Poison centre notifications

A GUIDE TO DOSSIER PREPARATION AND SUBMISSION

Version 2.1 May 2020

ECHA EUROPEAN CHEMICALS AGENCY

IUCLID 6

ECHA Cloud Services

ECHA Submission portal

Poison centres

Poison centres

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Getting access

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

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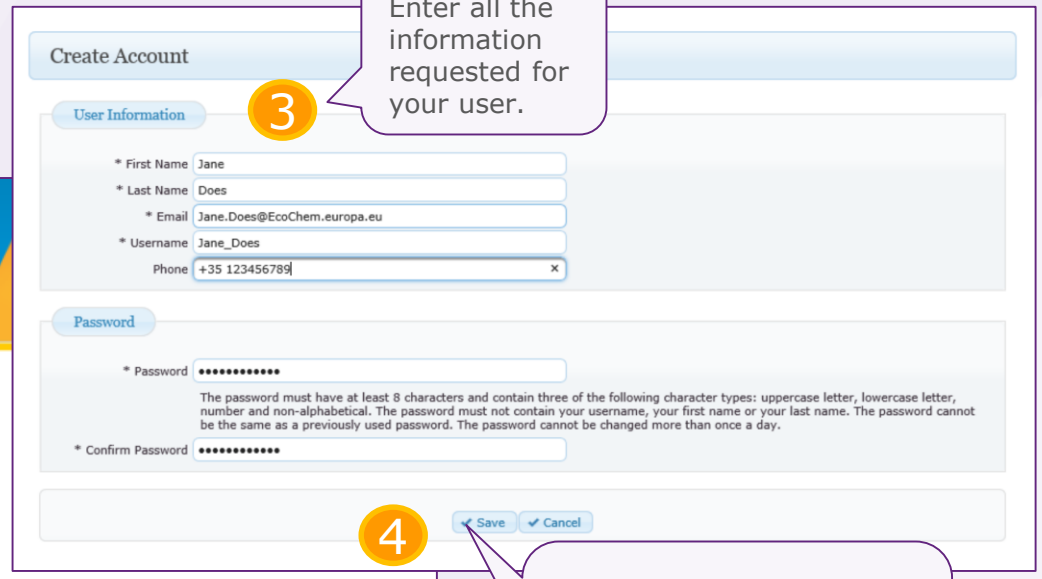
Creating an ECHA account

You must create an ECHA Account if you want to use the ECHA Cloud Services for preparing your notifications.

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

! Using the latest version of **Chrome**, **Firefox** and **Microsoft Edge** guarantees the best user experience.

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



Enter all the information requested for your user.

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

You can find more detailed information about managing your account in the ECHA Accounts Manual.

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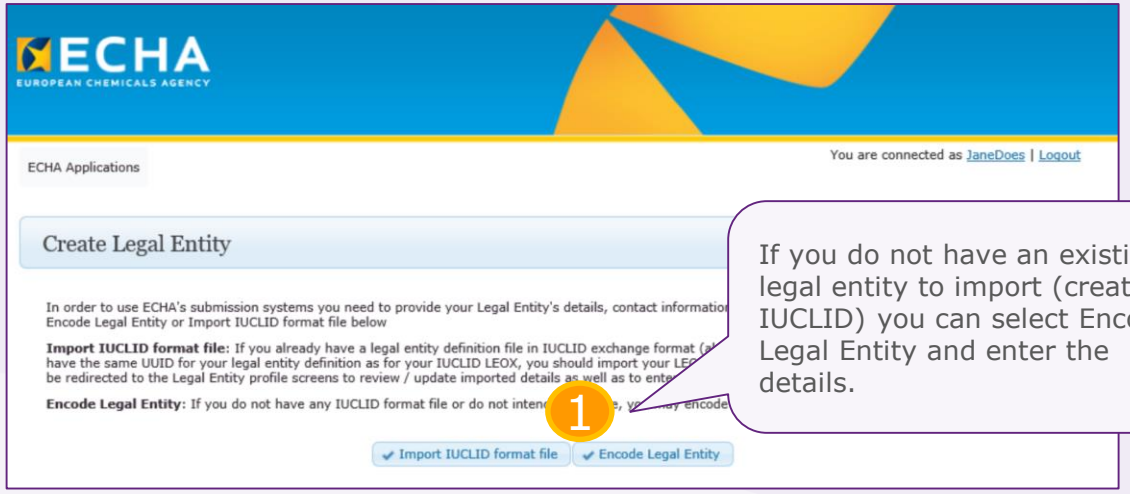
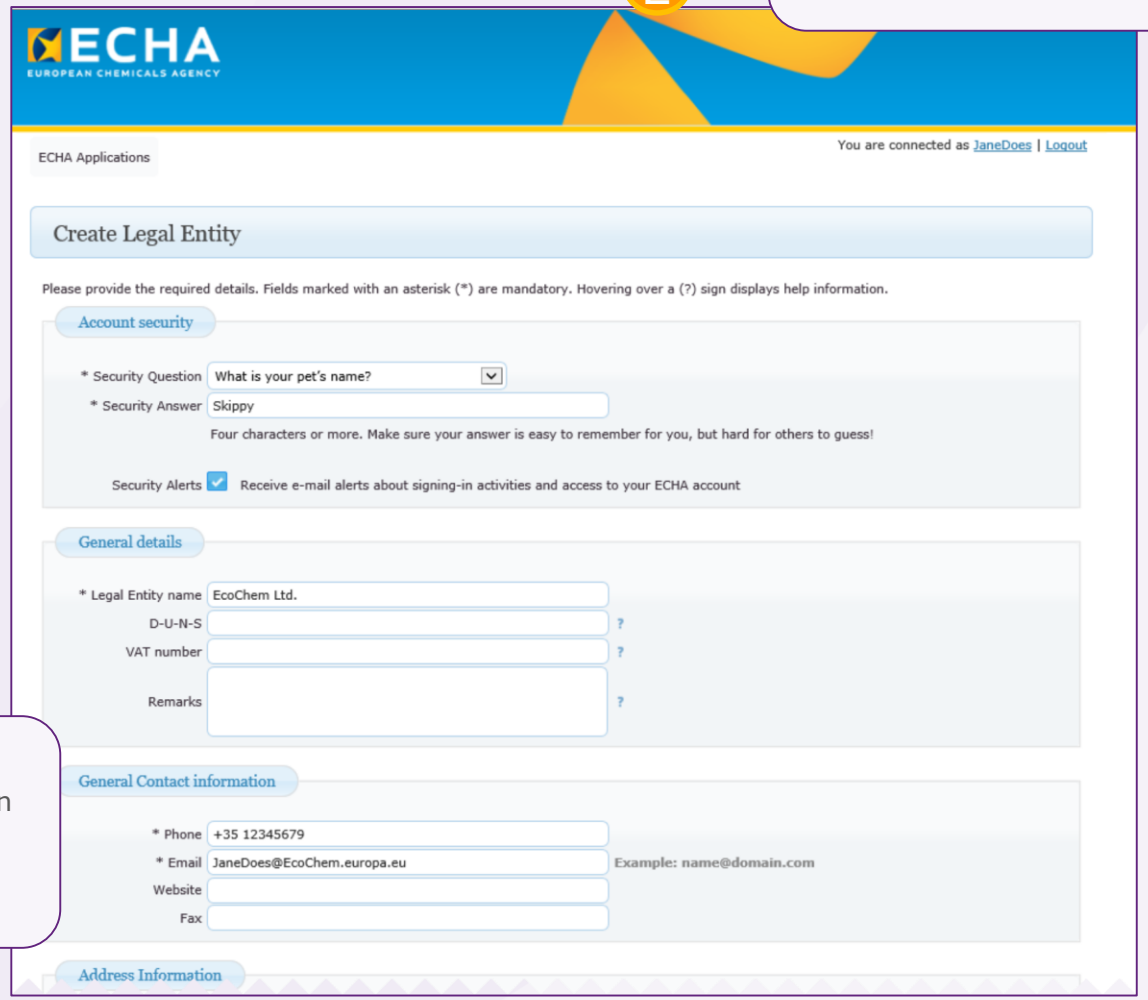
Assign the Legal Entity

Once you have created an ECHA Account, it needs to have a legal entity (LE) assigned to it. Then you will be able to access the ECHA IT applications.

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

The first user associated with a legal entity is a legal entity manager.





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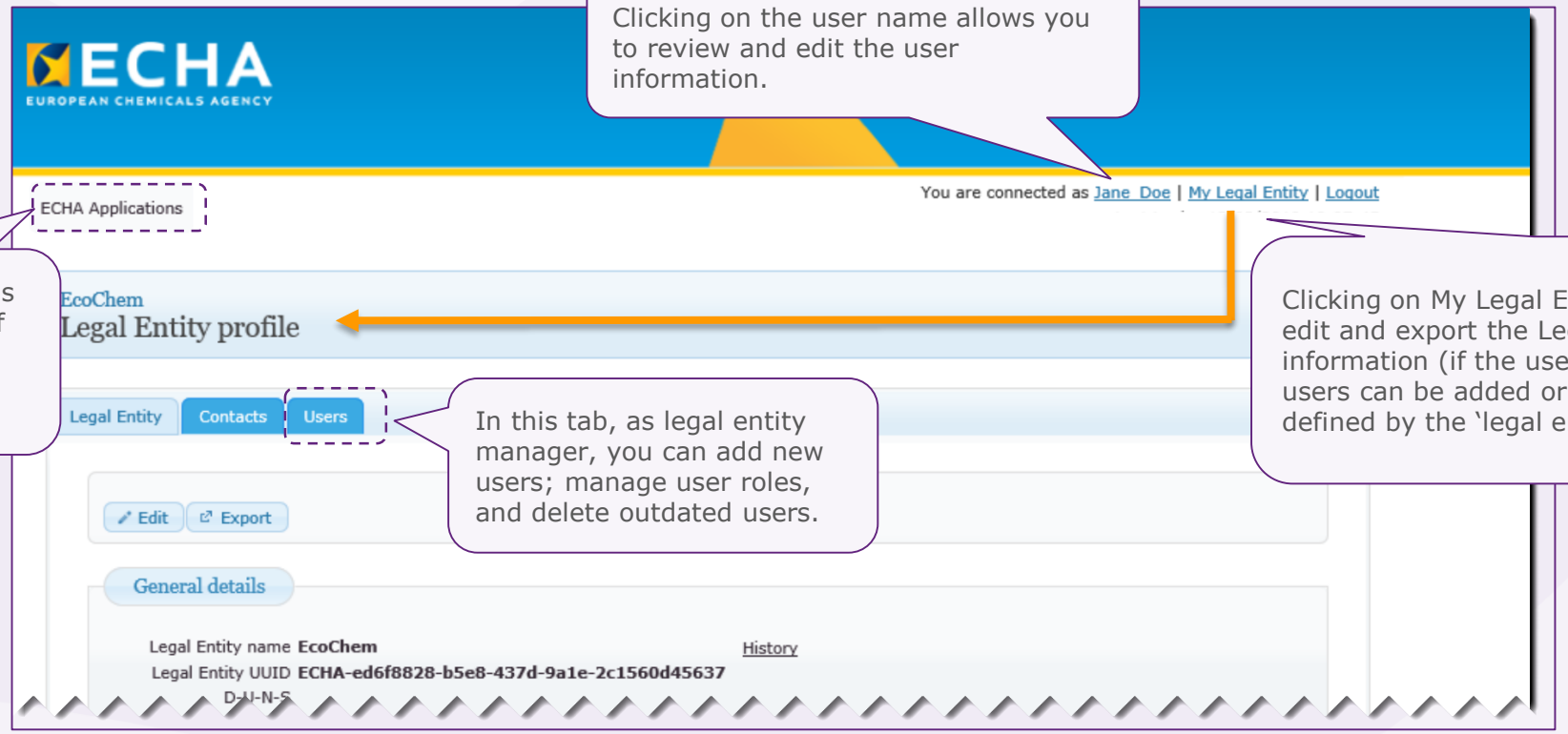
ECHA Accounts navigation



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

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

In this tab, as legal entity manager, you can add new users; manage user roles, and delete outdated users.

Clicking on My Legal Entity allows you 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'.

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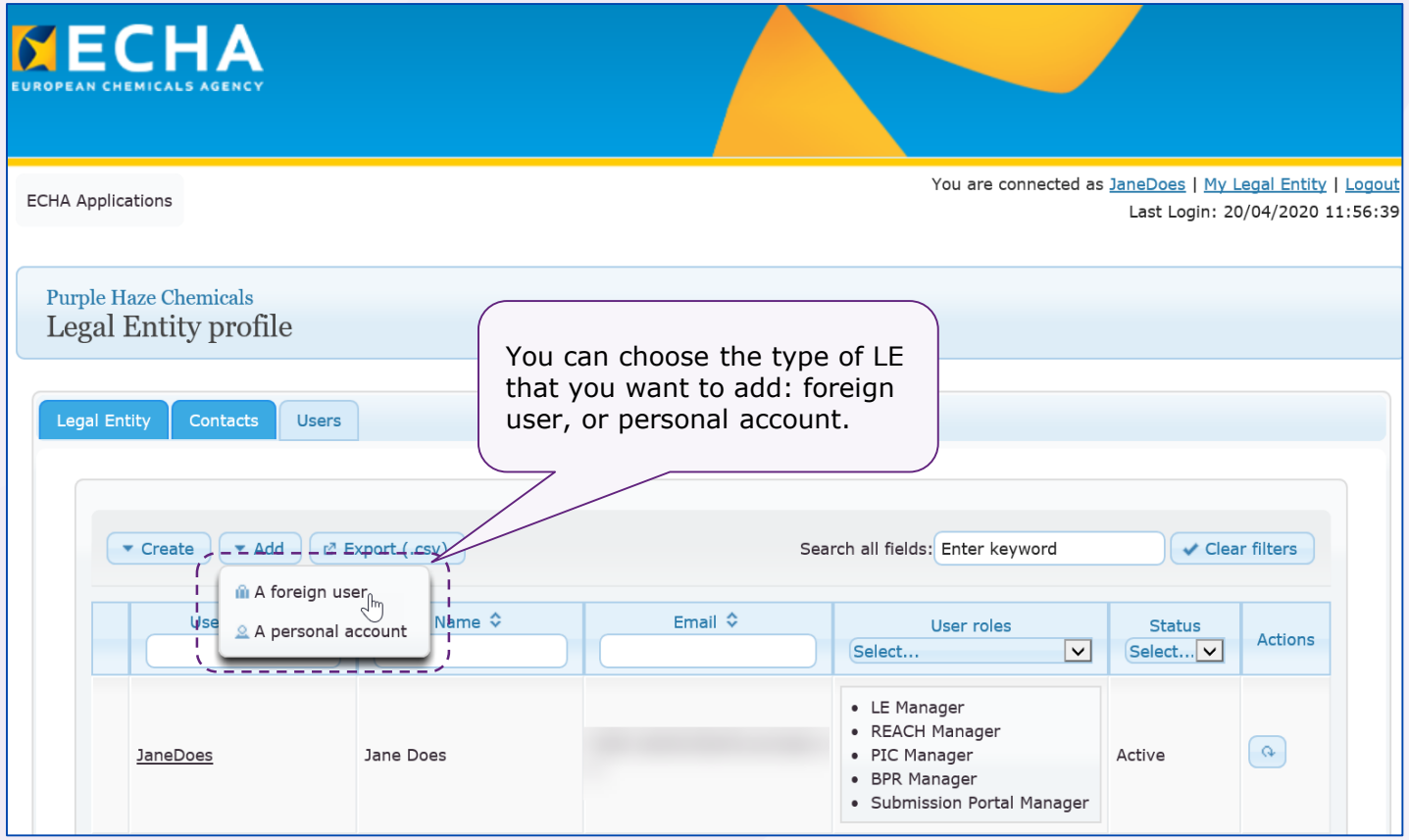
Assigning a foreign user

It is possible to add a foreign user, or a 'third party', in ECHA Accounts. This user can work on behalf a company using the IUCLID Cloud and ECHA Submission portal.

The foreign user can be, for example, a consultant or a mother company working on behalf a subsidiary.

The foreign user will also be able to see in ECHA Accounts the list of legal entities for which he works.

! If the legal entity of the submitter does not match the legal entity of the dossier (mixture level), the error BR570 will be triggered. It will appear in the validation report, and the submission will fail – you can find instructions in the **PCN: practical guide** at https://poisoncentres.echa.europa.eu/echa-submission-portal



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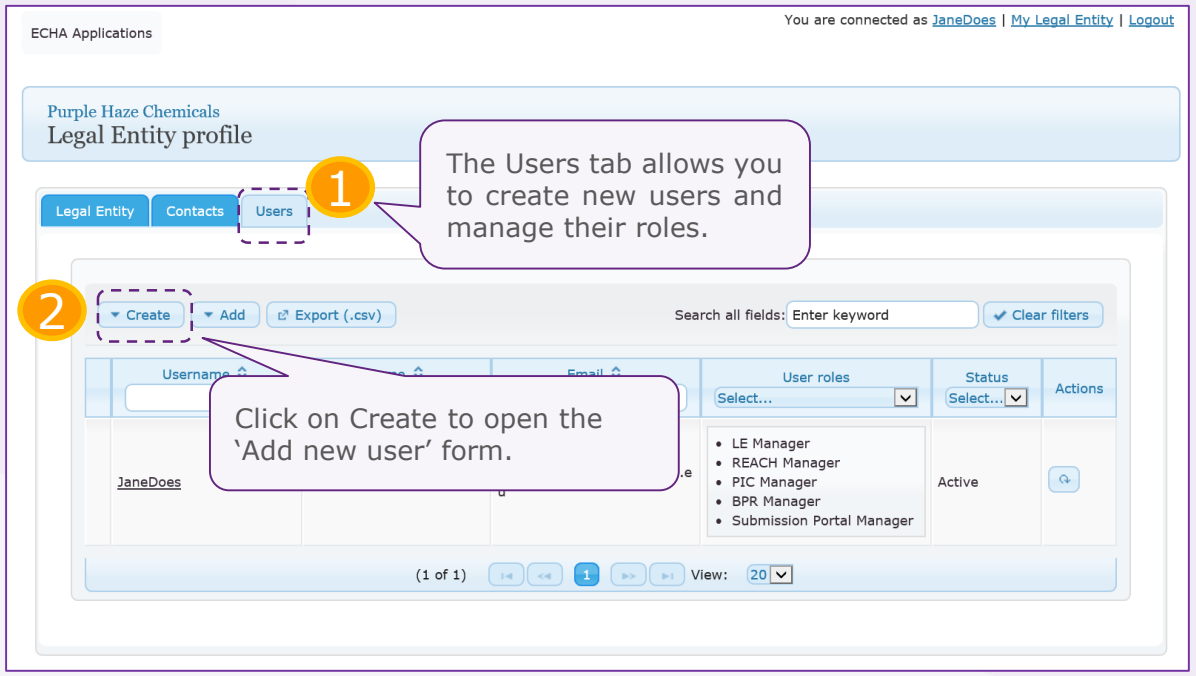
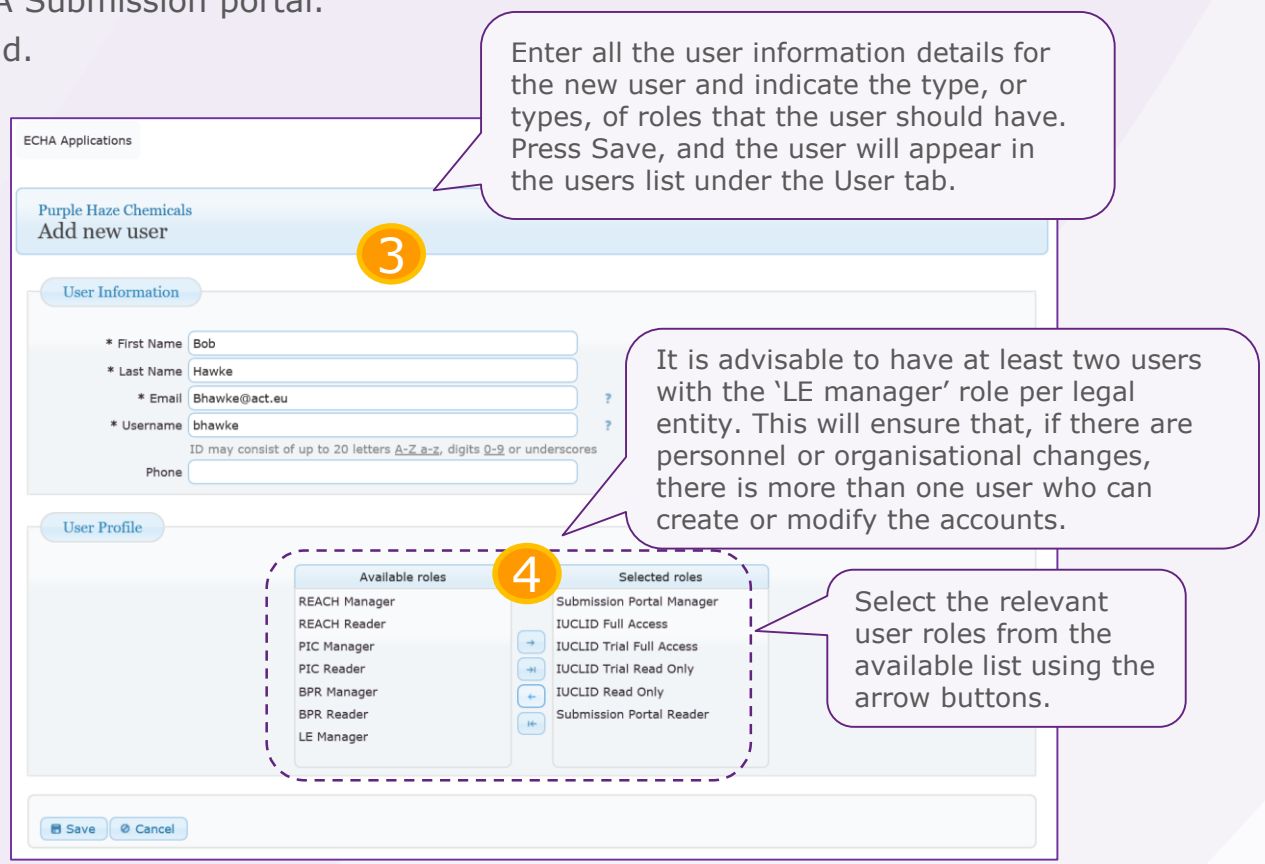
Defining the user roles

The user roles define the user access level within the ECHA IT applications. The PCN related roles include:

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





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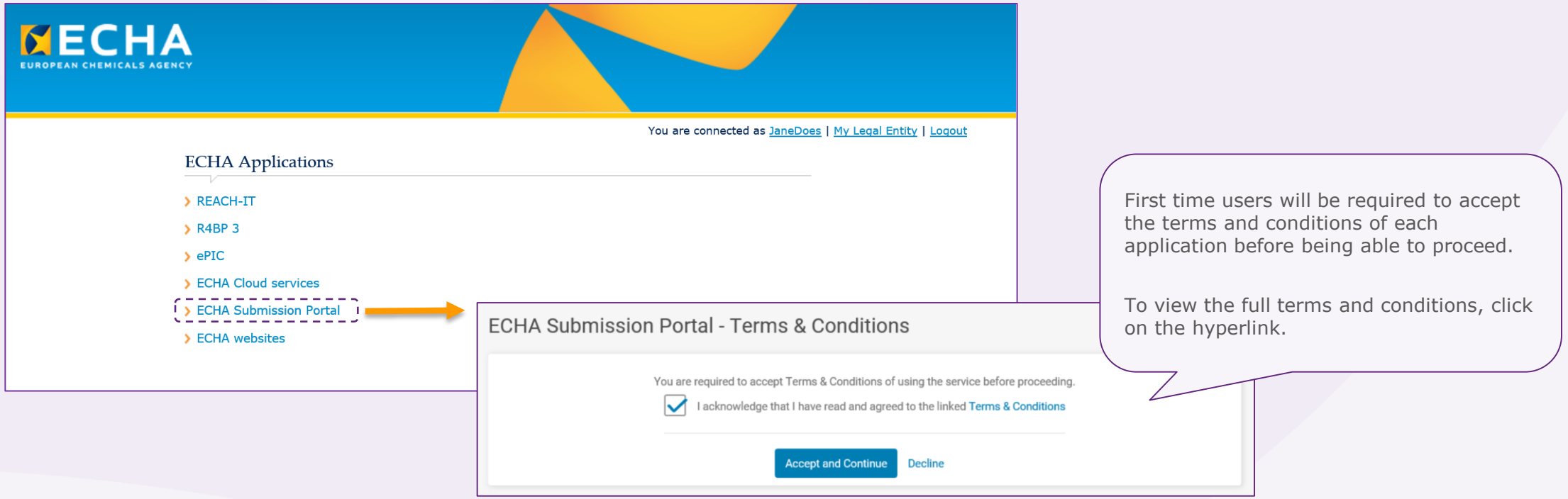
Terms and conditions



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 hyperlink.

