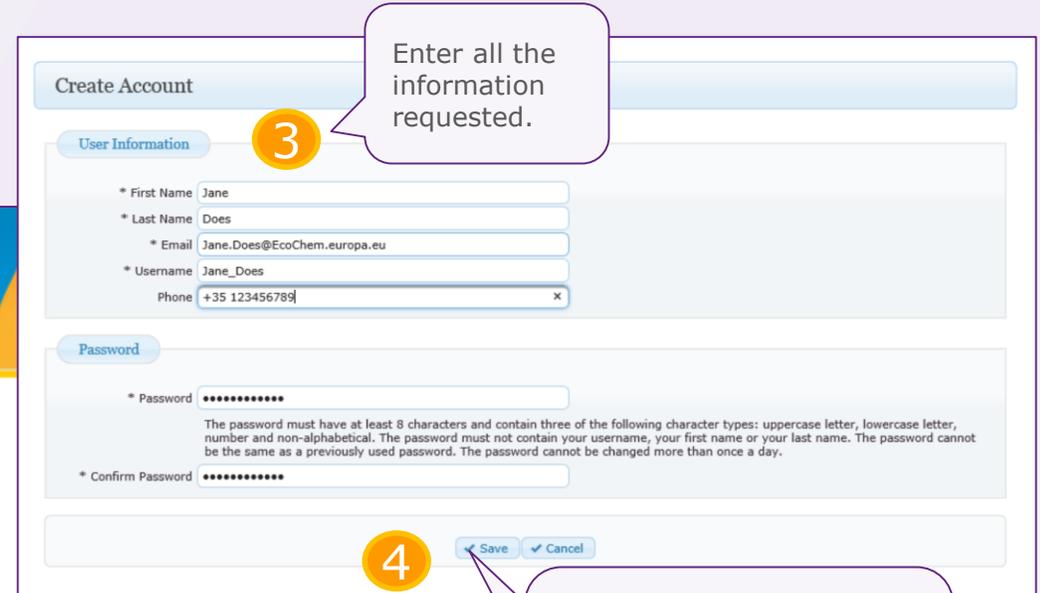


**1**

**2**

**5**

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



**3**

**4**

Enter all the information requested.

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

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



## 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.

**ECHA**  
EUROPEAN CHEMICALS AGENCY

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.

**ECHA**  
EUROPEAN CHEMICALS AGENCY

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

### 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

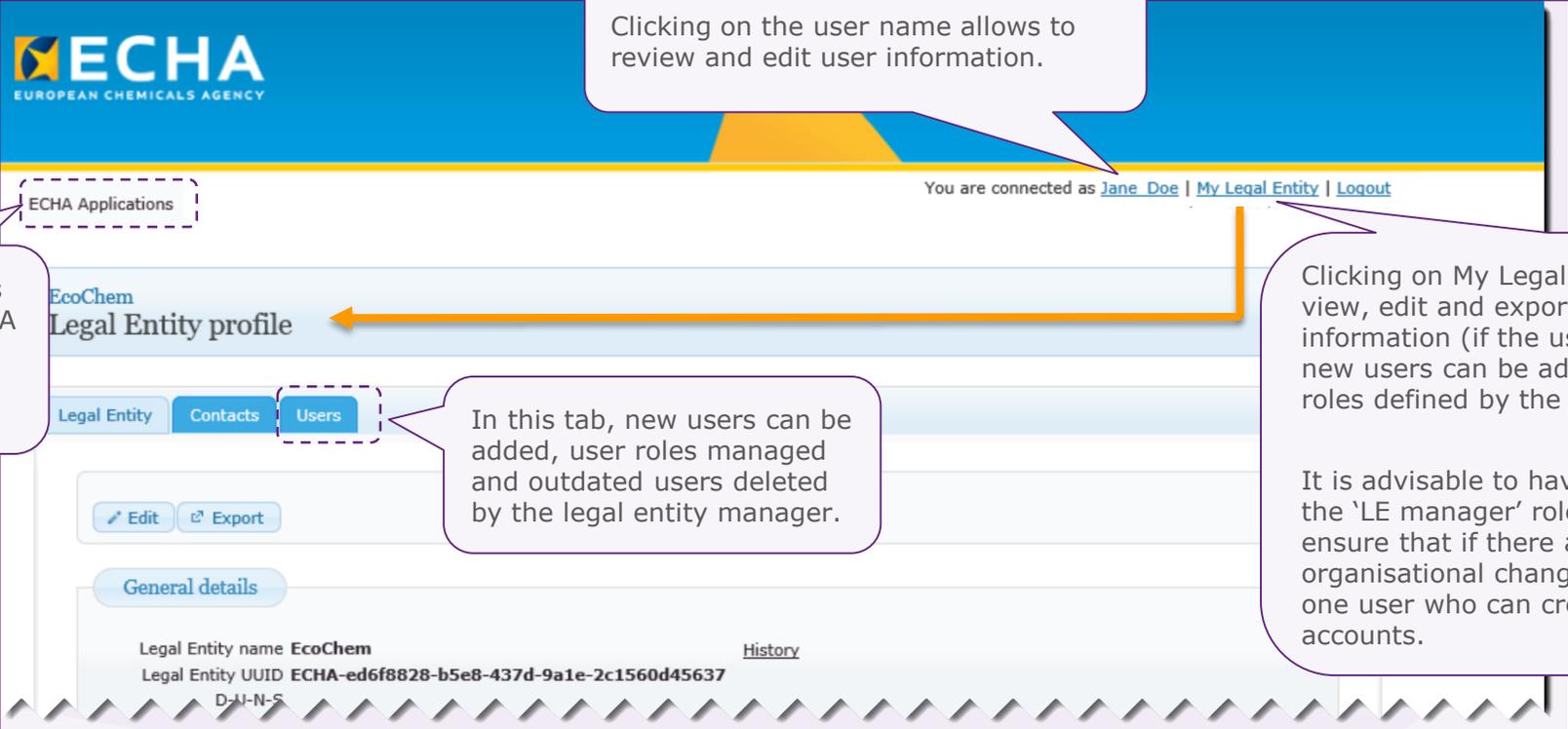
\* Phone   
 \* Email  Example: name@domain.com  
 Website   
 Fax

#### 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). The user is logged in as Jane Doe, with links for My Legal Entity and Logout. The main content area shows the 'Legal Entity profile' for 'EcoChem'. There are tabs for 'Legal Entity', 'Contacts', and 'Users'. The 'Users' tab is selected, showing 'Edit' and 'Export' buttons. Below the tabs is 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.

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'.

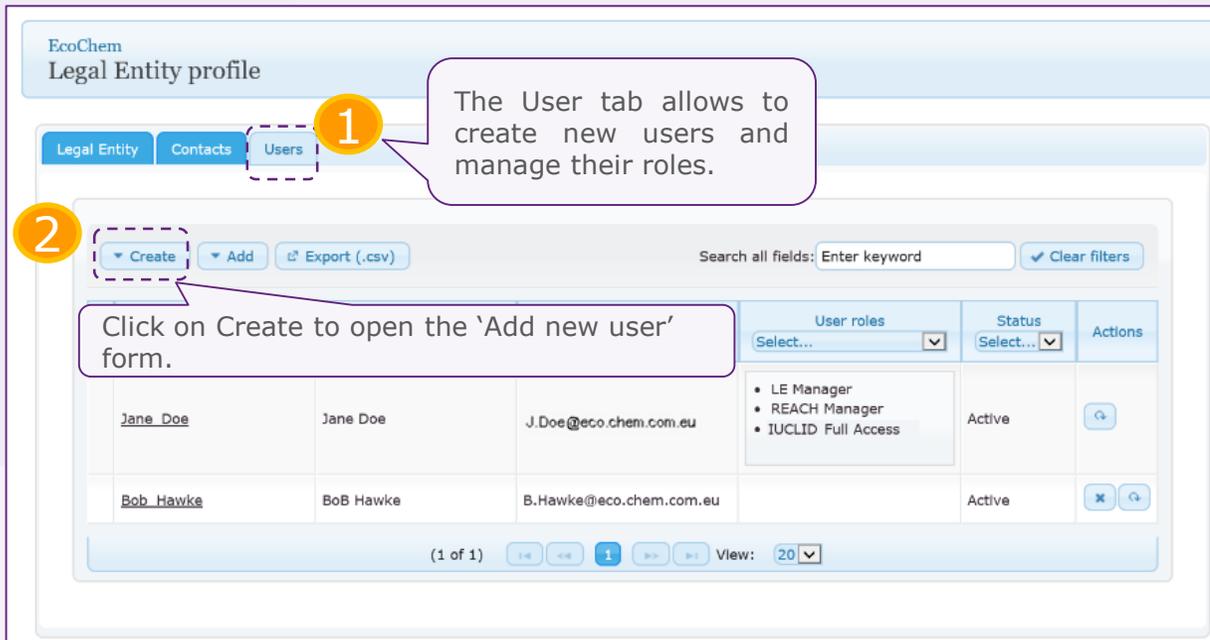
In this tab, new users can be added, user roles managed and outdated users deleted by the legal entity manager.

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:

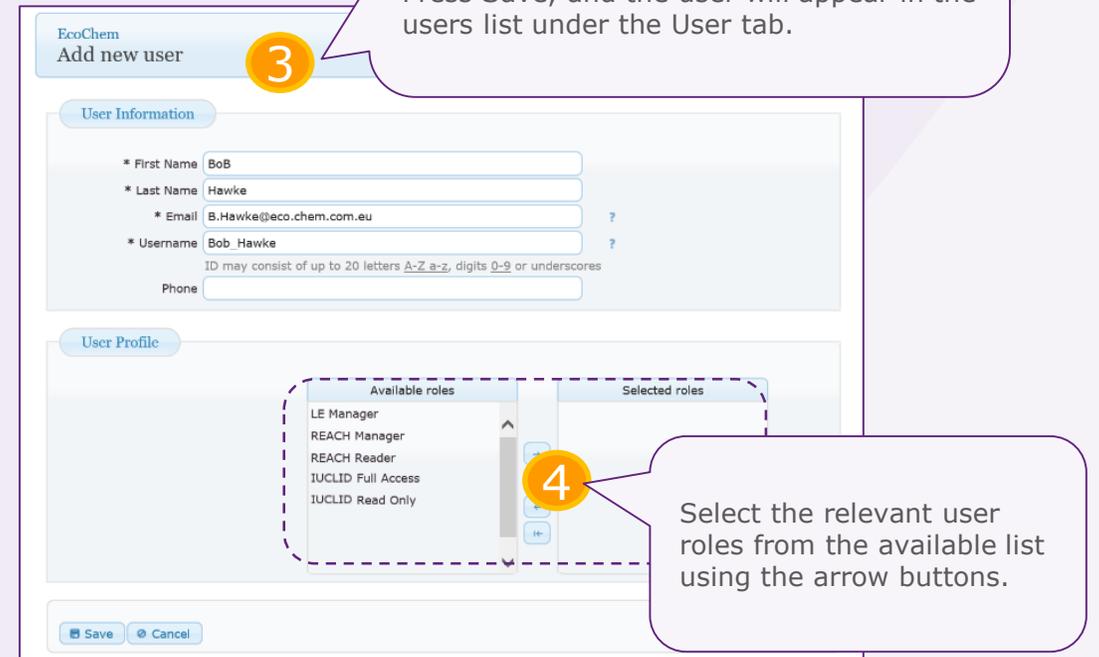
- **LE manager** -> can view and edit the LE account and add, remove or edit user's data and contacts.
- **REACH manager** -> can make submissions through ECHA Submission portal
- **IUCLID full access** -> can prepare submissions online in IUCLID Cloud.
- **'Reader' and 'Read' roles** are entitled to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

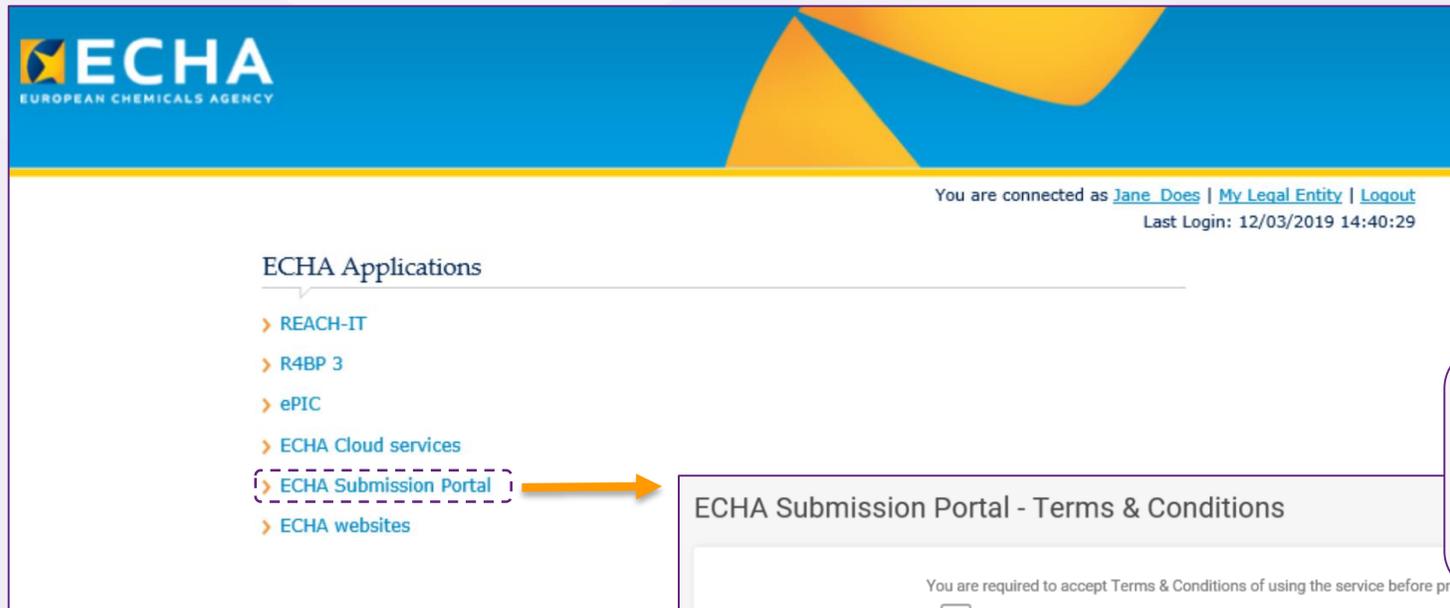
			User roles	Status	Actions
			Select...	Select...	
Jane Doe	Jane Doe	J.Doe@eco.chem.com.eu	<ul style="list-style-type: none"> <li>LE Manager</li> <li>REACH Manager</li> <li>IUCLID Full Access</li> </ul>	Active	
Bob Hawke	BoB Hawke	B.Hawke@eco.chem.com.eu		Active	



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



The screenshot shows the ECHA portal interface. At the top left is the ECHA logo (European Chemicals Agency). On the right, it indicates the user is connected as 'Jane Does' with links for 'My Legal Entity' and 'Logout', and shows the last login time as '12/03/2019 14:40:29'. A navigation menu under 'ECHA Applications' lists several options: REACH-IT, R4BP 3, ePIC, ECHA Cloud services, ECHA Submission Portal (highlighted with a dashed orange box and an arrow pointing to the right), and ECHA websites. Below this, a dialog box titled 'ECHA Submission Portal - Terms & Conditions' is displayed. It contains the text 'You are required to accept Terms & Conditions of using the service before proceeding' and a checked checkbox with the text 'I acknowledge that I have read and agreed to the linked Terms & Conditions'. At the bottom of the dialog are two buttons: 'Accept and Continue' and 'Decline'.

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

To view the full terms and conditions, click on the link.



