

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/>

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



1

ECHA
EUROPEAN CHEMICALS AGENCY

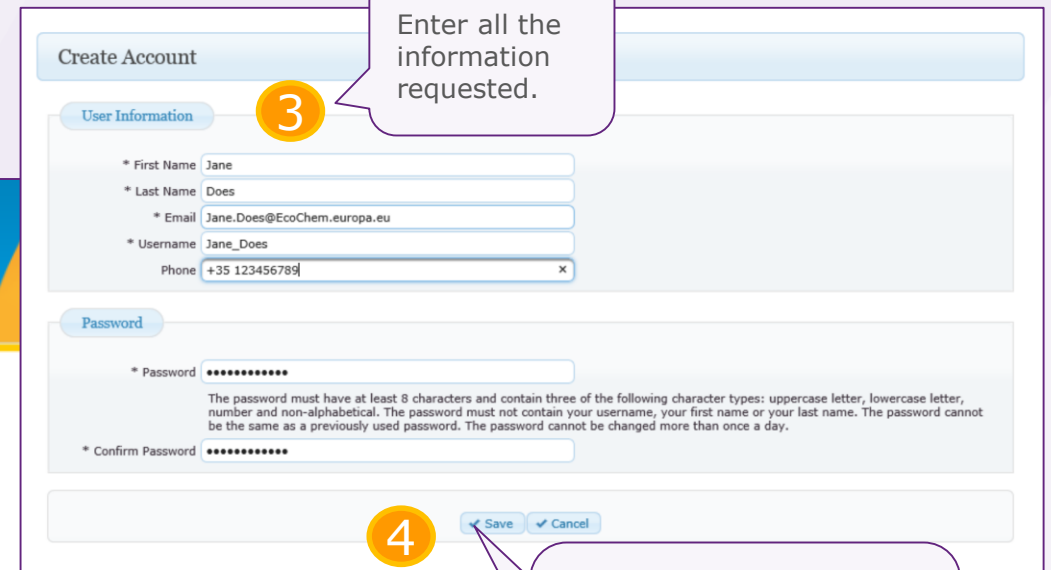
Username
Enter username...

Password
Enter password...

LOGIN

Help

- > Create an ECHA account
- > Forgot your password?
- > Forgot your username?
- > Change password
- > ECHA accounts Q&A
- > ECHA accounts informati



Create Account

3

User Information

* First Name Jane

* Last Name Does

* Email Jane.Does@EcoChem.europa.eu

* Username Jane_Does

Phone +35 123456789

Password

* Password

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

* Confirm Password

4

Save Cancel

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.

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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, and address information. You can either **Encode Legal Entity** or **Import IUCLID format file** below.

Import IUCLID format file: If you already have a legal entity definition file in IUCLID exchange format (e.g. .xml) and you have the same UUID for your legal entity definition as for your IUCLID LEOX, you should import your LEOX file. 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 manually encode your legal entity details.

1

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: ?

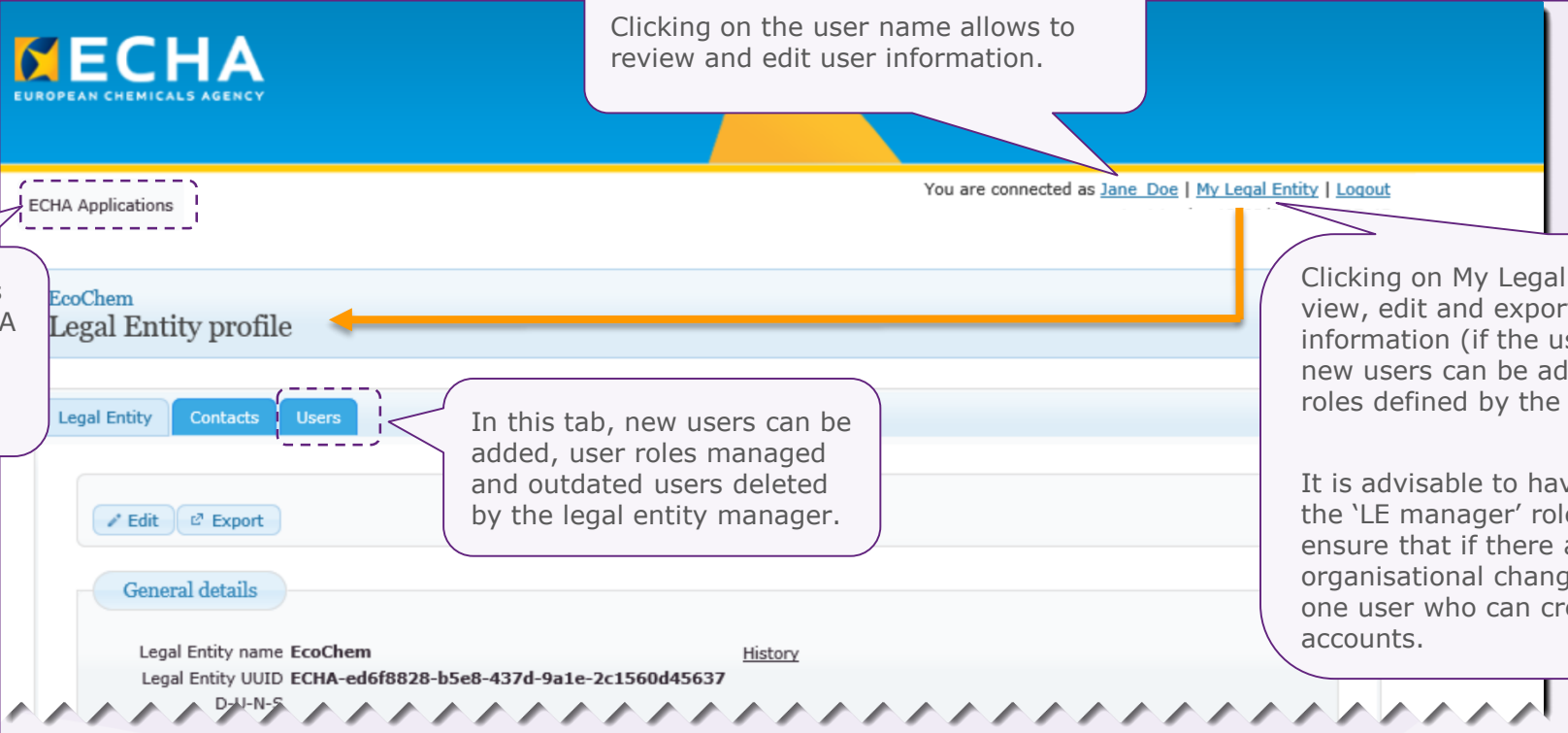
General Contact information

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

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. The top header features the ECHA logo and the text "EUROPEAN CHEMICALS AGENCY". Below the header, a navigation bar contains "ECHA Applications" (highlighted with a dashed box), "Legal Entity", "Contacts", and "Users" (highlighted with a dashed box). The main content area displays the "EcoChem Legal Entity profile" with tabs for "Legal Entity", "Contacts", and "Users". Below the tabs are buttons for "Edit" and "Export". A "General details" section shows the "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.

You are connected as [Jane Doe](#) | [My Legal Entity](#) | [Logout](#)

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'.

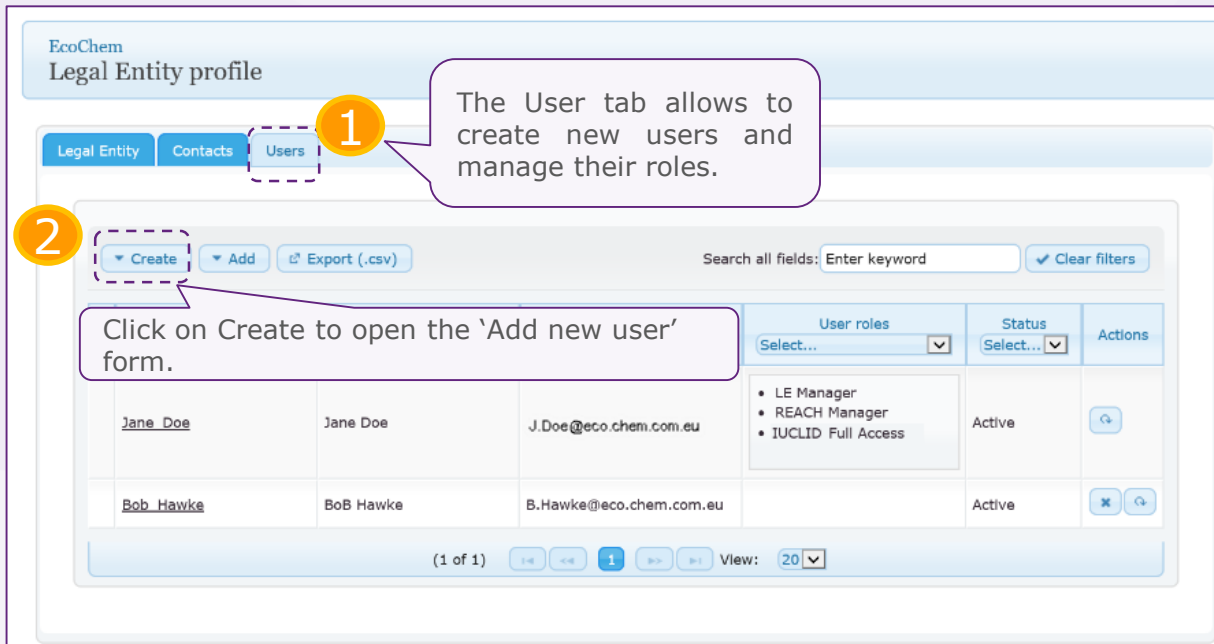
In this tab, new users can be added, user roles managed and outdated users deleted by the legal entity manager.

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:

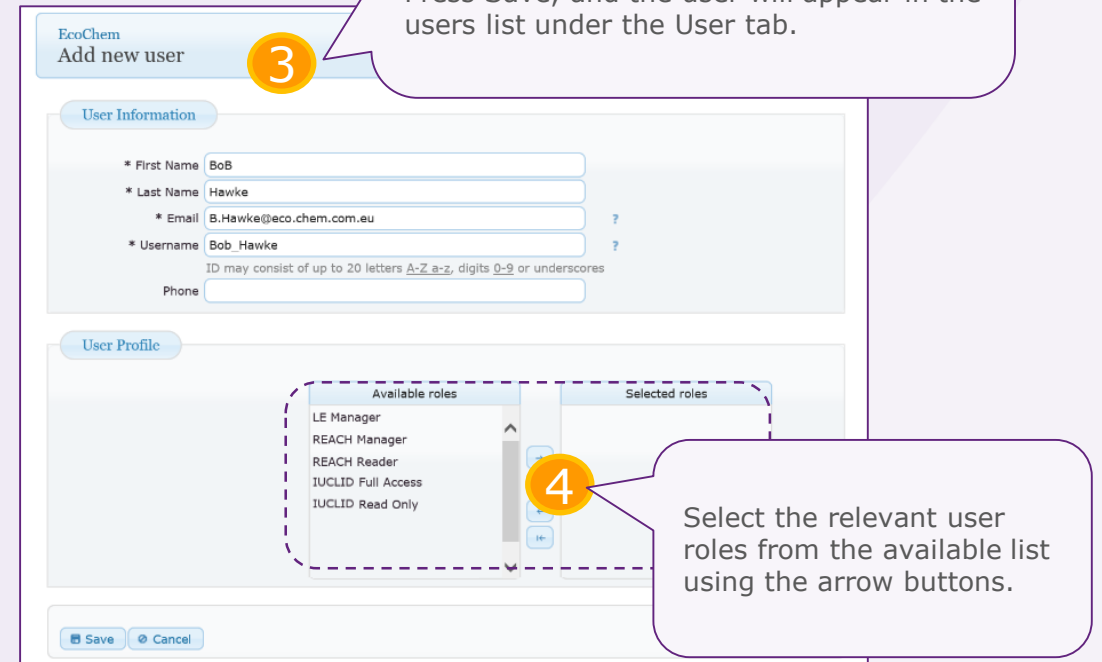
- **LE manager** -> can view and edit the LE account and add, remove or edit user's data and contacts.
- **REACH manager** -> can make submissions through ECHA Submission portal
- **IUCLID full access** -> can prepare submissions online in IUCLID Cloud.
- **'Reader' and 'Read' roles** are entitled to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



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

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

	User roles	Status	Actions
Jane Doe	<ul style="list-style-type: none"> LE Manager REACH Manager IUCLID Full Access 	Active	[Refresh]
Bob Hawke		Active	[Delete] [Refresh]

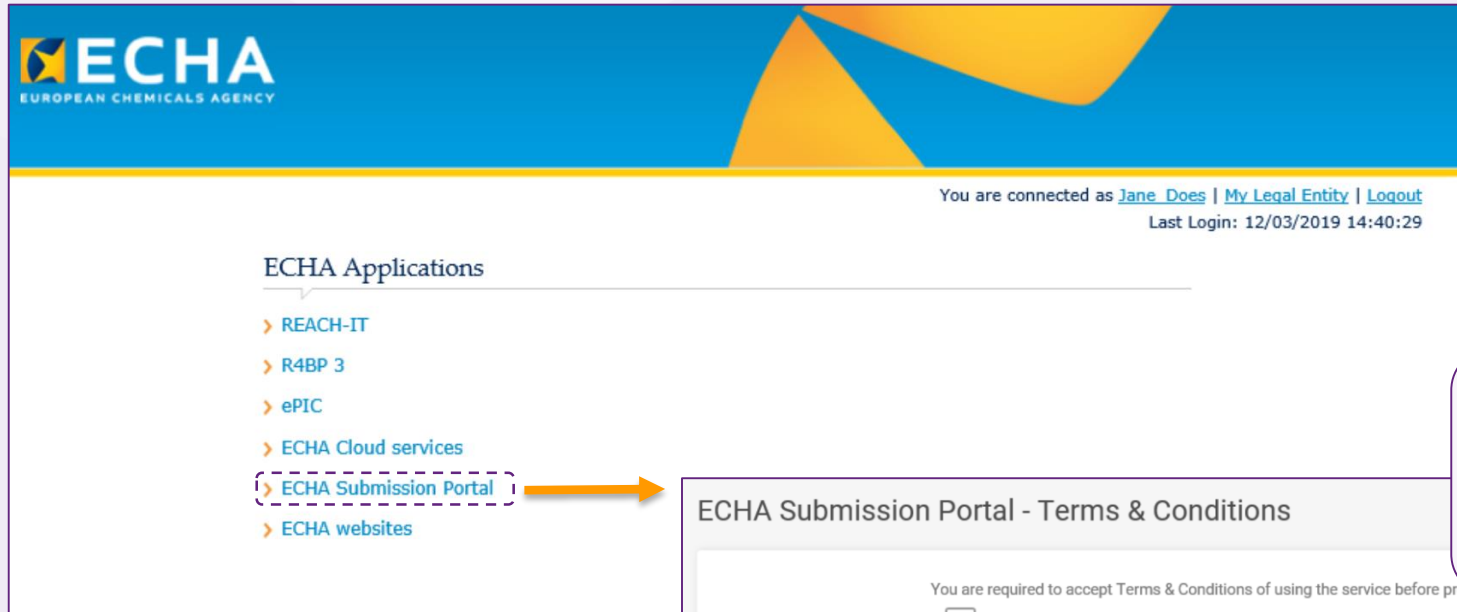


3 Enter all the user information details for the new user and indicate the type or types of roles that the user should have. Press Save, and the user will appear in the users list under the User tab.