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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
- searching for notifications

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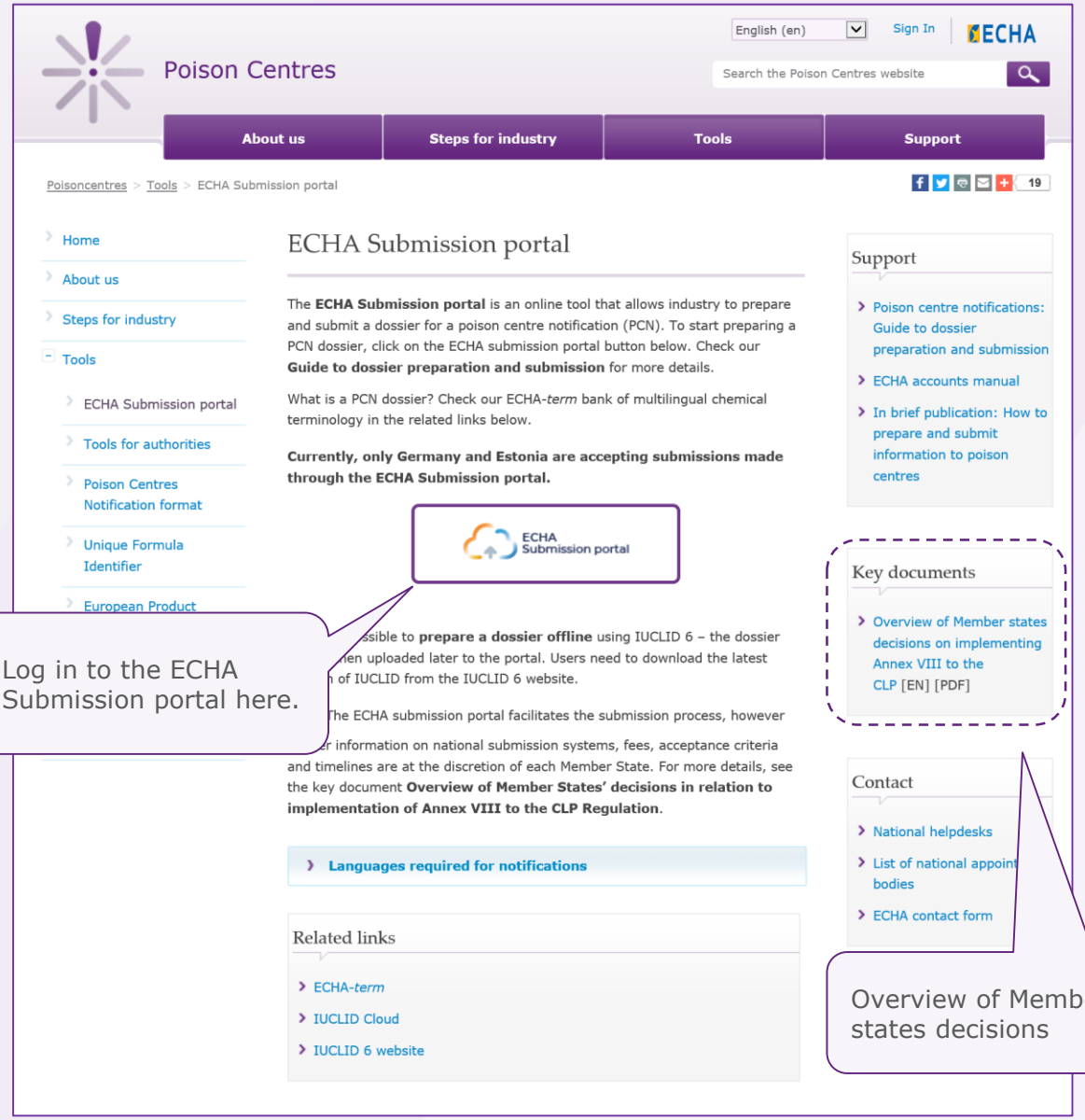
ECHA Submission portal webpage

The ECHA Submission portal webpage is available from the ECHA Poison Centre website, and directly at:

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

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

! Refer to the **Overview of Member States decisions on implementing Annex VIII to the CLP** key document which details which Member States are ready to receive notifications submitted through the ECHA Submission portal.



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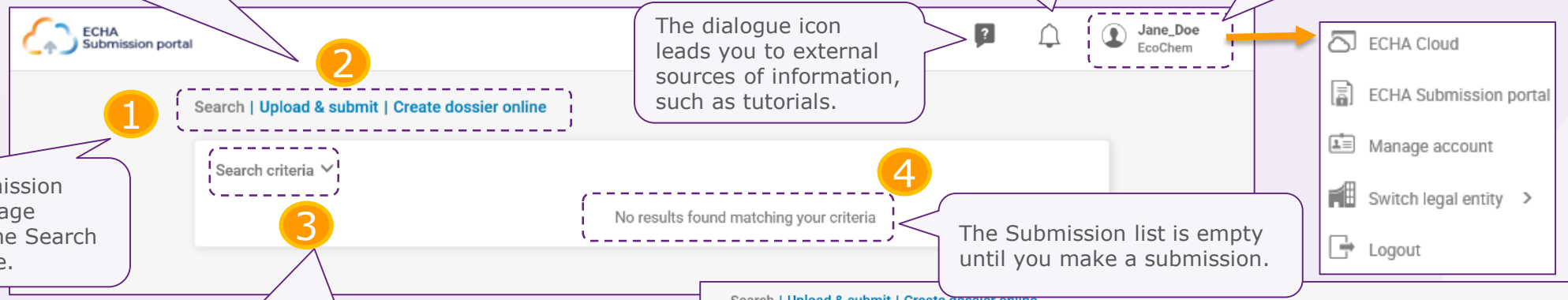
ECHA Submission portal landing page

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

The bell icon will alert you, for example, when new versions have been released.

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

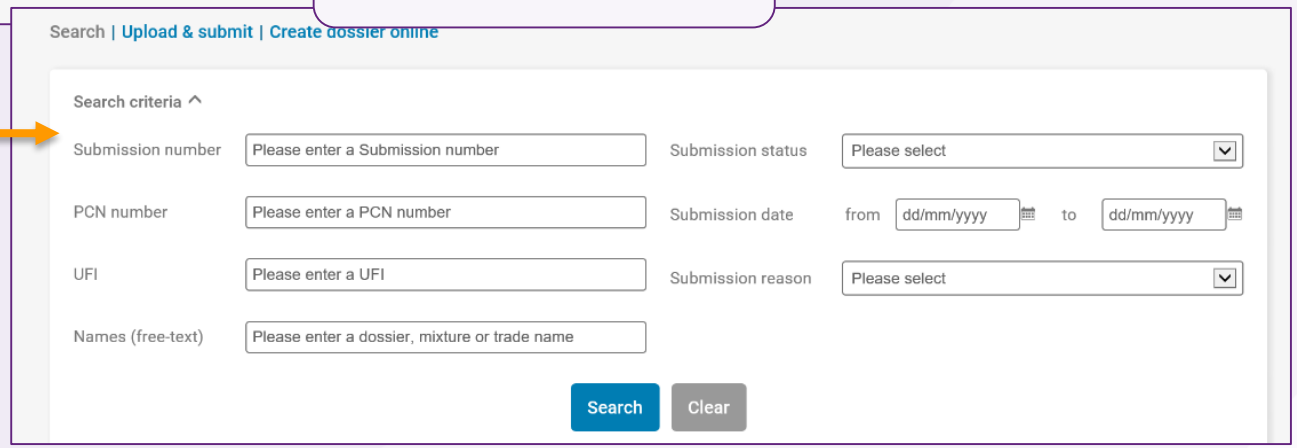
The dialogue icon leads you to external sources of information, such as tutorials.



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

The Submission list is empty until you make a submission.

Click here to expand or collapse the search criteria window.



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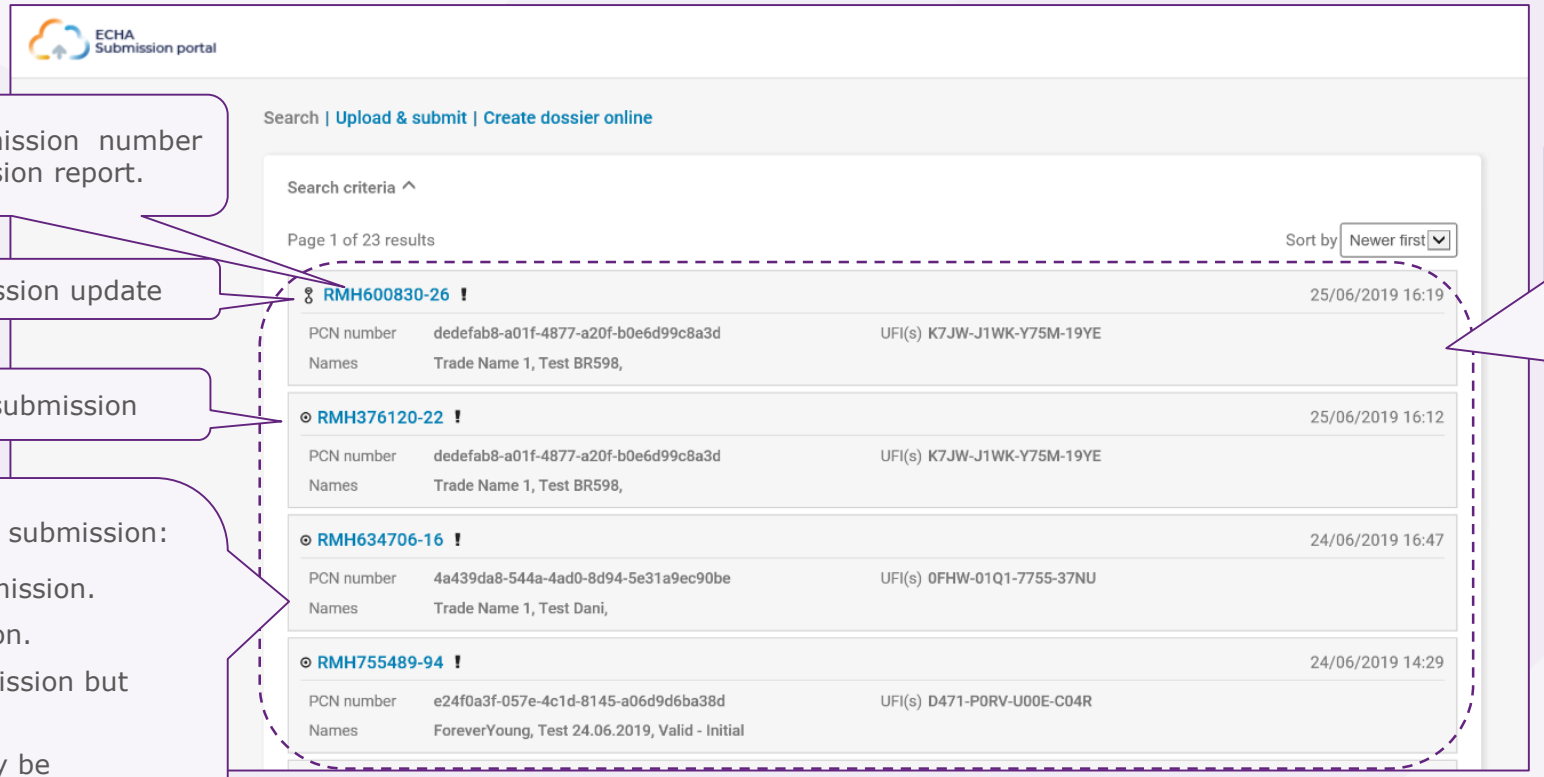
ECHA Submission portal Search page



Click on the submission number to view the submission report.

Symbol for submission update

Symbol for initial submission

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

Indicators on the status of the submission:

'✓' indicates a successful submission.

'X' indicates a failed submission.

'!' indicates a successful submission but which contains warnings.

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

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Submission number, PCN number, UFI – which is which?

Submission number: Number automatically assigned by the ECHA Submission portal after a submission. This number can be used to track or monitor a submission if any issues arise during the submission process. For example: **RMH755489-94**

PCN number: Number assigned to an initial notification and used by poison centres to track all related notification updates. A PCN number can be generated either in the dossier preparation tools, or by you, using one of the UUID generators available online, for example, https://www.uuidgenerator.net/. An example of a PCN number is **5b2faca2-fc5b-4c6b-9c64-84de096ae811**

Related PCN number: A related PCN number is in essence a new PCN number required for an update notification (where the mixture composition has significantly changed). This related PCN number must refer to the previous PCN number in the updated notification.

Unique formula identifier (UFI): The UFI is a 16-character alphanumeric code with a defined format (for example: **P200-U0CW-500A-QVFJ**). The UFI is required in the notification and on the label of your products. You can generate the UFI using the UFI Generator tool available from ECHA's Poison Centre Website https://poisoncentres.echa.europa.eu/ufi-generator

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The submission report

Validation succeeded - the submission has passed the validation checks. The dossier has been dispatched and is 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, who will need to make a new submission .

The submission number is automatically assigned by the system.

Submitter information and legal entity UUID.

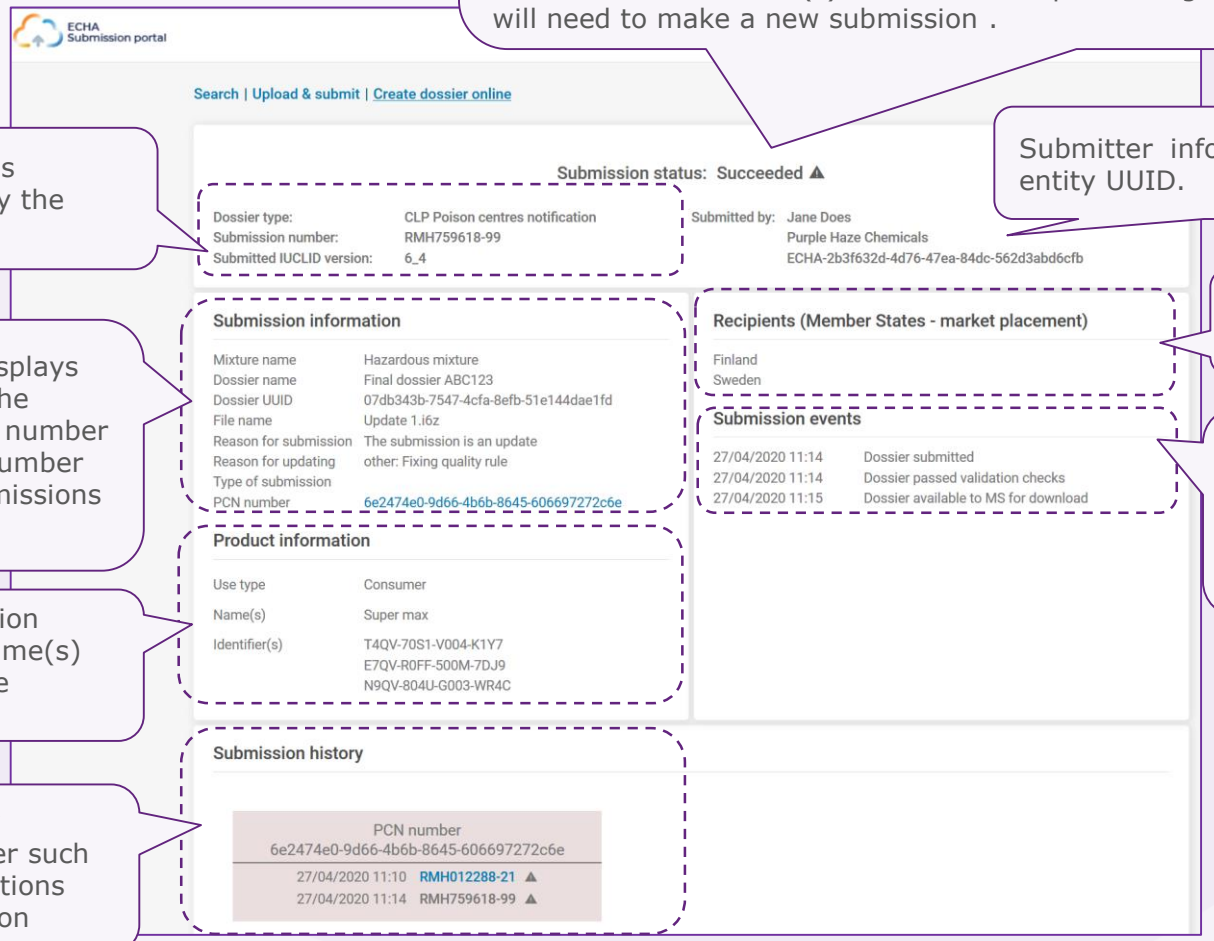
The submission information displays all the information related to the submission, including the PCN number for the notification. The PCN number is a link displaying all the submissions related to that number.

Here are listed the receiving Member States for the notification.

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.

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

The submission history displays how submissions are related to each other such as: initial, updates, and new notifications after significant change of composition



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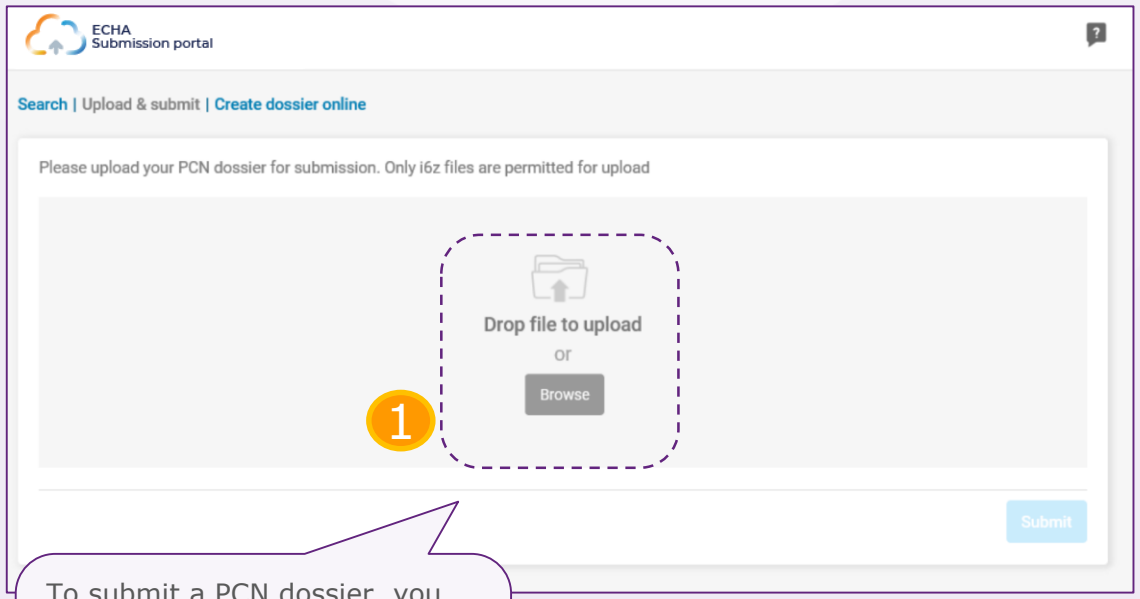
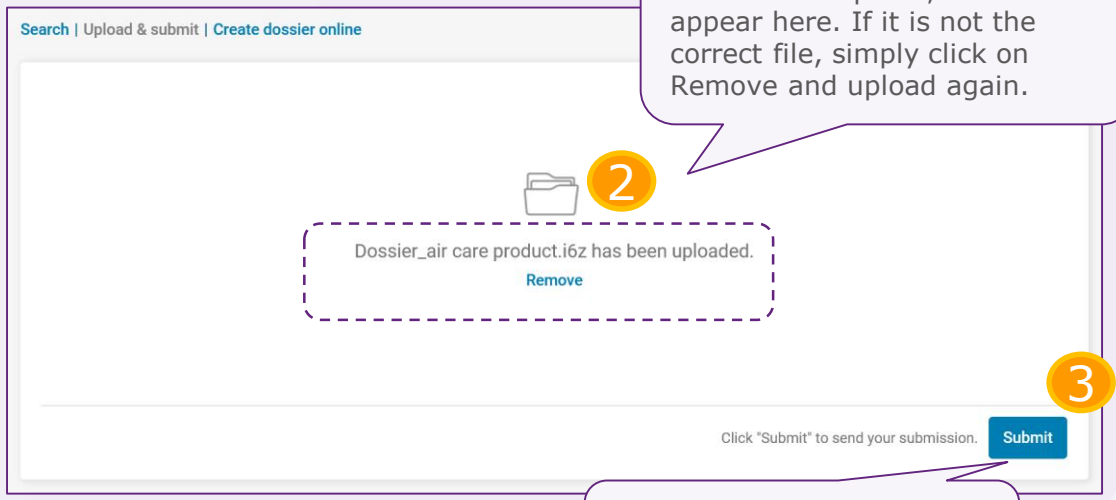
Upload and submit

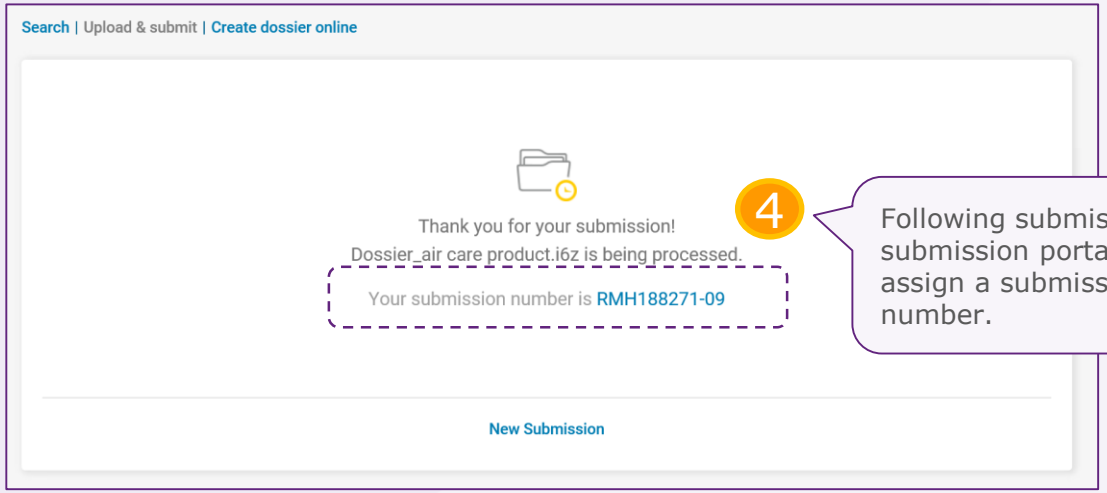


To submit a PCN dossier, you need to first upload it here by using either selecting the relevant file using the Browse button or the 'Drag and drop' functionality.