# **ECHA Submission portal for poison centre notifications**

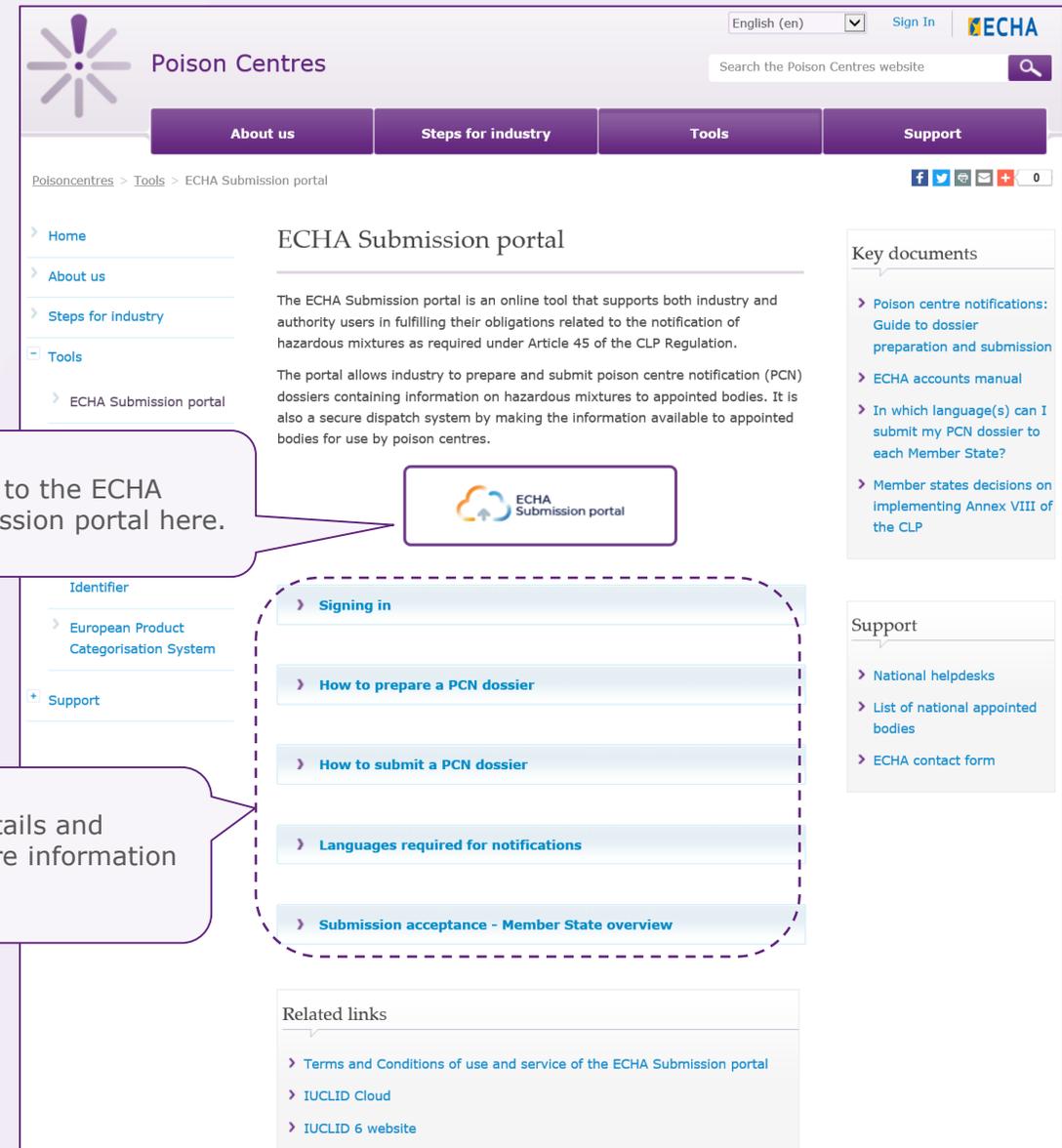
A navigational guide around the ECHA Submission portal; highlighting the three pillars of the notification process; dossier creation, dossier submission and searching for notifications.

## ECHA Submission portal webpage

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 webpage. The page title is "ECHA Submission portal". The main content area contains the following text:

**ECHA Submission portal**

The ECHA Submission portal is an online tool that supports both industry and authority users in fulfilling their obligations related to the notification of hazardous mixtures as required under Article 45 of the CLP Regulation.

The portal allows industry to prepare and submit poison centre notification (PCN) dossiers containing information on hazardous mixtures to appointed bodies. It is also a secure dispatch system by making the information available to appointed bodies for use by poison centres.

Callouts highlight the following features:

- Log in to the ECHA Submission portal here.** (Points to the "ECHA Submission portal" logo)
- Click for more details and where to find more information on these topics.** (Points to a list of links: Signing in, How to prepare a PCN dossier, How to submit a PCN dossier, Languages required for notifications, Submission acceptance - Member State overview)

Additional page elements include:

- Navigation:** Home, About us, Steps for industry, Tools, ECHA Submission portal.
- Key documents:**
  - Poison centre notifications: Guide to dossier preparation and submission
  - ECHA accounts manual
  - In which language(s) can I submit my PCN dossier to each Member State?
  - Member states decisions on implementing Annex VIII of the CLP
- Support:**
  - National helpdesks
  - List of national appointed bodies
  - ECHA contact form
- Related links:**
  - Terms and Conditions of use and service of the ECHA Submission portal
  - IUCLID Cloud
  - IUCLID 6 website

# 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.

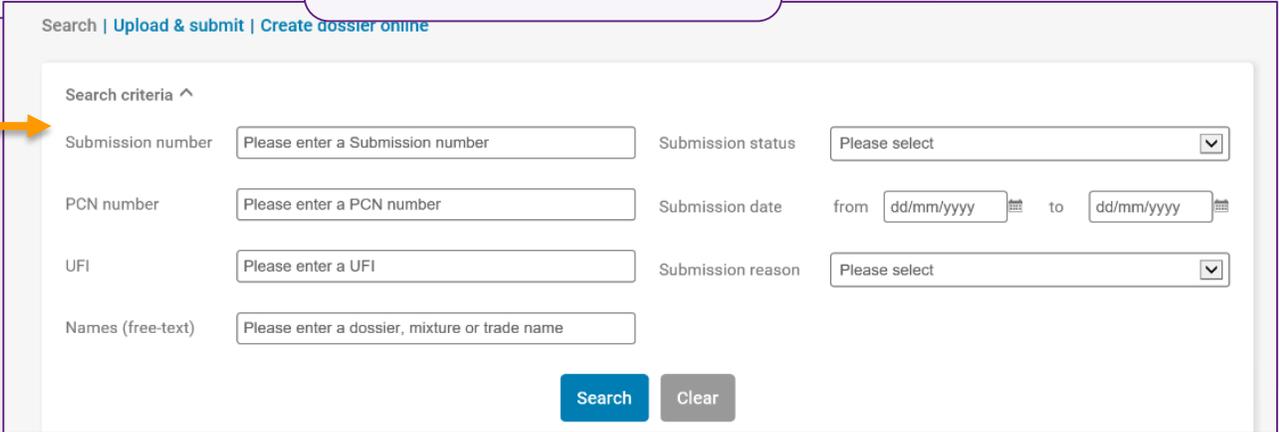
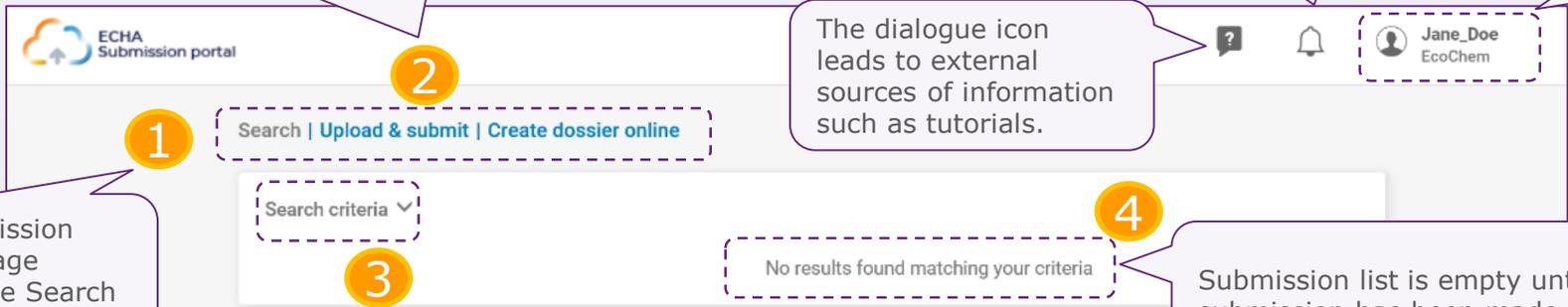
The user icon displays the name and legal entity of the user and, when clicked on, opens a new window for redirection to the ECHA Cloud dashboard, accounts management and the logout functionality.

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.



## ECHA Submission portal Search page

Click on the submission number to view the submission report.

Symbol for submission update

Symbol for initial submission

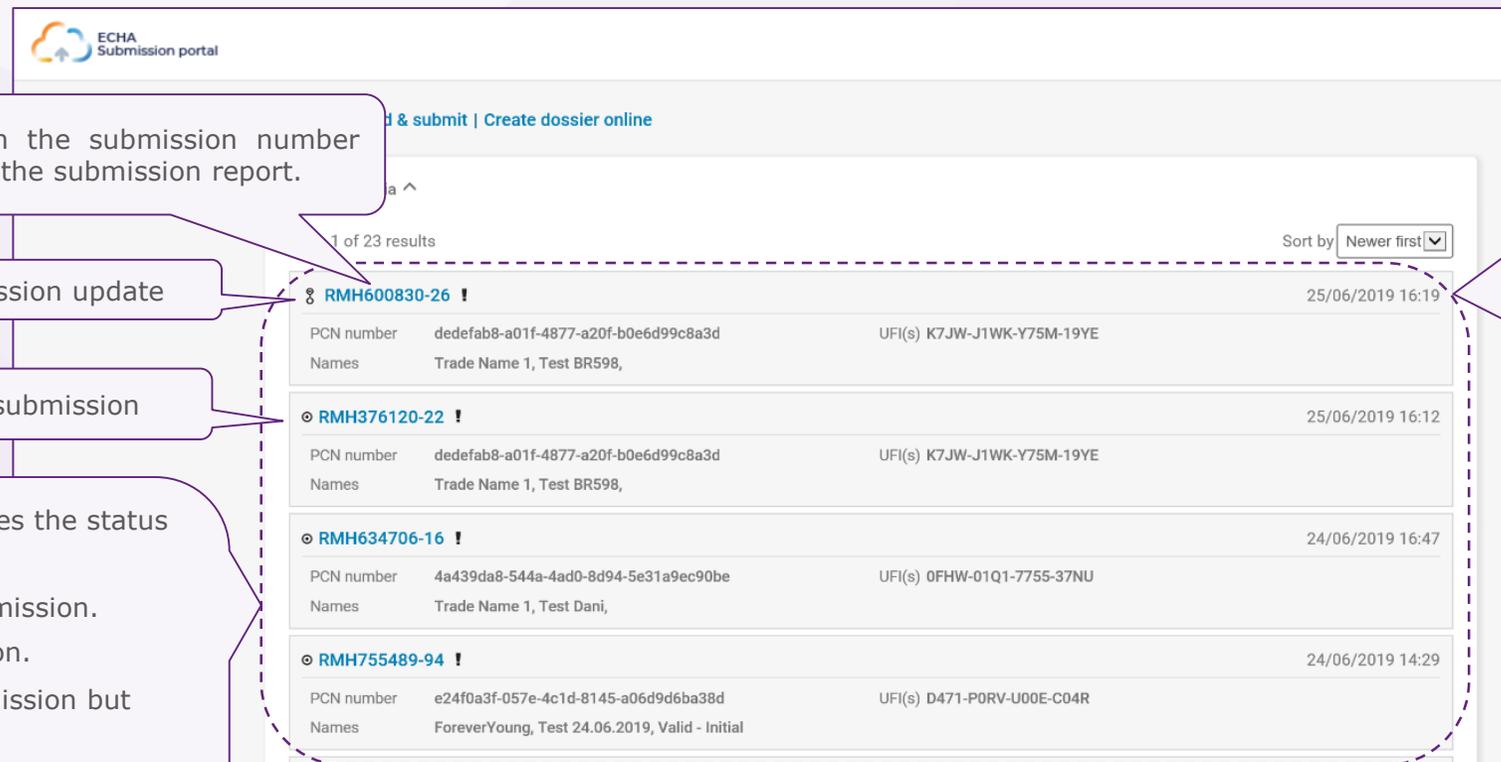
Each submission listed indicates the status of the submission:

✓ 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.



ECHA Submission portal

Log in & submit | Create dossier online

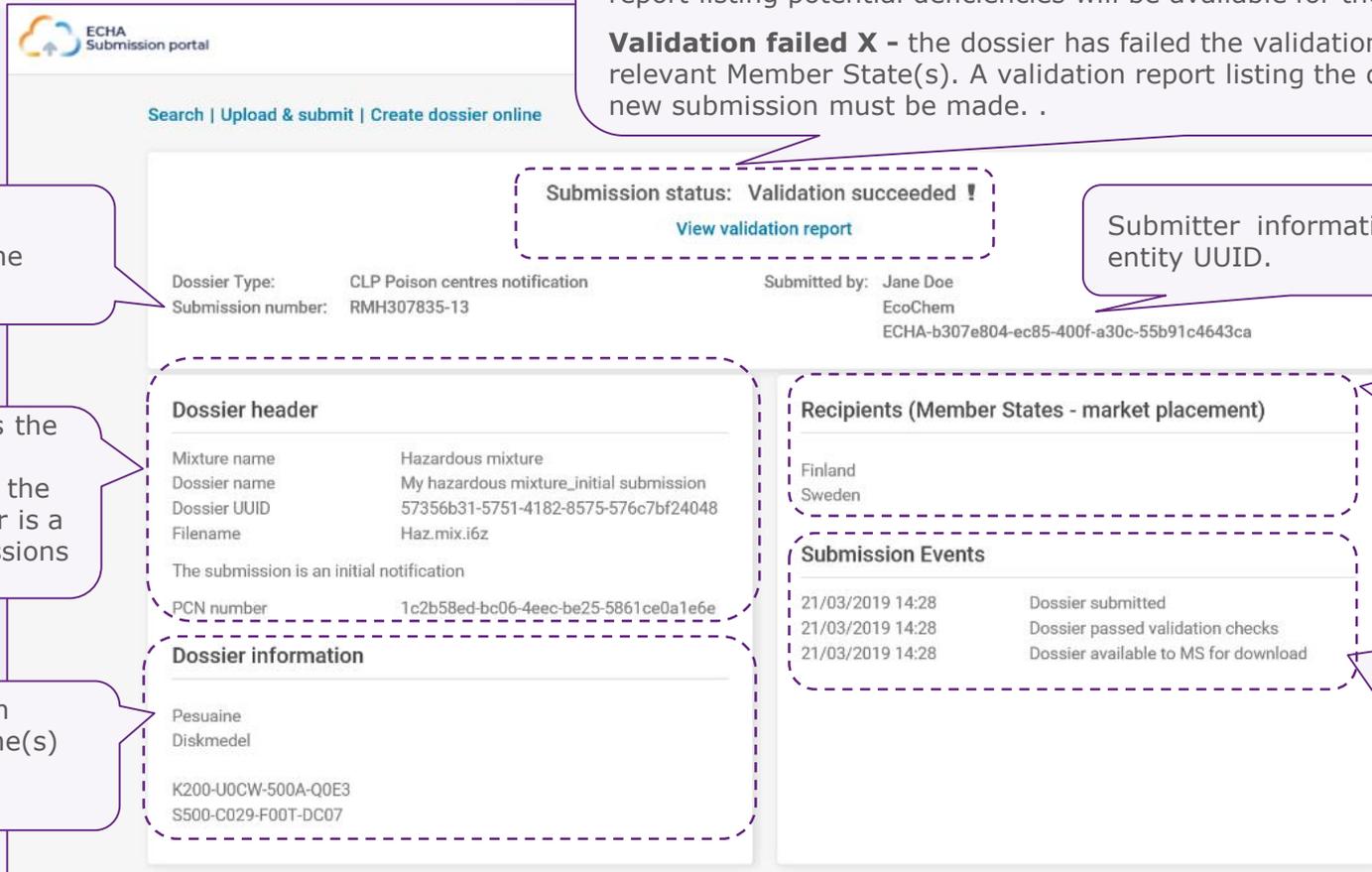
1 of 23 results

Sort by

✓ RMH600830-26 !	25/06/2019 16:19
PCN number dedefab8-a01f-4877-a20f-b0e6d99c8a3d	UFI(s) K7JW-J1WK-Y75M-19YE
Names Trade Name 1, Test BR598,	
⊙ RMH376120-22 !	25/06/2019 16:12
PCN number dedefab8-a01f-4877-a20f-b0e6d99c8a3d	UFI(s) K7JW-J1WK-Y75M-19YE
Names Trade Name 1, Test BR598,	
⊙ RMH634706-16 !	24/06/2019 16:47
PCN number 4a439da8-544a-4ad0-8d94-5e31a9ec90be	UFI(s) 0FHW-01Q1-7755-37NU
Names Trade Name 1, Test Dani,	
⊙ RMH755489-94 !	24/06/2019 14:29
PCN number e24f0a3f-057e-4c1d-8145-a06d9d6ba38d	UFI(s) D471-P0RV-U00E-C04R
Names ForeverYoung, Test 24.06.2019, Valid - Initial	

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.

# The submission report



**ECHA Submission portal**

Search | Upload & submit | Create dossier online

**Submission status: Validation succeeded !**  
[View validation report](#)

Dossier Type: CLP Poison centres notification  
 Submitted by: Jane Doe  
 Submission number: RMH307835-13  
 EcoChem  
 ECHA-b307e804-ec85-400f-a30c-55b91c4643ca

**Dossier header**

Mixture name	Hazardous mixture
Dossier name	My hazardous mixture_initial submission
Dossier UUID	57356b31-5751-4182-8575-576c7bf24048
Filename	Haz.mix.i6z

The submission is an initial notification

PCN number: 1c2b58ed-bc06-4eec-be25-5861ce0a1e6e

**Dossier information**

Pesuaine  
 Diskmedel

K200-U0CW-500A-Q0E3  
 S500-C029-F00T-DC07

**Recipients (Member States - market placement)**

Finland  
 Sweden

**Submission Events**

21/03/2019 14:28	Dossier submitted
21/03/2019 14:28	Dossier passed validation checks
21/03/2019 14:28	Dossier available to MS for download

**Validation succeeded** - the submission has passed the validation checks and the dossier has been dispatched and available to Member States for download.

**Validation succeeded !** - the submission has passed the validation checks with warnings. A validation report listing potential deficiencies will be available for the submitter and the receiving Member State.

**Validation failed X** - the dossier has failed the validation checks and has not been forwarded to the relevant Member State(s). A validation report listing the deficiencies is available for the submitter and a new submission must be made. .

The submission number is automatically assigned by the system.

Submitter information and legal entity UUID.