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

Available roles: LE Manager, REACH Manager, REACH Reader, IUCLID Full Access, IUCLID Read Only

Accessing ECHA applications for the first time



The screenshot shows the ECHA user interface. At the top left is the ECHA logo (European Chemicals Agency). On the right, it says "You are connected as Jane Does | My Legal Entity | Logout" and "Last Login: 12/03/2019 14:40:29". Under the heading "ECHA Applications", there is a list of links: REACH-IT, R4BP 3, ePIC, ECHA Cloud services, ECHA Submission Portal, and ECHA websites. The "ECHA Submission Portal" link is highlighted with a dashed orange box, and an orange arrow points from it to a callout box. The callout box shows the "ECHA Submission Portal - Terms & Conditions" page, which includes a checkbox that is checked and the text "I acknowledge that I have read and agreed to the linked Terms & Conditions". Below this 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. At the top, there is a navigation bar with 'About us', 'Steps for industry', 'Tools', and 'Support'. The main content area is titled 'ECHA Submission portal' and contains introductory text and a list of key documents. A callout box points to the 'Log in to the ECHA Submission portal here.' link. Another callout box points to a list of links including 'Signing in', 'How to prepare a PCN dossier', 'How to submit a PCN dossier', 'Languages required for notifications', and 'Submission acceptance - Member State overview'. On the right side, there are sections for 'Key documents' and 'Support' with various links. At the bottom, there is a 'Related links' section with links to 'Terms and Conditions of use and service of the ECHA Submission portal', 'IUCLID Cloud', and 'IUCLID 6 website'.

Log in to the ECHA Submission portal here.



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

- > Signing in
- > How to prepare a PCN dossier
- > How to submit a PCN dossier
- > Languages required for notifications
- > Submission acceptance - Member State overview

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.

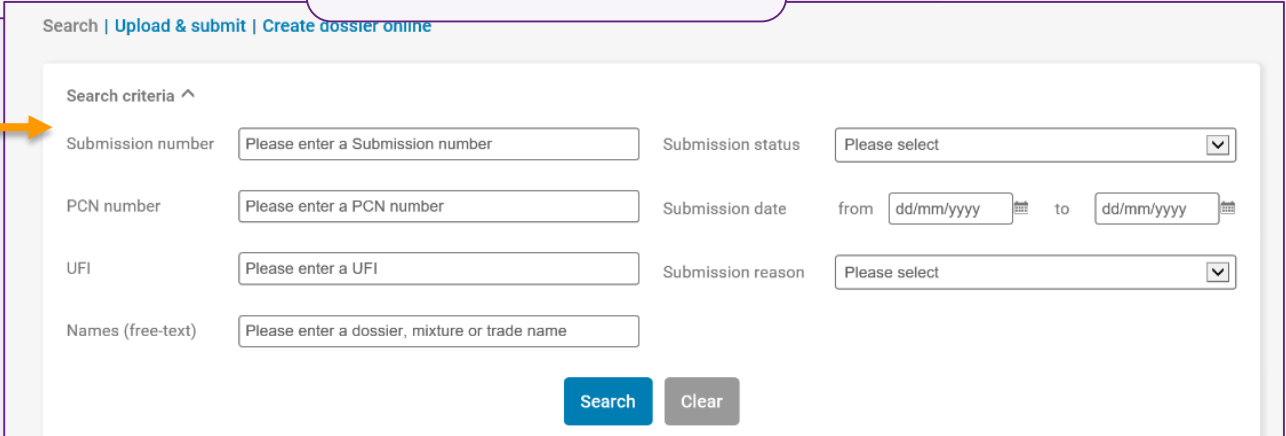
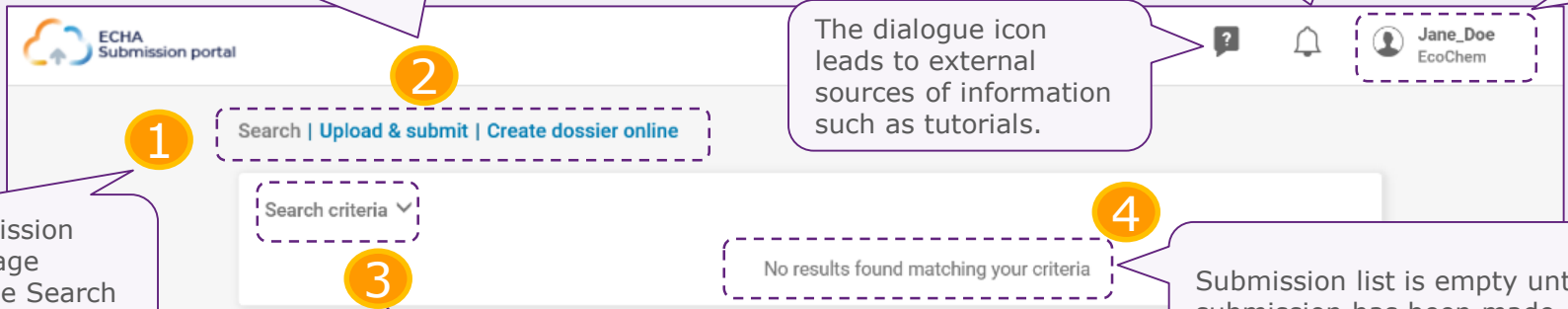
The user icon displays the name and legal entity of the user and, when clicked on, opens a new window for redirection to the ECHA Cloud dashboard, accounts management and the logout functionality.

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

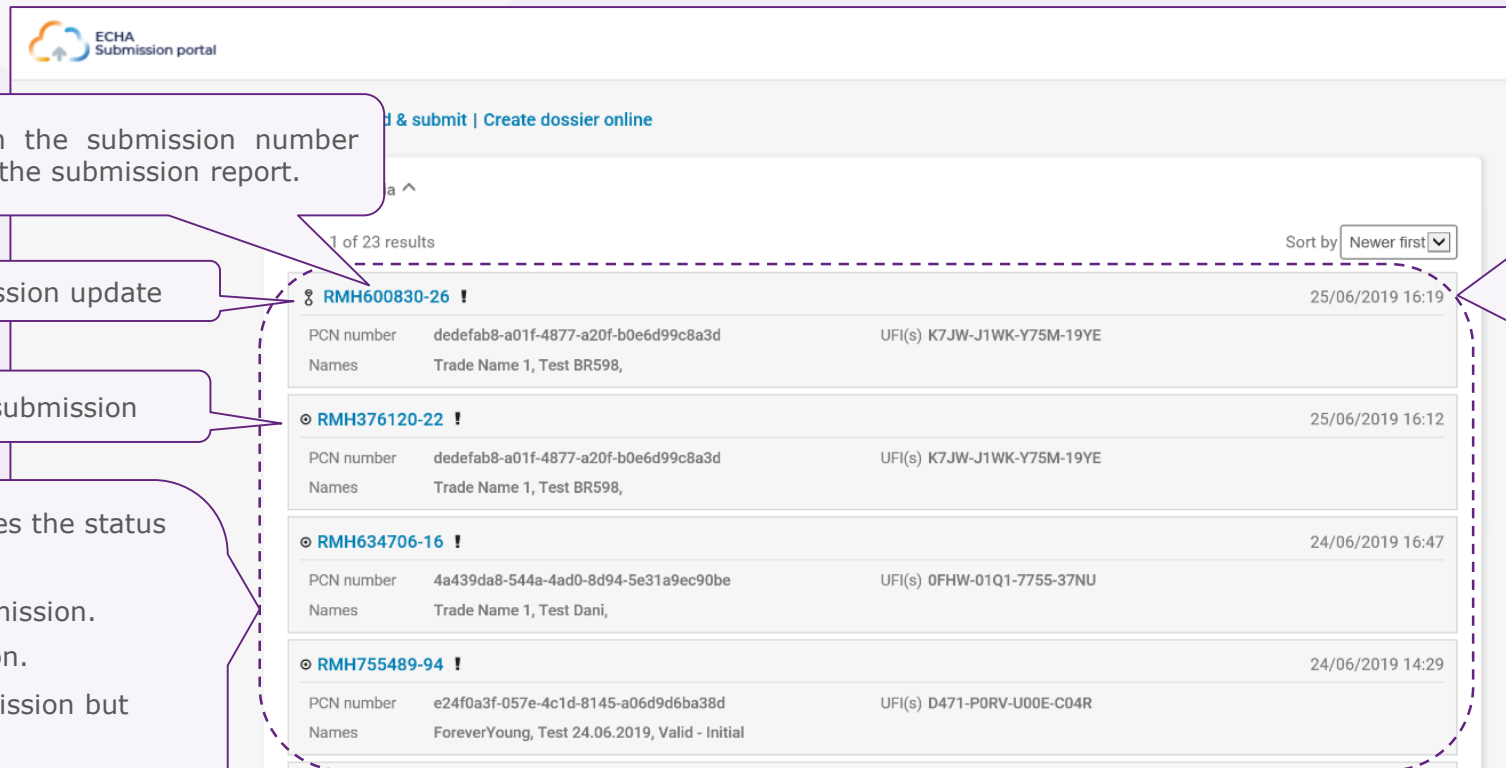
Each submission listed indicates the status of the submission:

✓ 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

Search & submit | Create dossier online

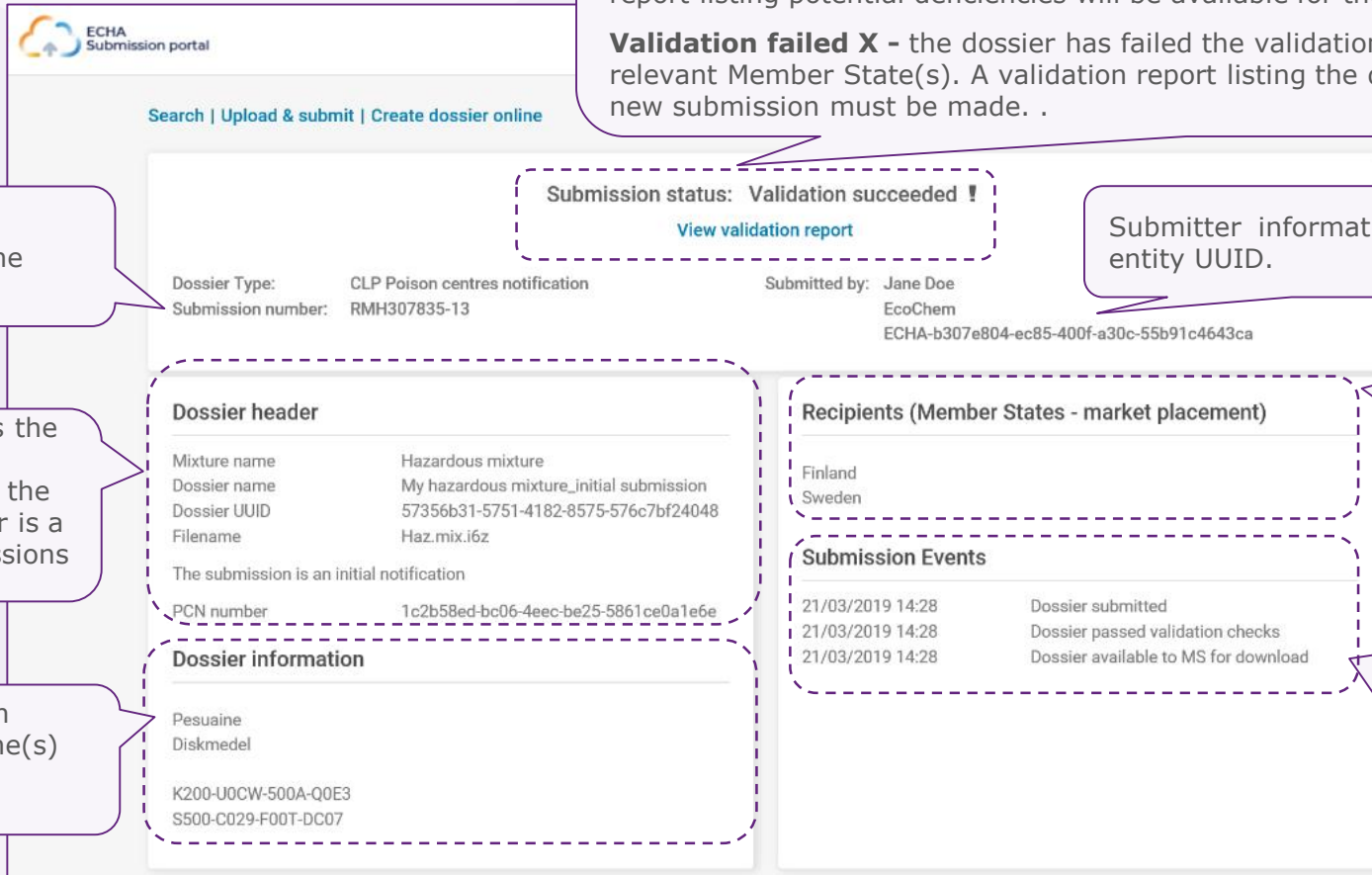
1 of 23 results

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.