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

When everything is ready, Submit the dossier!



Following submission, the submission portal will assign a submission number.

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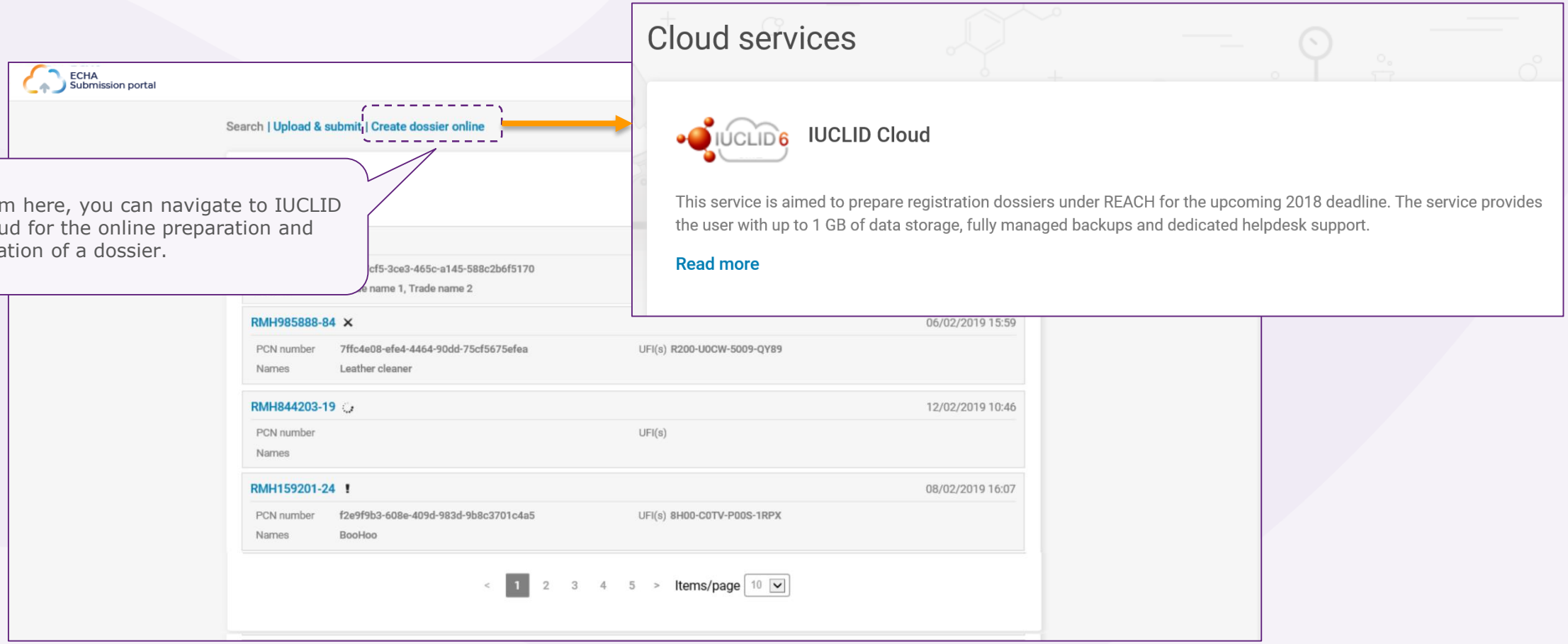
Create dossier online



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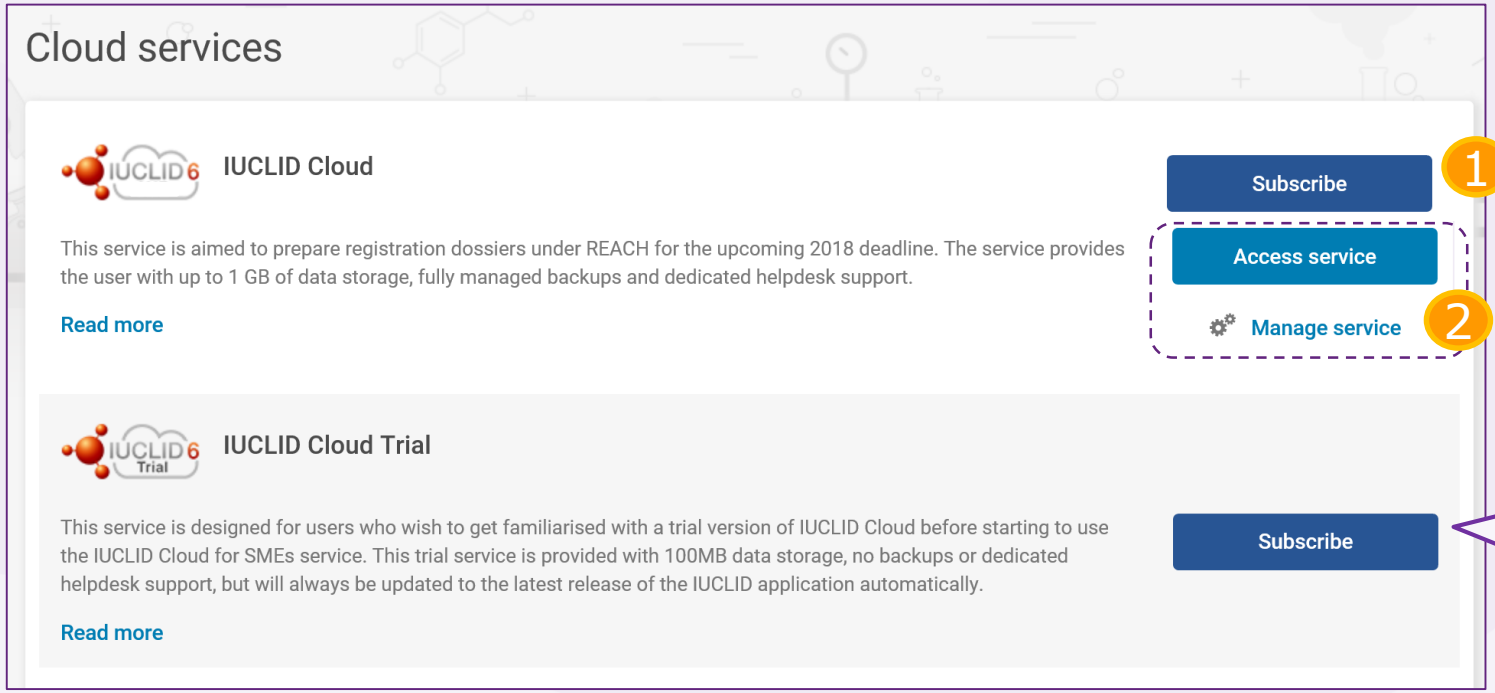
ECHA Cloud Services Dashboard

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

Only legal entity managers have the rights to subscribe to a service. For other users, this functionality will not be visible.



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 the Trial service allows you to get familiar with the tool. **It is not a test version** for submissions. Any submission made within will be forwarded to the Member State selected.

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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.

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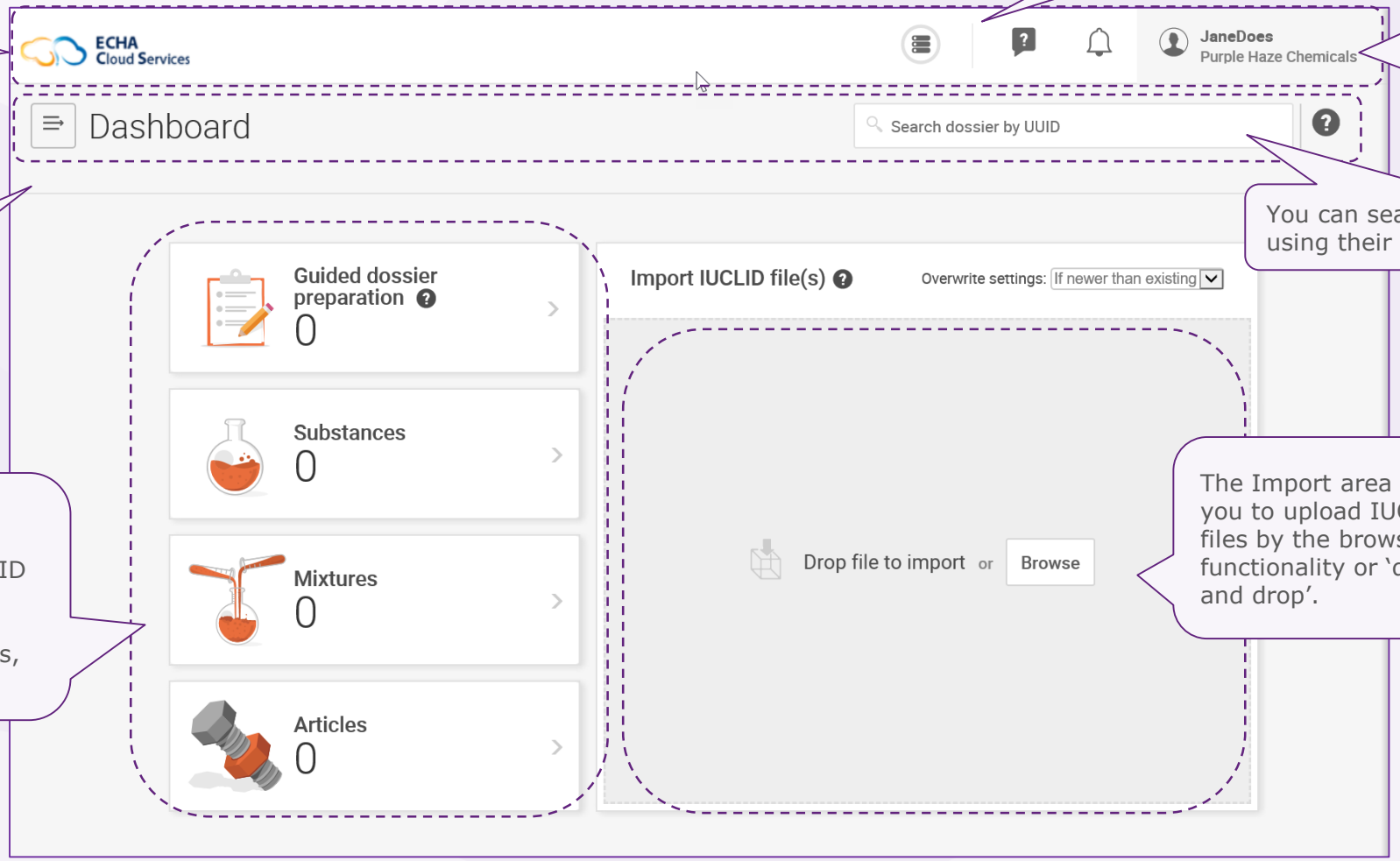
The IUCLID Dashboard for dossier preparation

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



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

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

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

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**.

You can search for dossiers using their UUID.

The Import area allows you to upload IUCLID files by the browse functionality or 'drag and drop'.

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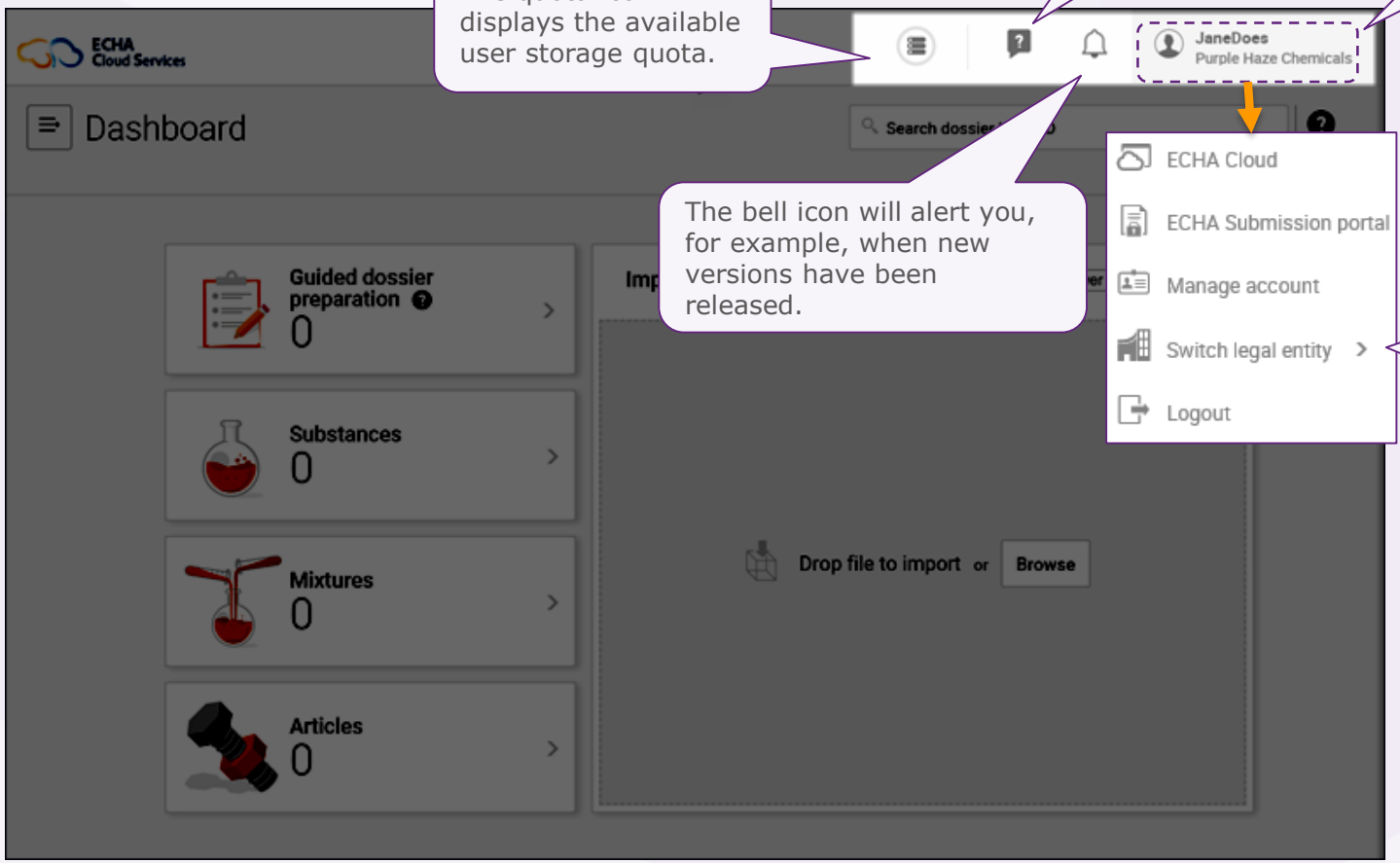
The dashboard top user bar

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

The user icon displays the name and legal entity of the user. 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 quota icon displays the available user storage quota.

The bell icon will alert you, for example, when new versions have been released.



The ‘Switch legal entity’ feature can be used by, for example, a third party working on behalf of a duty holder, using the foreign user functionality.

In the dashboard, the consultant can select the legal entity on whose behalf he will work on when using this feature.

! The legal entity UUID of the logged in user’s company must match the legal entity UUID in the PCN dossier (Mixture level). If there is a mismatch, the dossier will fail the Business rule BR570.

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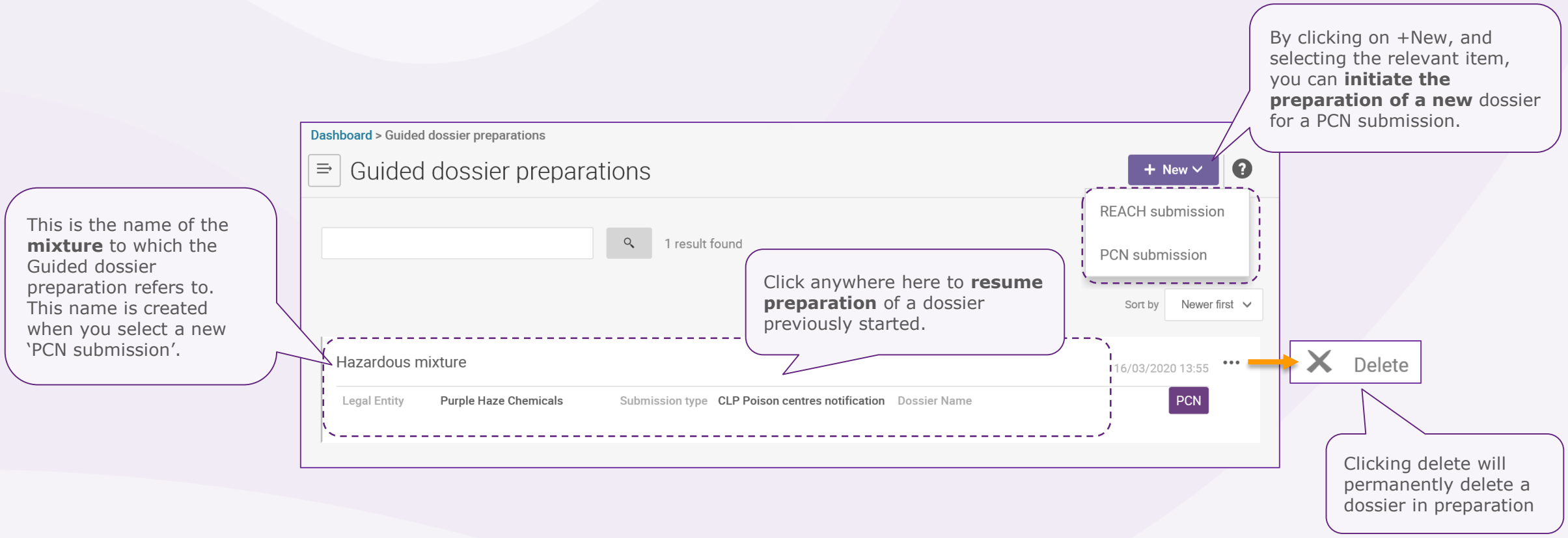
Initiating a guided dossier preparation

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'.



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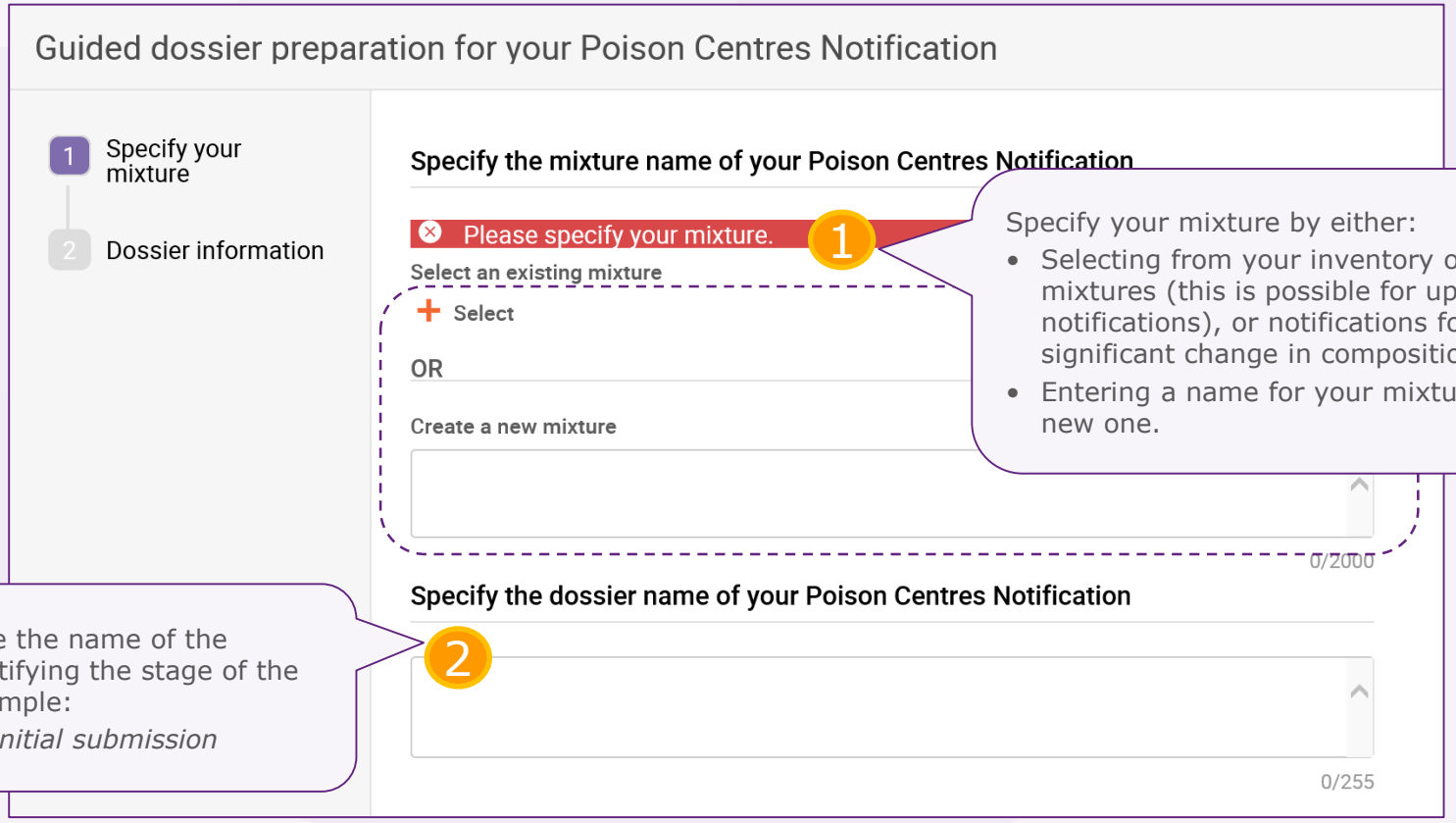
Establishing the submission context for a mixture – step 1

Once you initiate a dossier preparation for a PCN submission, the submission context is defined in a two-step process: Specify your mixture, and Dossier information.



Specify your mixture by either:

- Selecting from your inventory of existing mixtures (this is possible for update notifications), or notifications following a significant change in composition, OR
- Entering a name for your mixture, to encode a new one.