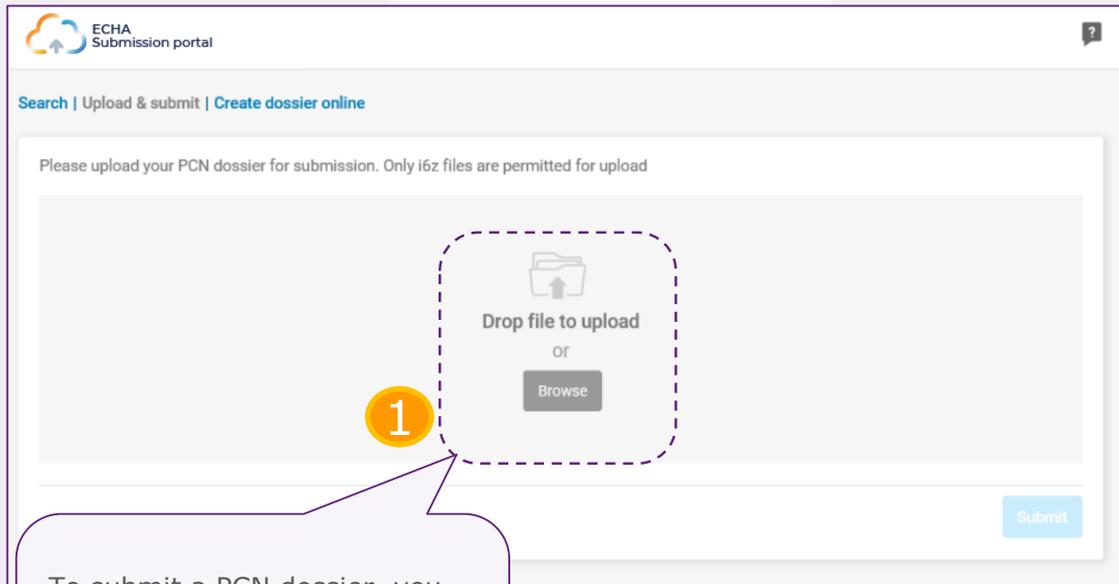
The dossier header describes the submission context and also displays the PCN number for the notification. The PCN number is a link displaying all the submissions related to that number.

The receiving Member States for the notification are listed here.

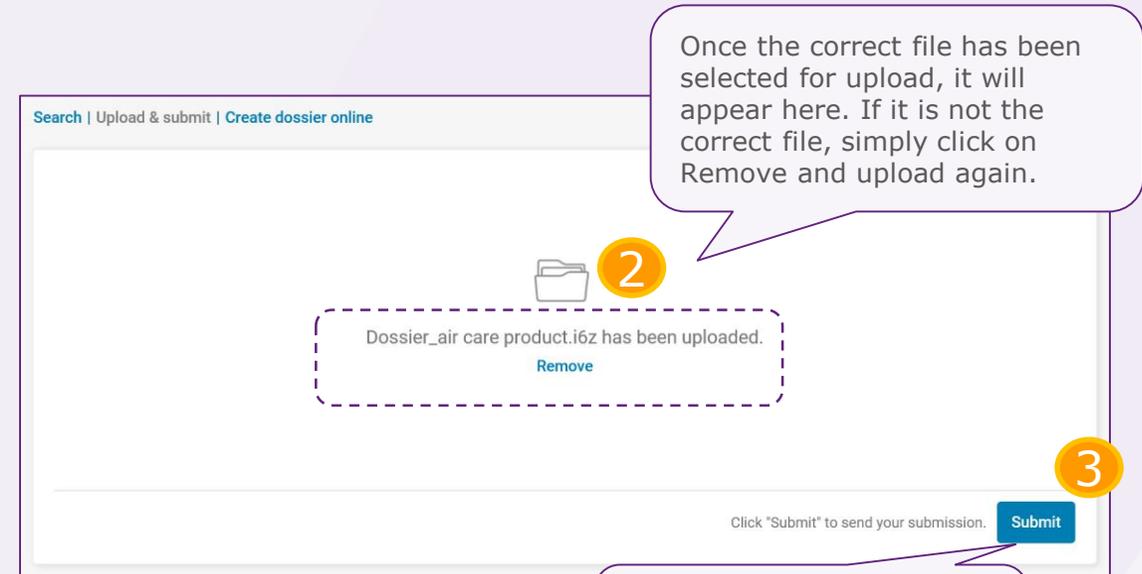
The dossier information contains the trade name(s) and the UFI(s) for the mixture.

The time stamped events in the submission process. The event when a dossier has been downloaded by the Member State will also be shown here.

# Upload and submit

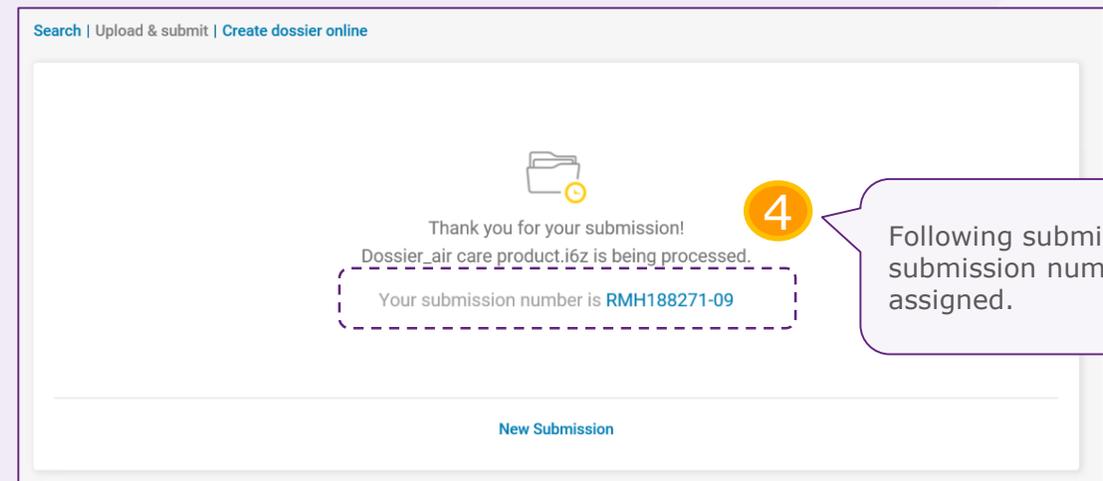


To submit a PCN dossier, you need to first upload it here by using either selecting the relevant file using the Browse or Drag and drop functionality.



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.

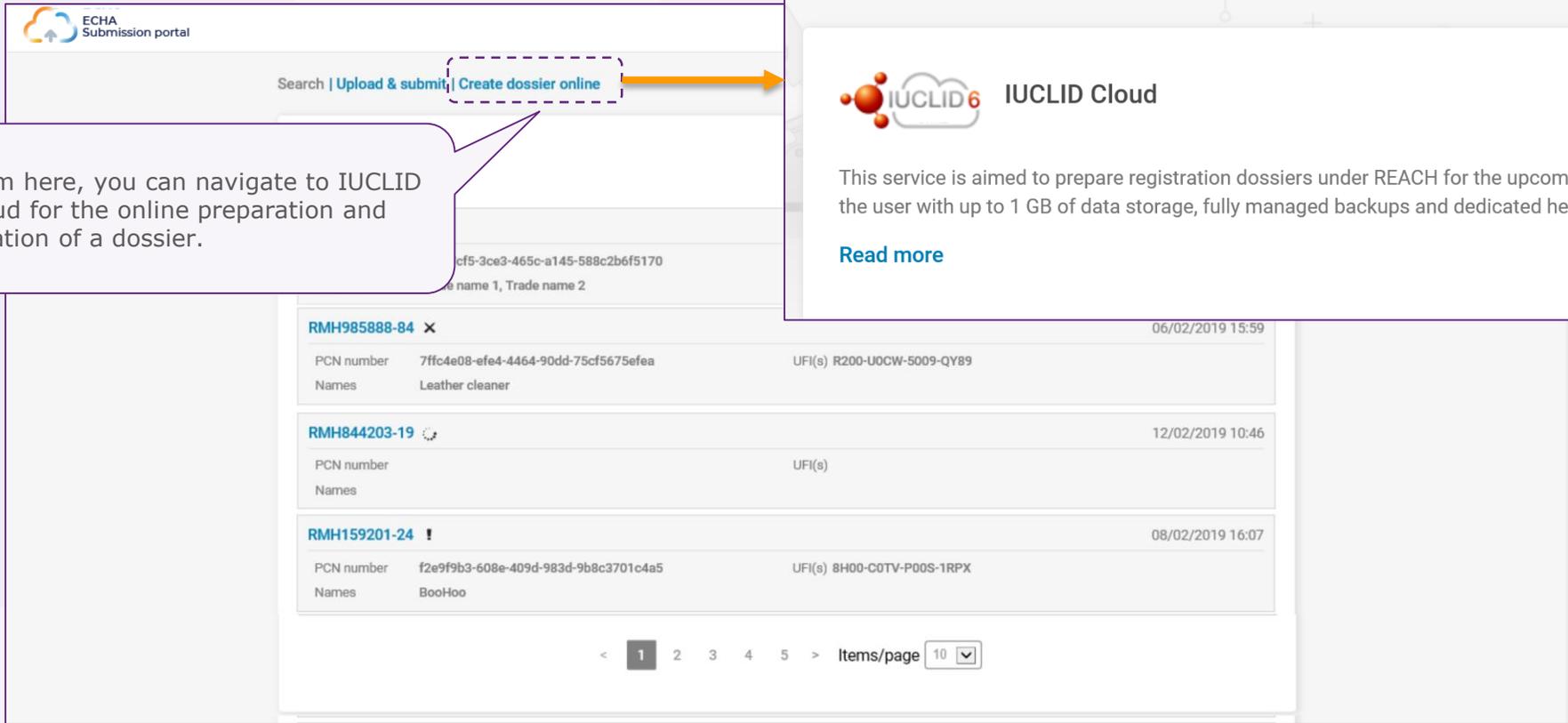
When everything is ready, Submit the dossier!



Following submission, a submission number is assigned.

# Create dossier online

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

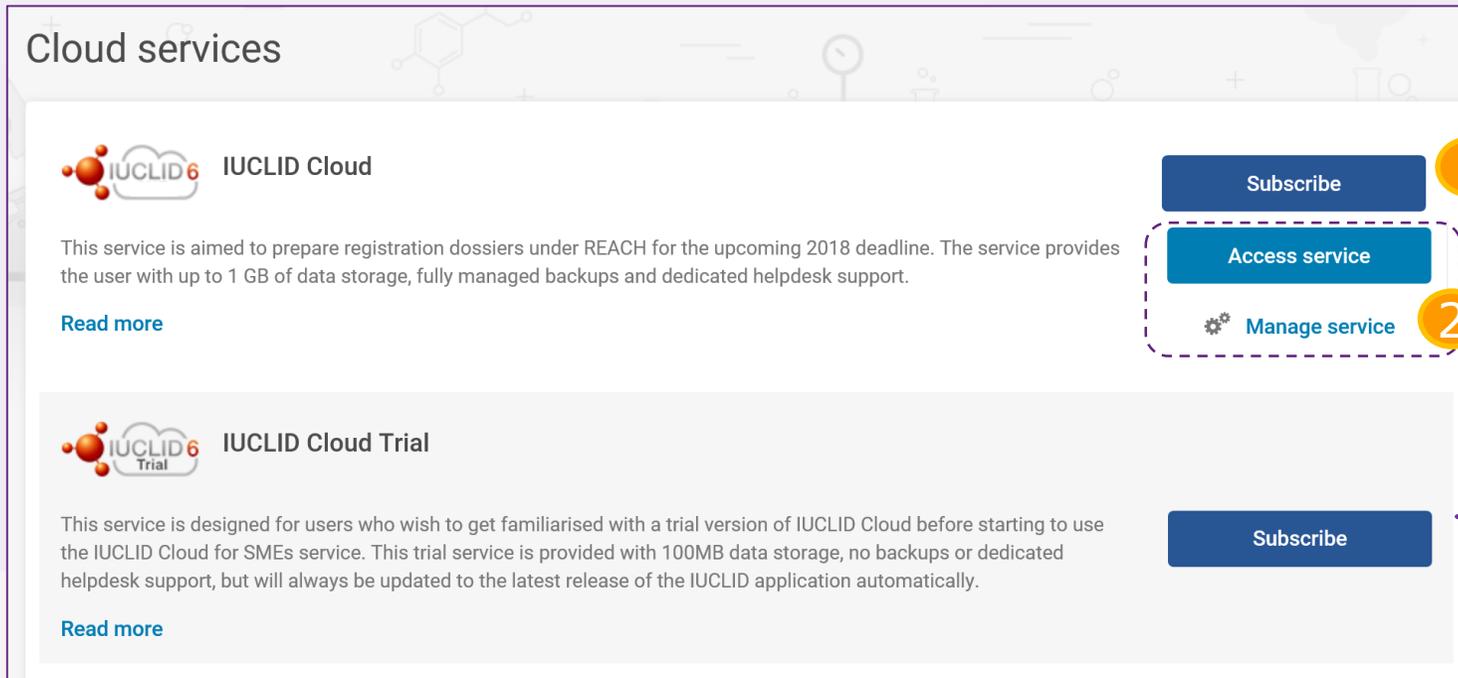


The screenshot shows the ECHA Submission portal interface. At the top, there are navigation links: Search | Upload & submit | **Create dossier online**. An orange arrow points from the 'Create dossier online' link to a callout box titled 'Cloud services'. This callout box highlights the 'IUCLID 6 IUCLID Cloud' service, which is described as a tool for preparing REACH registration dossiers for the 2018 deadline, offering up to 1 GB of storage and managed backups. Below the callout, a table lists existing dossiers with their PCN numbers, names, and UFI(s).

PCN number	Names	UFI(s)	Date
7ffc4e08-efe4-4464-90dd-75cf5675efea	Leather cleaner	R200-U0CW-5009-QY89	06/02/2019 15:59
f2e9f9b3-608e-409d-983d-9b8c3701c4a5	BooHoo	8H00-C0TV-P00S-1RPX	08/02/2019 16:07

## 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. Note that only legal entity managers have the rights to subscribe to a service, for other users, this functionality will not be visible.



The screenshot shows the 'Cloud services' section of the dashboard. It features two service cards. The first card is for 'IUCLID Cloud', which includes a 'Subscribe' button (marked with a yellow circle '1'), an 'Access service' button, and a 'Manage service' button (marked with a yellow circle '2'). The second card is for 'IUCLID Cloud Trial', which includes a 'Subscribe' button. Both cards provide a brief description of the service and a 'Read more' link.

**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](#)

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

Once subscribed, you can access and manage the service.

! Please note that while the Trial service allows you to get familiar with the tool, any submissions made within will be delivered to the Member State selected.



# 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.

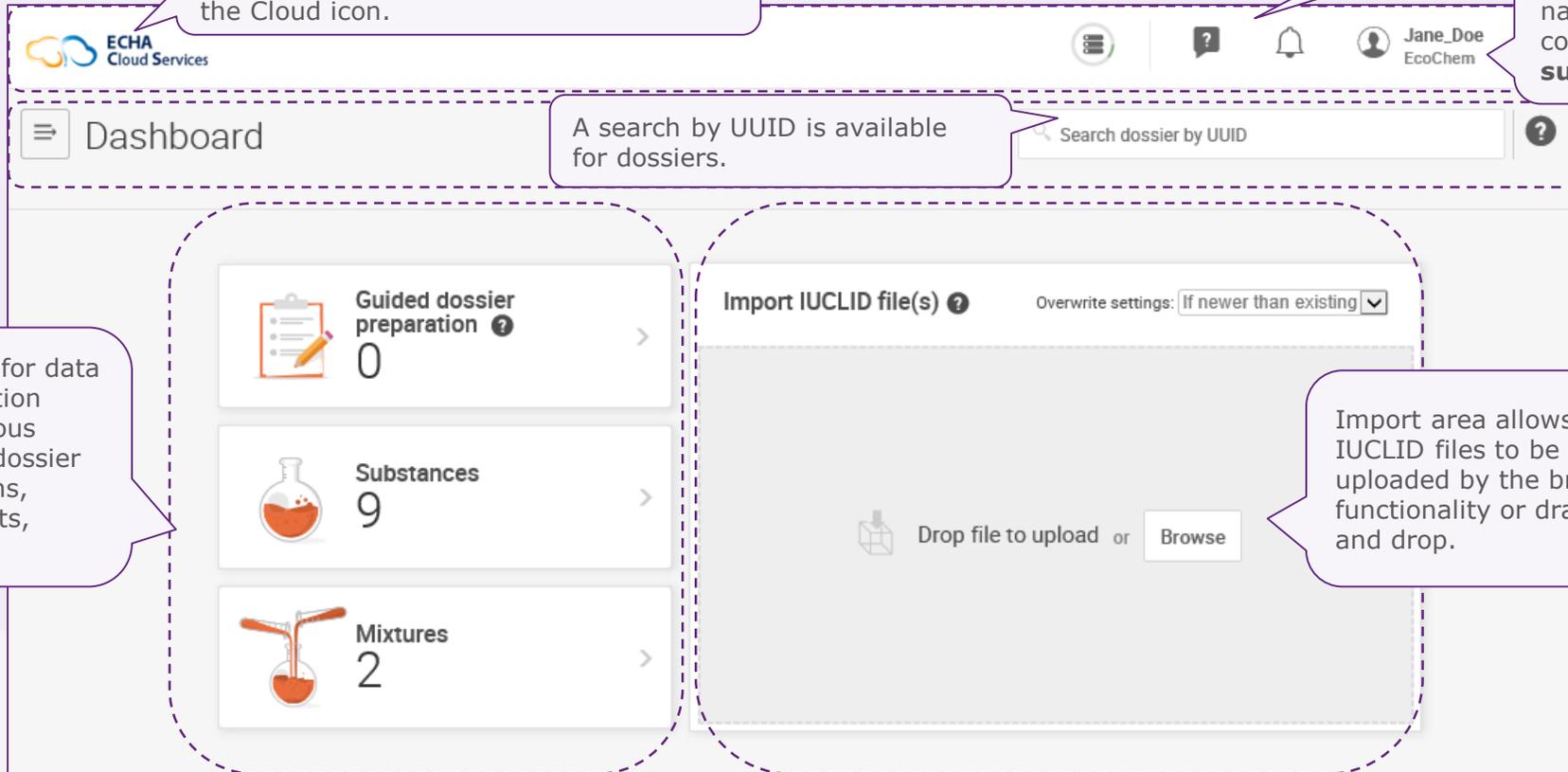
The top bar always contains the same options throughout the guided dossier preparation.