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.

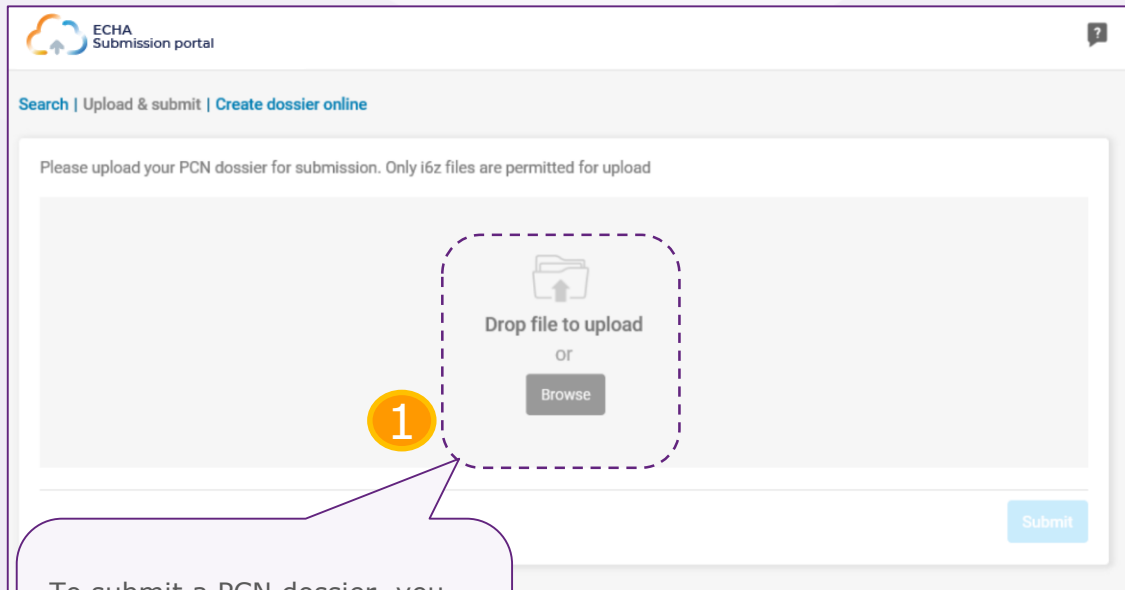
The dossier information contains the trade name(s) and the UFI(s) for the mixture.

Submitter information and legal entity UUID.

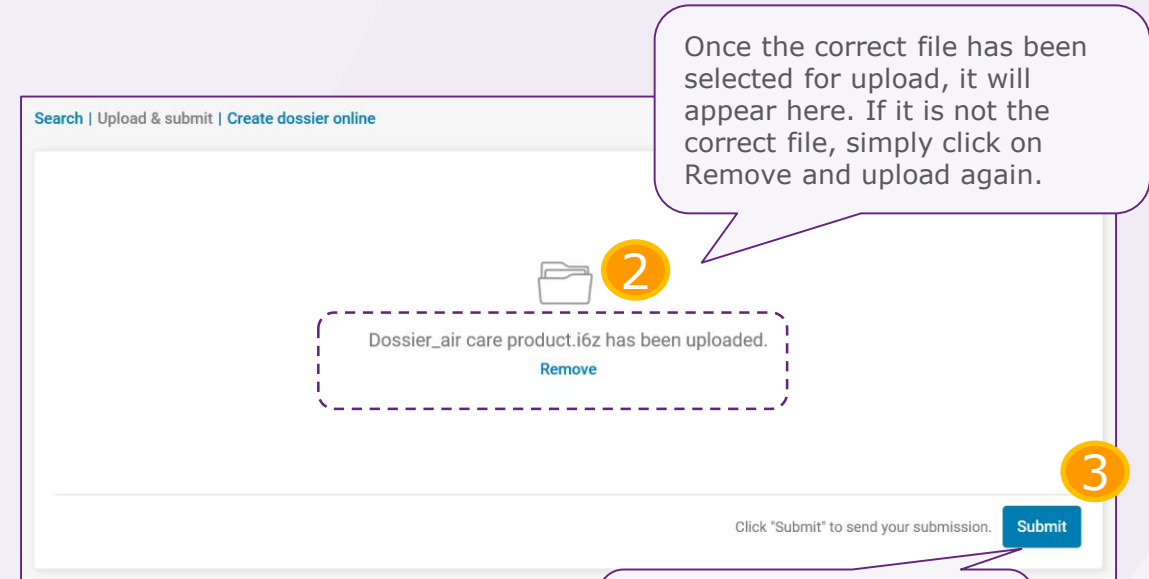
The receiving Member States for the notification are listed here.

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.

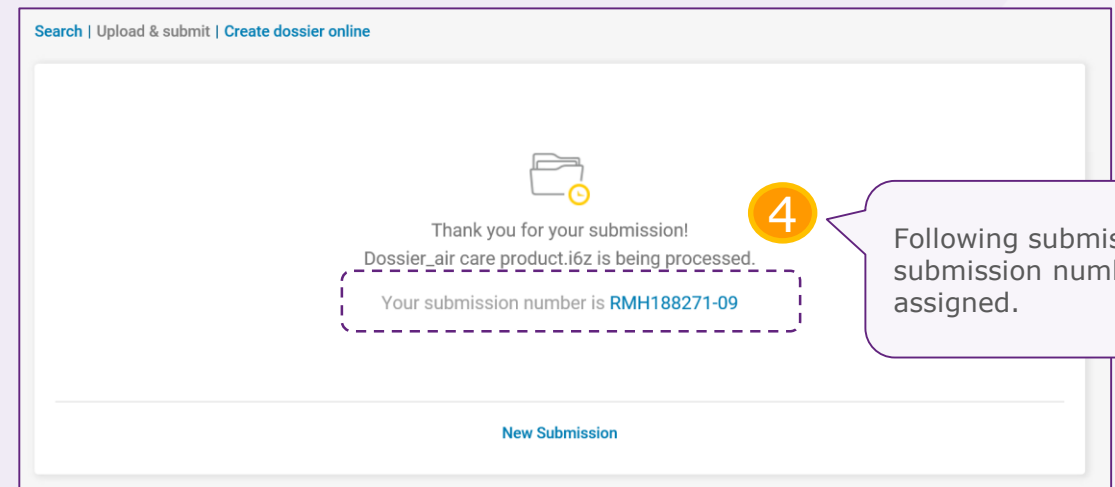
Upload and submit



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.



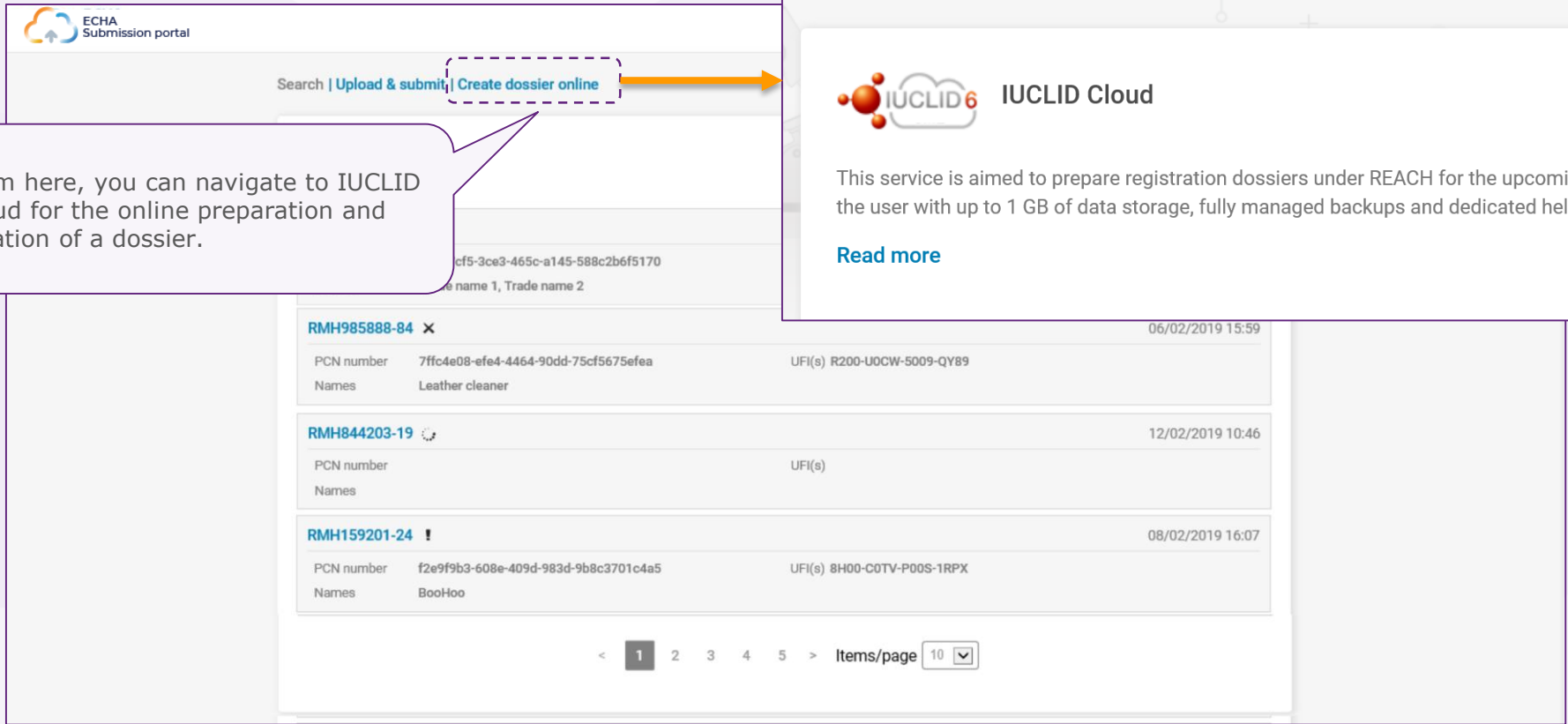
When everything is ready, Submit the dossier!



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.



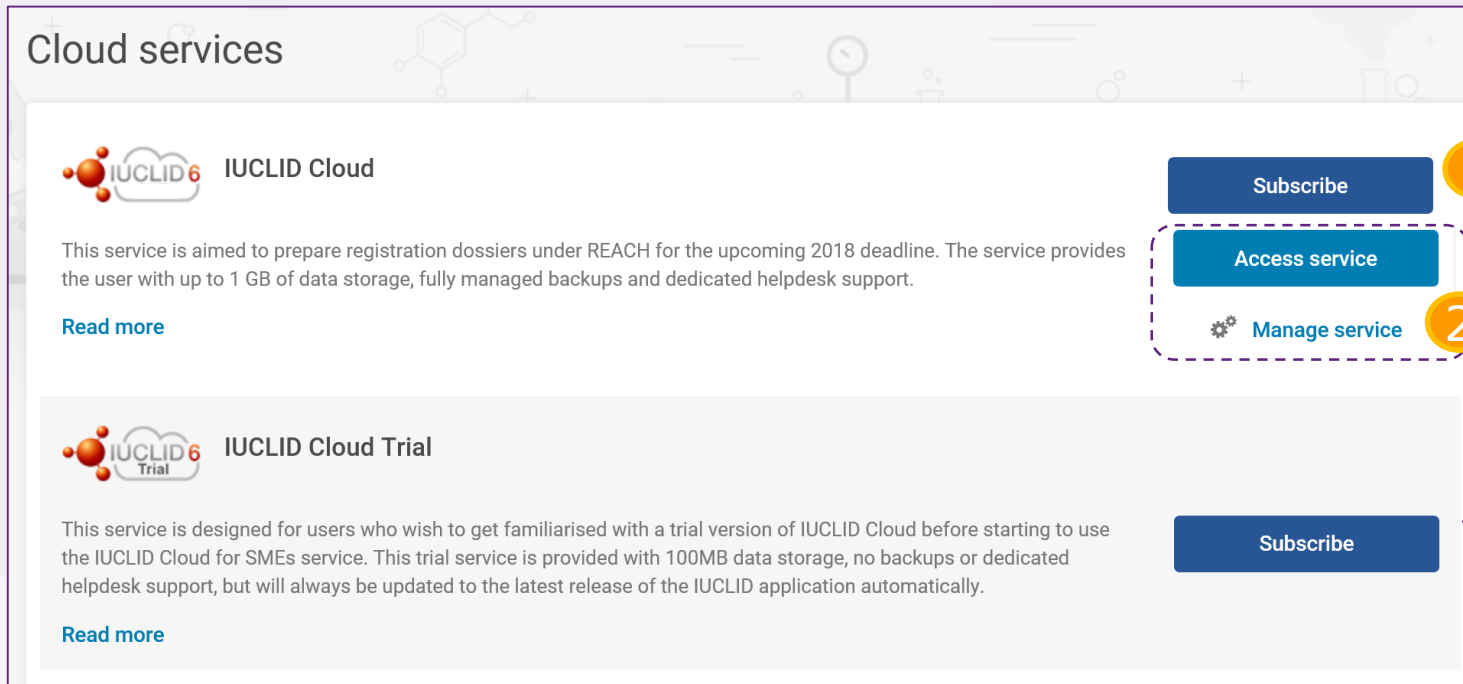
The screenshot shows the ECHA Submission portal interface. At the top, there are navigation links: Search | Upload & submit | **Create dossier online**. An orange arrow points from the 'Create dossier online' link to a callout box. The callout box, titled 'Cloud services', features the IUCLID 6 logo and the text: '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.' Below this text is a 'Read more' link. The main content area of the screenshot displays a table of registration dossiers.