Here you can optionally provide the name of the dossier. This may help you identifying the stage of the life cycle of the project. For example:

My hazardous mixture's name_initial submission

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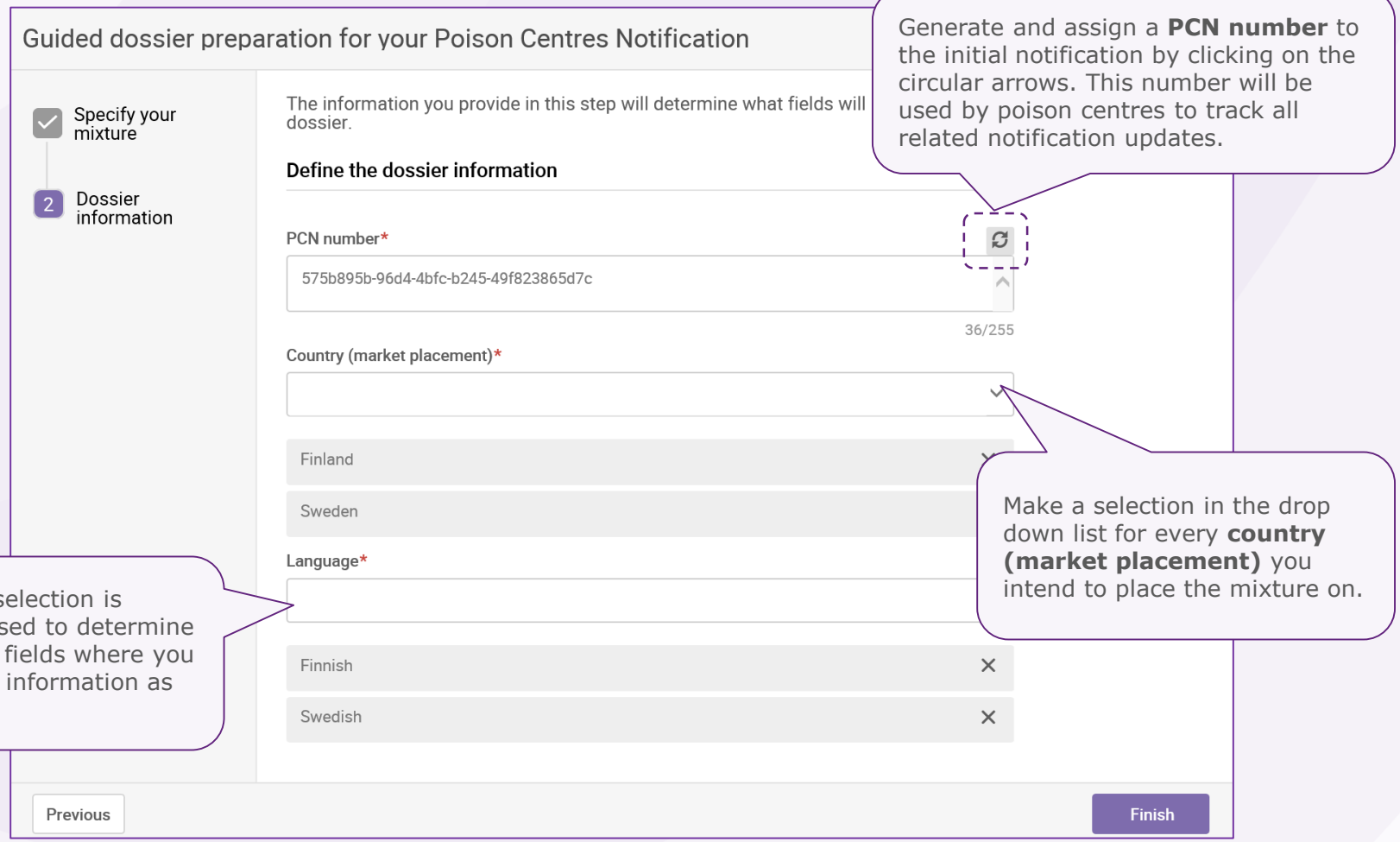
Dossier information

This page is called the **Dossier Header** page. It collects the information required to define the dossier so as to configure the relevant dossier fields (for example, for multilingual support), as well as determine the specific validation rules. For example, 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



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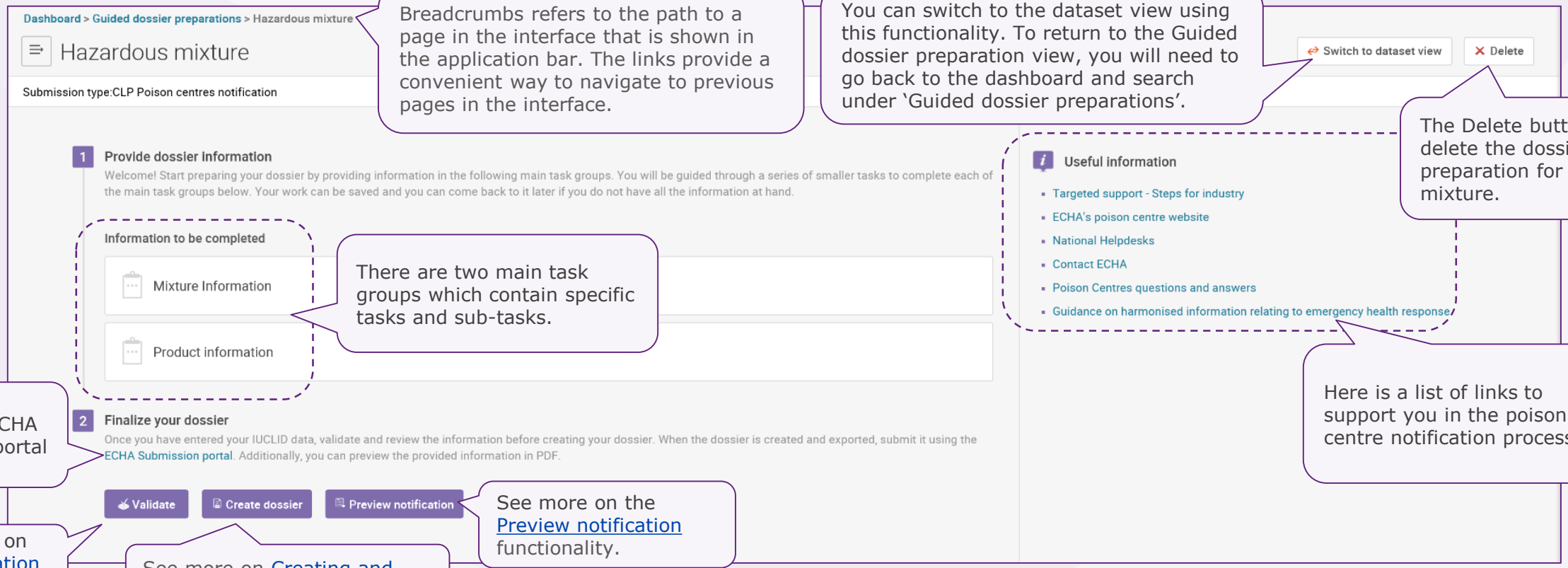
Guided dossier preparation ‘navigation page’

The navigation page for the mixture allows easy movement from the main functionalities: data entry, validation and dossier creation. You need to provide data entry 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.

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

Link to the ECHA Submission portal

See more on the Preview notification functionality.

See more on The validation assistant.

See more on Creating and exporting the dossier.

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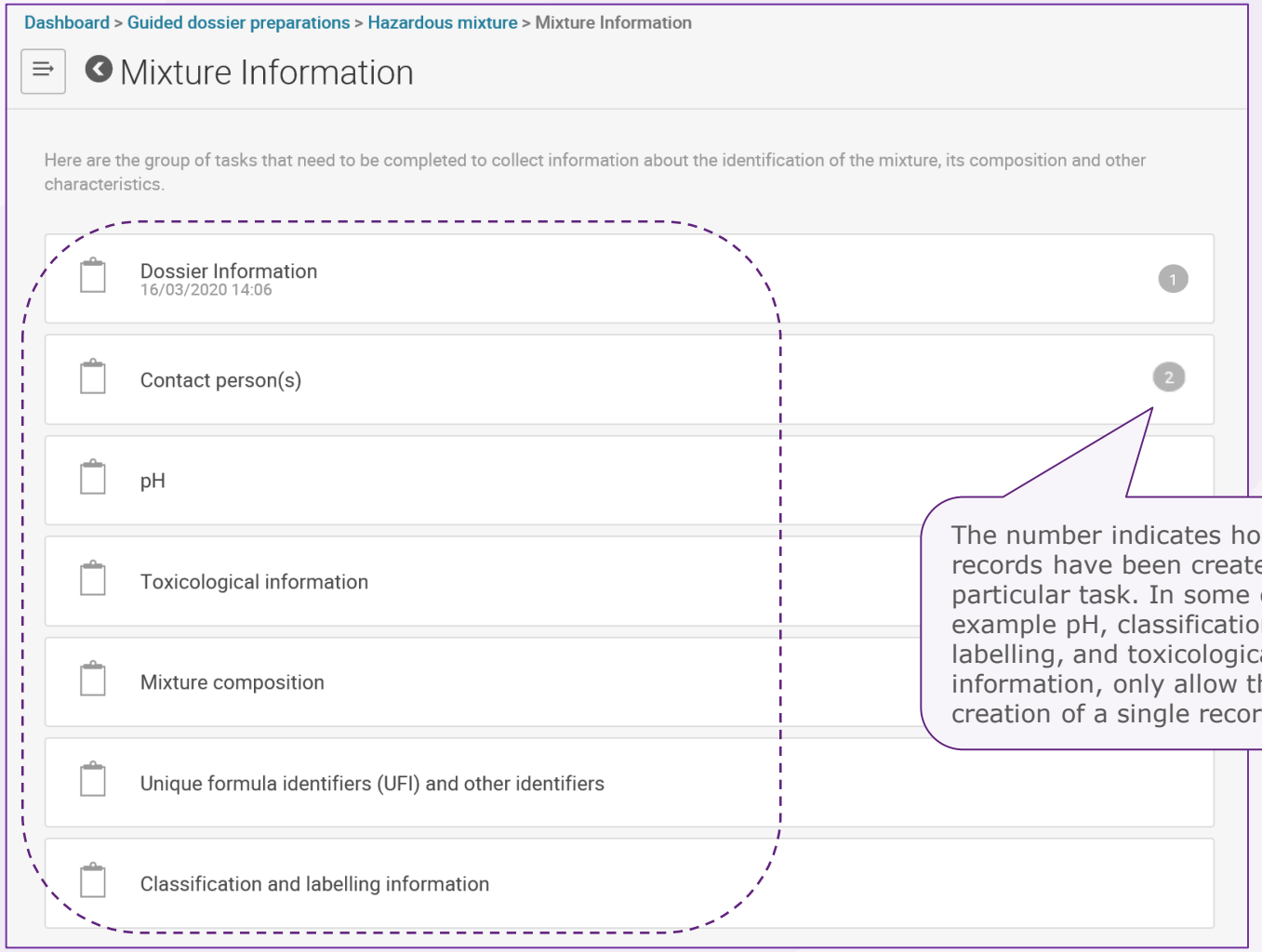
The task page

A specific task page exists for the Mixture information and the Product information. Here, in the Mixture information task page, is a list with the six tasks that you are required to complete for this section.

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 be created from existing information, where it is copied from another dossier.

The information contained in a record can be viewed and updated. You can delete records if needed.



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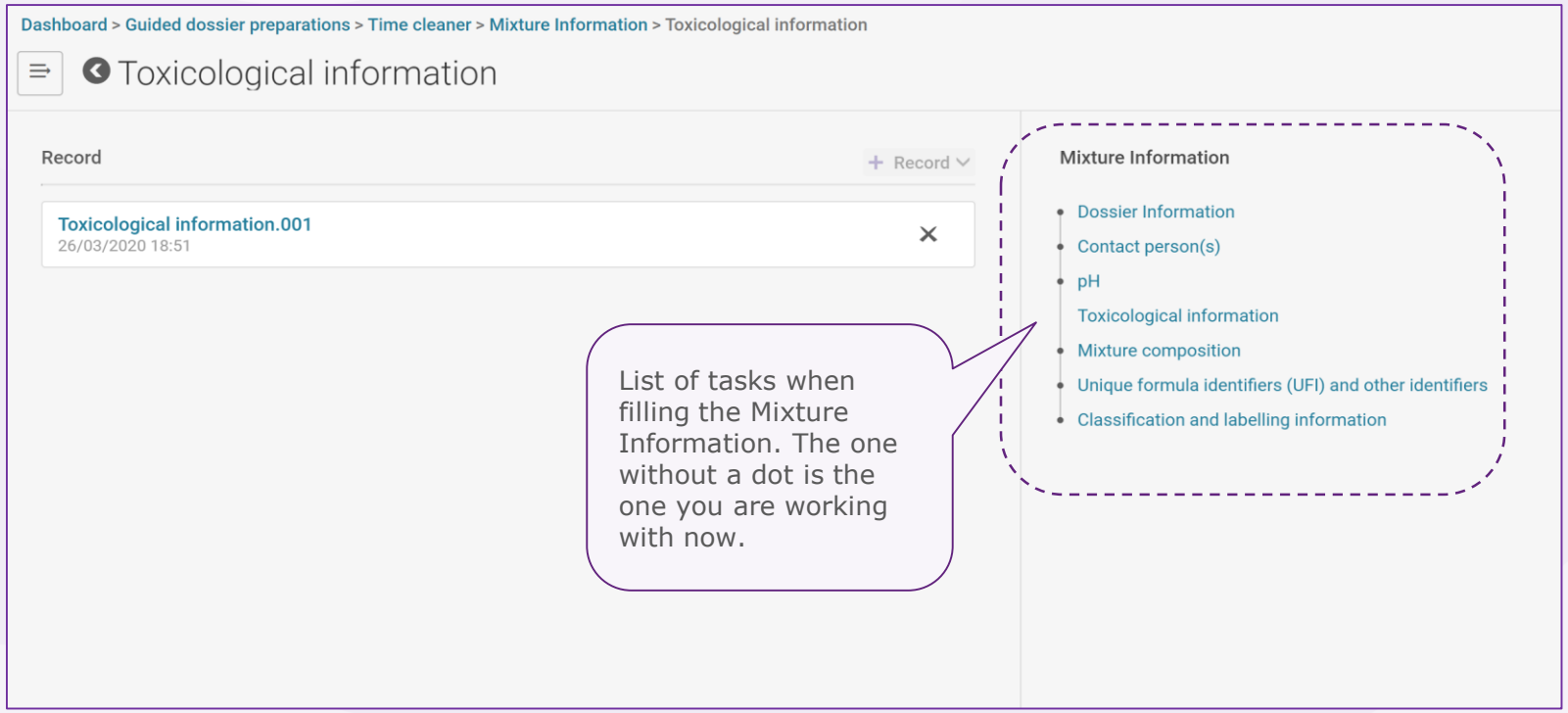
Moving between tasks

When finishing each task, the system will take you to the record view. Here you can add records or delete them. You can also move on to the following task, or any other, by clicking on its name on the right-hand side list of tasks.



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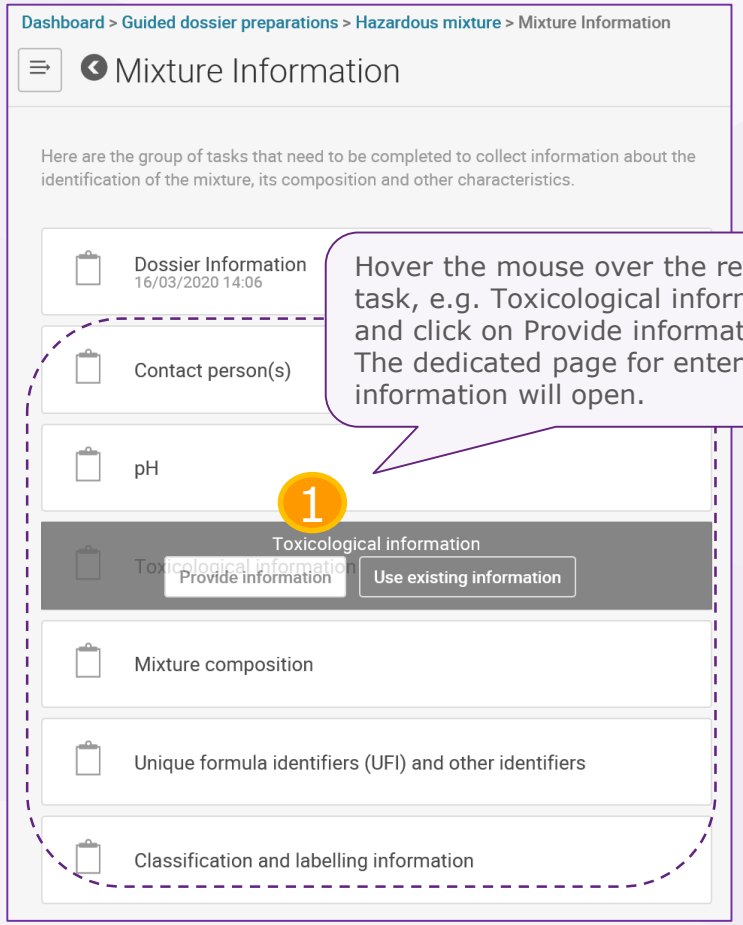
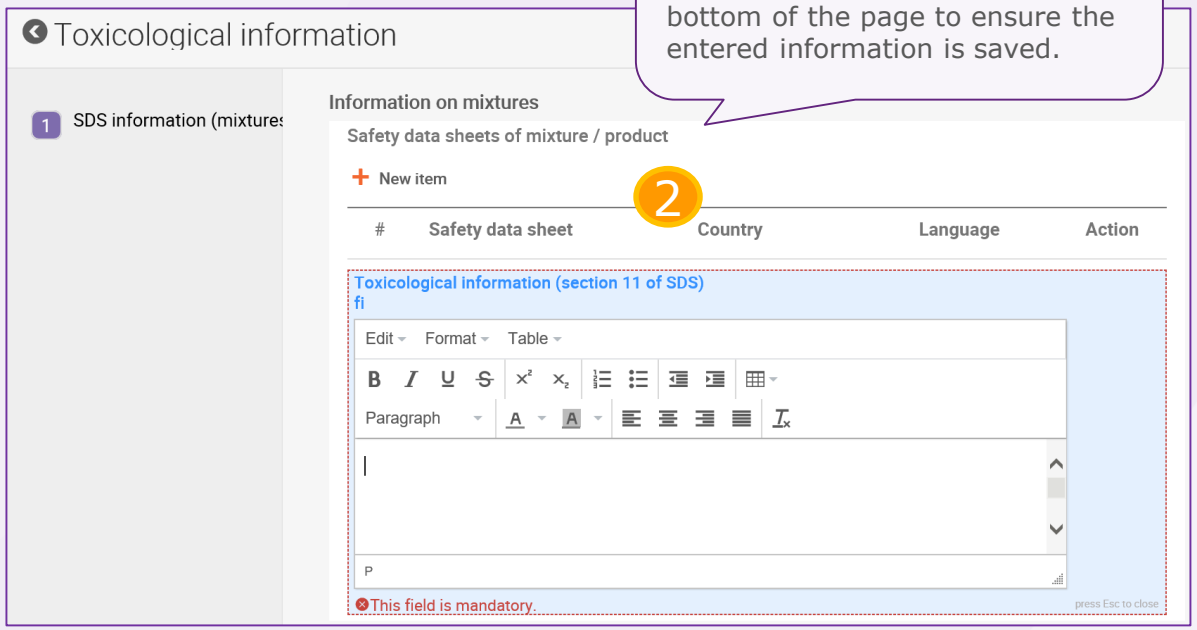
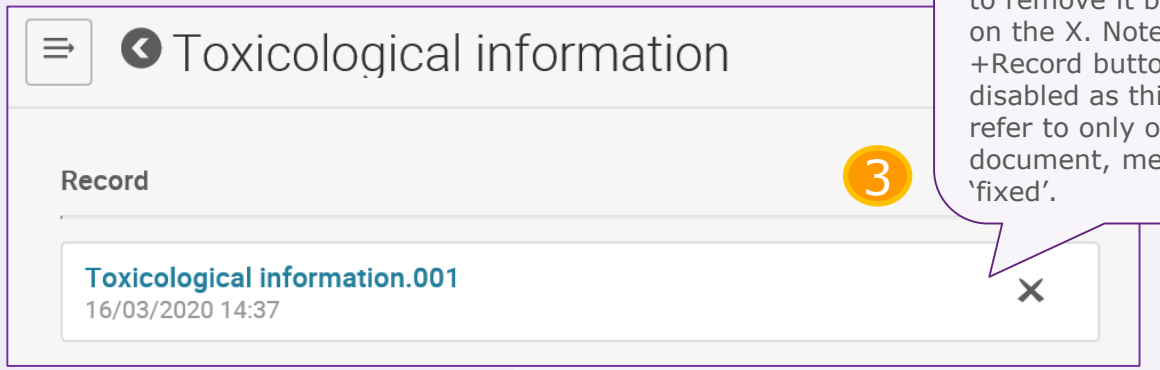
Creating a new record



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.



The record has 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.



Once you have saved the record, 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, meaning it is 'fixed'.