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.

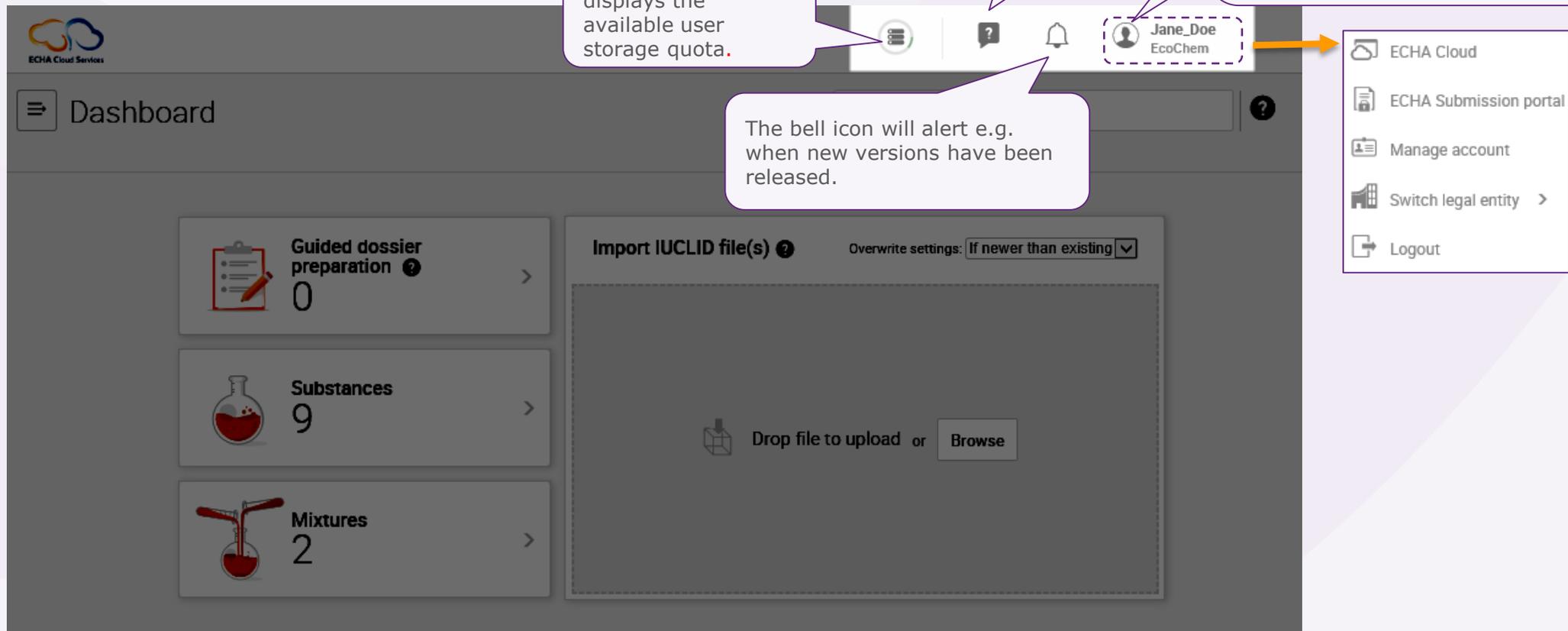
This area is used for data entry and navigation between the various IUCLID entities; dossier under preparations, substance datasets, mixture datasets.

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.

Dashboard

Guided dossier preparation 0

Substances 9

Mixtures 2

Import IUCLID file(s) ? Overwrite settings: If newer than existing

Drop file to upload or Browse

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



## 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
					<b>PCN</b>

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	
					<b>REACH</b>

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 submission context for a 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.

### Guided dossier preparation for your Poison Centres Notification

- 1 Specify your mixture
- 2 Dossier information

#### Specify the mixture name of your Poison Centres Notification

✖ Please specify your mixture. 1

Select an existing mixture

+ Select

OR

Create a new mixture

↑

0/2000

#### Specify the dossier name of your Poison Centres Notification

2

↑

0/255

Specify your mixture by either selecting from your inventory of existing mixtures e.g. this is possible in the case for update notifications, or notifications following a significant change in composition.

Or, enter a name for your mixture to encode a new one.

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*

## 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>

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

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.

Flag the **submission type** if alternatives to the standard information requirements are being notified.

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)\*

Country (market placement) field is mandatory.

Language\*

Language field is mandatory.

**Submission type**

Limited submission (industrial use only)

Voluntary submission

**Notification type**

Initial notification

New notification after a significant change of composition

The submission is an update

**Reason for updating**

Justification + New item

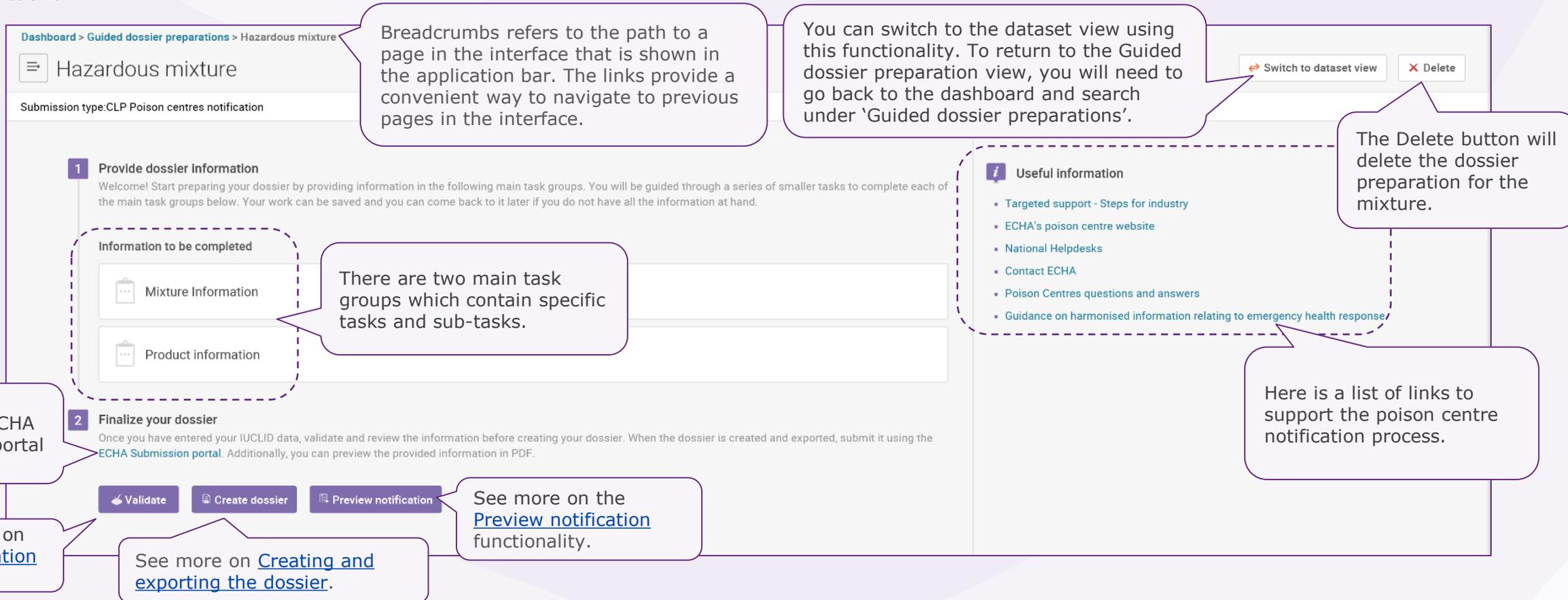
Generate and assign a **PCN number** to the initial notification by clicking on the circular arrows. This number will be used by poison centres to track all related notification updates.

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

Verify the **submission type**.

## 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.

You can switch to the dataset view using this functionality. To return to the Guided dossier preparation view, you will need to go back to the dashboard and search under 'Guided dossier preparations'.

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

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

Link to the ECHA Submission portal

See more on [The validation assistant](#).

See more on [Creating and exporting the dossier](#).

See more on the [Preview notification](#) functionality.

**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](#)

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

Dashboard > Guided dossier preparations > Hazardous mixture

Hazardous mixture

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

**2 Finalize your dossier**  
Once you have entered your IUCLID data, validate and review the information before creating your dossier. When the dossier is created and exported, submit it using the [ECHA Submission portal](#). Additionally, you can preview the provided information in PDF.

Validate Create dossier Preview notification

Switch to dataset view Delete



## 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
- Other support for UFI

Help and support text will be available and updated regularly.

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



# 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) 2

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**

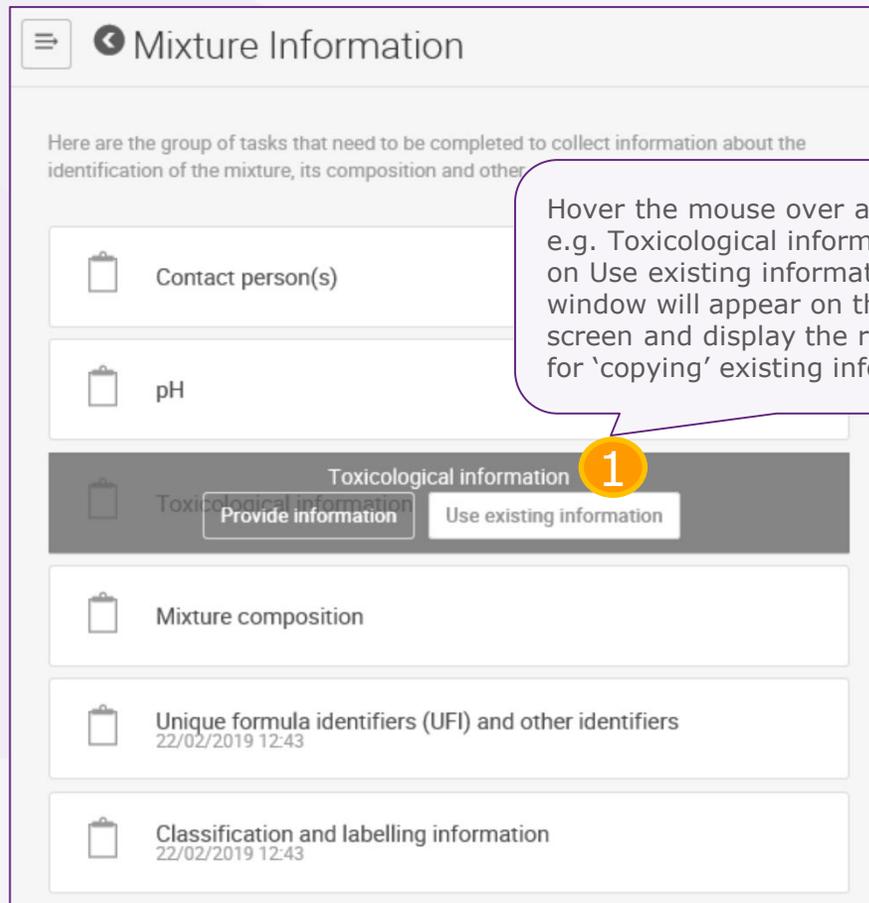
Record + Record

Toxicological Information(only) X

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



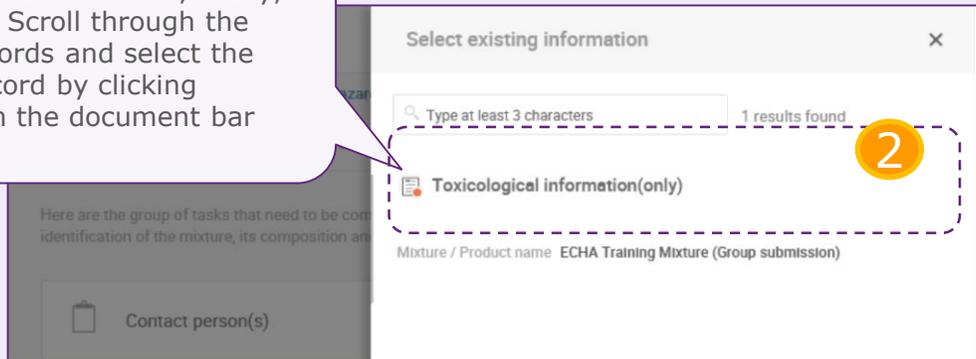
**Mixture Information**

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.

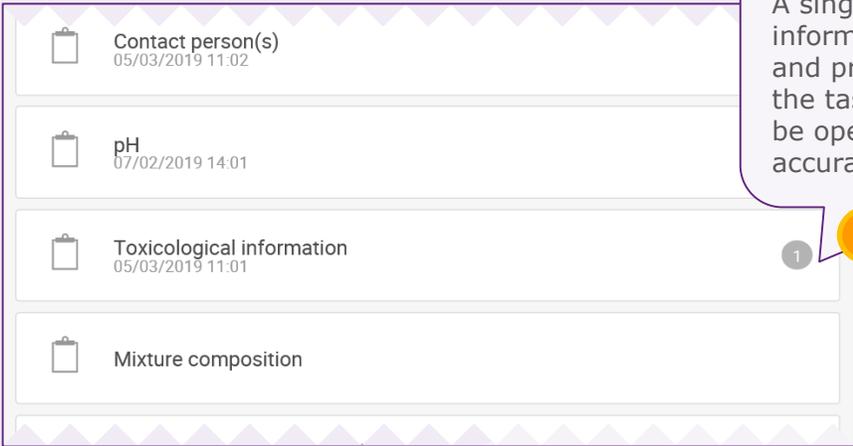


Select existing information

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** 1  
05/03/2019 11:01 3
- Mixture composition

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



## Dossier preparation: 'Mixture information'

An overview of how to use IUCLID to complete the tasks in the Mixture information section for the preparation of a PCN dossier. Full details on the information requirements can be found from the *Guidance on harmonised information relating to emergency health response* at:

<https://poisoncentres.echa.europa.eu/guidance>

## Mixture information task page

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

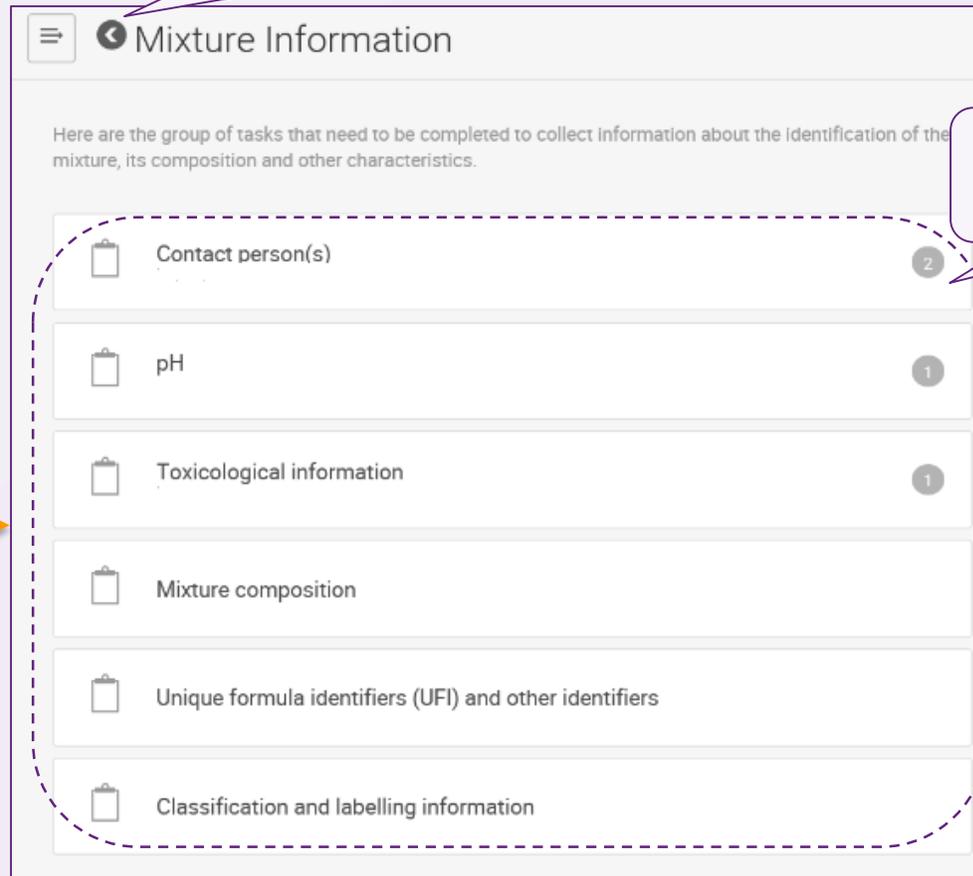
The back button is useful to navigate back from sub-tasks and tasks.