Registration Number	PCN number	Names	UF1(s)	Date
RMH985888-84 ✕	7ffc4e08-efe4-4464-90dd-75cf5675efea	Leather cleaner	R200-U0CW-5009-QY89	06/02/2019 15:59
RMH844203-19 🔄				12/02/2019 10:46
RMH159201-24 !	f2e9f9b3-608e-409d-983d-9b8c3701c4a5	BooHoo	8H00-C0TV-P00S-1RPX	08/02/2019 16:07

At the bottom of the table, there is a pagination control showing page 1 of 5 items, with a dropdown menu for 'Items/page' set to 10.

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.

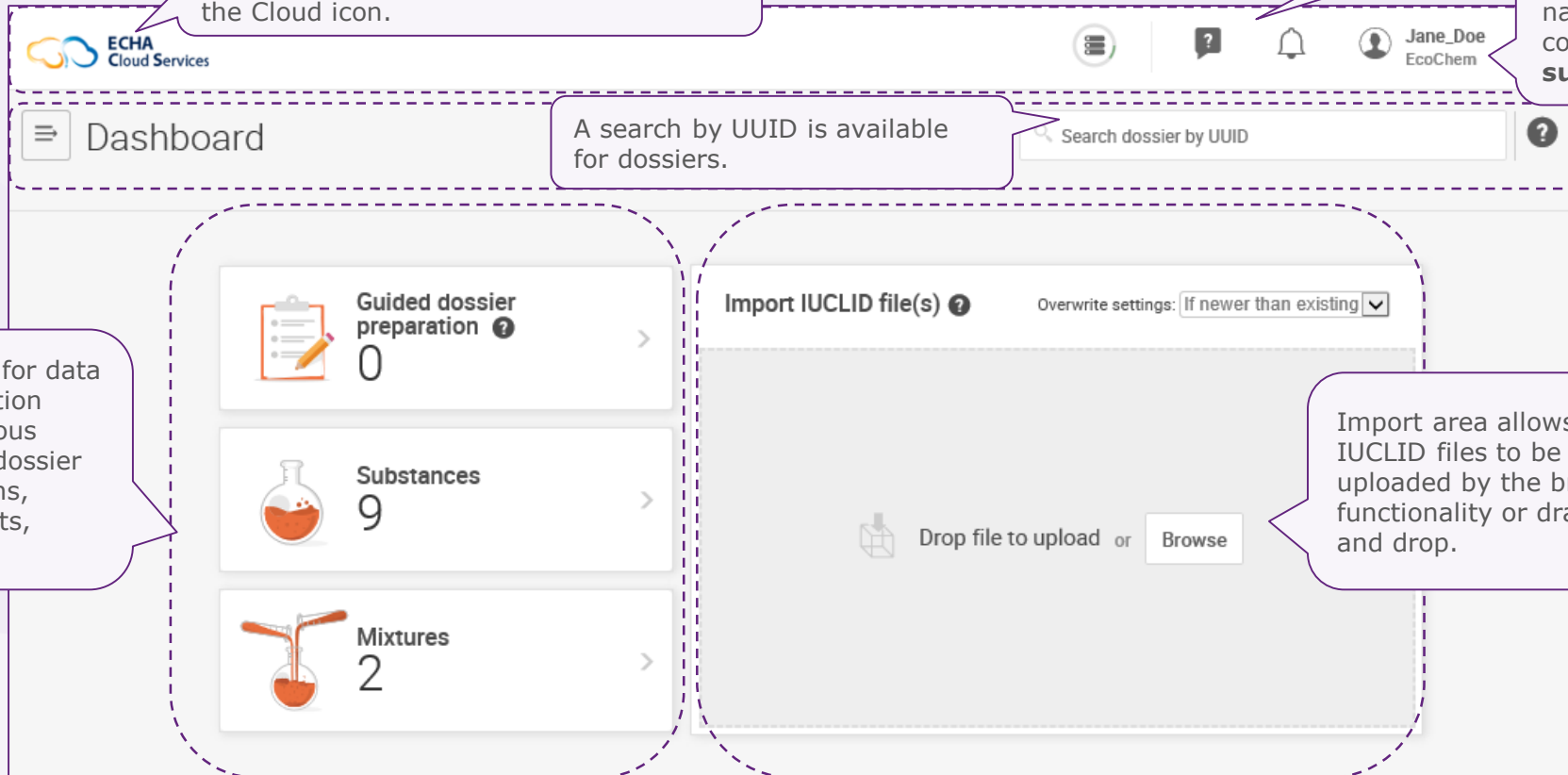
The top bar always contains the same options throughout the guided dossier preparation.

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.

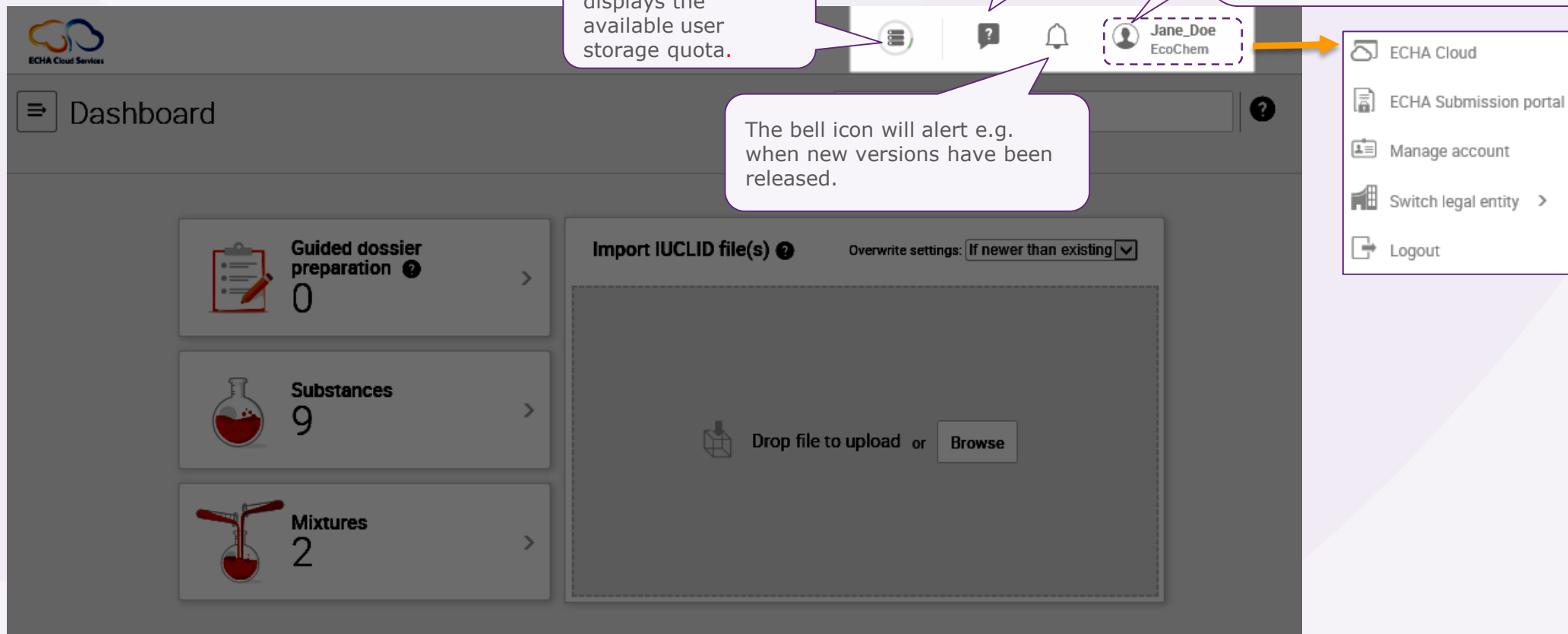
This area is used for data entry and navigation between the various IUCLID entities; dossier under preparations, substance datasets, mixture datasets.

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 question mark icon, a bell icon, and a user profile icon for Jane_Doe EcoChem. Below the navigation bar is a search bar labeled '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 contains 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 dashboard top user bar contains several icons and a user profile section. The icons include a quota icon, a dialogue icon, a bell icon, and a user icon. The user icon displays the name and legal entity of the user, and when clicked, 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.

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

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

The quota icon displays the available user storage quota.

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.

The dropdown menu contains the following options:

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

The dashboard also displays the following information:

- Guided dossier preparation: 0
- Substances: 9
- Mixtures: 2

The main content area shows the "Import IUCLID file(s)" section with an "Overwrite settings" dropdown set to "If newer than existing". Below this is a "Drop file to upload" area with a "Browse" button.



Initiating a guided dossier preparation

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

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

Dashboard > Guided dossier preparations

Guided dossier preparations

2 results found

+ New ▾

REACH submission

PCN submission

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

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

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

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

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

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

Dossier types are colour coded.



Establishing the 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.



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.

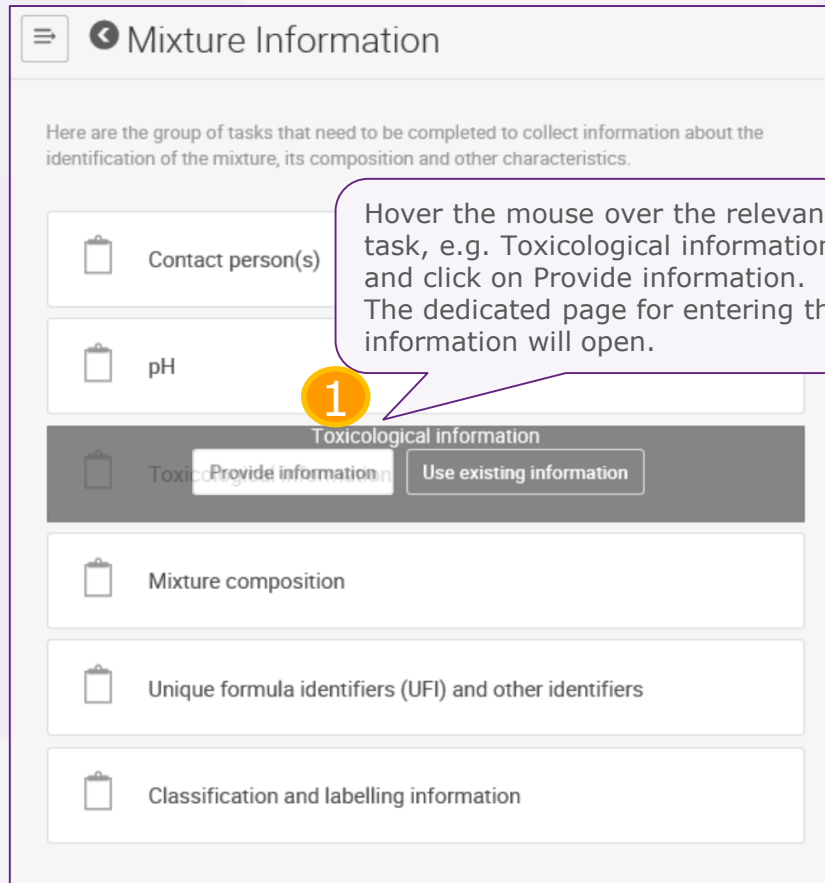
Useful information

- 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



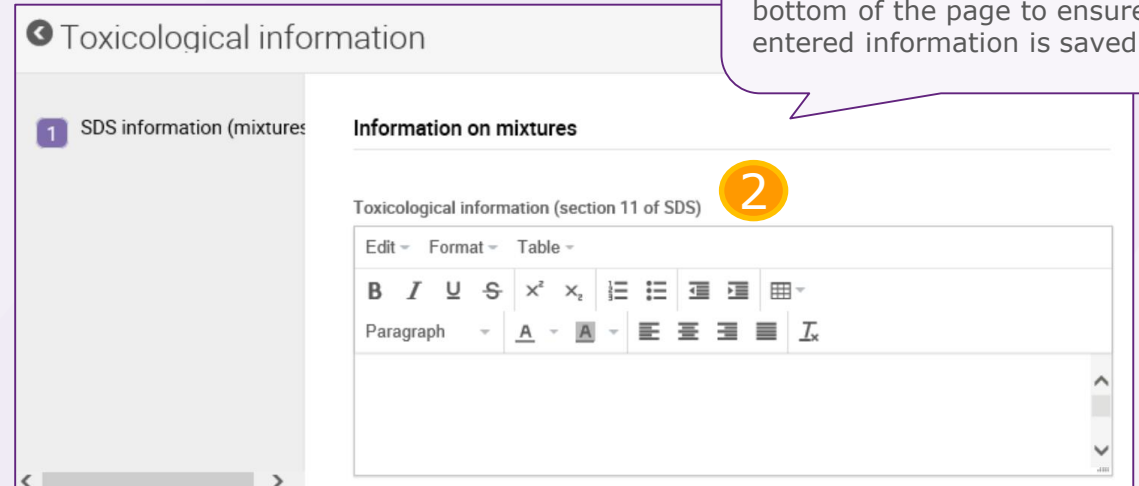
Mixture Information

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.

1



Toxicological information

1 SDS information (mixtures)

Information on mixtures

Toxicological information (section 11 of SDS) 2

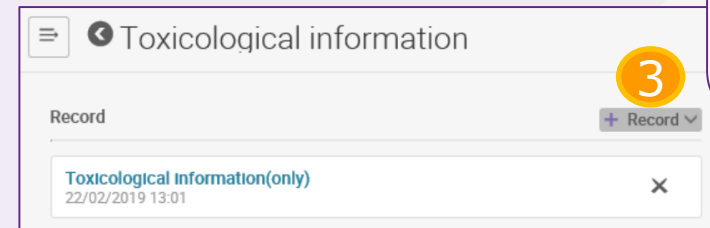
Edit Format Table

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.