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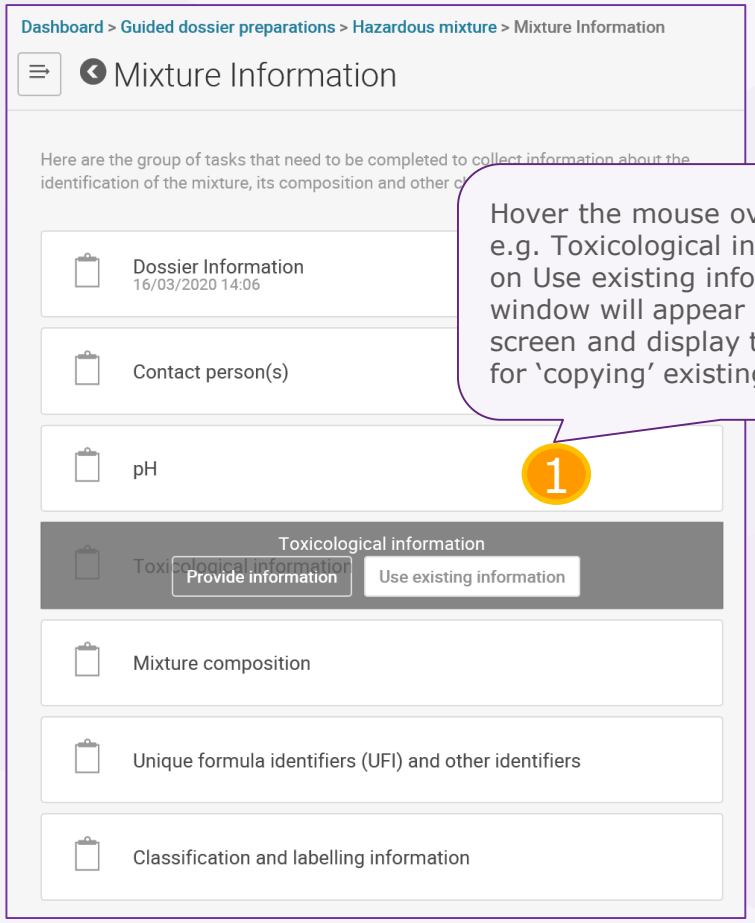
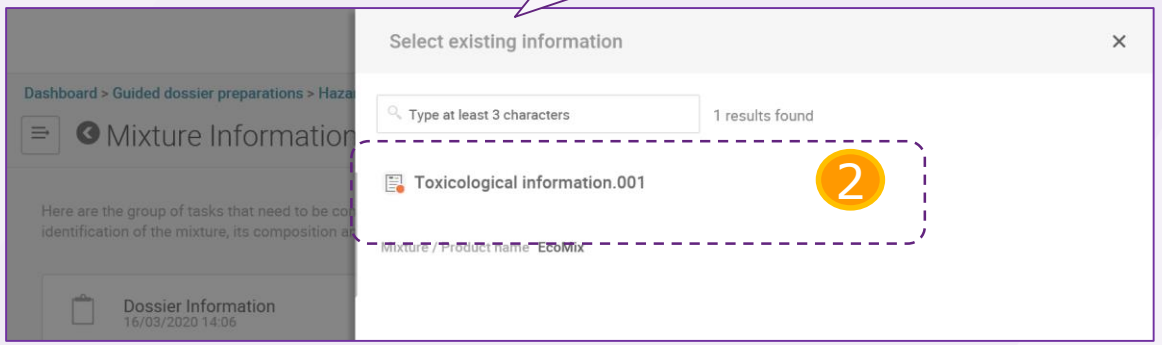
Creating a record from existing information

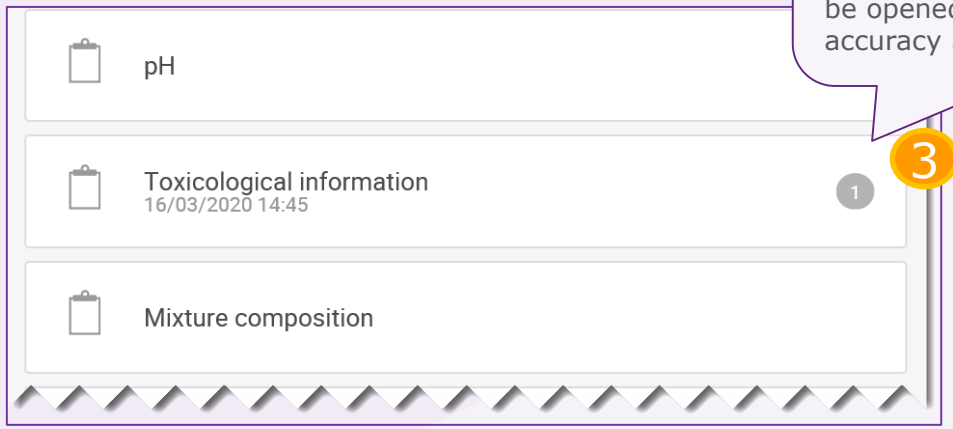


Hover the mouse over a specific task, e.g. Toxicological information, and click on Use existing information, a sliding window will appear on the left of the screen and display the records available for 'copying' existing information from.

1



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.



3

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.

Poison centres

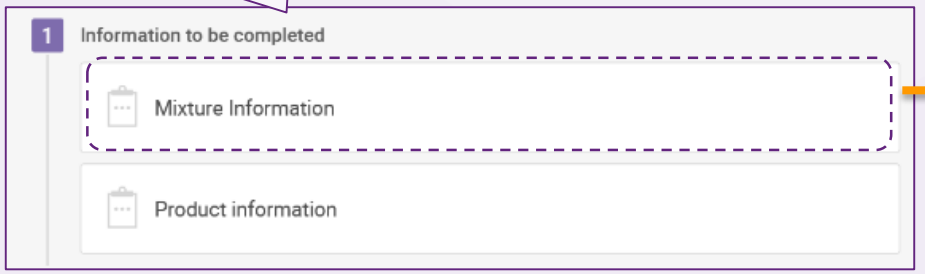
Dossier preparation: ‘Mixture information’

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 inthe *Guidance on harmonised information relating to emergency health response* at:
https://poisoncentres.echa.europa.eu/guidance

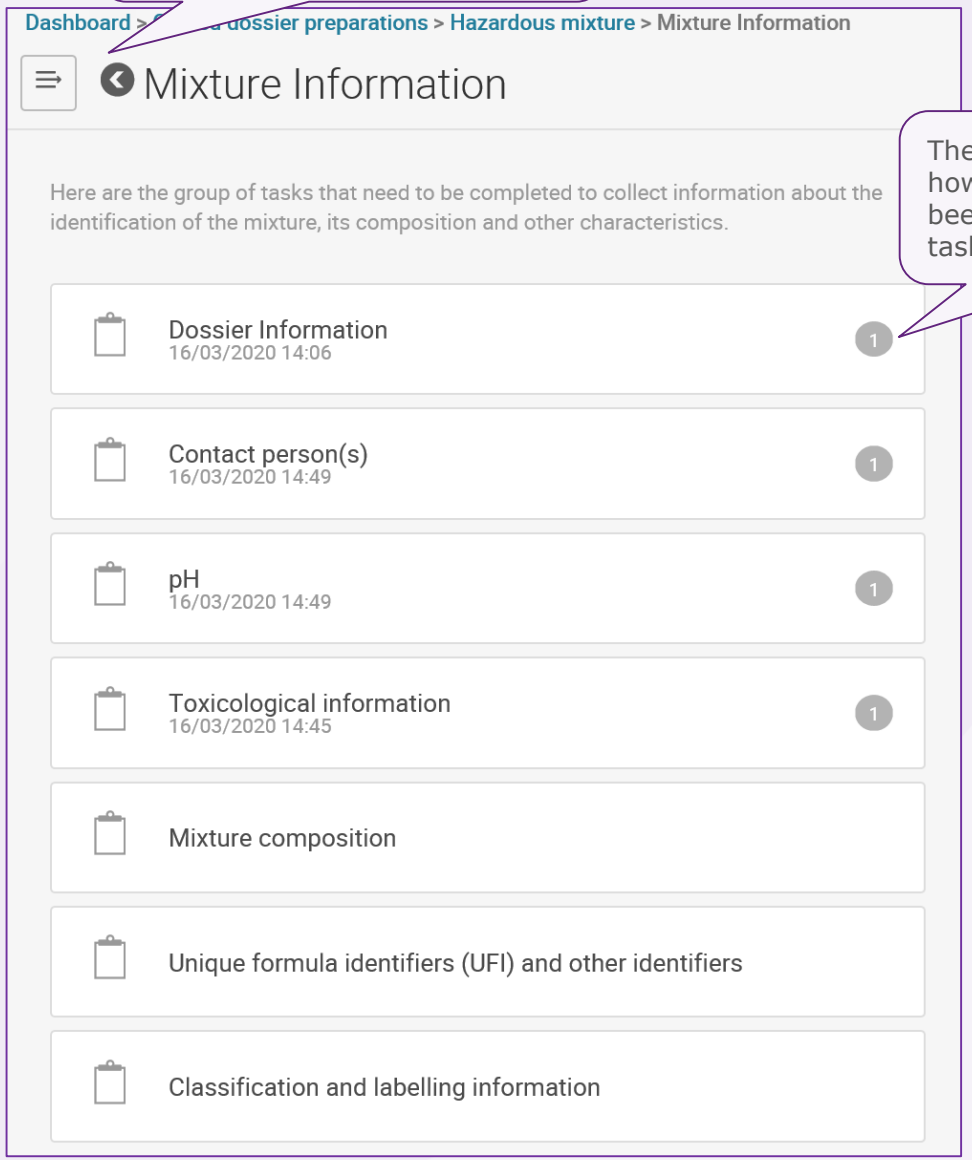
Poison centres

Mixture information task page

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



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



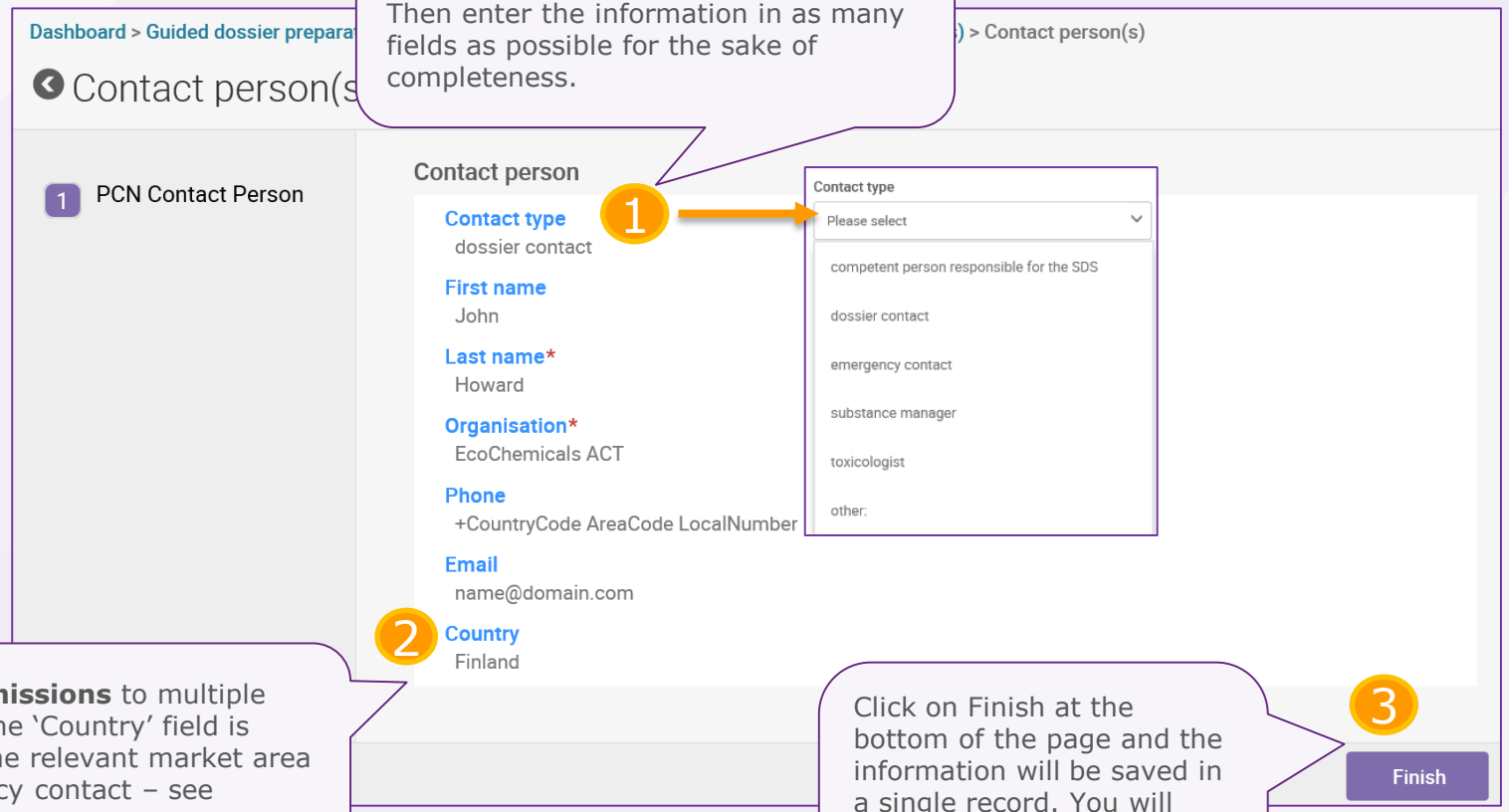
The number indicate how many records have been created for each task.

Poison centres

The ‘Contact person(s)’ task

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

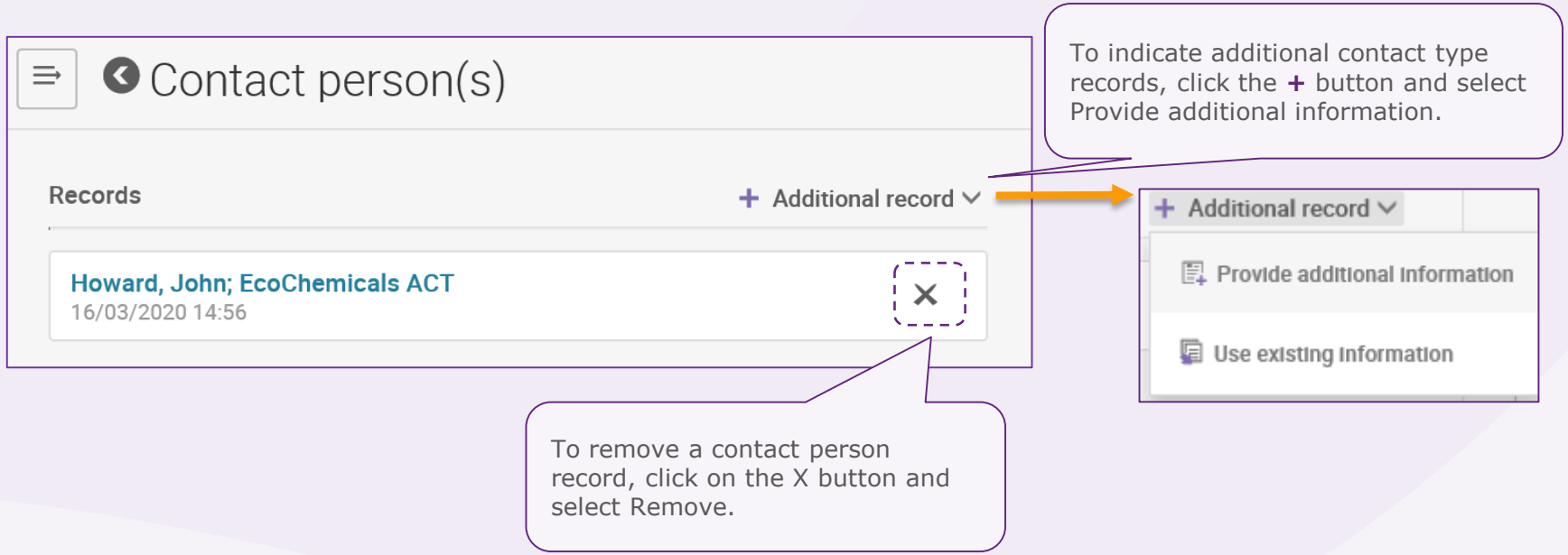
If the Contact type picklist does not contain the correct type of contact you wish to specify, you can select ’Other’ and enter the information in the free text field.



Poison centres

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 you must provide only one emergency contact record containing this information. If the submission is for multiple market areas, then you need to provide multiple Contact person(s) records. Each record will contain the ‘Emergency contact’ person information for each country, specified in the ‘Country’ field, even if the same details are applicable for all the countries. See below how to add additional contact person records.

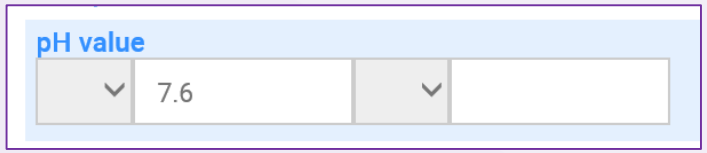


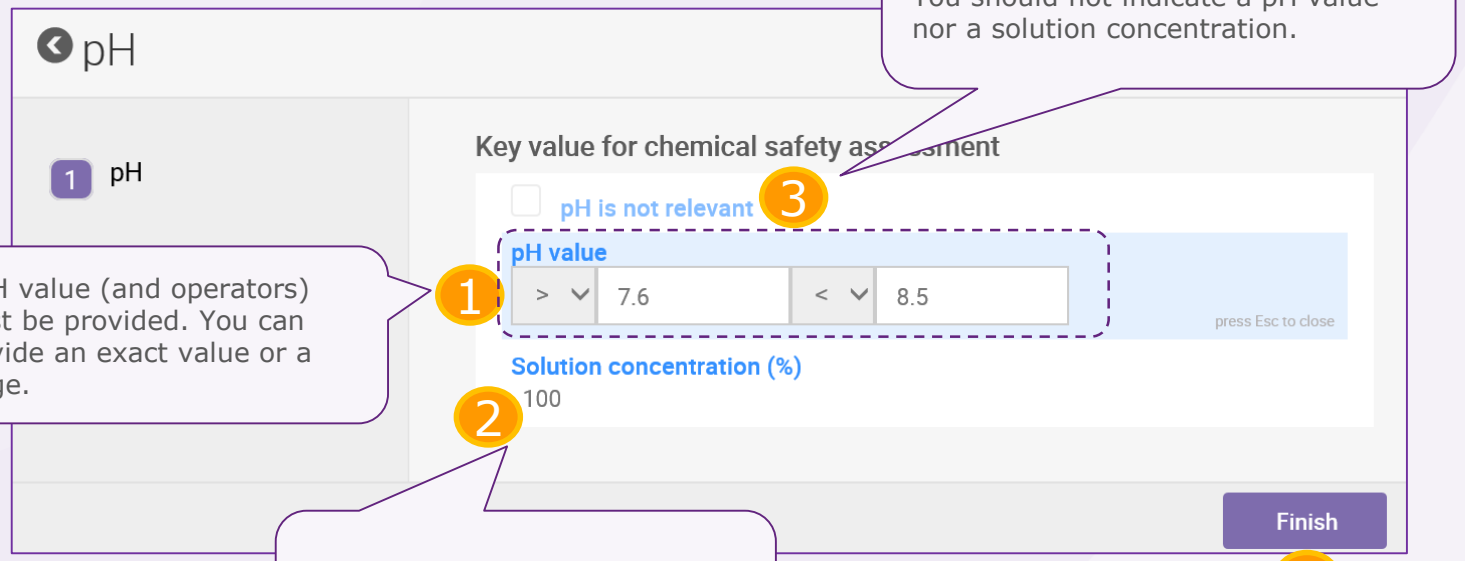
Poison centres

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:





If the pH cannot be measured, you must tick the ‘pH is not relevant’ box. You should not indicate a pH value nor a solution concentration.

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

When you provide the pH value, the solution concentration must be given in any case.

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

Poison centres

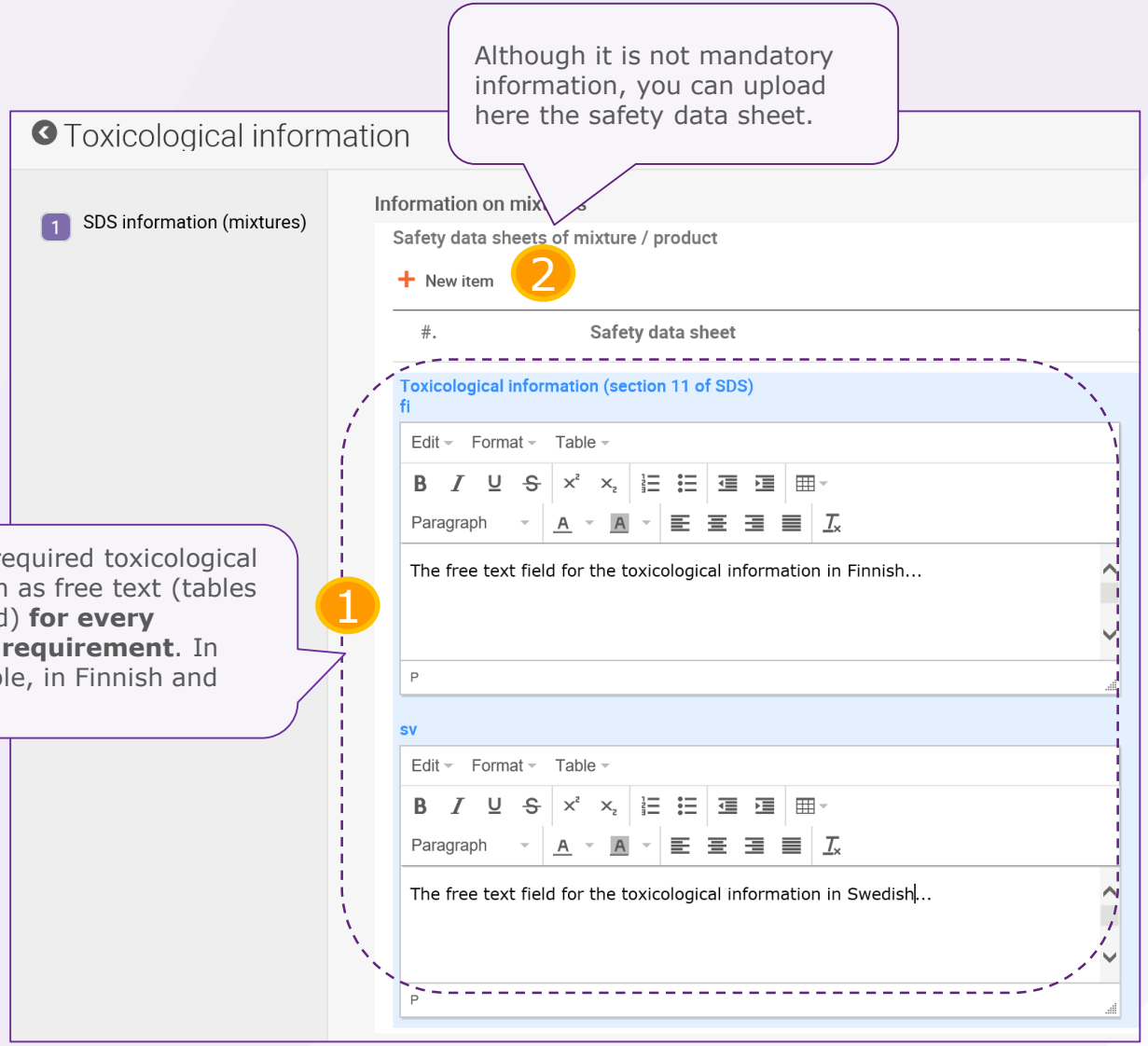
The ‘Toxicological information’ task

Only one toxicological record can be created from the mixture information task. However, if the submission is for multiple markets or 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, as required in **Section 11 of the safety data sheet** for the mixture.

You must ensure that the information entered here is ‘stand alone’ information and does not contain, for example, cross-references to other sections of the SDS.