The number here indicates how many records have been created.

### 1 Information to be completed

Mixture Information

Product 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 characteristics.

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

If the Contact type picklist does not contain the correct type of contact you wish to specify, you can select 'Other' and enter the information in the free text field.

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)	Provide Information	Use existing information
PH 05/02/2019 14:01	1	1
Toxicological information 05/02/2019 14:02	1	1
Mixture composition 05/02/2019 14:02	6	1
Unique formula Identifiers (UFI) and other Identifiers 05/02/2019 13:59	1	1
Classification and labelling information 05/02/2019 14:04		

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

Title: Mr

First name: John

Last name\*: Howard

Organisation\*: EcoChem ACT.

Phone: e.g. +358 09 123456789

Email: name@domain.com

Country: Finland

Finish

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.

2

**Contact type**

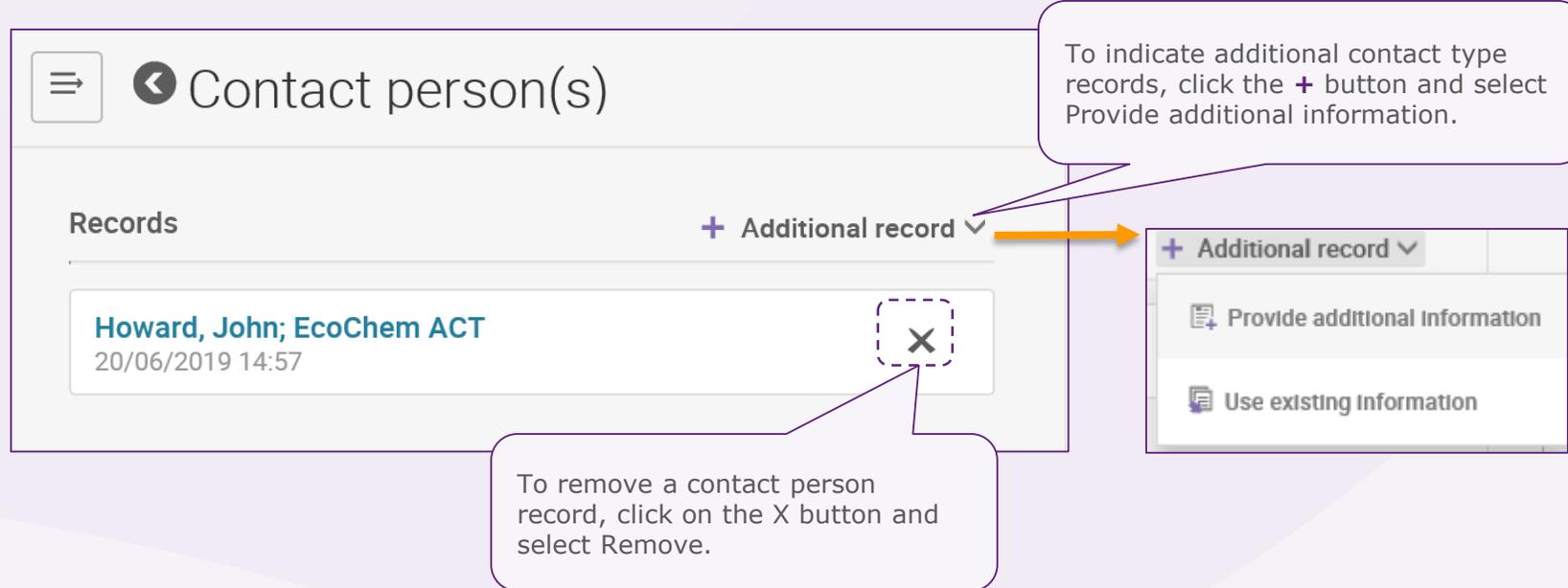
Please select

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

4 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. At the top, there is a back arrow and a hamburger menu icon. Below this is the title 'Contact person(s)'. Underneath, there is a 'Records' section with a '+ Additional record' button and 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.' Below the records section, there is a record for 'Howard, John; EcoChem ACT' with a timestamp '20/06/2019 14:57'. A dashed box highlights an 'X' button on the right side of this record. A callout box points to this 'X' button, stating: 'To remove a contact person record, click on the X button and select Remove.' To the right of the main interface, a dropdown menu is shown, containing 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 (%)

2 100

4 Finish

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.

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

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

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

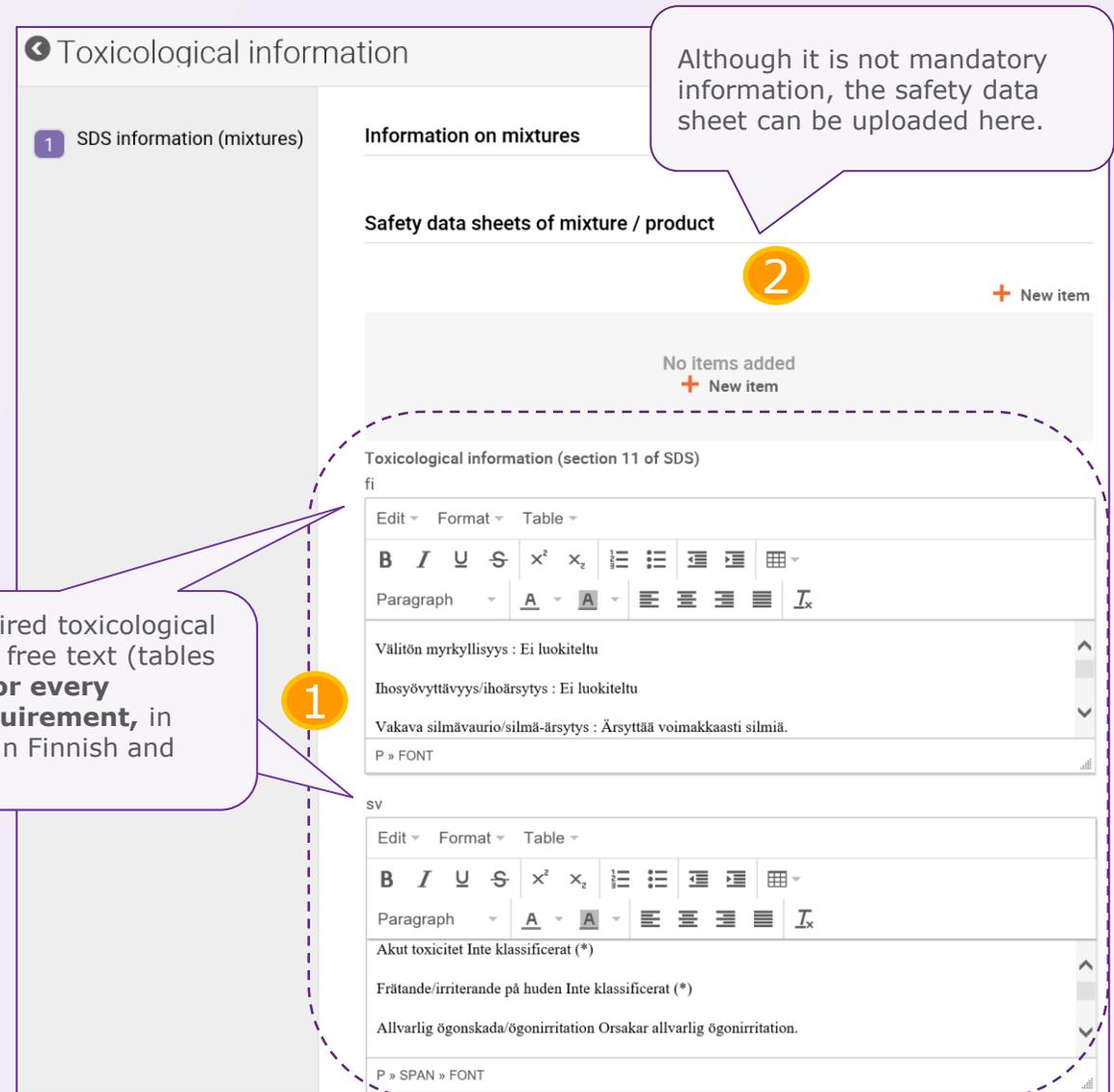
## The 'Toxicological information' task

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 area for 'Information on mixtures' and 'Safety data sheets of mixture / product', and a text editor for 'Toxicological information (section 11 of SDS)'. The text editor shows content in Finnish (fi) and Swedish (sv).

**1** Enter the required toxicological information as free text (tables are allowed) **for every language requirement**, in this example, in Finnish and Swedish.

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

**fi**

Välitön myrkyllisyys : Ei luokiteltu

Ihosityövyttävyyys/ihoärsytys : Ei luokiteltu

Vakava silmävaurio/silmä-ärsytys : Ärsyttää voimakkaasti silmiä.

P » FONT

**sv**

Akut toxicitet Inte klassificerat (\*)

Frätande/irriterande på huden Inte klassificerat (\*)

Allvarlig ögonskada/ögonirritation Orsakar allvarlig ögonirritation.

P » SPAN » FONT

## 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, other mixtures (referred to as mixture in mixtures or **MiMs**) or generic product identifiers (**GPIs**).

☰
◀
Mixture composition

**Mixture components** +Mixture component

---

No components have been added yet.

**Substance components** +Substance component

---

No components have been added yet.

**Generic Product Identifier components** +Generic Product Identifier component

---

No components have been added yet.

☰
◀
Mixture Information

☰ Mixture in Mixture information

---

☰ Classification and Labelling information

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

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

---

☰ 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](#).

☰ Function and concentration

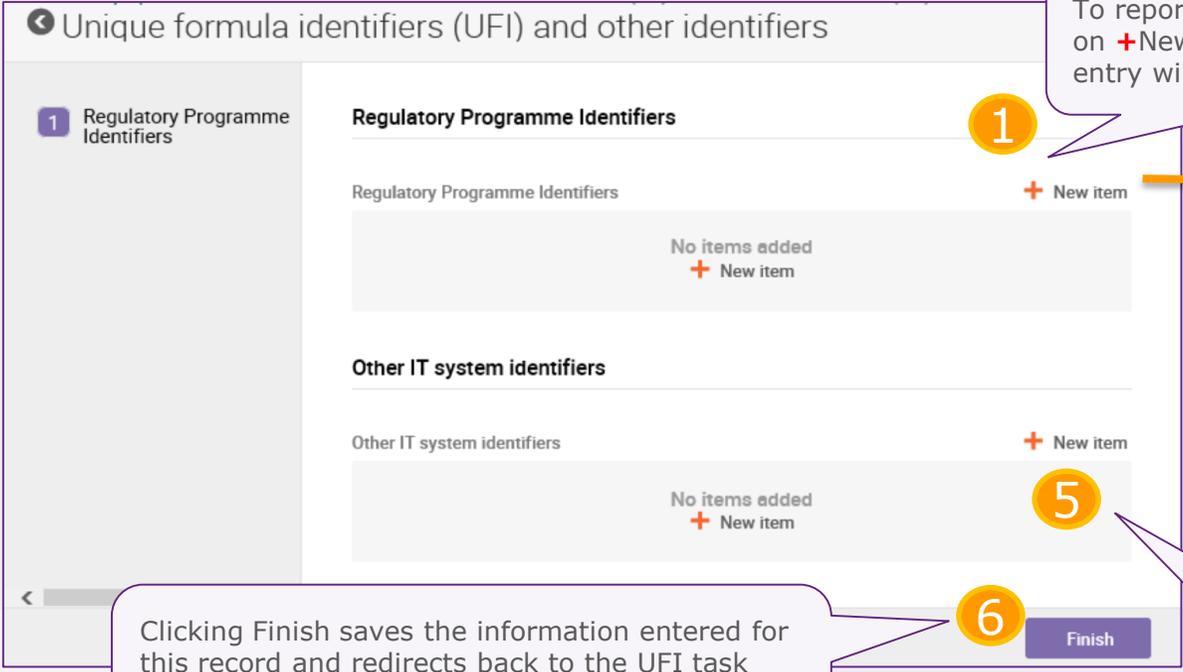
---

☰ Classification and labelling information of the substance

The sub-tasks for GPI components are further explained - see [GPI 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** Select CLP Unique Formula Identifier (UFI).

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

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

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

**6** 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.

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

Regulatory Programme Identifiers

Other IT system identifiers

CLP related PCN number

CLP unique formula identifier (UFI)

Id

Close

Finish



## 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.

In this example, multiple records exist; each record consists of one UFI item. When additional records are created, they are listed together here 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	×

In this example, multiple UFI items exist in a single record; When additional items are created, they are listed together from within the record.

Unique formula identifiers (UFI) and other identifiers

**1** Regulatory Programme Identifiers

Regulatory Programme Identifiers **b**

Regulatory Programme Identifiers + New item

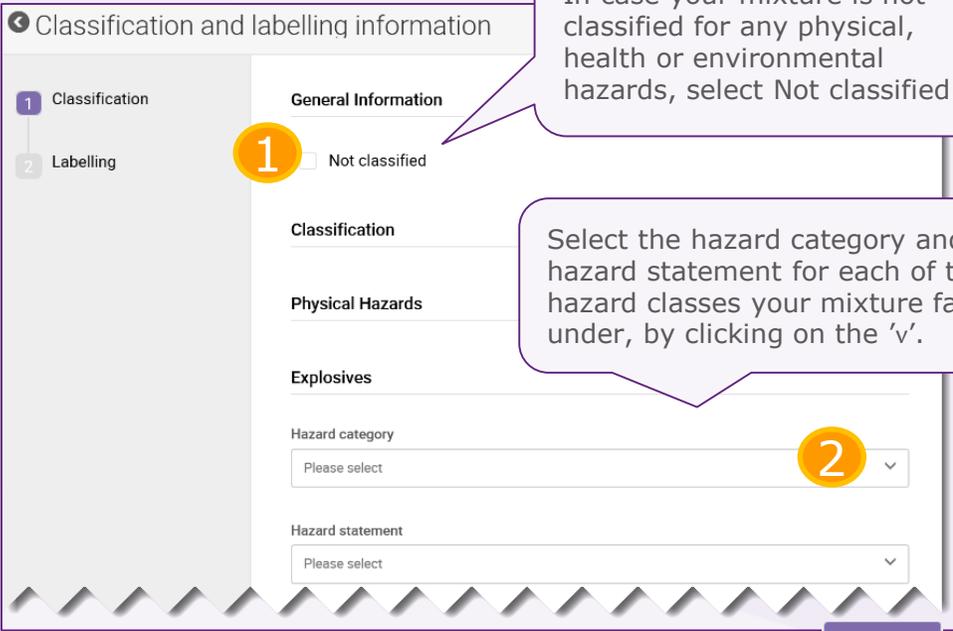
CLP unique formula identifier (UFI)	✎	×
CLP unique formula identifier (UFI)	✎	×
CLP unique formula identifier (UFI)	✎	×

# 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.

**!** Note that **multilingual text** may be required for this section.



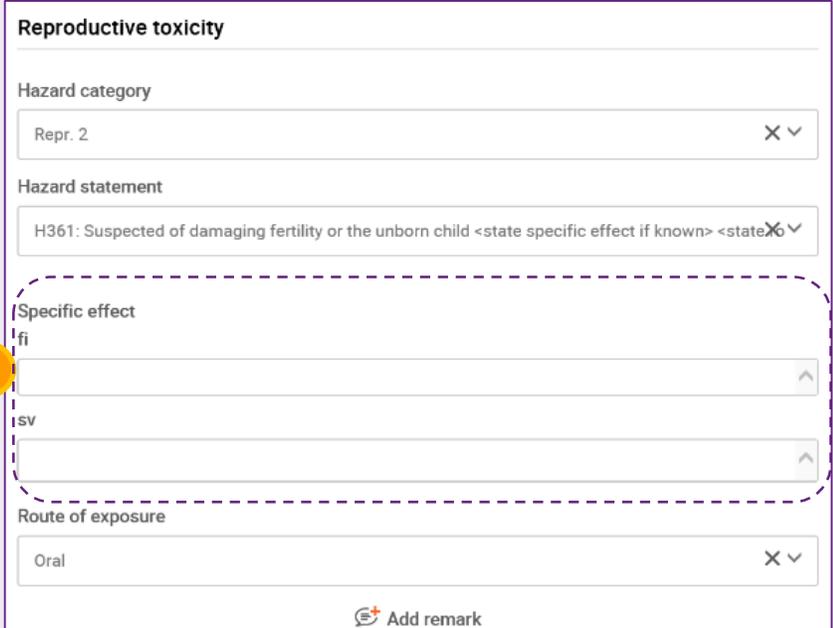
In case your mixture is not classified for any physical, health or environmental hazards, select Not classified.

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.**

**1** **Classify your mixture** by providing:

- Hazard category
- Hazard statements
- Any relevant additional information



**Reproductive toxicity**

Hazard category  
Repr. 2

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

Specific effect  
fi  
sv

Route of exposure  
Oral

Add remark

## The 'Classification and labelling' task - step 2

! Note that **multilingual text** may be required for this section.

### 2 Labelling of your mixture:

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

Classification and labelling information

1 Classification

2 Labelling

Signal word

Warning

Hazard pictogram

1

+ New item

GHS07: exclamation mark

Hazard statements

2

H319: Causes serious eye irritation.

Precautionary statements

3

+ New item

P264: Wash ... thoroughly after handling.

Additional labelling requirements

+ New item

Finish

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.