2



Toxicological information

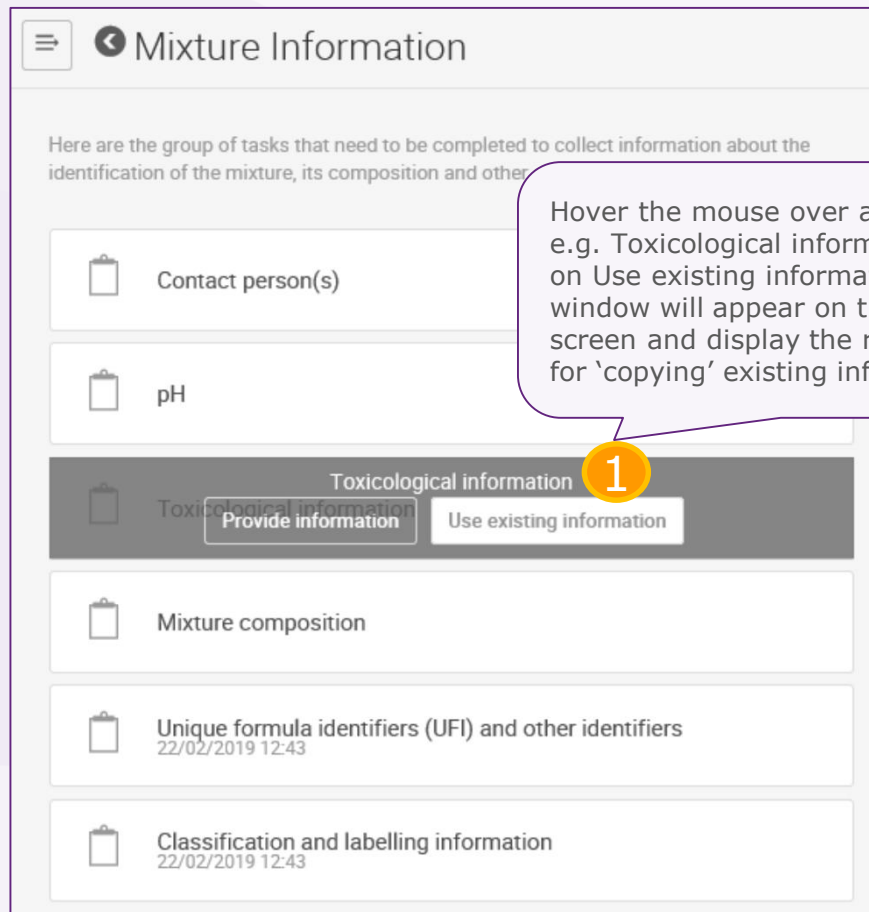
Record + Record

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

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'.

3

Creating a record from existing information



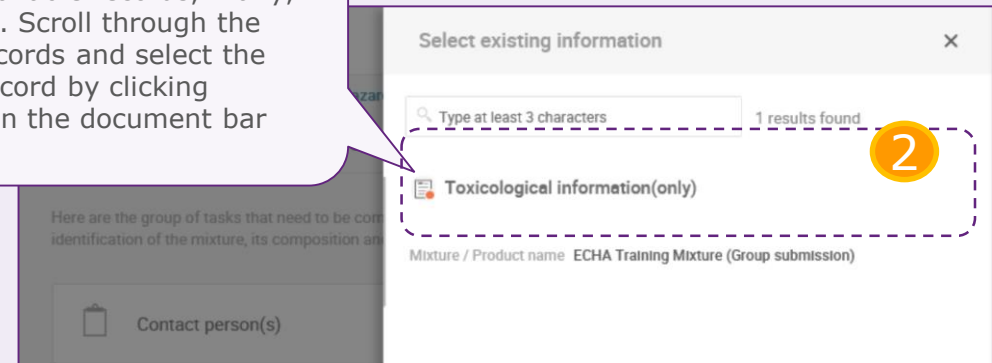
Mixture Information

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**
 - 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.

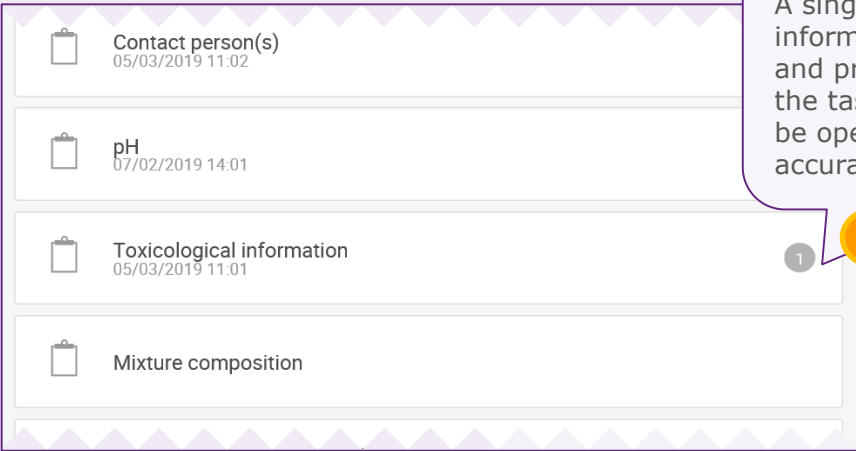


Select existing information

Type at least 3 characters 1 results found

Toxicological information(only)

Mixture / Product name ECHA Training Mixture (Group submission)



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

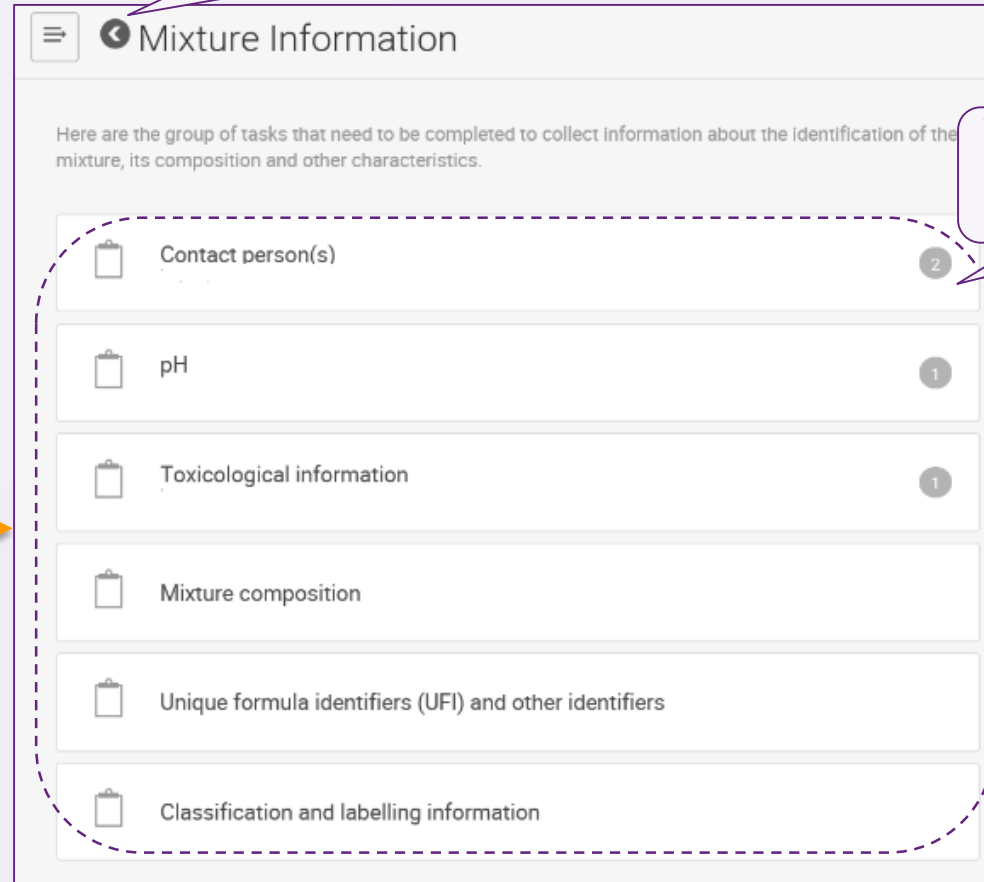
<https://poisoncentres.echa.europa.eu/guidance>

Mixture information task page

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

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

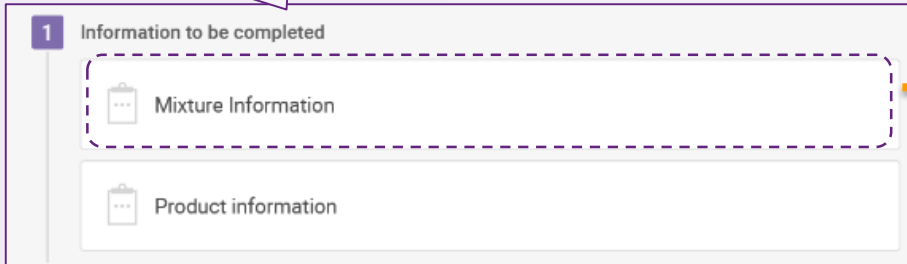
The number here indicates how many records have been created.



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

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

A dashed purple box highlights the first three tasks: 'Contact person(s)', 'pH', and 'Toxicological information'.



A snippet of the navigation menu is shown, titled '1 Information to be completed'. It contains two items: 'Mixture Information' and 'Product information'. A dashed purple box highlights the 'Mixture Information' item, with an orange arrow pointing from it to the main task page screenshot.



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

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.](#)

3

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

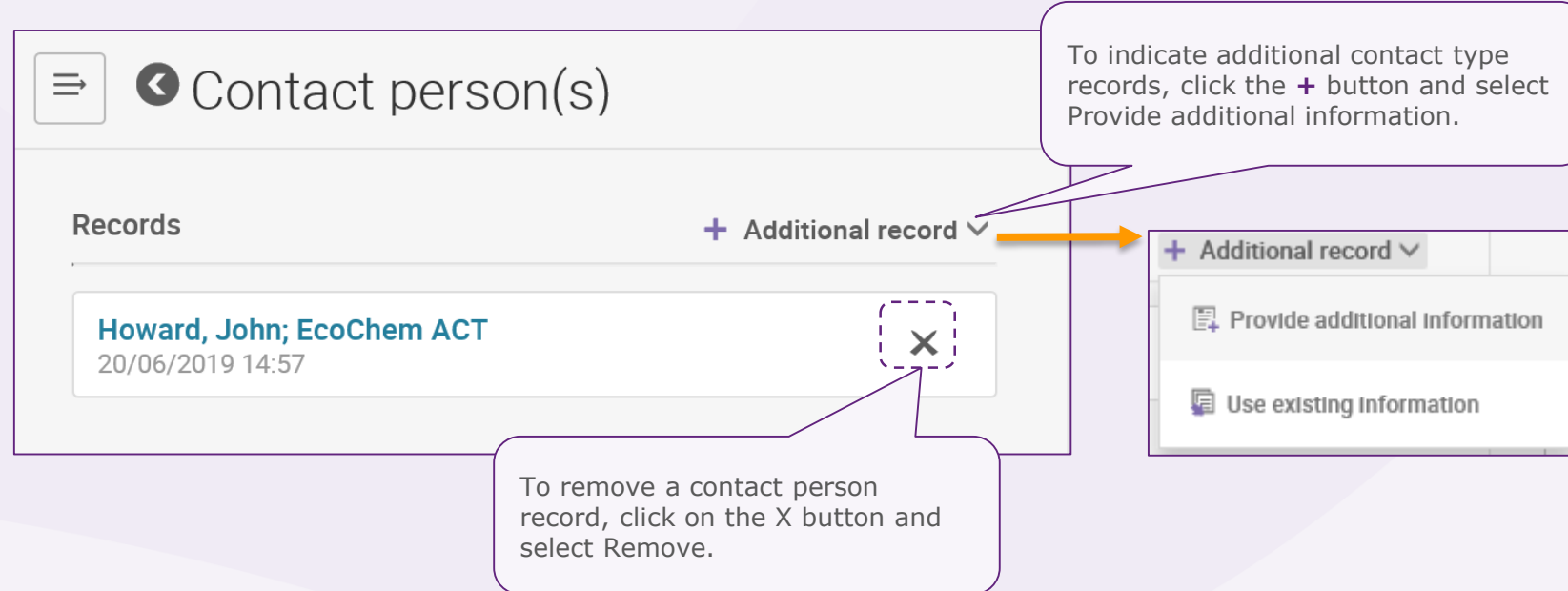
- competent person responsible for the SDS
- dossier contact
- emergency contact
- substance manager
- toxicologist
- other:

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.

4

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, with a callout box 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.

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

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

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

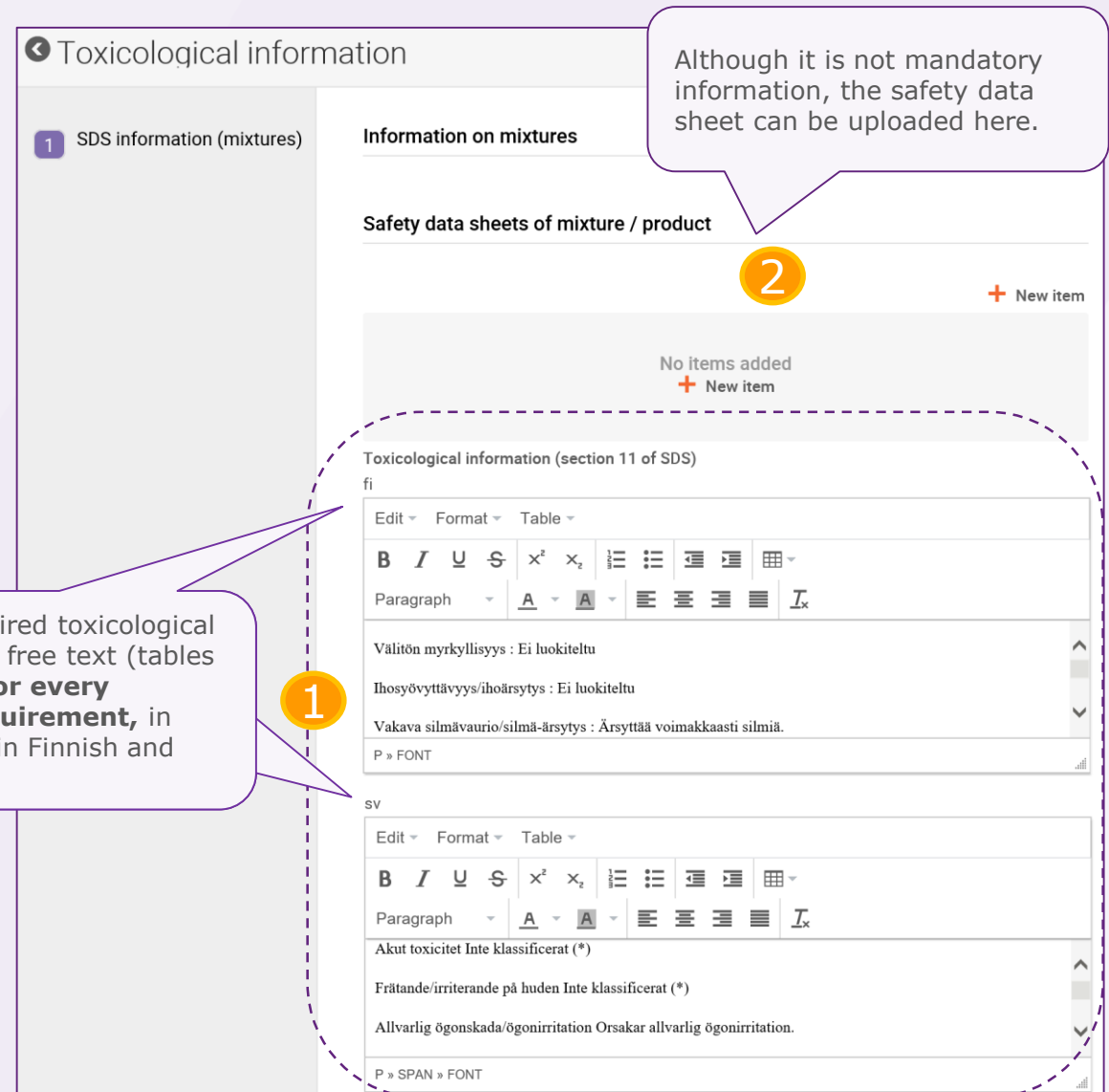
The 'Toxicological information' task

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.