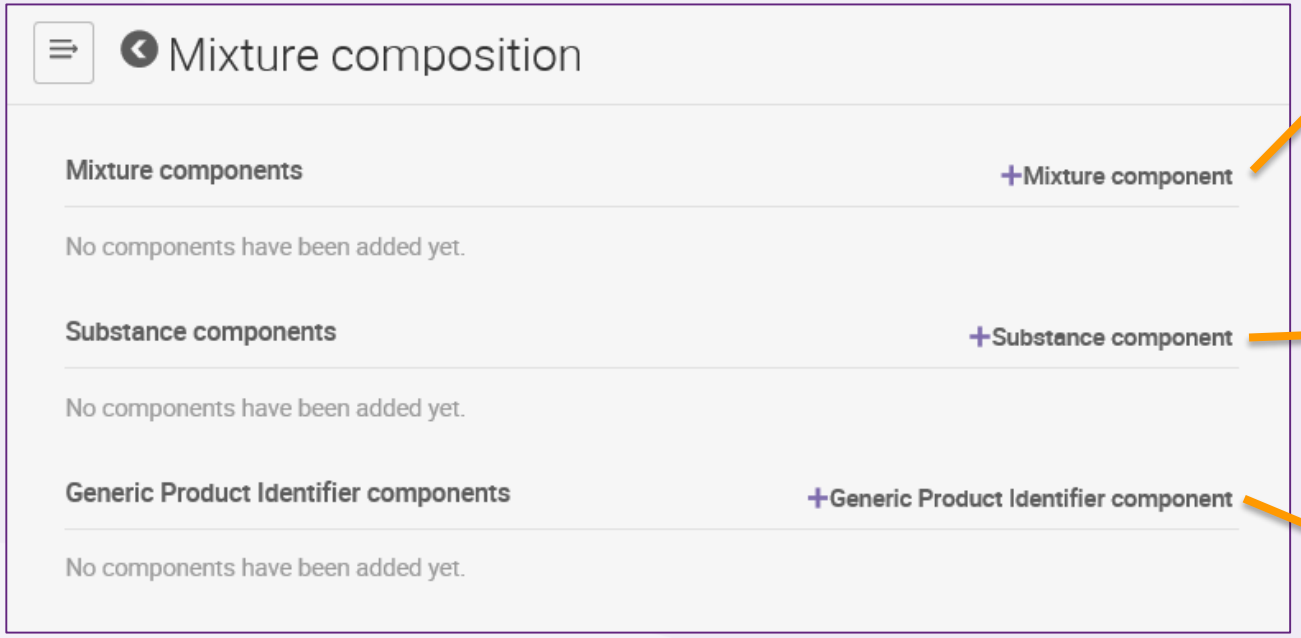
! If your mixture/product is related to a **multi-component** product, then all relevant information (e.g. on the mixture created upon use) should be included in the toxicological information field.

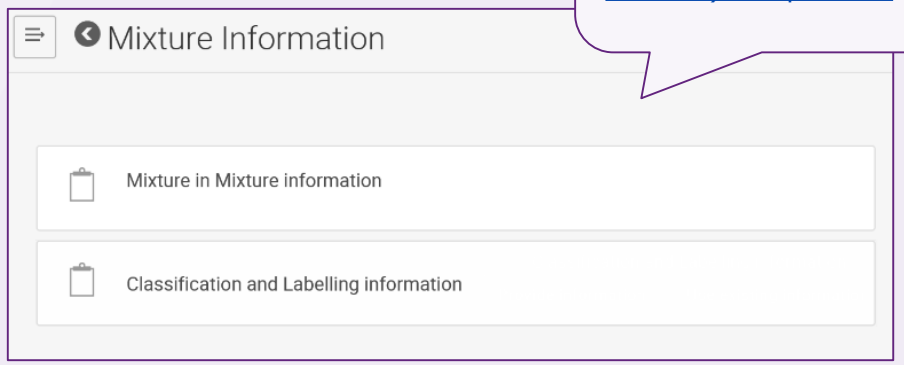


Poison centres

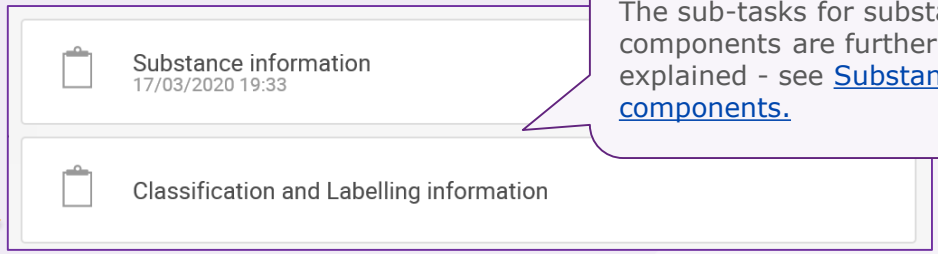
The ‘Mixture composition’ task

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 **MiM**s) or generic product identifiers (**GPI**s).

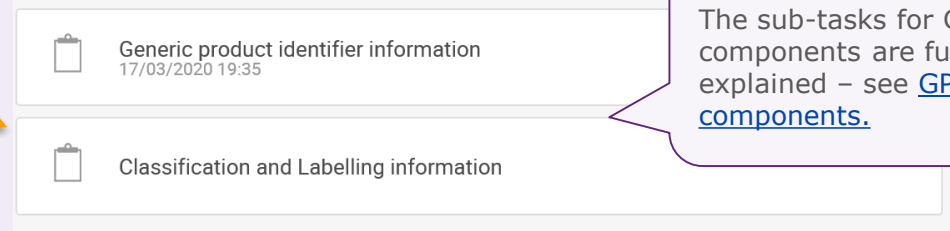




The sub-tasks for mixture components are further explained - see Mixture (in mixture) components.



The sub-tasks for substance components are further explained - see Substance components.

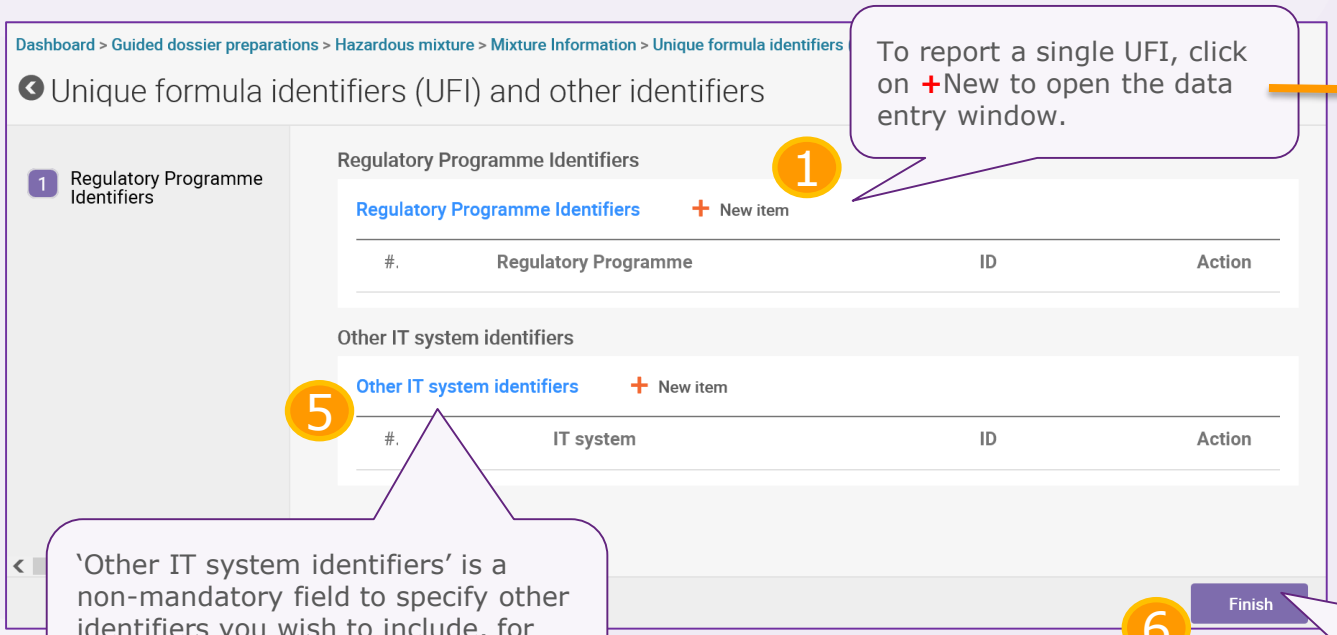


The sub-tasks for GPI components are further explained – see GPI components.

Poison centres

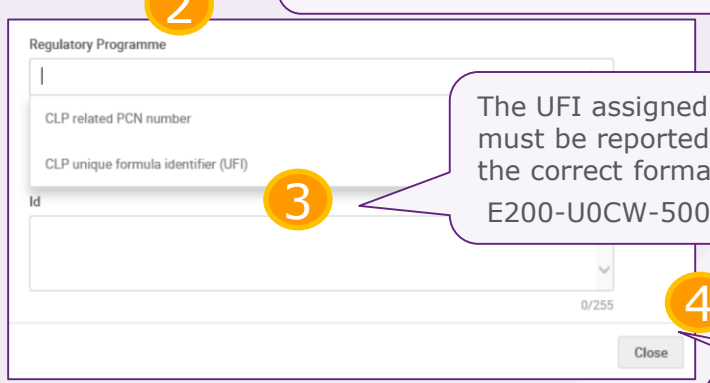
The ‘UFI and other identifiers’ task

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.



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

1



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, for example: 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, for example, 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.

Poison centres

Reporting multiple UFIs for the mixture

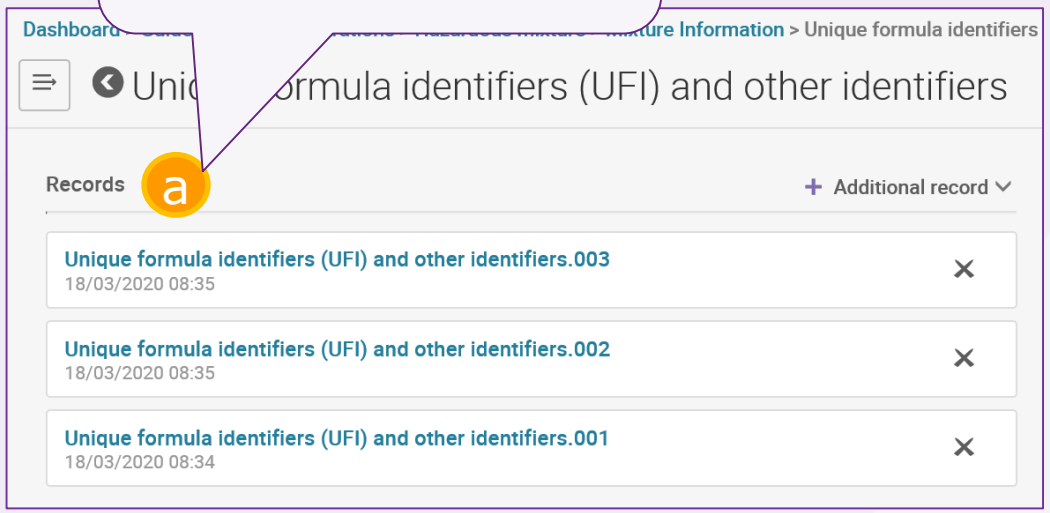
Multiple UFIs can be included in a notification in a flexible way, depending on your business needs. There are two ways to report them, either

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

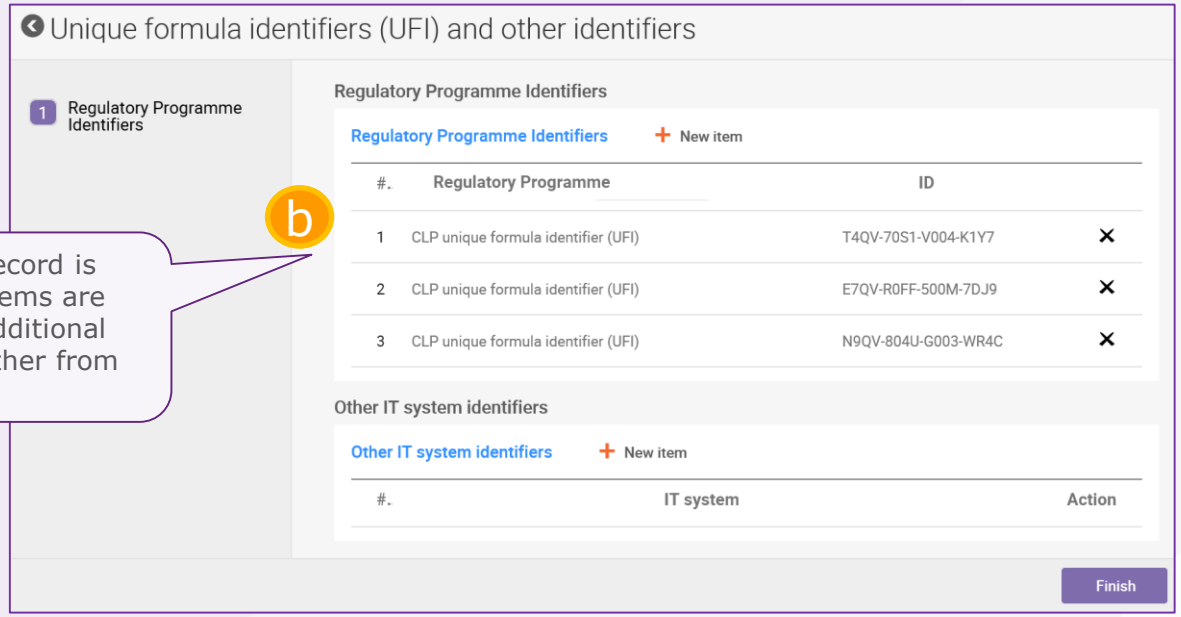
The way in which multiple UFIs are recorded depends on the preferred method of assigning each UFI to a specific product.

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 you create additional records, they are listed together here, on the UFI task page.



In this example, one UFI record is created and multiple UFI items are added. When you create additional items, they are listed together from within the record.



Poison centres

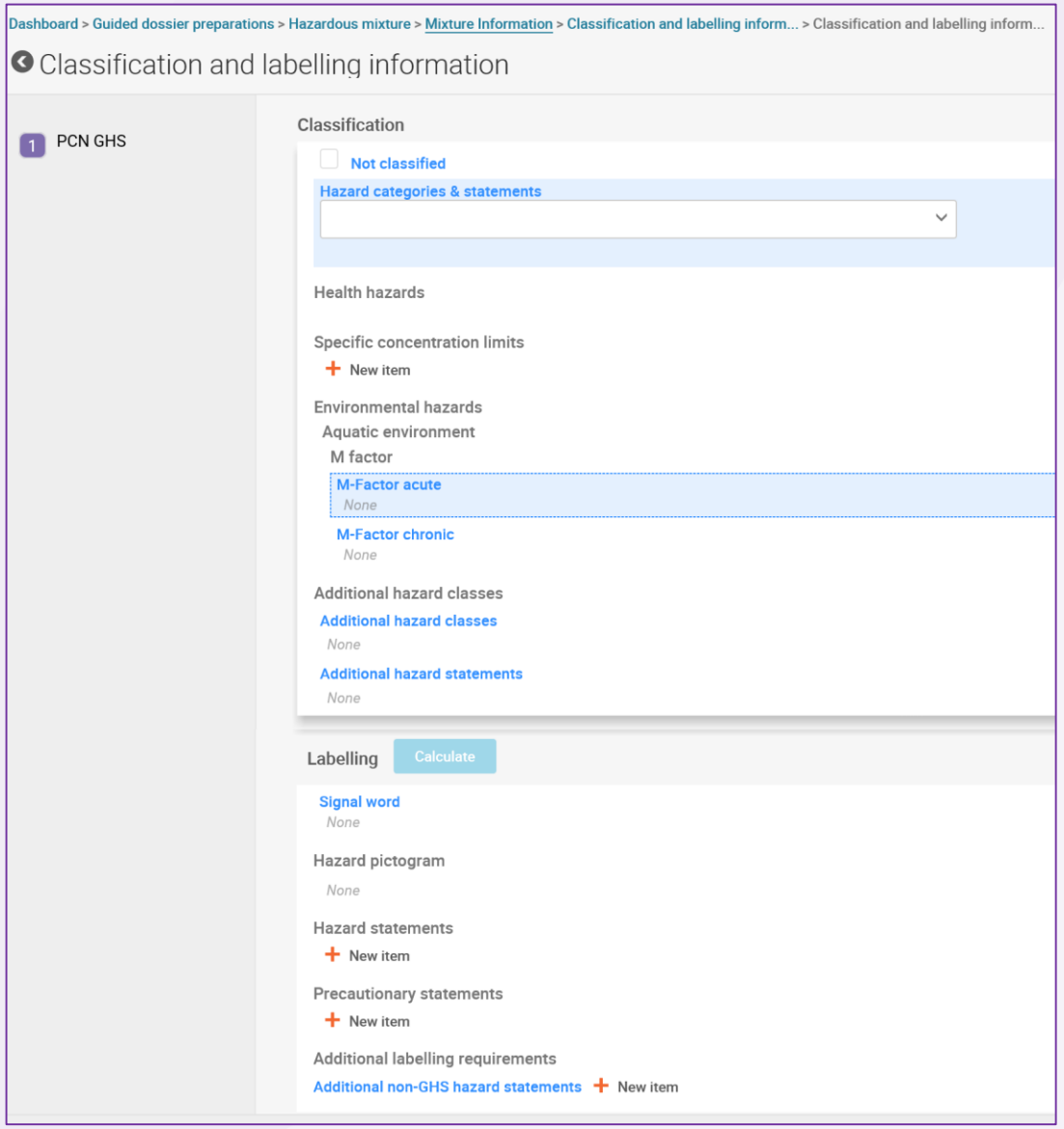
The ‘Classification and labelling’ task

Only a single classification and labelling record can exist for a mixture for a standard submission. The following slides will cover the classification and the labelling separately.

If your mixture is not classified for any physical, health or environmental hazards, select Not classified. This selection freezes the classification fields.

Environmental hazards may be included, but are not mandatory to indicate.

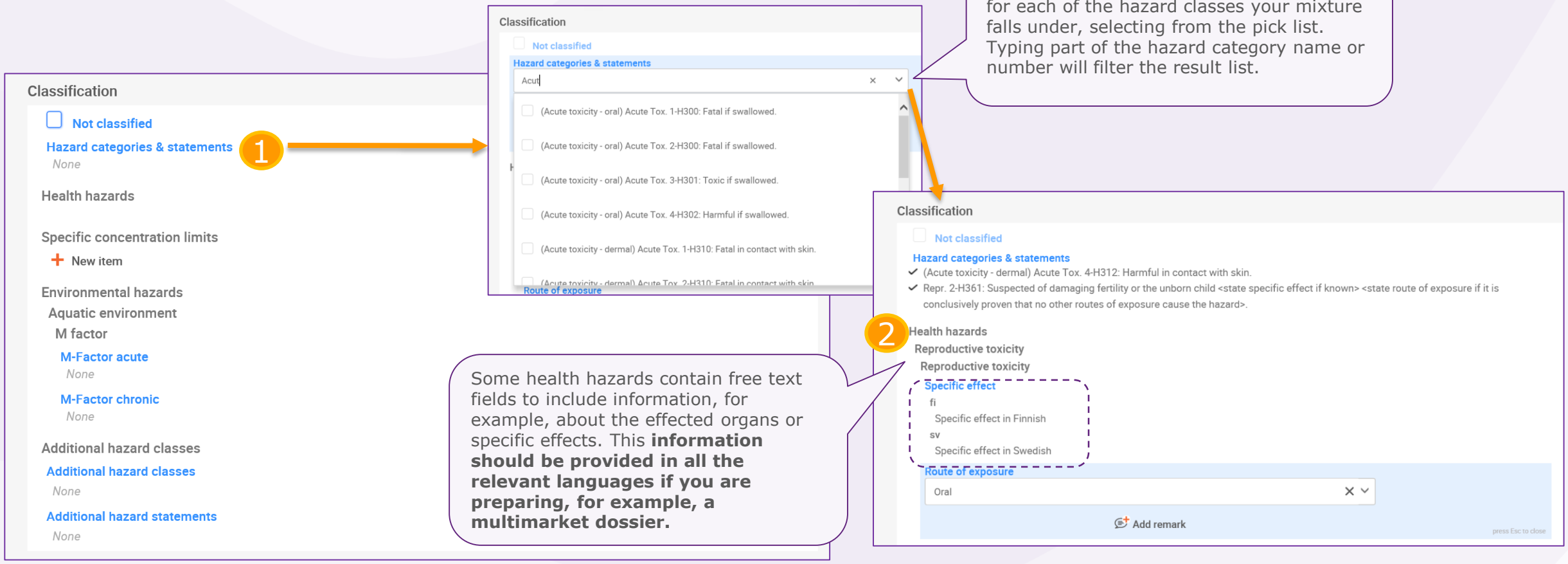
! If you are preparing a multimarket submission covering several languages, then **multilingual text** will be required to complete this section.



Poison centres

‘Classification’

Enter the **classification of your mixture** by providing the Hazard category and statements, and any other relevant additional information.

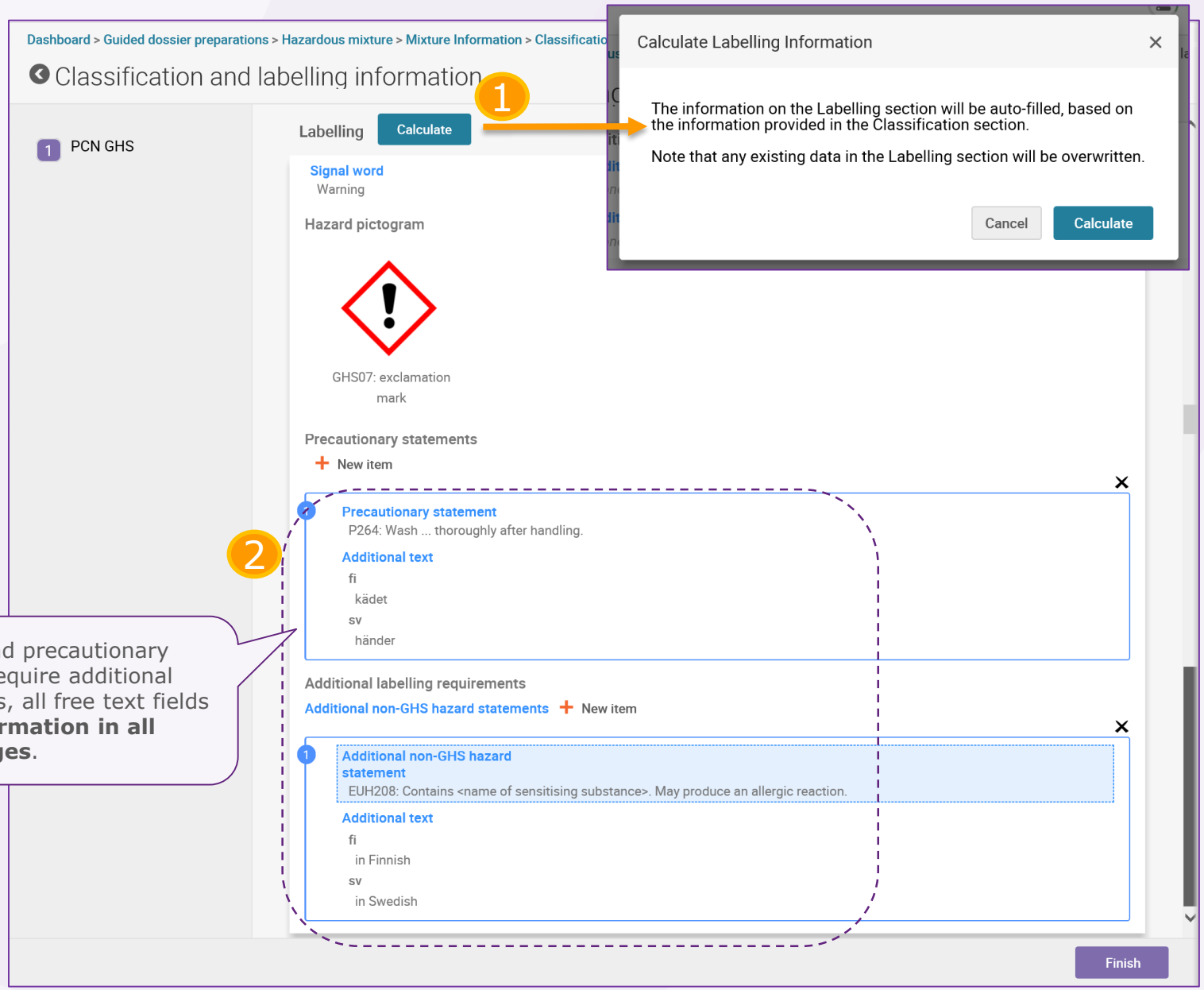


Poison centres

‘Labelling’

You can use the ‘Calculate’ functionality which will auto-fill the labelling information based on the information you entered for the classification. You will still need to enter free text field where relevant.