Some hazard and precautionary statements may require additional text. In such cases, all free text fields must contain **information in all relevant languages**.

P264: Wash ... thoroughly after handling.

Precautionary statement

P264: Wash ... thoroughly after handling.

Additional text

fi

kädet

sv

hander

Close



# Reporting mixture (in mixture) components

An overview of how to use IUCLID to complete the sub-tasks for mixture (in mixture) components. Full details on the information requirements can be found from the *Guidance on harmonised information relating to emergency health response* at:

<https://poisoncentres.echa.europa.eu/guidance>



# 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** +Mixture component

No components have been added yet.

**Substance components** +Substance component

No components have been added yet.

**Generic Product Identifier components** +Product Identifier component

No components have been added yet.

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.

Provide mixture in mixture (MiM) information ×

When the composition of a mixture in mixture is fully known, the substance components should be included in the mixture composition of the final mixture.

Please check the available guidance for more information on how to report mixture in mixtures in cases when the full composition of the mixture in mixture is not known

**Specify your MiM component**

2 ✖ Please specify your MiM component.

Select an existing mixture

+ Select

OR

Provide a mixture name

? Continue

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.

☰ Mixture Information 3

Mixture in Mixture information

Classification and Labelling information

Once the mixture component (MiM) has been specified with a name, a number of sub-tasks will be displayed.



# Sub-task 'Mixture in mixture information'

**Mixture in Mixture information**

1 Mixture in mixture information

**Mixture-in-mixture p**

Name\* 1

This is the name of the MiM as provided in the previous step. It is editable.

**Function and concentration**

Function 2

Function is not mandatory information but may be added if preferred.

**Typical concentration**

**Concentration range**

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.

**Mixture-in-mixture composition**

**Components** + New item

Click on +New item to list the substance components of the MiM. Each substance required you to enter the concentration (%(w/w) or %(v/v)) and link to a reference substance. To link to a reference substance, click on +Select in the sliding wondow, and either select a reference substance from the list or create one and provide the relevant information – see [Substance components](#) for more details.

**Unique formula identifier (UFI)** 5 + New item

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

**6 Supplier**

Manufacturer / Importer / Formulator

+ Select

Click on +Select and either make a selection from the list of available suppliers i.e. legal entities, or, if the details are not listed, select +Create and fill in relevant details for the MiM supplier.

**7 Safety data sheets** + New item

Click on +New item to begin the process. A sliding window will open – upload the relevant file and select the relevant country and language. Note that multiple SDSs i.e. items, can be added.

- colourant
- complexing agent
- conditioner
- controlled release agent
- crystal growth regulator
- dehydrating agent

## Sub-task 'Classification of the mixture in mixture'

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

! Note that **multilingual text** may be required for this section.

Classification and labelling information of the mixture-in-mixture

1 Classification

2 Labelling

**General Information**

Not classified

**Classification**

**Physical Hazards**

**Explosives**

**Hazard category**

Please select

**Hazard statement**

Please select

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

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.**

2 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'.

**Specific target organ toxicity - single**

**Hazard category**

STOT Single Exp. 3

**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

3



# Reporting substance components

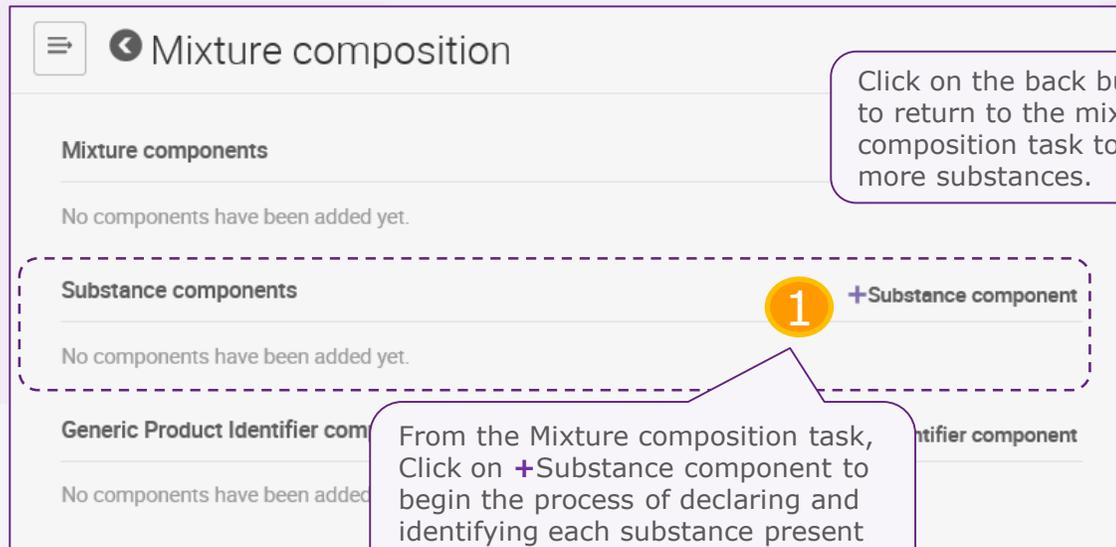
An overview of how to use IUCLID to complete the sub-tasks for substance components. Full details on the information requirements can be found from the *Guidance on harmonised information relating to emergency health response* at:

<https://poisoncentres.echa.europa.eu/guidance>

# Substance components

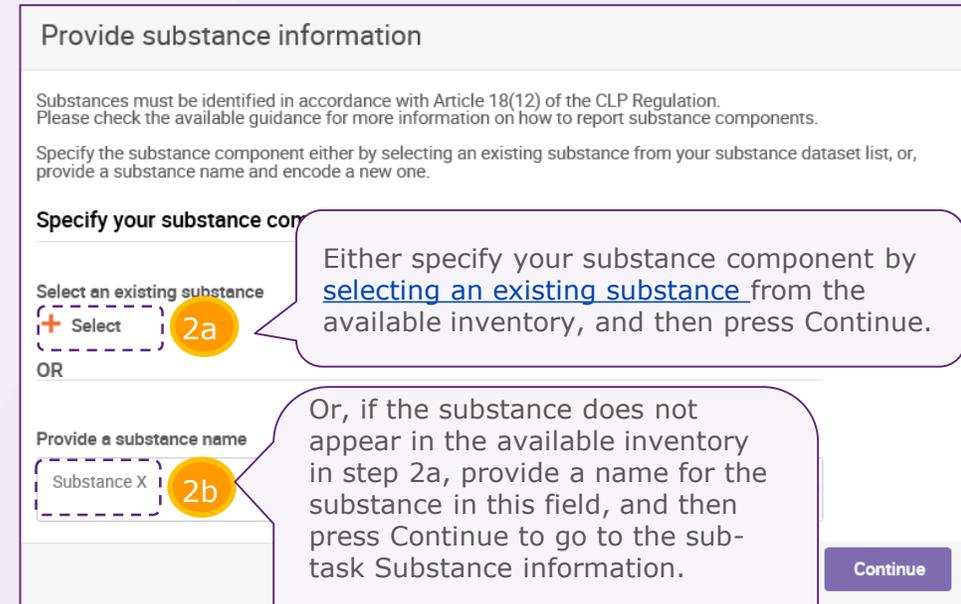
A substance component requires a record that contains information about function and concentration, its identity and its classification. Each substance component is linked to a **Reference Substance**.

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.



**Provide substance information**

Substances must be identified in accordance with Article 18(12) of the CLP Regulation. Please check the available guidance for more information on how to report substance components.

Specify the substance component either by selecting an existing substance from your substance dataset list, or, provide a substance name and encode a new one.

**Specify your substance component**

2a Select an existing substance  
+ Select

OR

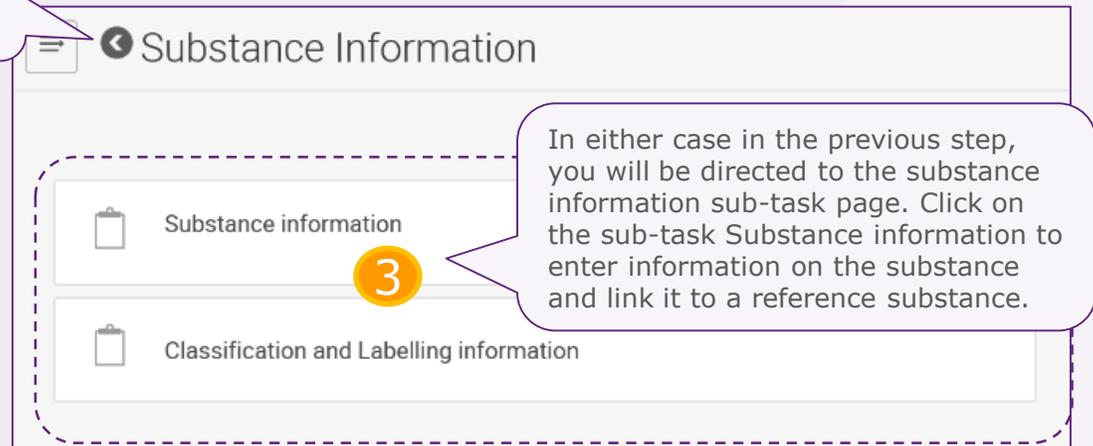
2b Provide a substance name  
Substance X

Continue

Either specify your substance component by [selecting an existing substance](#) from the available inventory, and then press Continue.

Or, if the substance does not appear in the available inventory in step 2a, provide a name for the substance in this field, and then press Continue to go to the sub-task Substance information.

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



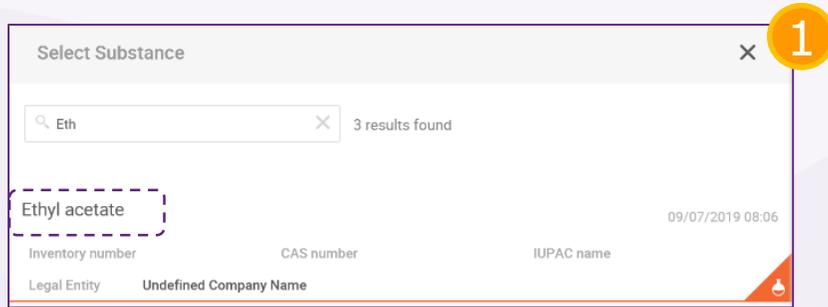
**Substance Information**

3 Substance information

Classification and Labelling information

In either case in the previous step, you will be directed to the substance information sub-task page. Click on the sub-task Substance information to enter information on the substance and link it to a reference substance.

## Selecting an existing substance



1

Select Substance

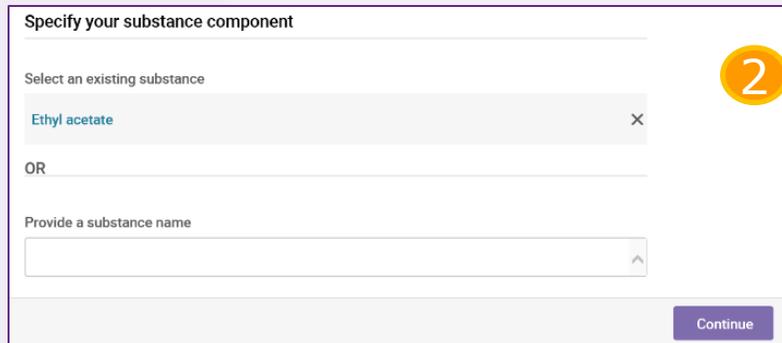
Eth 3 results found

Ethyl acetate 09/07/2019 08:06

Inventory number CAS number IUPAC name

Legal Entity Undefined Company Name

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 component

Select an existing substance

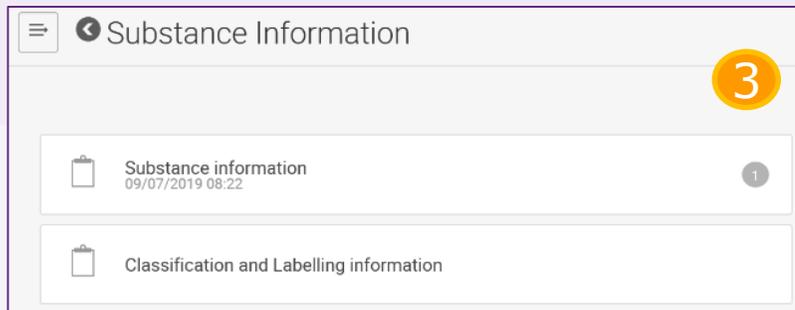
Ethyl acetate

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 sub-tasks.



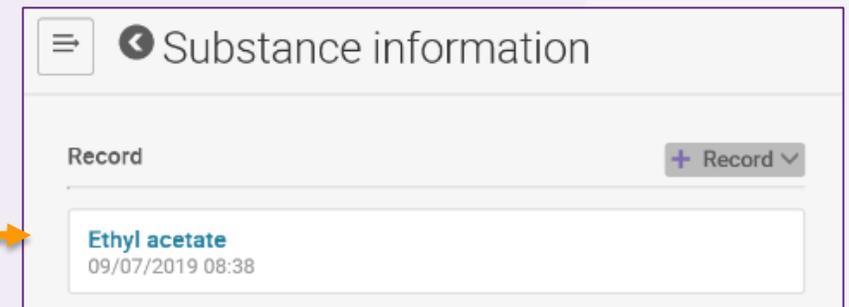
3

Substance Information

Substance information 09/07/2019 08:22

Classification and Labelling information

The sub-tasks for the substance are now displayed. Click on Substance information and open the substance record by clicking on it's name, in this example, Ethyl acetate.



Substance information

Record + Record

Ethyl acetate 09/07/2019 08:38

## Sub-task 'Substance information' for the substance

Whether you select an existing substance or provide a name for a new one, you will need to enter the information for the substance.

← Substance information

**1** Substance information

**Substance name**

Name\*

Ethyl acetate

**Function and concentration**

Function

Please select

Typical concentration

▼
▼

Concentration range

▼
▼
▼

**Substance identification**

Reference substance

+ Select

Finish

This is the name you provided or selected in an earlier step – it is possible to edit it.

Function can be optionally selected from the picklist.

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.

Click on + Select to [establish a link to the reference substance.](#)

# Establishing a link to a reference substance

Reference substance Edit

**General information**

Reference substance name  
ethyl acetate

**Inventory**

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

**Reference substance information**

IUPAC name  
ethyl acetate  
CAS number  
141-78-6  
CAS name  
None  
Synonyms

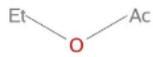
1 Identifier  
None  
Identity  
Acetic acid ethyl ester

2 Identifier  
None  
Identity  
Acetic acid ethyl ester

3 Identifier  
None  
Identity  
Acetic acid ethyl ester

**Molecular and structural information**

Molecular formula  
C<sub>4</sub>H<sub>8</sub>O<sub>2</sub>  
Molecular weight  
88.105  
SMILES notation  
CCOC(=O)C  
InChI  
InChI=1/C4H8O2/c1-3-4-2/[2]/NH2L1-2H3  
Structural formula



Select Reference substance

Type at least 3 characters

1 ethyl acetate

CAS number 141-78-6  
Inventory number 205-500-4

2 + Create X

09/07/2019 08:05

IUPAC name ethyl acetate

20/06/2019 08:21

IUPAC name

Inventory number 205-500-4

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.

By selecting +Create, an empty document will open in which information about the substance identity can be entered.

By selecting an existing reference substance, the substance identifiers, molecular and structural information will be prefilled.

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

New Reference substance

**General information**

Reference substance name\*

Reference substance name field is mandatory.

**Inventory**

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

**Reference substance information**

IUPAC name  
CAS number  
CAS name  
Synonyms

**Molecular and structural information**

formula  
weight  
SMILES notation  
InChI  
Structural formula  
Select file  
Remarks

Save

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

## 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.

! Note that **multilingual text** may be required for this section.

Classification and labelling information of the substance

1 Classification

2 Labelling

**General Information**

Not classified **1**

**Classification**

**Physical Hazards**

**Explosives**

**Hazard category**

Please select **2**

**Hazard statement**

Please select

In case the substance 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.**

Specific target organ toxicity - single

**Hazard category**

STOT Single Exp. 2 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

Close



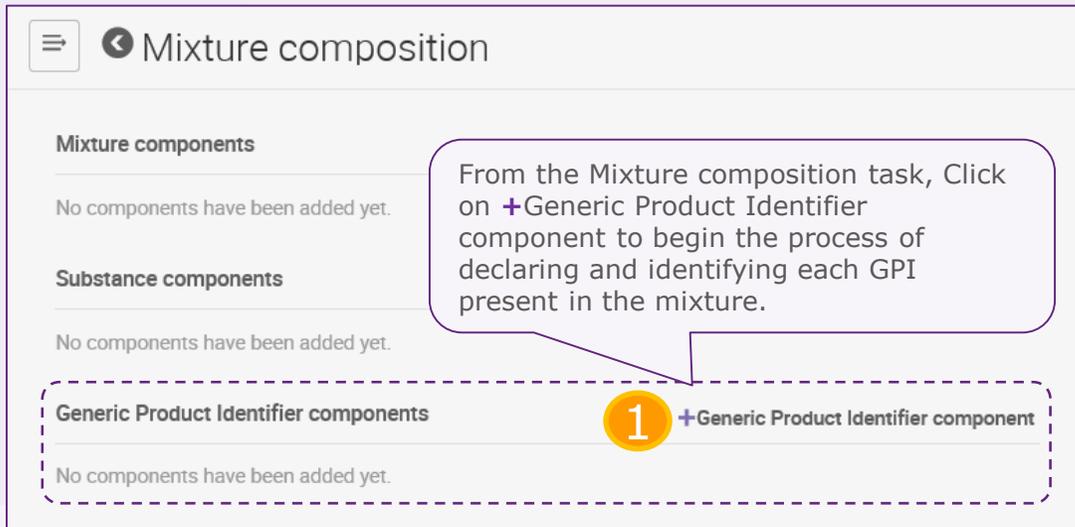
# Reporting generic product identifier components

An overview of how to use IUCLID to complete the sub-tasks for generic product identifier (GPI) components. Full details on the information requirements can be found from the *Guidance on harmonised information relating to emergency health response* at:

<https://poisoncentres.echa.europa.eu/guidance>

## Generic product identifier components

The generic product identifiers include only those components (either substances or MiMs) used exclusively to add **perfume, fragrance or colour**, only if they are **not classified for any health hazard**, and the concentration of a given GPI does not exceed in total 5% for the sum of perfumes or fragrances and 25% for the sum of colouring agents.