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.

The screenshot shows the 'Toxicological information' task interface. It includes a sidebar with '1 SDS information (mixtures)', a main area for 'Information on mixtures' with a 'Safety data sheets of mixture / product' section (marked with '2'), and a rich text editor for 'Toxicological information (section 11 of SDS)'. The editor shows two language versions: Finnish (fi) and Swedish (sv). The Finnish version contains text: 'Välitön myrkyllisyys : Ei luokiteltu', 'Ihosityövyttävyys/ihoärsytys : Ei luokiteltu', and 'Vakava silmävaurio/silmä-ärsytys : Ärsyttää voimakkaasti silmiä.' The Swedish version contains: 'Akut toxicitet Inte klassificerat (*)', 'Frätande/irriterande på huden Inte klassificerat (*)', and 'Allvarlig ögonskada/ögonirritation Orsakar allvarlig ögonirritation.' Both editors have a 'P » FONT' button at the bottom.



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

No components have been added yet.

[+Mixture component](#)

Substance components

No components have been added yet.

[+Substance component](#)

Generic Product Identifier components

No components have been added yet.

[+Generic Product Identifier component](#)

☰
← 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](#).

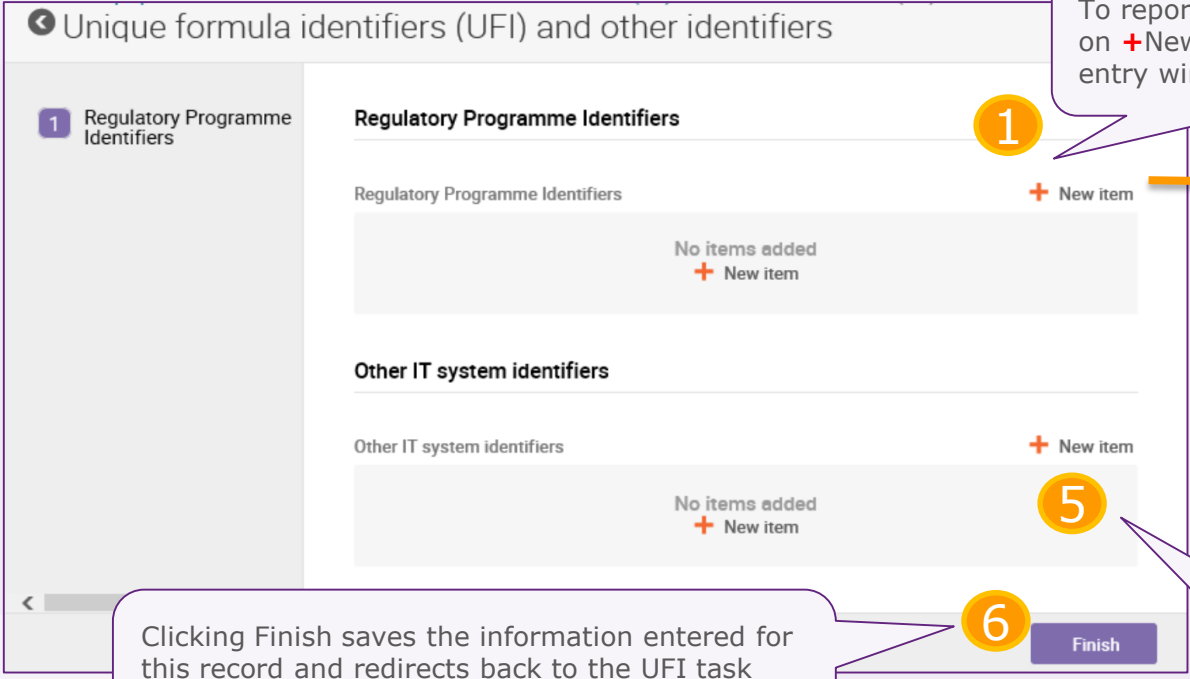
Function and concentration

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

0/255

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.

The screenshot shows a mobile application interface for 'Unique formula identifiers (UFI) and other identifiers'. At the top, there is a title bar with a back arrow and the text 'Unique formula identifiers (UFI) and other identifiers'. Below the title bar, there is a section labeled 'Records' with a yellow circle containing the letter 'a' next to it. To the right of 'Records' is a '+ Additional record' button with a dropdown arrow. Below this, there is a list of three records, each in a white box with a blue header and a grey body. The records are:

- 'Unique formula identifiers (UFI) and other identifiers.003' with a timestamp of '22/02/2019 15:01' and a close button (X).
- 'Unique formula identifiers (UFI) and other identifiers.002' with a timestamp of '22/02/2019 15:01' and a close button (X).
- 'Unique formula identifiers (UFI) and other identifiers.001' with a timestamp of '22/02/2019 14:43' and a close button (X).

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

The screenshot shows a mobile application interface for 'Unique formula identifiers (UFI) and other identifiers'. At the top, there is a title bar with a back arrow and the text 'Unique formula identifiers (UFI) and other identifiers'. Below the title bar, there is a section labeled 'Regulatory Programme Identifiers' with a yellow circle containing the letter 'b' next to it. To the right of 'Regulatory Programme Identifiers' is a '+ New item' button. Below this, there is a list of three items, each in a white box with a grey header and a grey body. The items are:

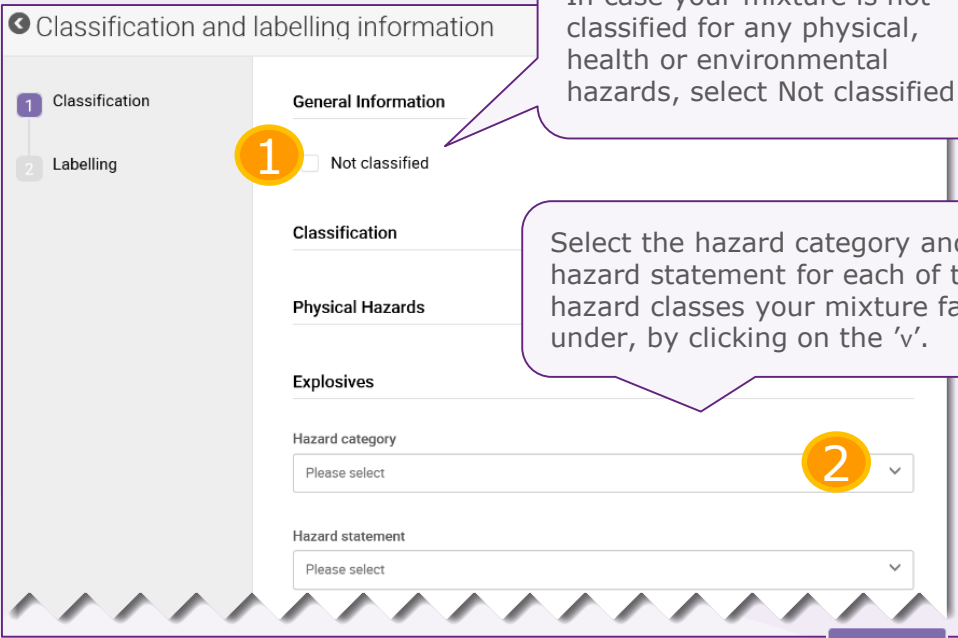
- 'CLP unique formula identifier (UFI)' with a timestamp of '22/02/2019 15:01' and a close button (X).
- 'CLP unique formula identifier (UFI)' with a timestamp of '22/02/2019 15:01' and a close button (X).
- 'CLP unique formula identifier (UFI)' with a timestamp of '22/02/2019 14:43' and a close button (X).

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.



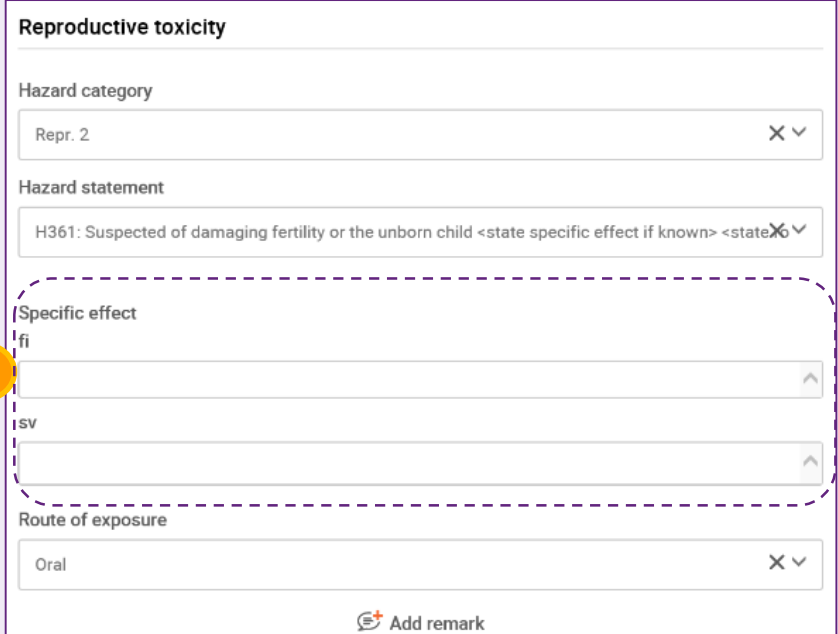
In case your mixture is not classified for any physical, health or environmental hazards, select Not classified.

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

Specific effect

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

GHS07: exclamation mark

Hazard statements

H319: Causes serious eye irritation.

Precautionary statements

P264: Wash ... thoroughly after handling.

Additional labelling requirements

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

1

+ New item

2

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

3

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. x v

Additional text

fi

kädet

sv

hander

Close

Finish



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
MIM 1

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

Function and concentration

Function 2
Please select

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

Typical concentration 3
Concentration range

Mixture-in-mixture composition

Components 4 + New item

Unique formula identifier (UFI) 5 + New item

Supplier 6
Manufacturer / Importer / Formulator
+ Select

Safety data sheets 7 + New item

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

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 +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 window, and either select a reference substance from the list or create one and provide the relevant information – see [Substance components](#) for more details.

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.

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.

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

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



Reporting substance components

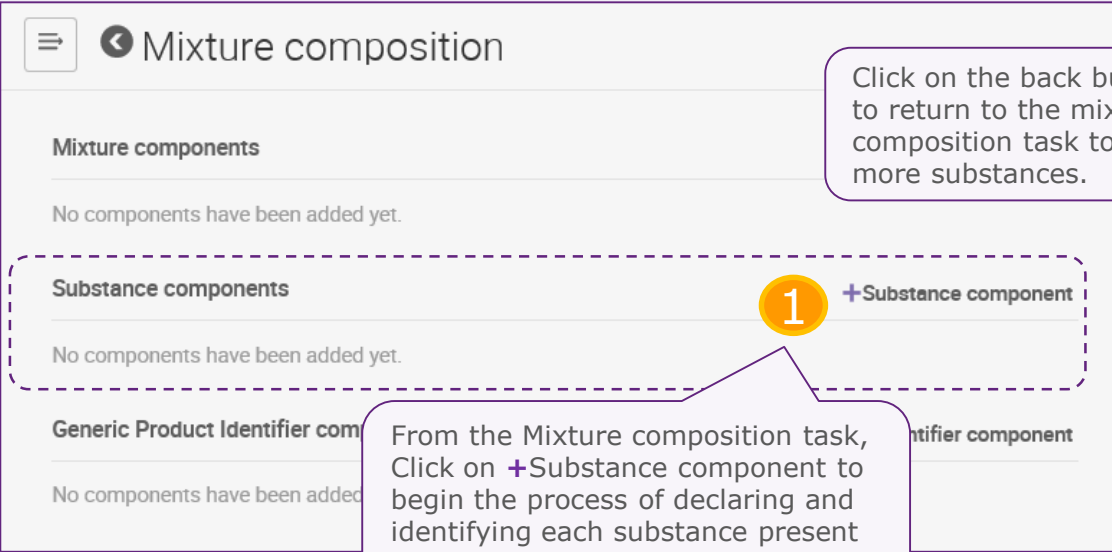
An overview of how to use IUCLID to complete the sub-tasks for substance components. Full details on the information requirements can be found from the *Guidance on harmonised information relating to emergency health response* at:

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

Substance components

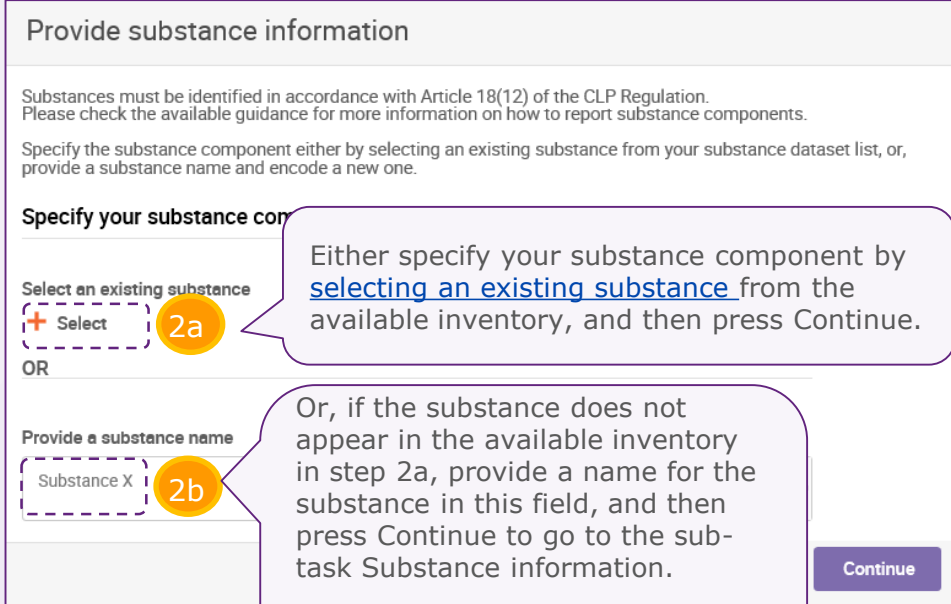
A substance component requires a record that contains information about function and concentration, its identity and its classification. Each substance component is linked to a **Reference Substance**.