Alternatively, you can enter each of the **labelling information elements for your mixture** by selecting the relevant information from the drop down lists.



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

Poison centres

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:

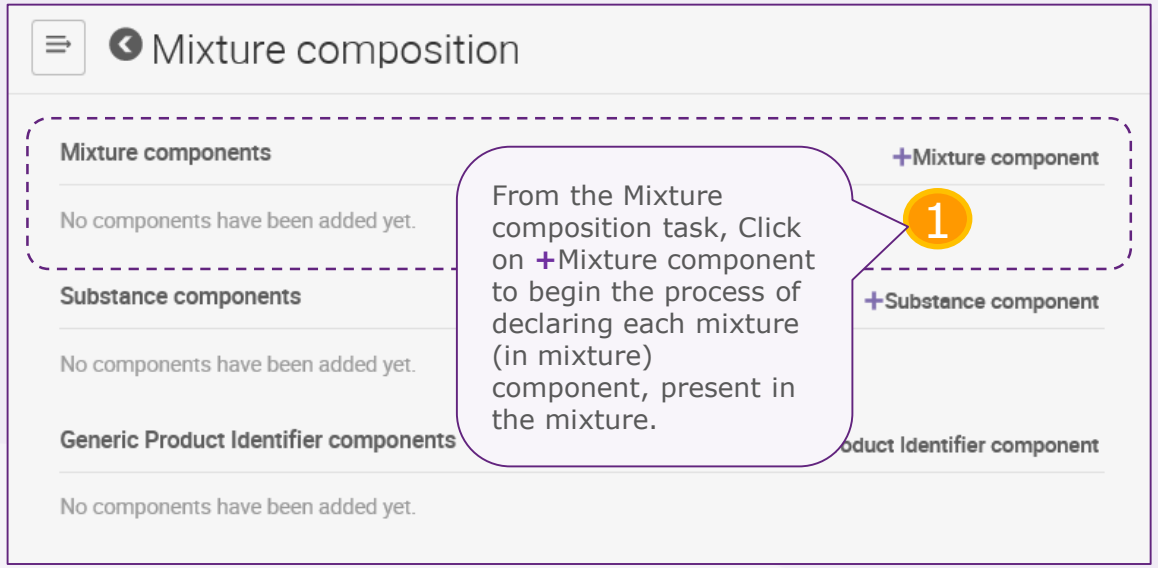
https://poisoncentres.echa.europa.eu/guidance

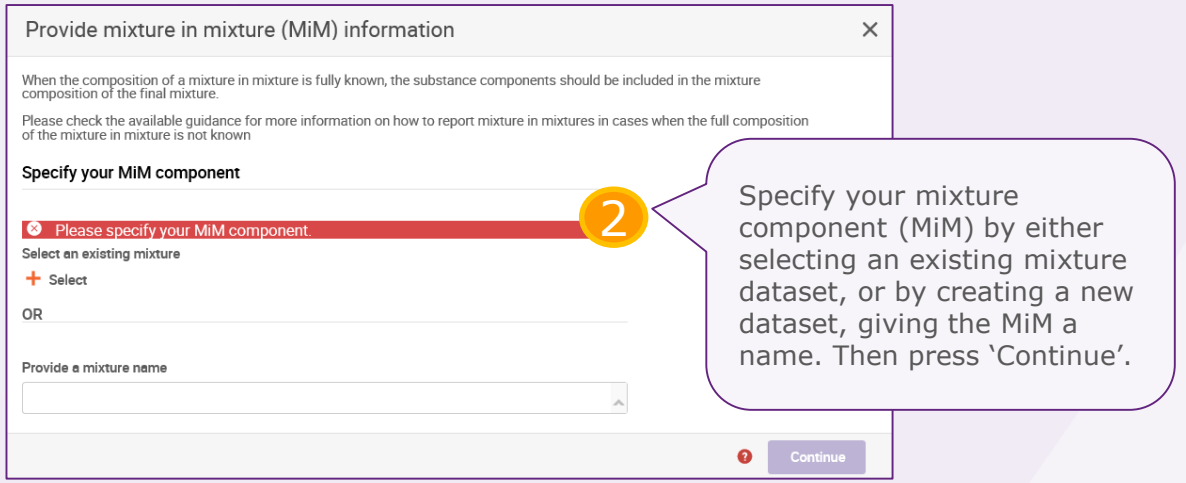
Poison centres

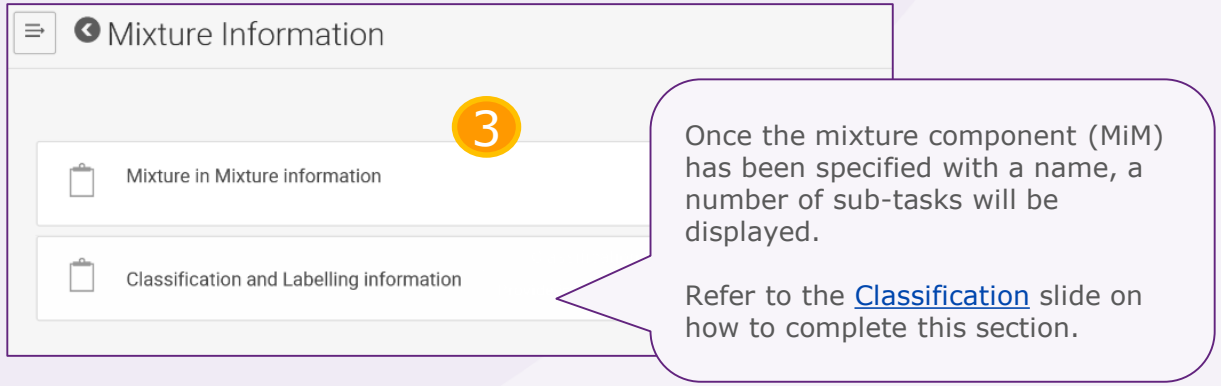
Mixture (in mixture) components

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.







Poison centres

Sub-task ‘Mixture in mixture information’

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

‘Function’ is not mandatory information but you may add it if you want.

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

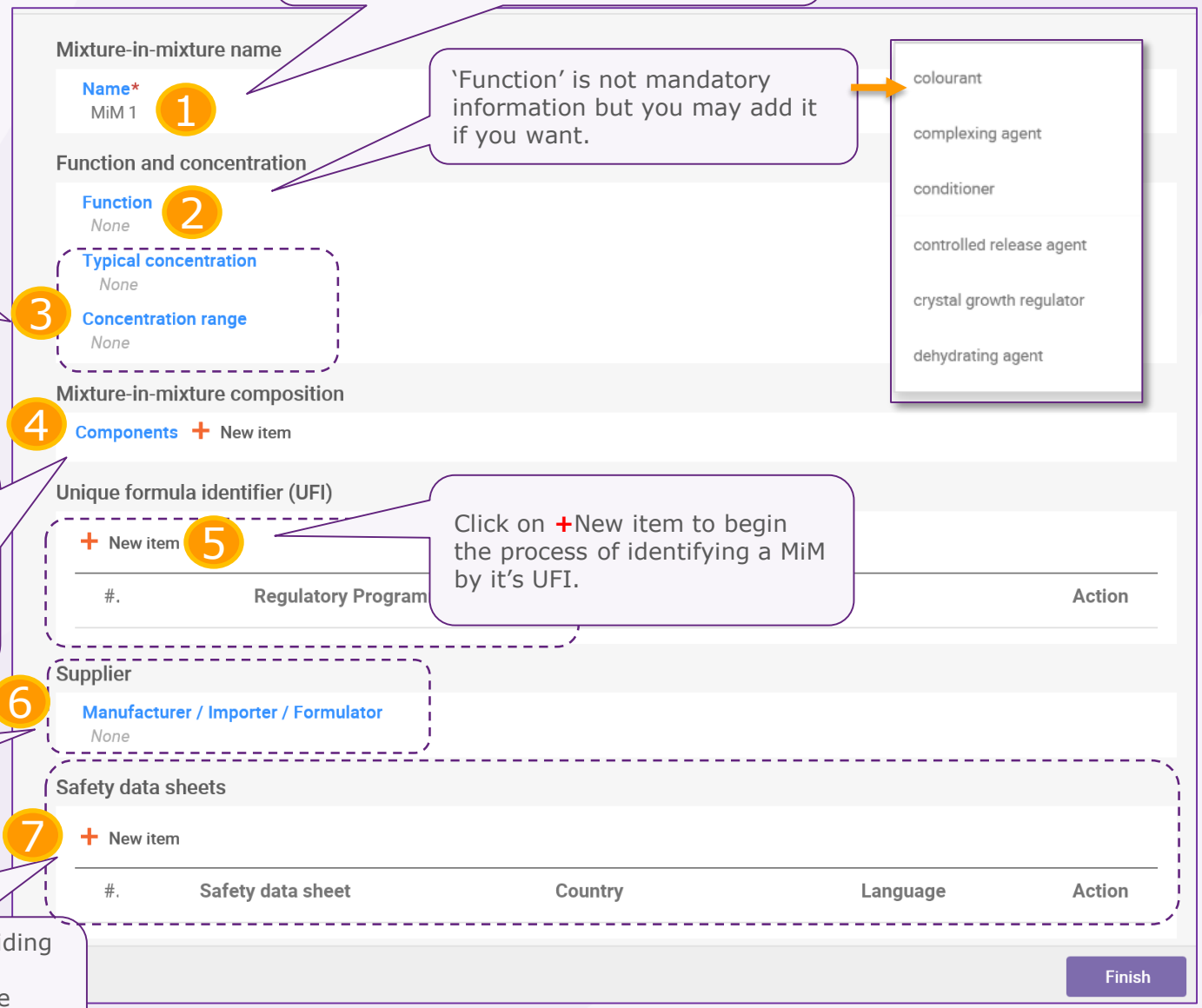
You may declare the concentration of components either as a ‘typical’ concentration or as a concentration range, and expressed in either % (w/w) or % (v/v). Operators must be included.

Click on +New item to list the substance components of the MiM. Each substance requires 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 +New item to begin the process of identifying a MiM by it’s UFI.

Click on +Select and either make a selection from the list of available suppliers (meaning, 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 SDS (‘items’ in the system) can be added.



Poison centres

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:

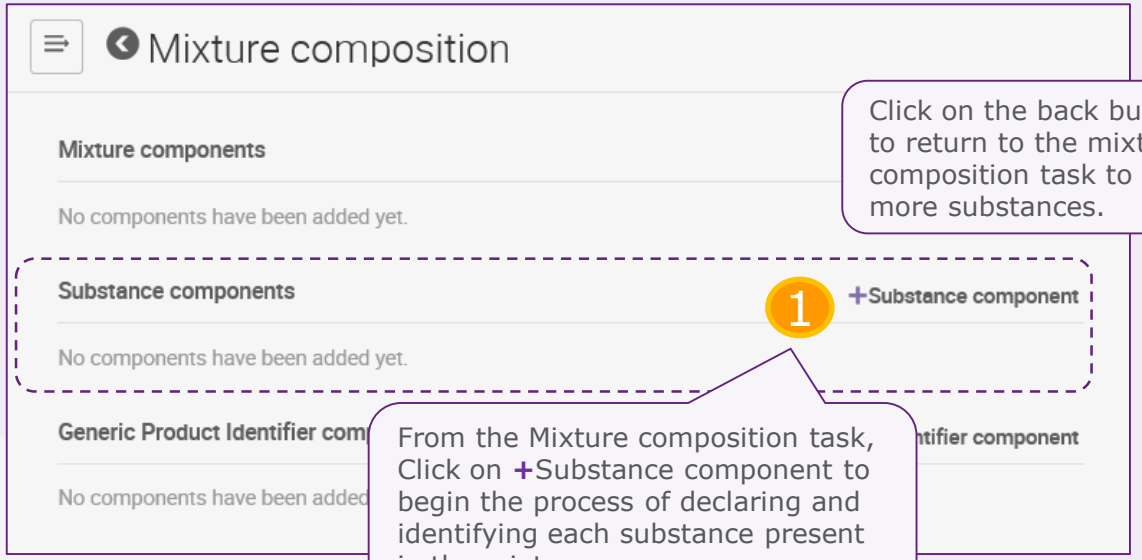
https://poisoncentres.echa.europa.eu/guidance

Poison centres

Substance components

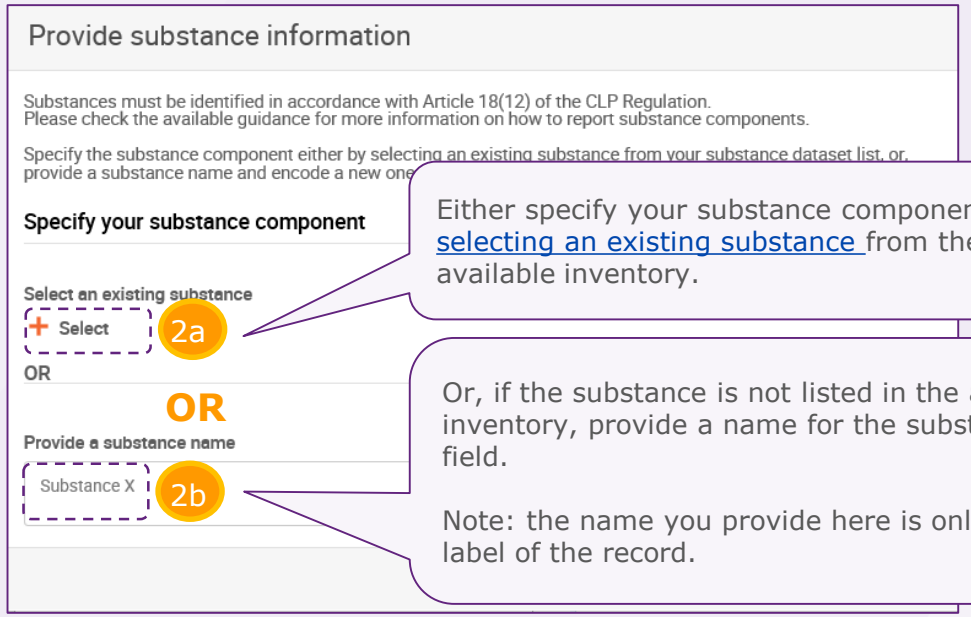
Specifying a substance component can be done either by selecting an existing substance (option 2a, from the available inventory), or providing a name and creating a new one (option 2b).

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



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

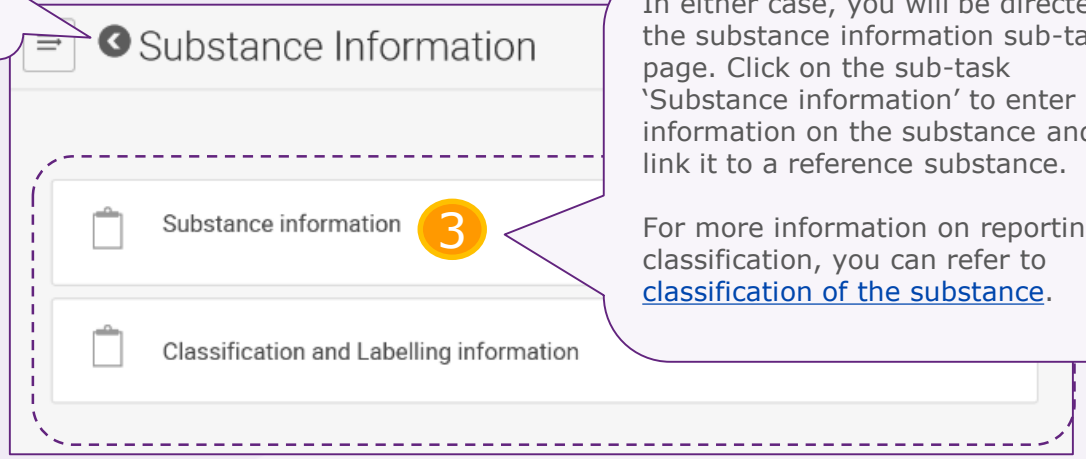
Click on the back button '<' to return to the mixture composition task to add more substances.



Either specify your substance component by selecting an existing substance from the available inventory.

Or, if the substance is not listed in the available inventory, provide a name for the substance in this field.

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



In either case, 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.

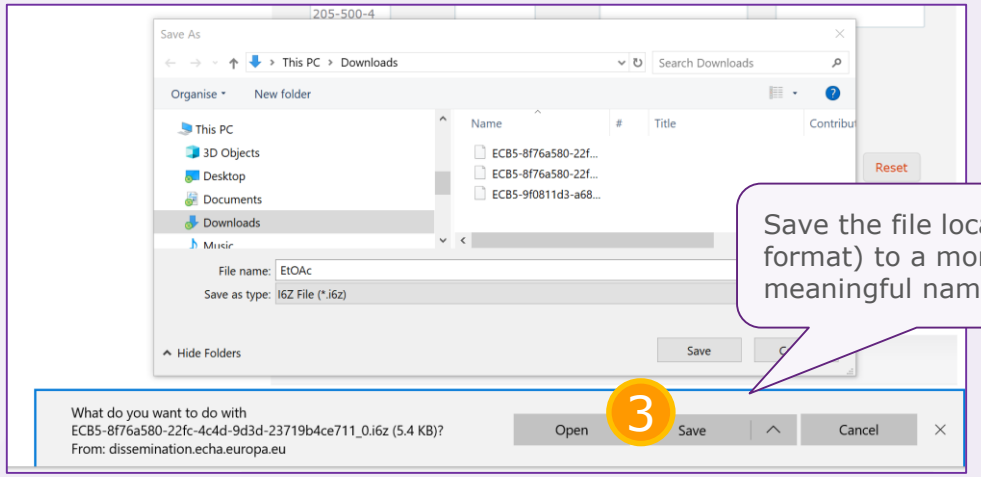
For more information on reporting classification, you can refer to classification of the substance.

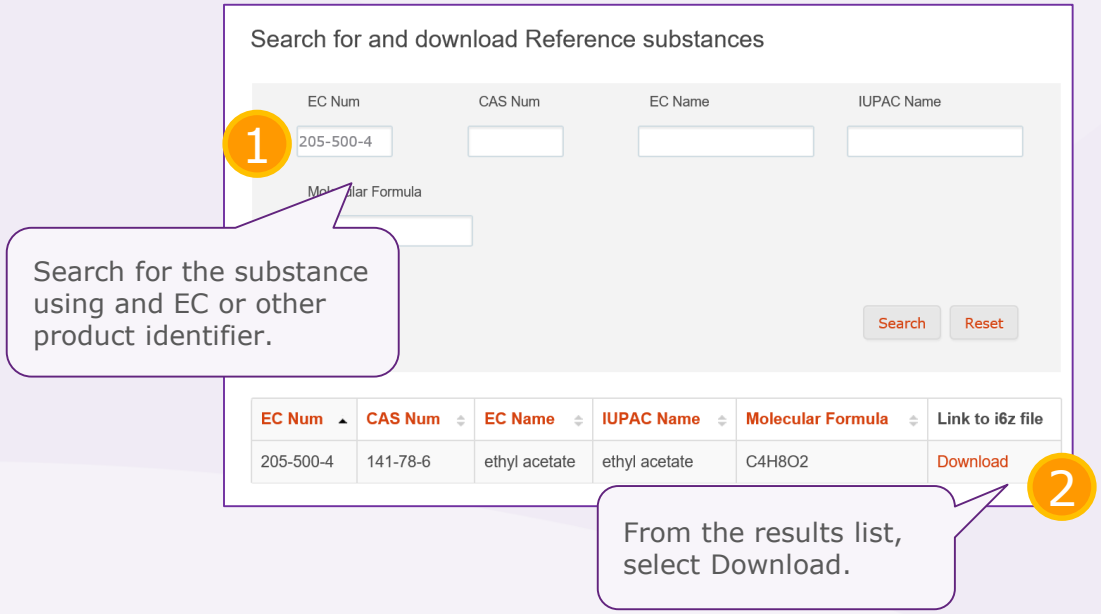
Poison centres

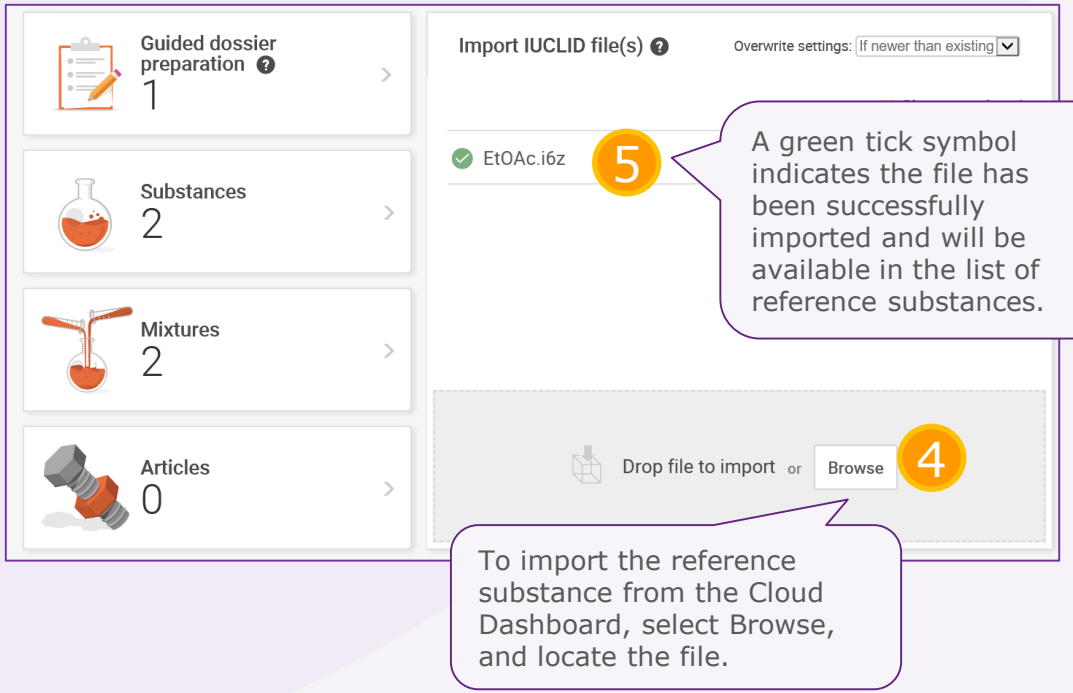
Downloading and importing a Reference substance

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. You can create reference substance documents during dossier preparation. However, it is also possible and more efficient to download and import them as a ready-made set from the IUCLID web site.

https://iuclid6.echa.europa.eu/get-reference-substances



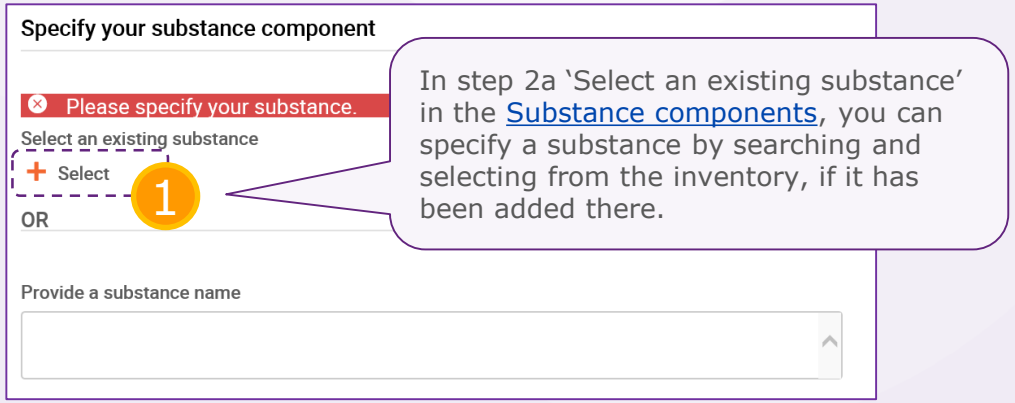




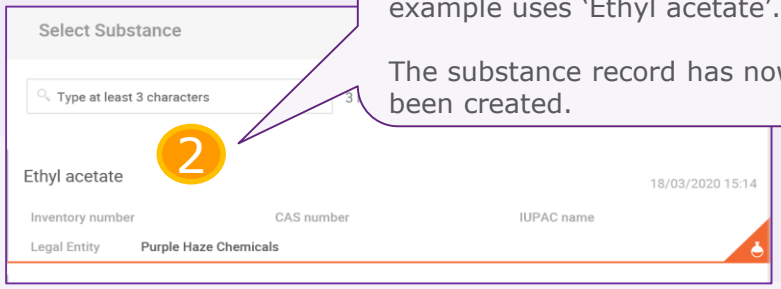
Poison centres

How to ‘Select an existing substance’

You can specify a substance component by selecting an existing substance (from the available inventory), but only if it has been previously created.