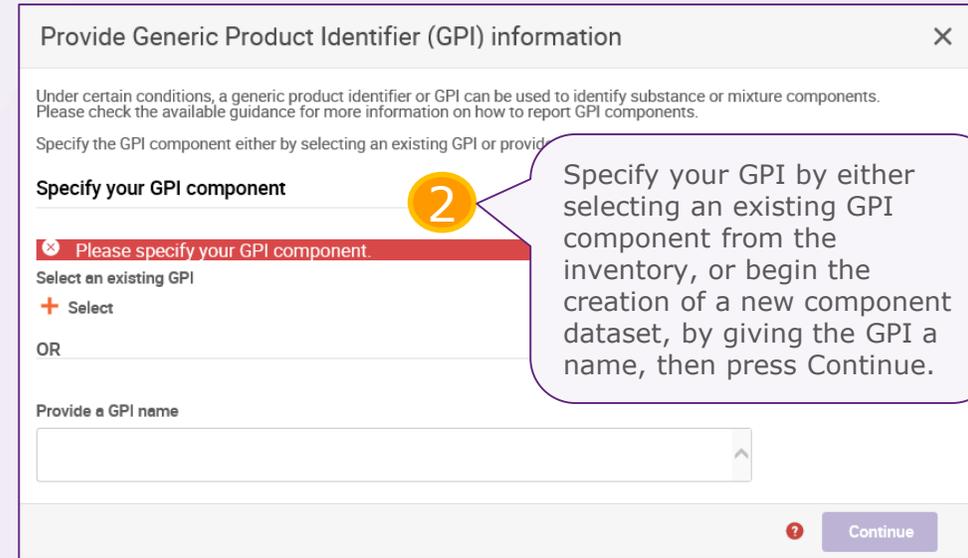
**Mixture composition**

**Mixture components**  
No components have been added yet.

**Substance components**  
No components have been added yet.

**Generic Product Identifier components** 1 +Generic Product Identifier component  
No components have been added yet.

From the Mixture composition task, Click on +Generic Product Identifier component to begin the process of declaring and identifying each GPI present in the mixture.



**Provide Generic Product Identifier (GPI) information**

Under certain conditions, a generic product identifier or GPI can be used to identify substance or mixture components. Please check the available guidance for more information on how to report GPI components.

Specify the GPI component either by selecting an existing GPI or providing a new one.

**Specify your GPI component** 2

✘ Please specify your GPI component.

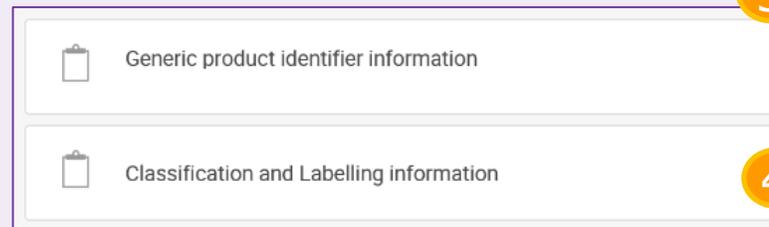
Select an existing GPI  
+ Select

OR

Provide a GPI name

Continue

Specify your GPI by either selecting an existing GPI component from the inventory, or begin the creation of a new component dataset, by giving the GPI a name, then press Continue.



Generic product identifier information

Classification and Labelling information

The following sub-tasks are triggered for GPI information, and classification.

For more information on reporting classification, you can refer to [classification of the substance](#).

## Sub-task 'Generic product identifier information' for the GPI

Generic product identifier information

1 GPI Information

**GPI name**

Name\*

GPI 1

The name of the GPI you entered in the previous step is displayed here and is editable.

**Function and concentration**

Function

Please select 2

Function is **mandatory** information but can be added if preferred. Selections are limited to colourant or perfume.

Typical concentration

Concentration range

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.

Function

Please select

colourant

perfume



## Dossier preparation: 'Product information'

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. Full details on the information requirements can be found from the *Guidance on harmonised information relating to emergency health response* at:

<https://poisoncentres.echa.europa.eu/guidance>



# Navigating to the Product details page

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 tasks. You can return to this page later if you do not have all the information at hand.

Information to be completed

- Mixture Information
- Product information **1**

**2 Finalize your dossier**  
Finalise your guided dossier preparation by validating and reviewing the information before you create your dossier. Additionally, you can preview the provided information in PDF.

Validate Create dossier Preview notification

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

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 09/07/2019 10:06 **2**

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

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

By clicking on the Product details task, you will be referred to the all the product records

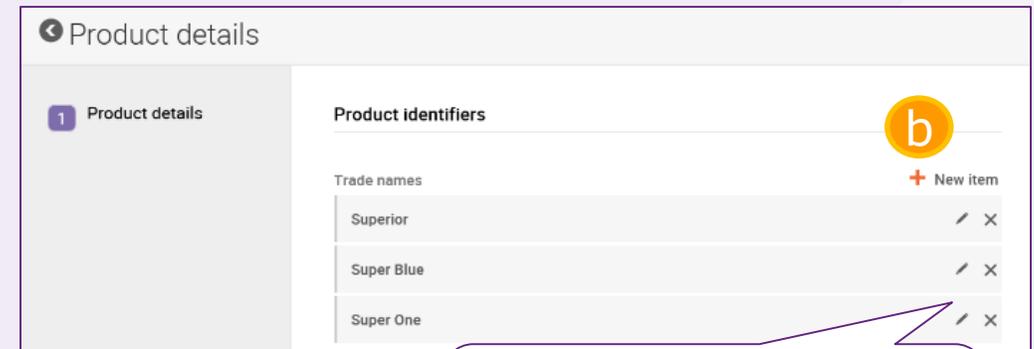
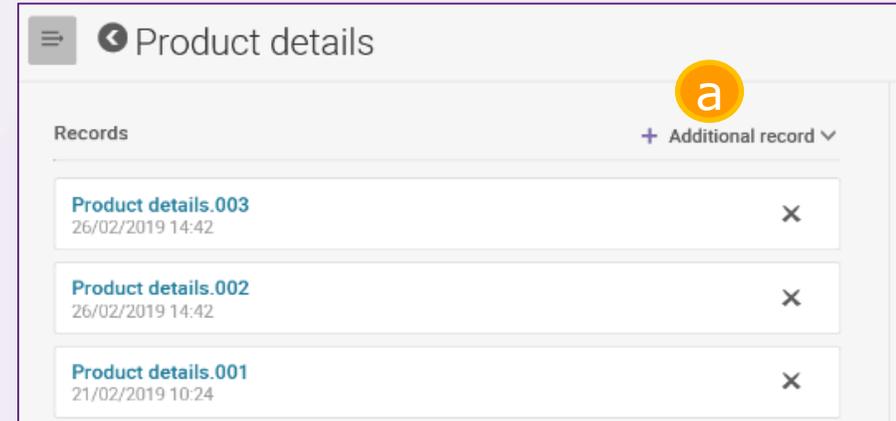


## Reporting multiple products

Reporting a single product with a single trade name and UFI 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.

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

- a) numerous '**Product records**' can be created where each one can be distinguished from the other i.e. products with different trade names or UFIs, market areas, or packaging types for instance.
- b) numerous products are listed as '**items**' and reported in a single Product details record.



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

# Product details page

By clicking **+Select**, the UFIs that were declared earlier in the Mixture information 'UFI task' are listed and can be linked to specific products.

See [Unique formula identifiers](#).

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.

**Product details**

1 Product details

**Product identifiers**

Trade names **+ New item**

Other names **+ New item**

Unique Formula Identifiers (UFI) **+Select**

**Additional information**

**Colour and physical state**

Link to the information about colour and physical state **+Select**

**Packaging**

Product not packaged

Link to the packaging information **+Select**

**Product use category**

Use type

Main intended use

Secondary uses

**Market placement**

Country

Finish

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.

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

See [Colour and physical state](#).

See [Packaging](#).

See [Product use category](#)



# 'Unique formula identifier'

**Product identifiers**

Trade names + New item

Trade names 01 ✎ ✕

Other names + New item

No items added + New item

Unique Formula Identifiers (UFI) + Select

1

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.

Select existing document + Create ✕

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

2

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.

3

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.

Regulatory Programme

CLP unique formula identifier (UFI) ✕ ▾

Id\*

✕ Id field is mandatory. 0/255

## 'Colour and physical state'

**Colour and physical state**

Link to the information about colour and physical state

+ Select

1

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.

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.

Select existing document

+ Create X

No items found

2

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

**Key value for chemical safety assessment**

Physical state at 20°C and 1013 hPa

Please select

Form

Please select

Colour

Colour intensity

Please select

Save

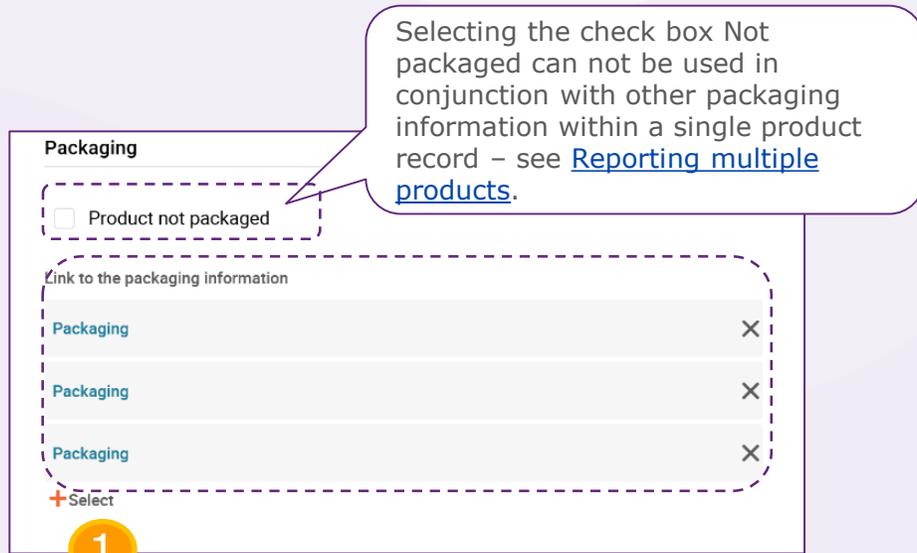
3

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.

# '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.



**Packaging**

Product not packaged

Link to the packaging information

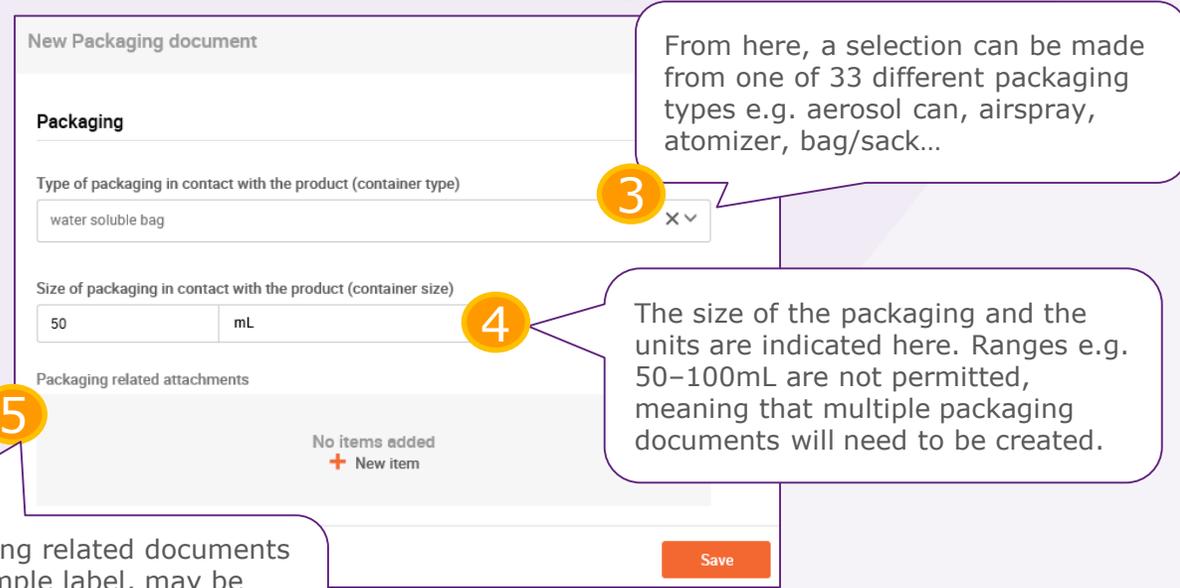
Packaging	X
Packaging	X
Packaging	X

+ 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.



**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  
No items added  
+ New item

Save

Select +Create to open a new document.

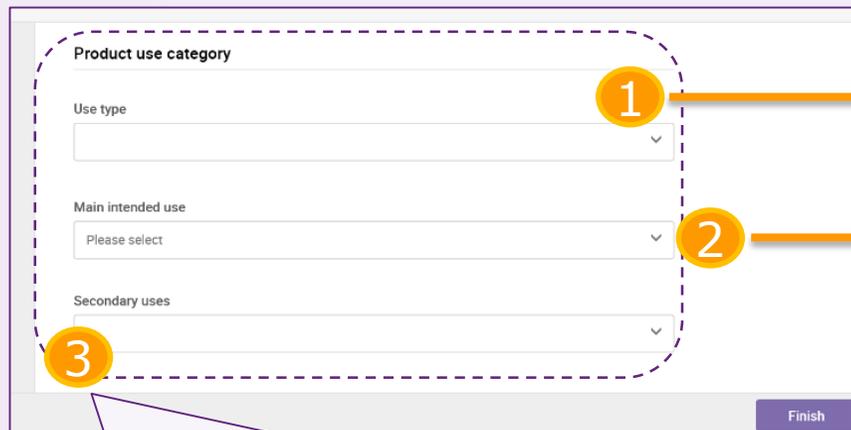
From here, a selection can be made from one of 33 different packaging types e.g. aerosol can, airspray, atomizer, bag/sack...

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.

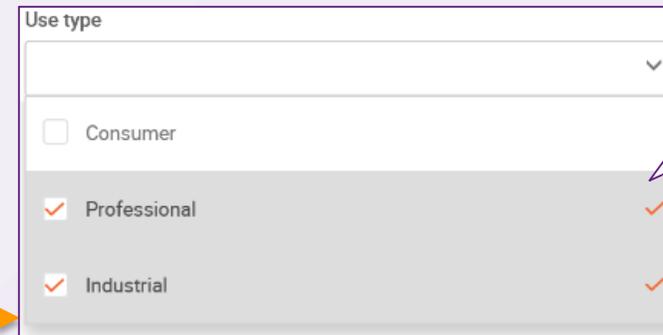
## 'Product use category'

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.



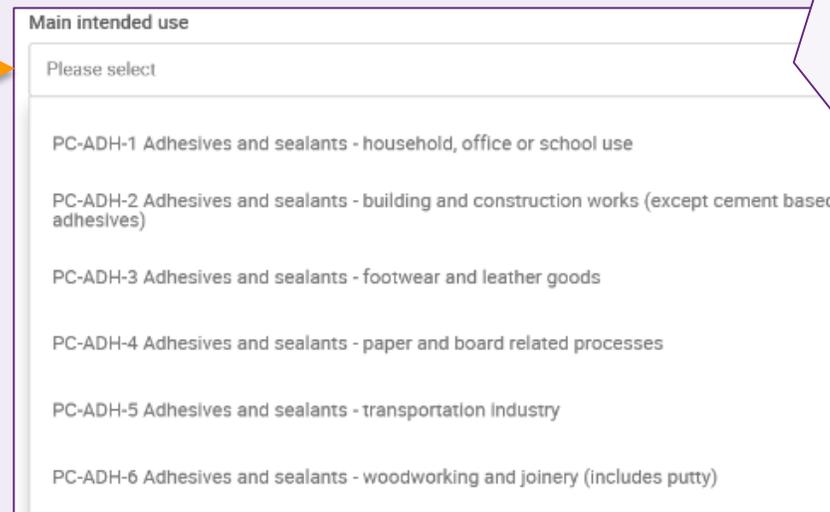
The screenshot shows a form titled "Product use category" with three sections: "Use type", "Main intended use", and "Secondary uses". Callout 1 points to the "Use type" dropdown menu. Callout 2 points to the "Main intended use" dropdown menu. Callout 3 points to the "Secondary uses" dropdown menu. A "Finish" button is located at the bottom right of the form.

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.



The "Use type" dropdown menu is expanded, showing three options: "Consumer" (unchecked), "Professional" (checked), and "Industrial" (checked). Each checked option has a small orange checkmark to its right.

Selection of multiple use types for the mixture is possible.