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

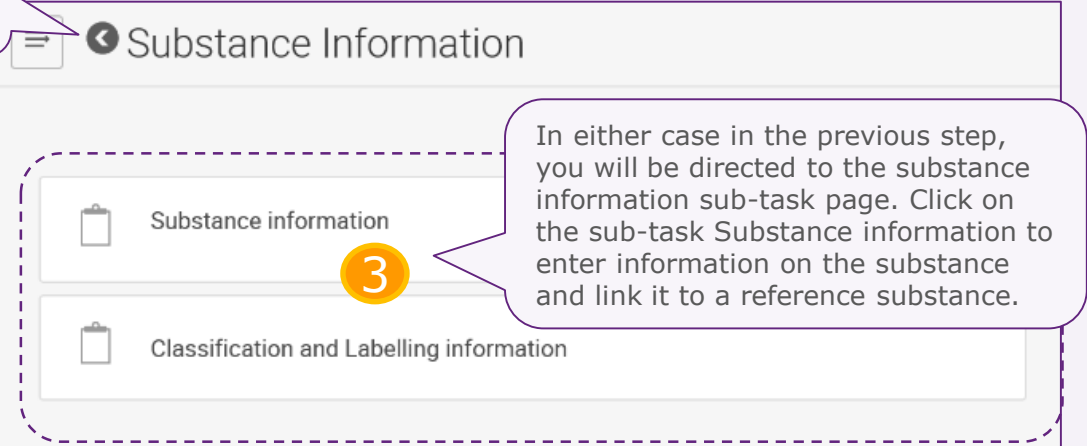
2b Provide a substance name
Substance X

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
143-78-6
CAS name
None
Synonyms

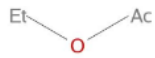
1 Identifier
None
Identity
Acetic acid ethyl ester

2 Identifier
None
Identity
Acetic acid ethyl ester

3 Identifier
None
Identity
Acetic acid ethyl ester

Molecular and structural information

Molecular formula
C₄H₈O₂
Molecular weight
88.105
SMILES notation
CCOC(=O)C
InChI
InChI=1/C4H8O2/c1-3-6-4/[2]/N3Z1-2H3
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 201-771-2

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.

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

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

3



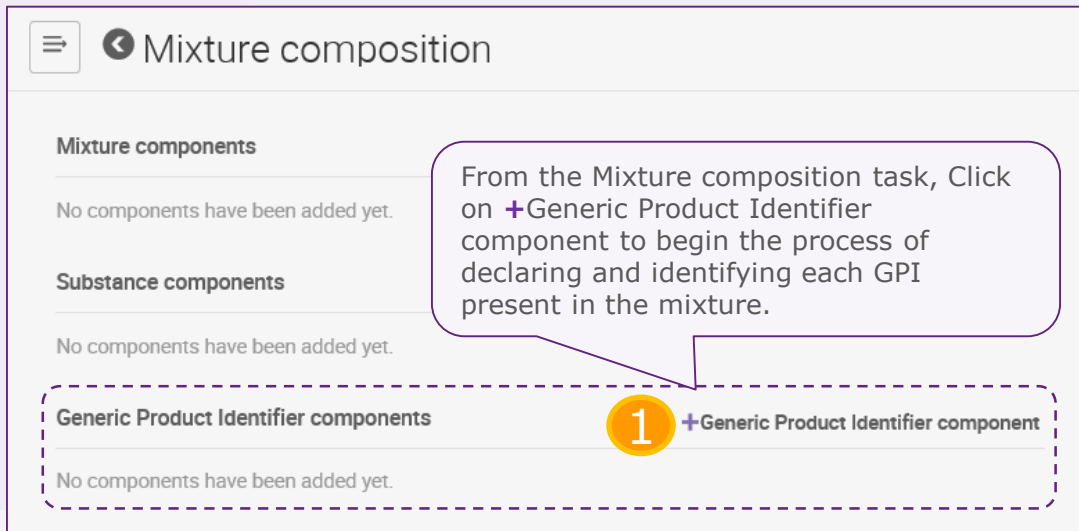
Reporting generic product identifier components

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.



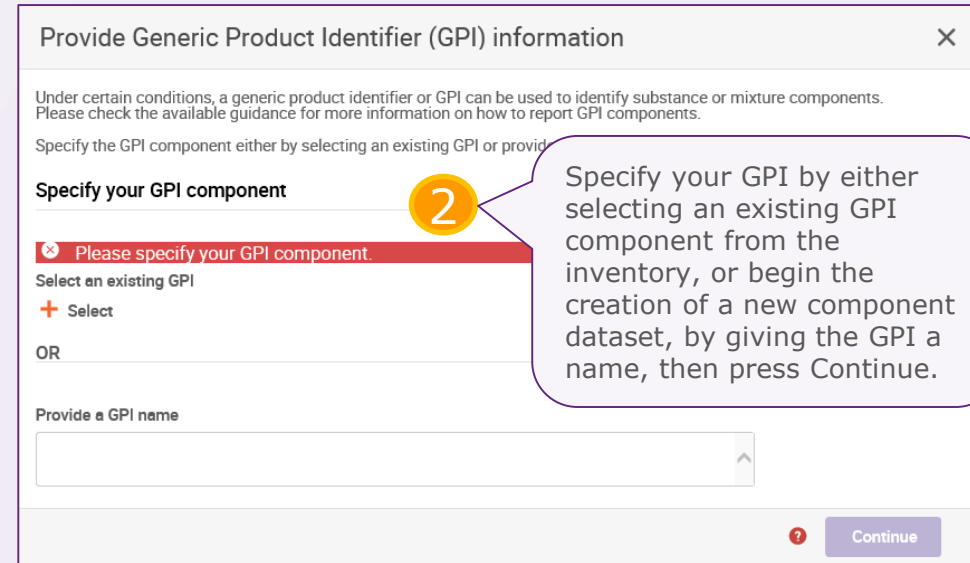
Mixture composition

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.

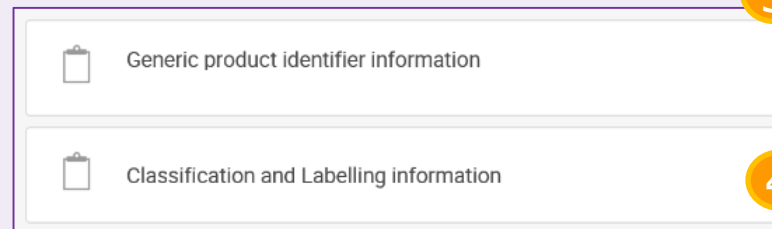
Select an existing GPI
+ Select

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 3

Classification and Labelling information 4

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

This screenshot shows the 'Hazardous mixture 1' dashboard. At the top, it displays the breadcrumb 'Dashboard > Guided dossier preparations > Hazardous mixture 1' and a hamburger menu icon. Below this is the title 'Hazardous mixture 1' and the submission type 'CLP Poison centres notification'. The main content area is divided into two sections: '1 Provide dossier information' and '2 Finalize your dossier'. Under '1 Provide dossier information', there is a list of tasks to be completed: 'Mixture Information' and 'Product information'. The 'Product information' task is highlighted with a yellow circle containing the number '1'. A speech bubble points to this task with the text: 'Once you have clicked on Product information section from the dossier preparation navigation page, the Product details task appears.' At the bottom of the page, there are three buttons: 'Validate', 'Create dossier', and 'Preview notification'.

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

This screenshot shows the 'Product information' page. It features a breadcrumb 'Product information' and a hamburger menu icon. The main heading is 'Product information'. Below the heading, there is a text block: '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.' Below this text is a task card titled 'Product details' with a timestamp '09/07/2019 10:06' and a small grey circle containing the number '3'. A yellow circle with the number '2' is positioned to the right of the task card. A speech bubble points to this task card with the text: '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.'

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.

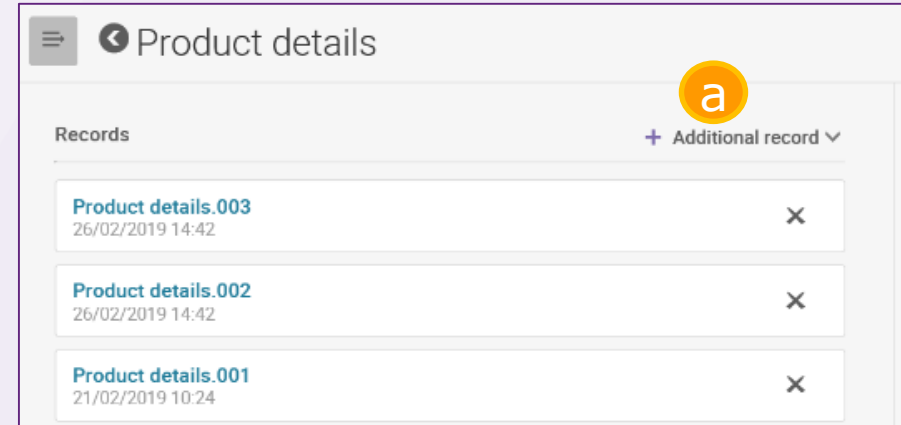
By clicking on the Product details task, you will be referred to the all the product records

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:

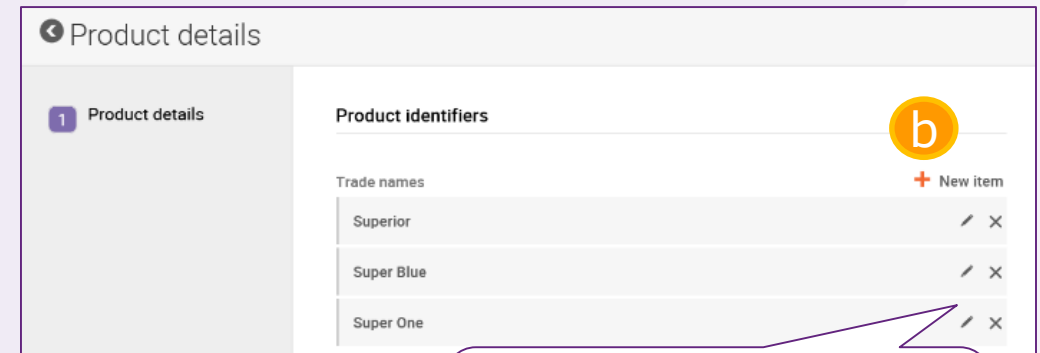
- a) numerous '**Product records**' can be created where each one can be distinguished from the other i.e. products with different trade names or UFIs, market areas, or packaging types for instance.
- b) numerous products are listed as '**items**' and reported in a single Product details record.



Product details

Records + Additional record ▾

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



Product details

1 Product details

Product identifiers + New item

Trade names	
Superior	✎ ✕
Super Blue	✎ ✕
Super One	✎ ✕

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.

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

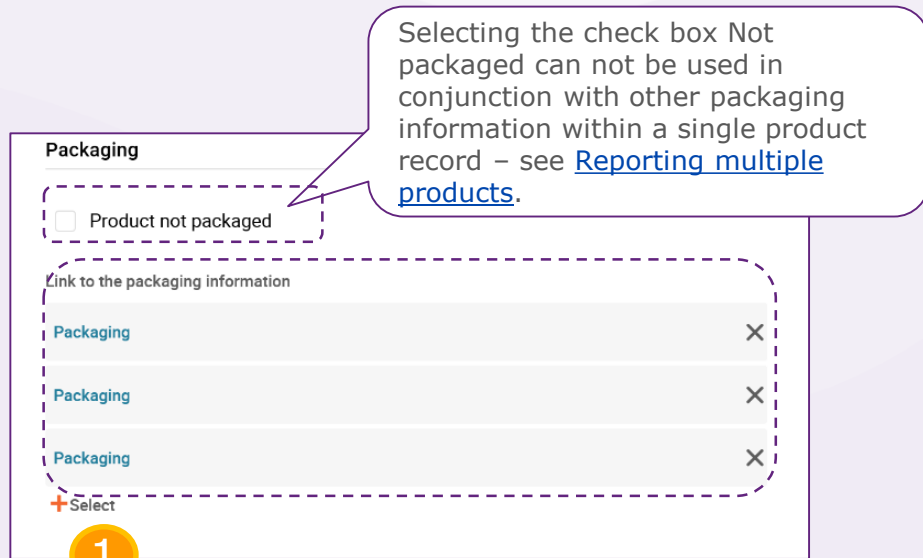
3

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.