The "Main intended use" dropdown menu is expanded, showing a list of categories: "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", and "PC-ADH-6 Adhesives and sealants - woodworking and joinery (includes putty)".

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>



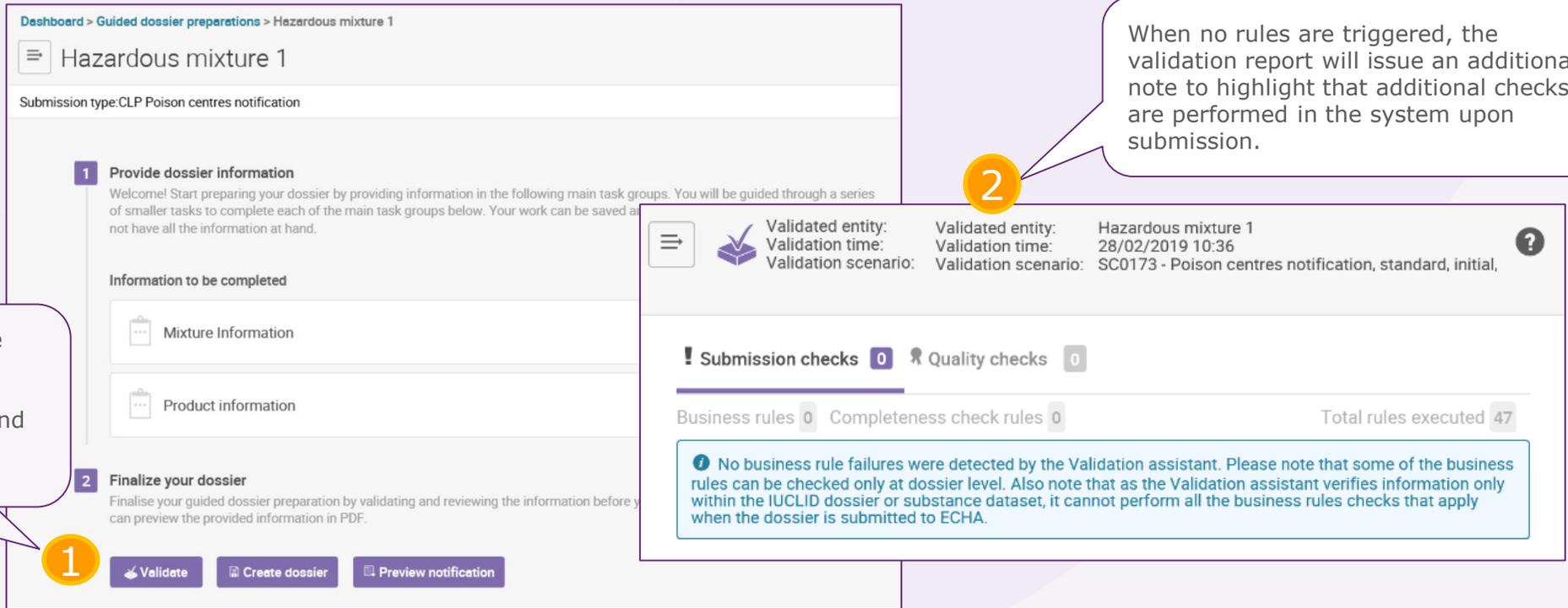
# Validate information, create dossier and preview notification

An explanation of the functionalities to finalise the dossier preparation process; validate, create a dossier, and preview notification.

## 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 rules will determine if the dossier will pass, pass with warnings or fail according to the rules in place.

The outcome of the validation is a report, which lists the rules (if any) for which the validation assistant was triggered. For a list of the rules, you may refer to the Annex available at: <https://poisoncentres.echa.europa.eu/poison-centres-notification-format>



The screenshot shows the 'Hazardous mixture 1' dossier preparation page. It includes a progress indicator with two steps: '1 Provide dossier information' and '2 Finalize your dossier'. The 'Validate' button is highlighted with a yellow circle '1'. A callout box explains that clicking 'Validate' displays the Dossier header page for final review, and clicking it again from the dossier header page displays the Validation report.

On the right, a validation report summary is shown with a yellow circle '2' pointing to it. A callout box explains that 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 report summary includes:

- 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 blue information box at the bottom of the report 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."

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.

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 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**

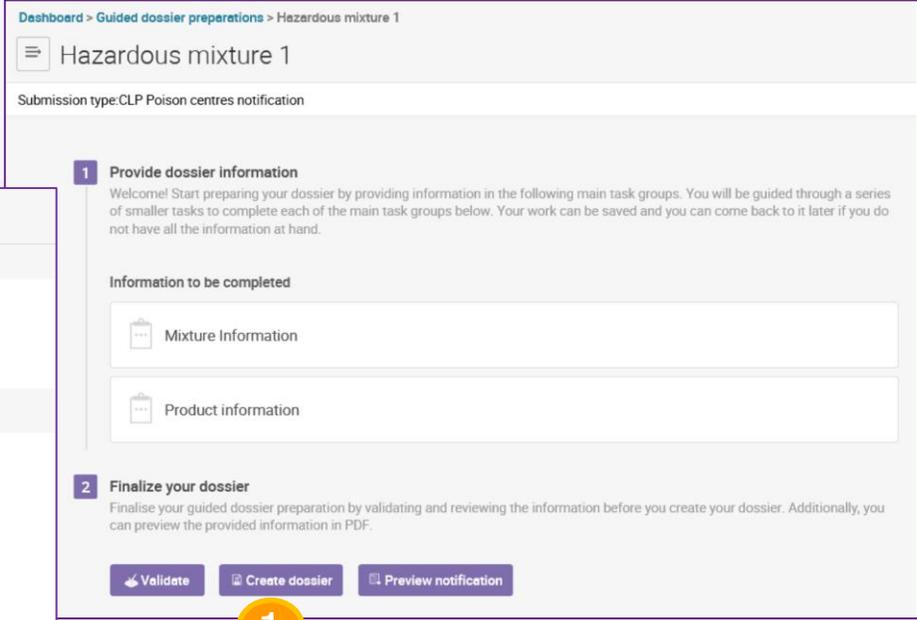
Trade names + New item

Trade names 01 ✎ ✕

[Save](#)

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

# Creating and submitting (or 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 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. Additionally, you can preview the provided information in PDF.

Validate Create dossier Preview notification

**CLP Poison centres notification**

header

- Dossier name (given by user)  
None
- Dossier submission remark  
None

Specific submissions

- PCN number\*  
74ae95f2-02ba-45df-a0d3-88b816e0ba2b
- Country (market placement)\*  
 Finland  
 Sweden
- Language\*  
 Finnish  
 Swedish

Submission type

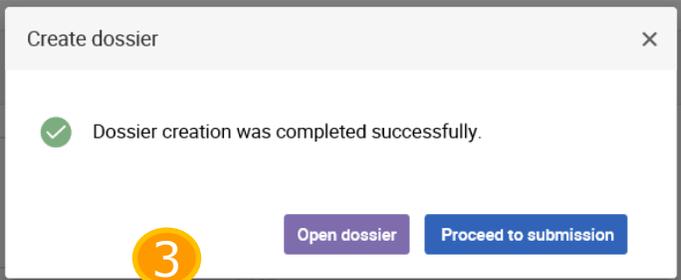
- Limited submission (industrial use only)
- Group submission
- Voluntary submission

Notification type

- Initial notification

Create dossier

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.

Open dossier Proceed to submission

If the dossier did not trigger any warnings or errors, and the creation was successful, you can proceed to the ECHA Submission portal to submit.

Note, clicking **Proceed to submission** automatically uploads the dossier to the ECHA Submission portal – you will still need to use the Submit functionality – see [Upload and submit](#).

Alternatively, you can export the dossier locally by clicking **Open dossier**, clicking '...' in the top left corner and selecting Export to i6z. Give the dossier a meaningful name to assist with dossier management.



## 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 image shows a sequence of screenshots from the IUCLID Dashboard. On the left, the 'Dashboard' page features three main 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 purple border. A callout points to the 'Mixtures' card, stating: "Clicking on the name of the mixture, redirects to the View dossier page." The main screenshot shows the 'Mixture / Products' page. At the top, there is a search bar containing the text 'Hazardous' and a search icon, with the text '1 result found' to its right. Below the search bar, there are tabs for 'Datasets' and 'Dossiers', with 'Dossiers' being the active tab. A table lists one entry: 'Hazardous mixture 1'. The table has columns for 'Subject name' (Hazardous mixture), 'Submission type' (CLP Potson centres notification), and a date '24/06/2019 13:38'. A lock icon is visible in the bottom right corner of the table row. A callout points to the lock icon, stating: "In View dossier mode, the lock symbol denotes a dossier file." Another callout points to the 'Dossiers' tab, stating: "Switch between View dossier and View mixture dataset". A third callout points to the search bar, stating: "The search function based on the name of the mixture."

Dashboard

Guided dossier preparation 2

Substances 15

Mixtures 10

Dashboard > Mixture / Products

Mixtures

+ New mixture / product

Hazardous 1 result found

Datasets Dossiers

Sort by Newer first

Hazardous mixture 1 24/06/2019 13:38

Subject name Hazardous mixture Submission type CLP Potson centres notification

The search function based on the name of the mixture.

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

Switch between View dossier and View mixture dataset

In View dossier mode, the lock symbol denotes a dossier file.

# Preview notification

Once you press Preview notification, open the document to view the report.

☰
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

**2 Finalize your dossier**

Finalise your guided dossier preparation by validating and reviewing the can preview the provided information in PDF.

Validate
Create dossier
Preview notification

The Preview notification generates a pdf report containing all the information you entered.

2

1

## 1. PCN Preview Report

### 1.1. Dossier information

Dossier name:	
Dossier UUID	fc611069-aa4d-4b08-8ec3-515424fb95a9/0
PCN number in dossier header	ac56a6db-97af-487b-966f-41f03ba26f65
Country (market placement)	Finland [FI] ; Sweden [SE]
Language	Finnish [Language] ; Swedish [Language]
Type of submission	Initial notification

### 1.2. Submitter information

Submitting legal entity	
Legal Entity name: ECHA Chemicals Phone: +358 0405607172 E-mail: ECHA.Chemicals@telia.fi	Address 1: Helsingintie 1 Address 2: Postal code: 15900 Town: Helsinki Country: Finland [FI]

### 1.3. Mixture information

**Mixture name:** Hazardous mixture 1

pH	
<b>pH is relevant</b>	pH value: >7.8 - <8.8 Solution concentration (%): 100
Contact persons	
No emergency contact information provided	
Name: Malmgren, Hilde Organisation: ECS Contact type: competent person responsible for the SDS	Phone: Mobile phone: e-mail: hmalmgren@ecs.europa.eu Country: Sweden [SE]
UFI and other identifiers	
CLP unique formula identifier (UFI)	7F8K-T0SR-R002-J569

### 1.4. Mixture composition

Substance components



# Updating dossier information

An explanation on how to prepare for a dossier update.

## Updating dossier information

Once a dossier has been created from a data set, it is possible to update that data and create an updated dossier.

Dashboard > Guided dossier preparations

Guided dossier preparations

2 results found

Hazardous mixture 1		Submission type	CLP Poison centres notification	Dossier Name
Legal Entity	EcoChem			
				1314-13-2
LE		Submission type	REACH Registration member of a joint submission - general case	Dossier Name

1 From the guided dossier preparations list, click on the name of the mixture for which you wish to modify information in the notification.

1 Provide

Welcome of smaller not have all the information...

Information to be completed

Mixture Information

Product information

2 Finalize your dossier

Finalise your guided dossier preparation by validating and reviewing the information. You can preview the provided information in PDF.

3 Validate

4 Create dossier

Preview notification

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

3 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.

4 When you click on Create dossier, the dossier header page will be displayed. Note that the information can be edited where relevant [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.

5 It may be that an update reason is not listed in the picklist, 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.

Click on Create dossier to finalise the process.

CLP Poison centres notification

1 header

Dossier name (given by user)  
Hazardous mixture 1 update

Dossier submission remark  
None

2 Specific submissions

PCN number\*  
74ae95f2-02ba-45df-a0d3-88b816e0ba2b

Country (market placement)\*  
 Finland  
 Sweden

Language\*  
 Finnish  
 Swedish

Submission type  
 Limited submission (industrial use only)  
 Group submission  
 Voluntary submission

Notification type  
 The submission is an update

Reason for updating  
 Justification + New item

4 Justification  
 new toxicological information available

Remarks  
None

Create dossier

5

- change in the mixture classification
- change in the product identifier
- correction of error
- new toxicological information available
- other:

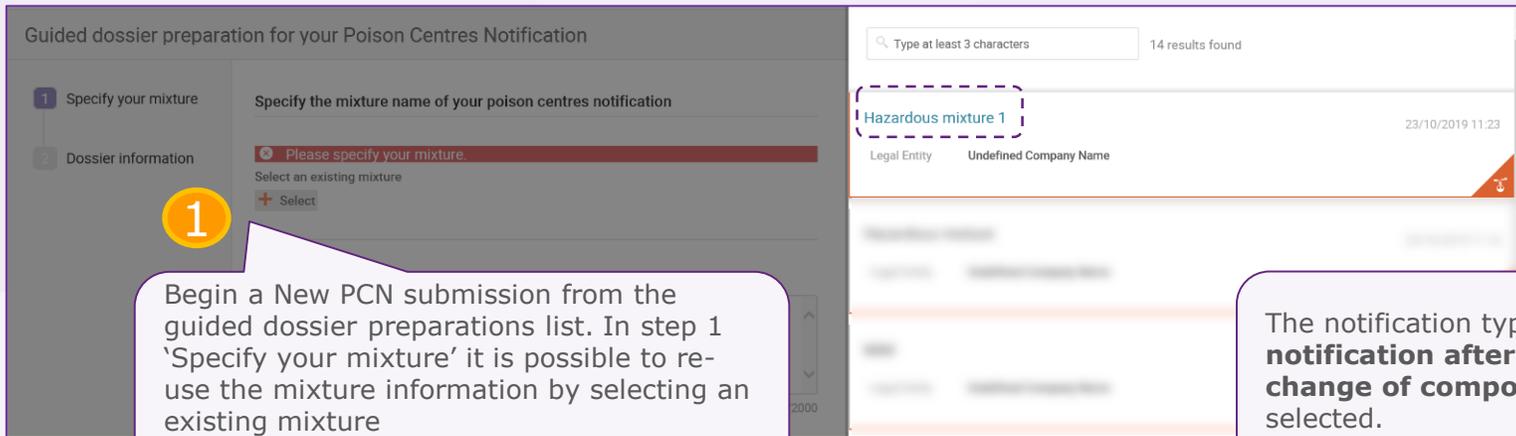
# Updating the dossier header when the mixture significantly changes in composition

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.

In step 2 'Dossier information', the dossier header must be filled in and 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](#).

2



Guided dossier preparation for your Poison Centres Notification

1 Specify your mixture Specify the mixture name of your poison centres notification

2 Dossier information Please specify your mixture. Select an existing mixture + Select

1

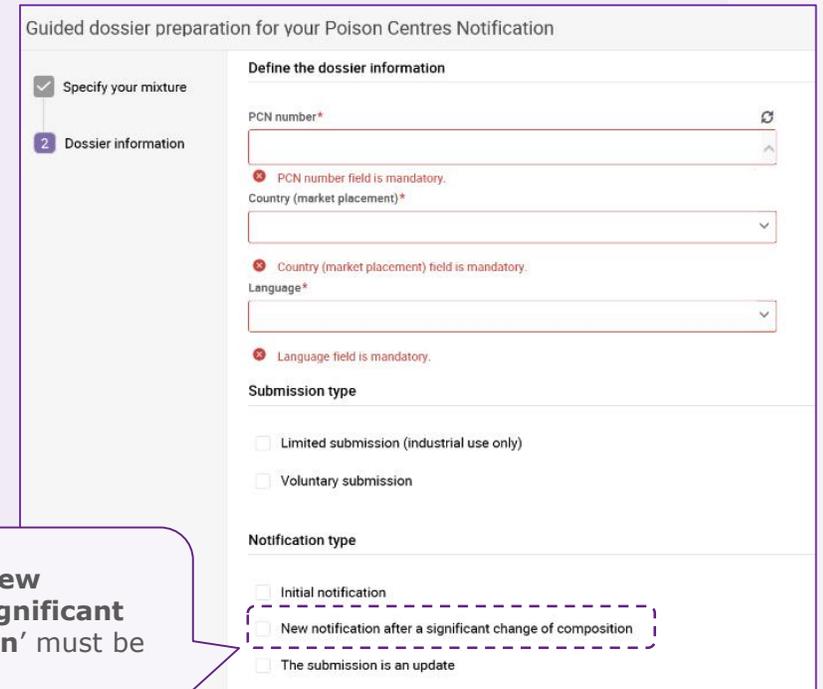
Begin a New PCN submission from the guided dossier preparations list. In step 1 'Specify your mixture' it is possible to re-use the mixture information by selecting an existing mixture

Type at least 3 characters 14 results found

Hazardous mixture 1 23/10/2019 11:23

Legal Entity Undefined Company Name

The notification type '**New notification after a significant change of composition**' must be selected.



Guided dossier preparation for your Poison Centres Notification

Specify your mixture

2 Dossier information

Define the dossier information

PCN number\*

PCN number field is mandatory.

Country (market placement)\*

Country (market placement) field is mandatory.

Language\*

Language field is mandatory.

Submission type

Limited submission (industrial use only)

Voluntary submission

Notification type

Initial notification

New notification after a significant change of composition

The submission is an update