Product not packaged

Link to the packaging information

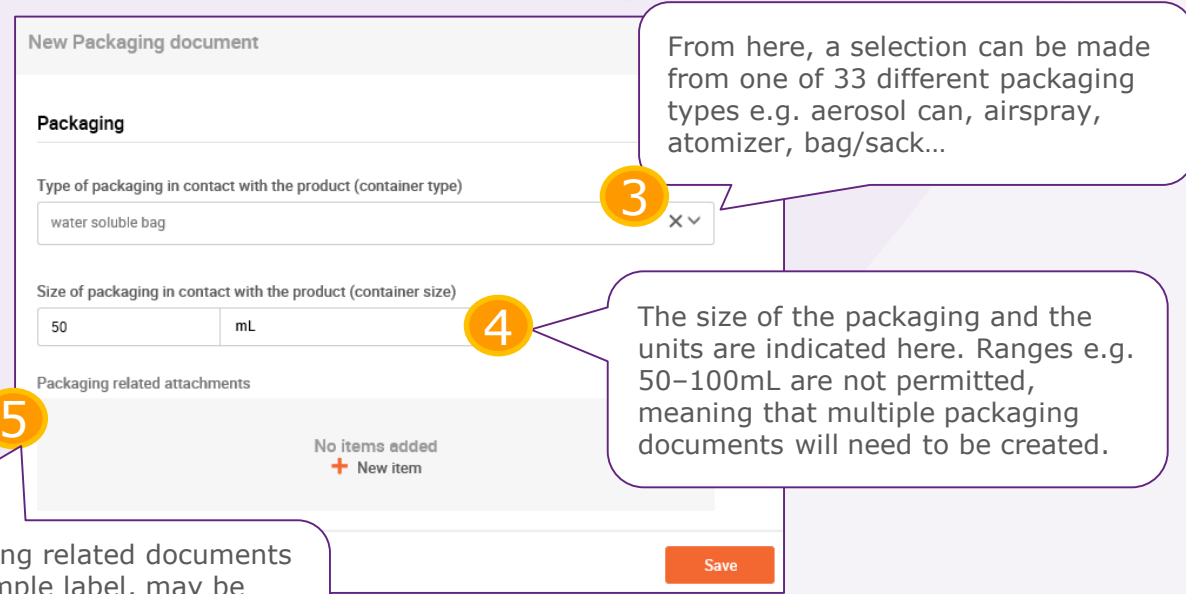
Packaging	X
Packaging	X
Packaging	X

+ 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.

Use type

▼

Consumer

Professional ✓

Industrial ✓

Selection of multiple use types for the mixture is possible.

Product use category

Use type

Main intended use

Secondary uses

Finish

1

2

3

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.

Main intended use

Please select

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

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

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

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

PC-ADH-5 Adhesives and sealants - transportation industry

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

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>



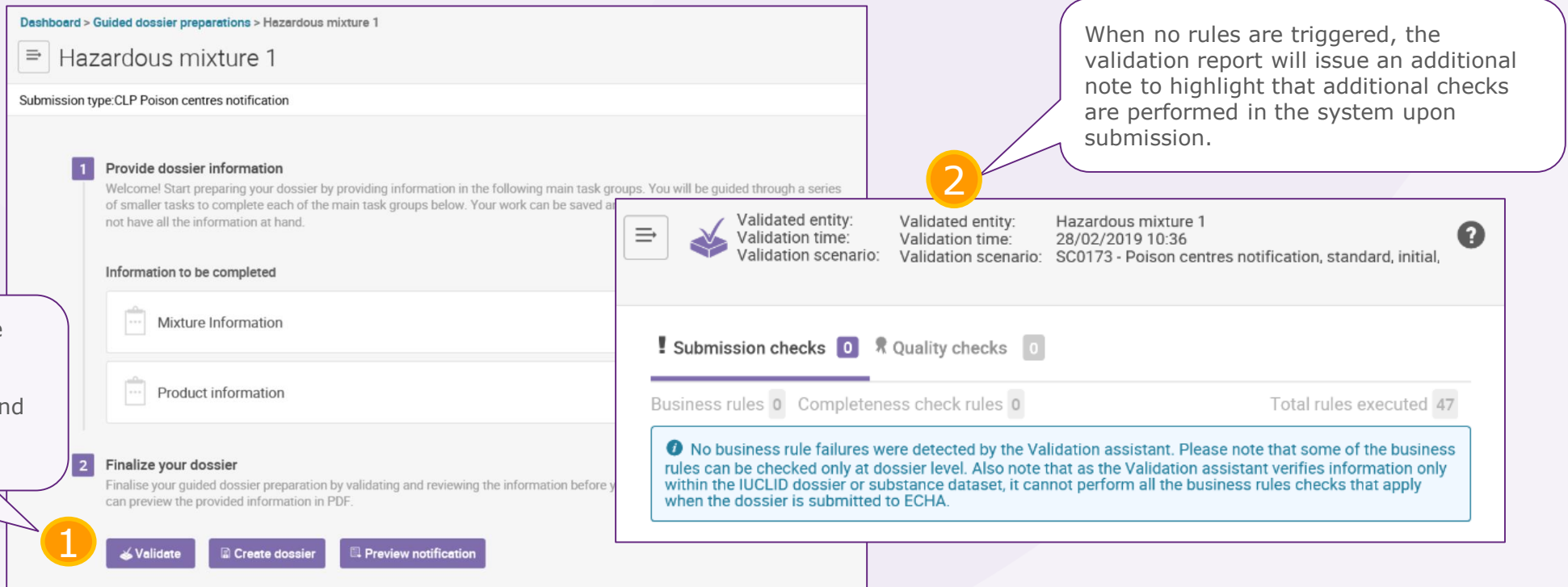
Validate information, create dossier and preview notification

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 shows the Validation report.

On the right, a validation summary box 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 summary box displays the following information:

- 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

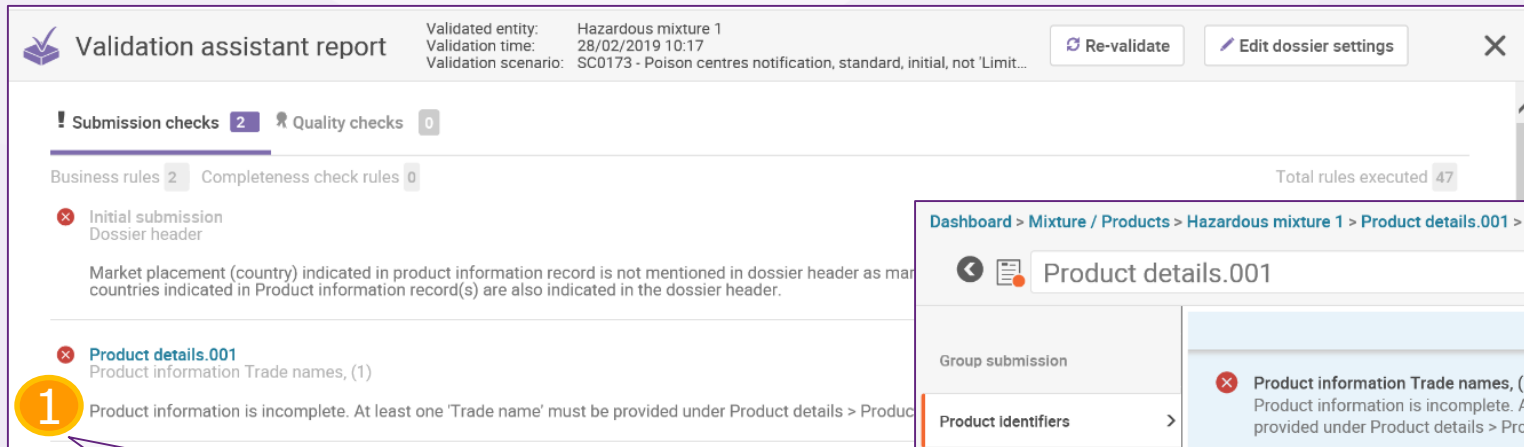
A blue information box at the bottom of the validation summary states: "No business rule failures were detected by the Validation assistant. Please note that some of the business rules can be checked only at dossier level. Also note that as the Validation assistant verifies information only within the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

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...

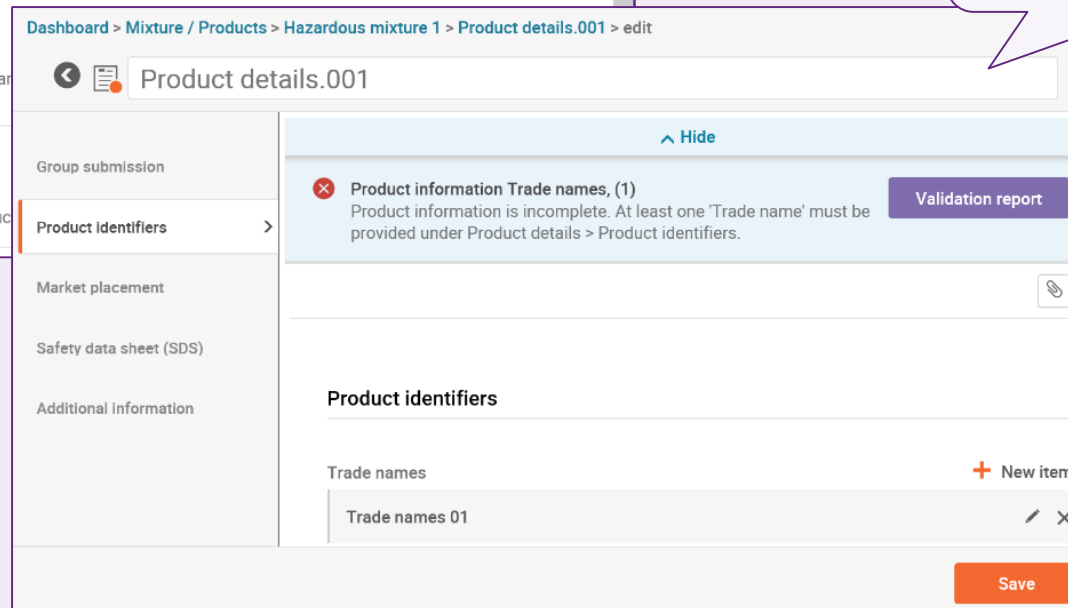
Re-validate Edit dossier settings

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

1 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

Hide

- Group submission
- Product identifiers** >
- Market placement
- Safety data sheet (SDS)
- Additional information

Product information Trade names, (1)
Product information is incomplete. At least one 'Trade name' must be provided under Product details > Product identifiers. Validation report

Product identifiers

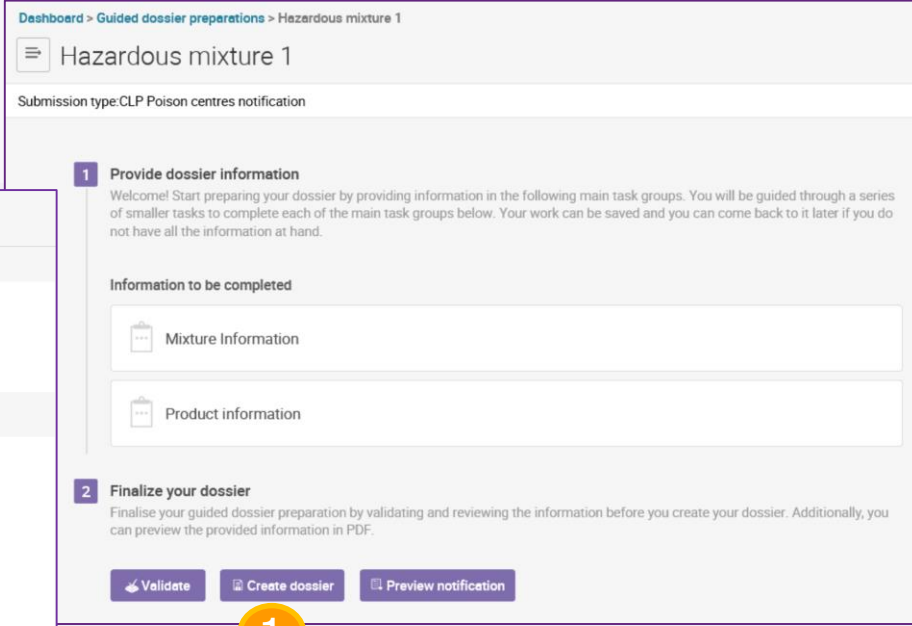
Trade names + New item

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

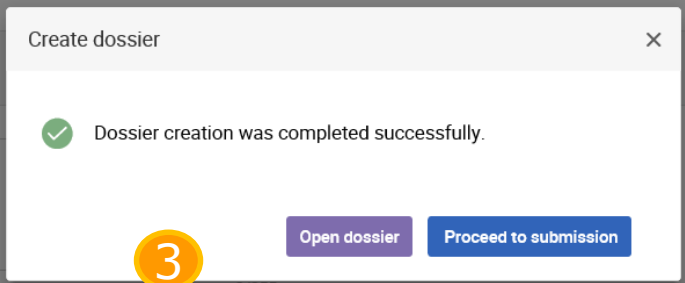
- Limited submission (industrial use only)
- Group submission
- Voluntary submission

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 two screenshots from the IUCLID Dashboard. The first screenshot shows the main dashboard with three cards: "Guided dossier preparation 2", "Substances 15", and "Mixtures 10". The "Mixtures 10" card is highlighted with a dashed purple border. A callout box points to this card with the text: "Clicking on the name of the mixture, redirects to the View dossier page." The second screenshot shows the "Mixtures" page. At the top, there is a search bar containing the text "Hazardous" and a search icon, with "1 result found" displayed to the right. Below the search bar is a table with one entry: "Hazardous mixture 1". The table has columns for "Subject name" (Hazardous mixture) and "Submission type" (CLP Poison centres notification). To the right of the table entry is a date "24/06/2019 13:38" and a lock icon. A callout box points to the lock icon with the text: "In View dossier mode, the lock symbol denotes a dossier file." Another callout box points to the "Dossiers" tab in the top right corner of the page with the text: "Switch between View dossier and View mixture dataset".

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 Poison 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.

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

Switch between View dossier and View mixture dataset

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	
pH is relevant	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