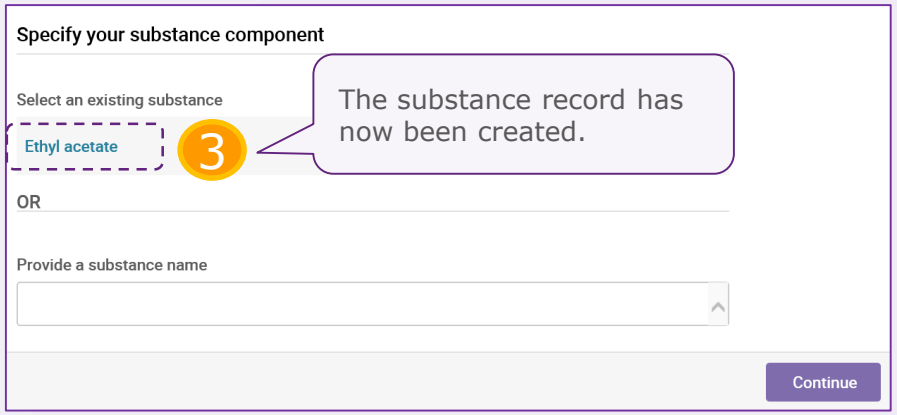


In step 2a ‘Select an existing substance’ in the Substance components, you can specify a substance by searching and selecting from the inventory, if it has been added there.

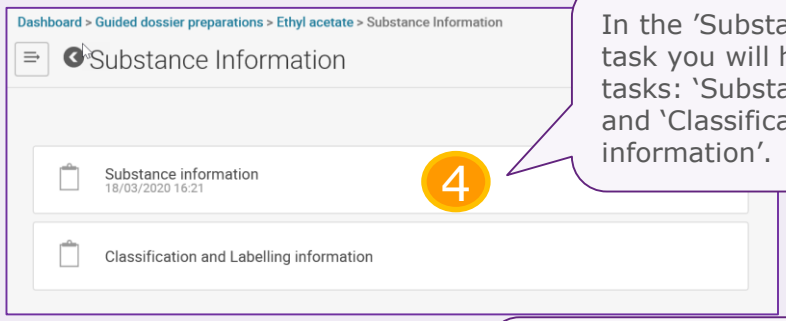


Select the substance and press continue (not shown) to create the substance record. This example uses ‘Ethyl acetate’.

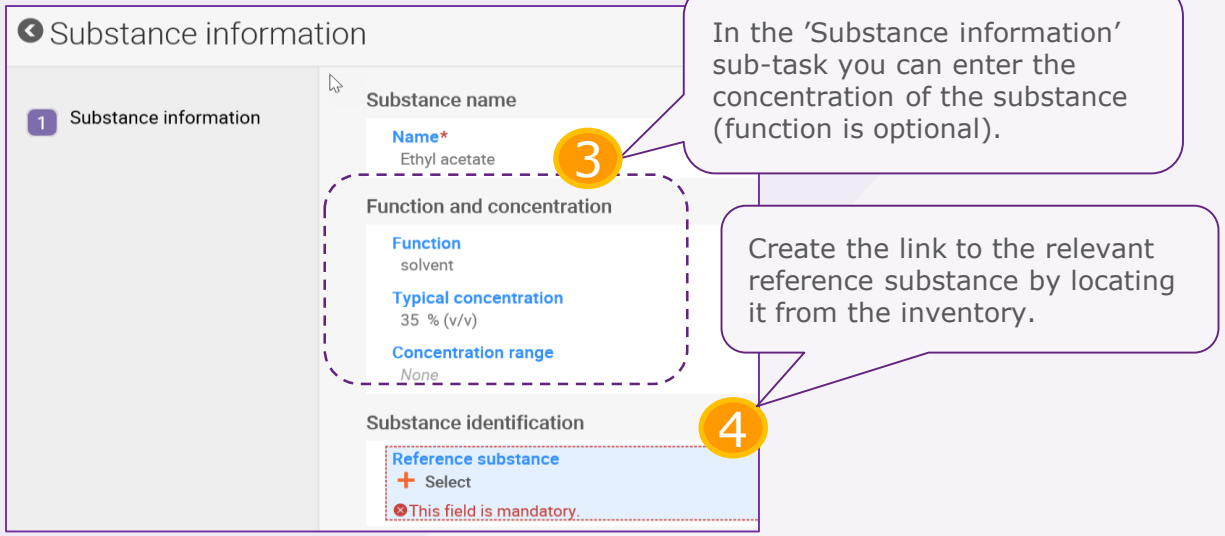
The substance record has now been created.



The substance record has now been created.



In the ‘Substance information’ task you will have two sub-tasks: ‘Substance information’ and ‘Classification and labelling information’.

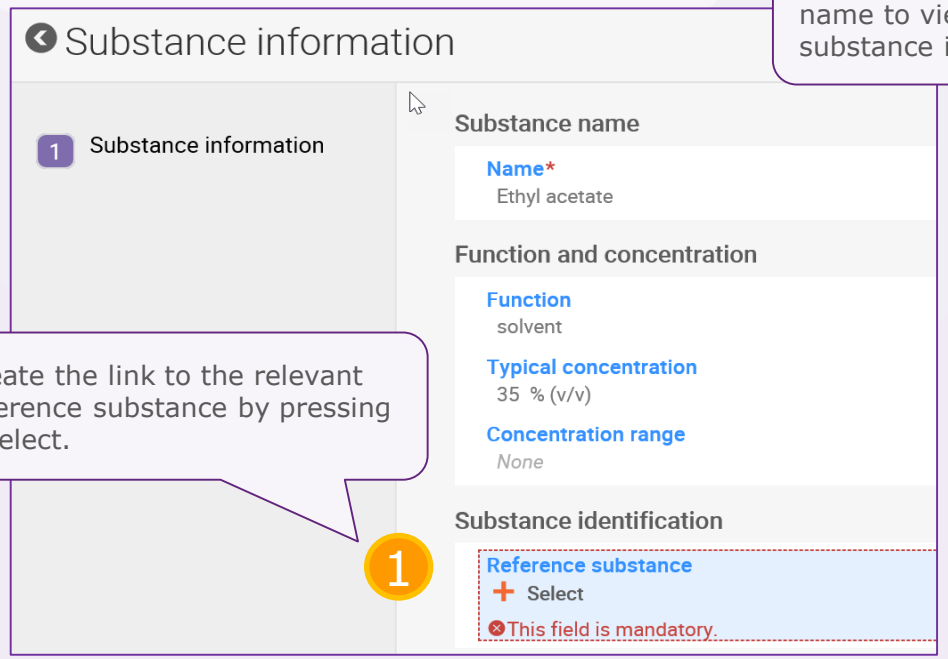


In the ‘Substance information’ sub-task you can enter the concentration of the substance (function is optional).

Create the link to the relevant reference substance by locating it from the inventory.

Poison centres

Establishing a link to an existing reference substance

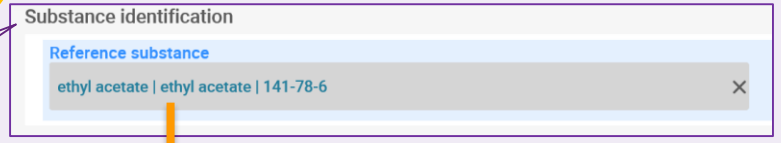


Create the link to the relevant reference substance by pressing +Select.

1

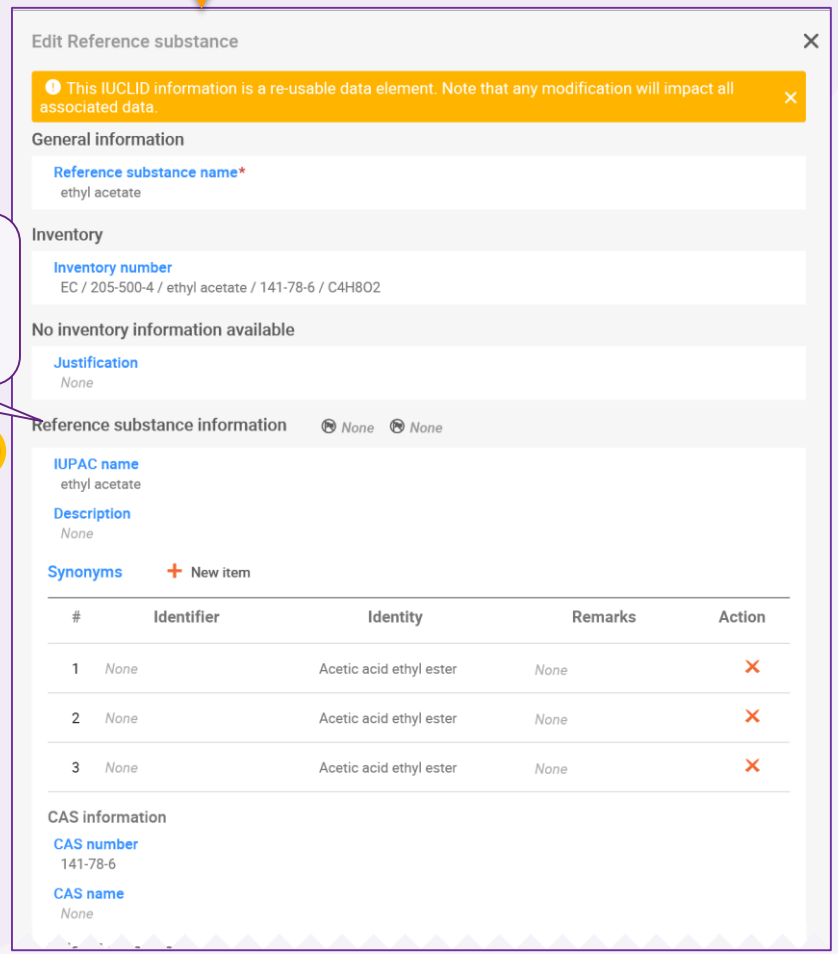
Click on the reference substance name to view the reference substance information.

3



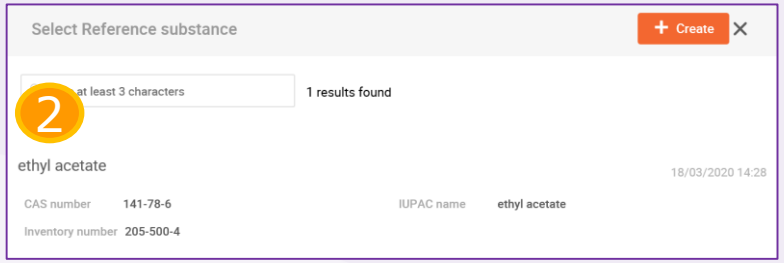
You can edit the reference substance information, if required.

4



Locate the reference substance from the inventory and click on the name.

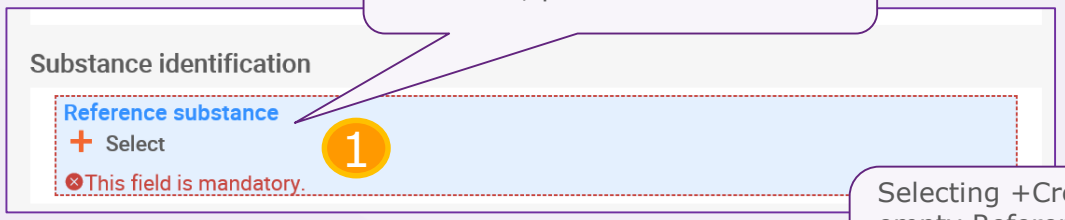
2



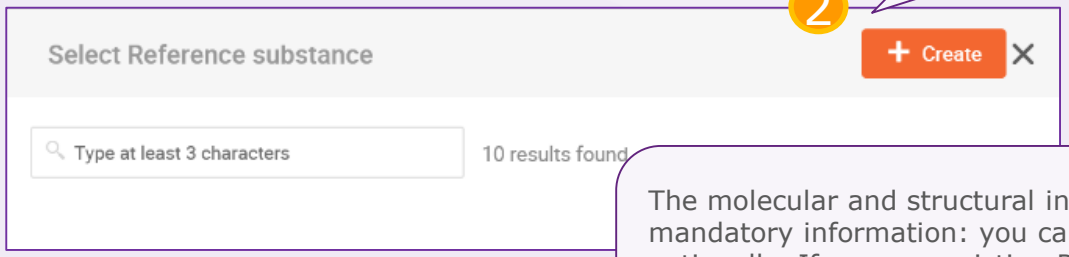
Poison centres

Creating a Reference substance

To create a reference substance document, press +Select.

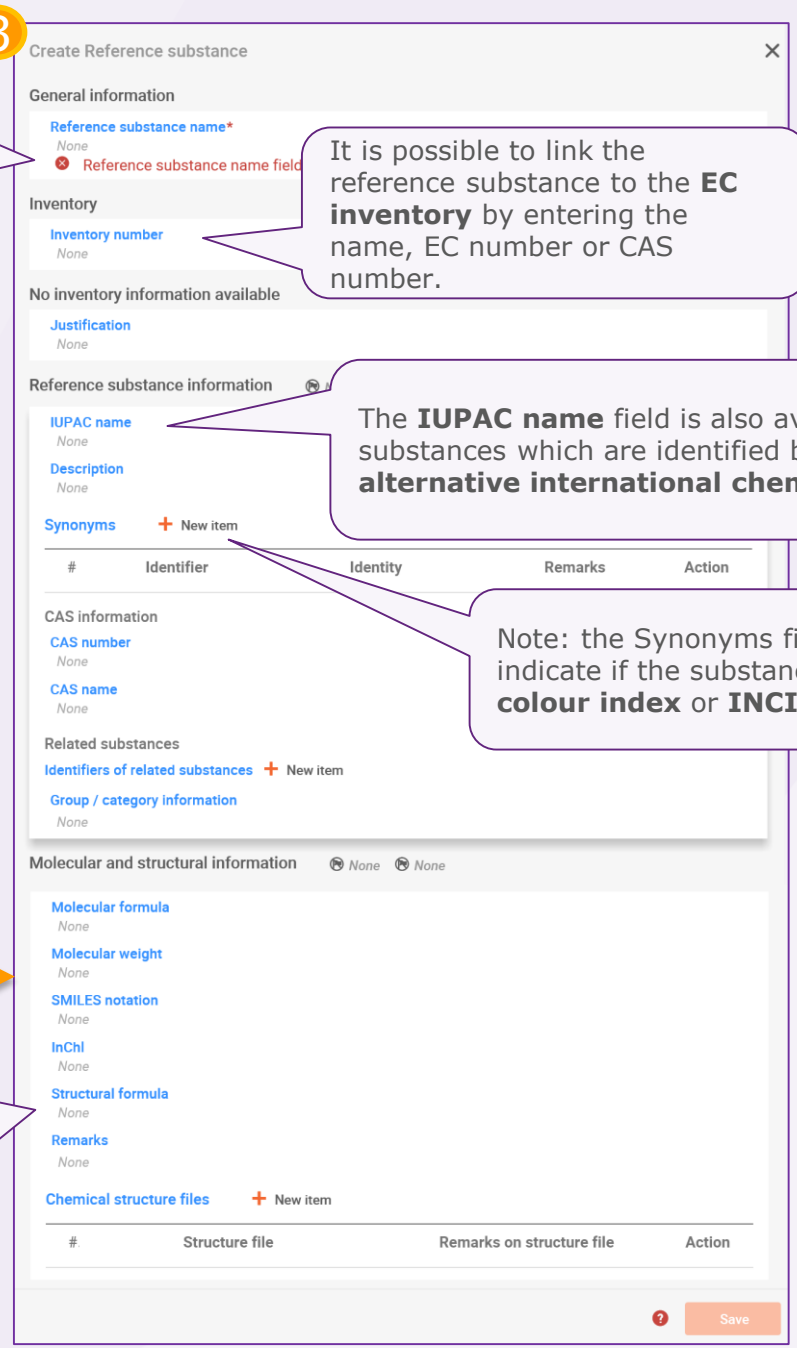


Selecting +Create, will open an empty Reference Substance document in which you can enter information about the substance identity.



The molecular and structural information is not mandatory information: you can be add it optionally. If you use existing Reference substances downloaded from the IUCLID website, the substance identifiers, molecular and structural information will be prefilled.

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



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

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

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

Poison centres

Reporting generic product identifier components

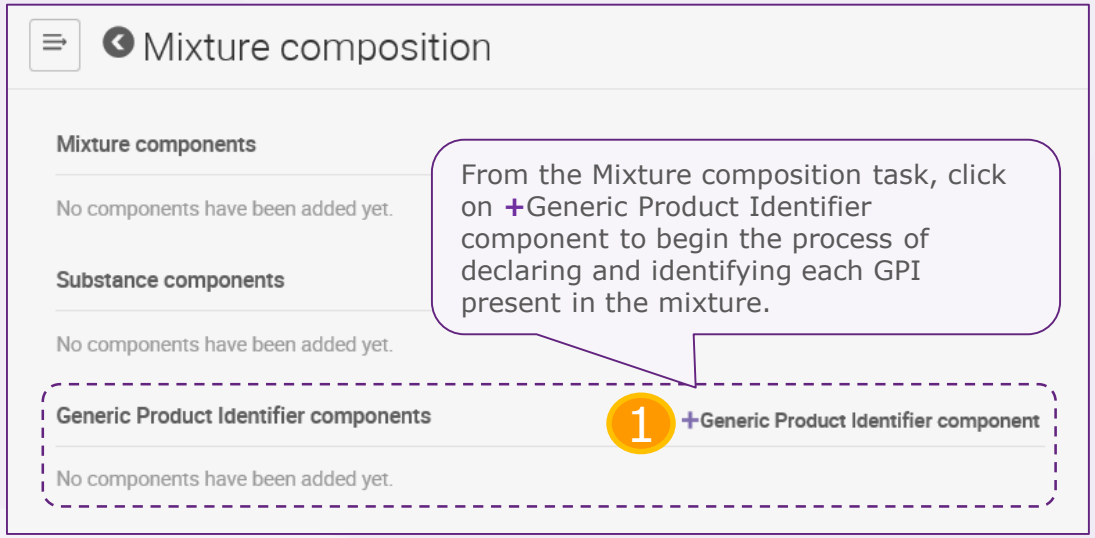
An overview of how to use IUCLID to complete the sub-tasks for generic product identifier (GPI) components. Full details on the information requirements can be found from the *Guidance on harmonised information relating to emergency health response* at:

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

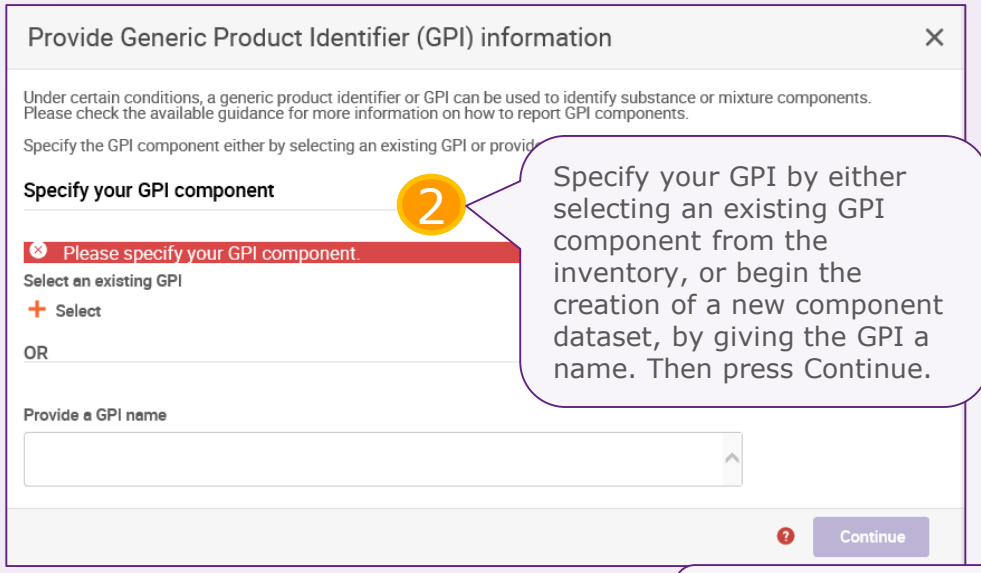
Poison centres

Generic product identifier components

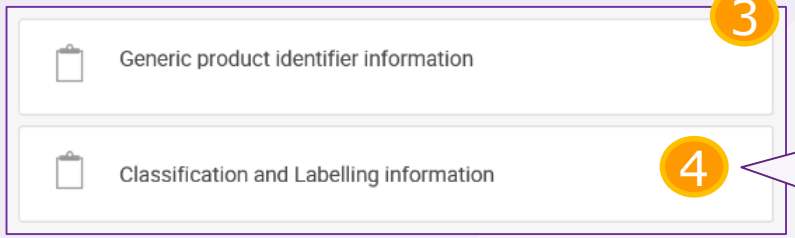
The generic product identifiers include only those components (either substances or MiMs): used exclusively to add **perfume, fragrance or colour**; only if they are **not classified for any health hazard**, and the concentration of a given GPI does not exceed in total 5% for the sum of perfumes or fragrances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



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.



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.



3

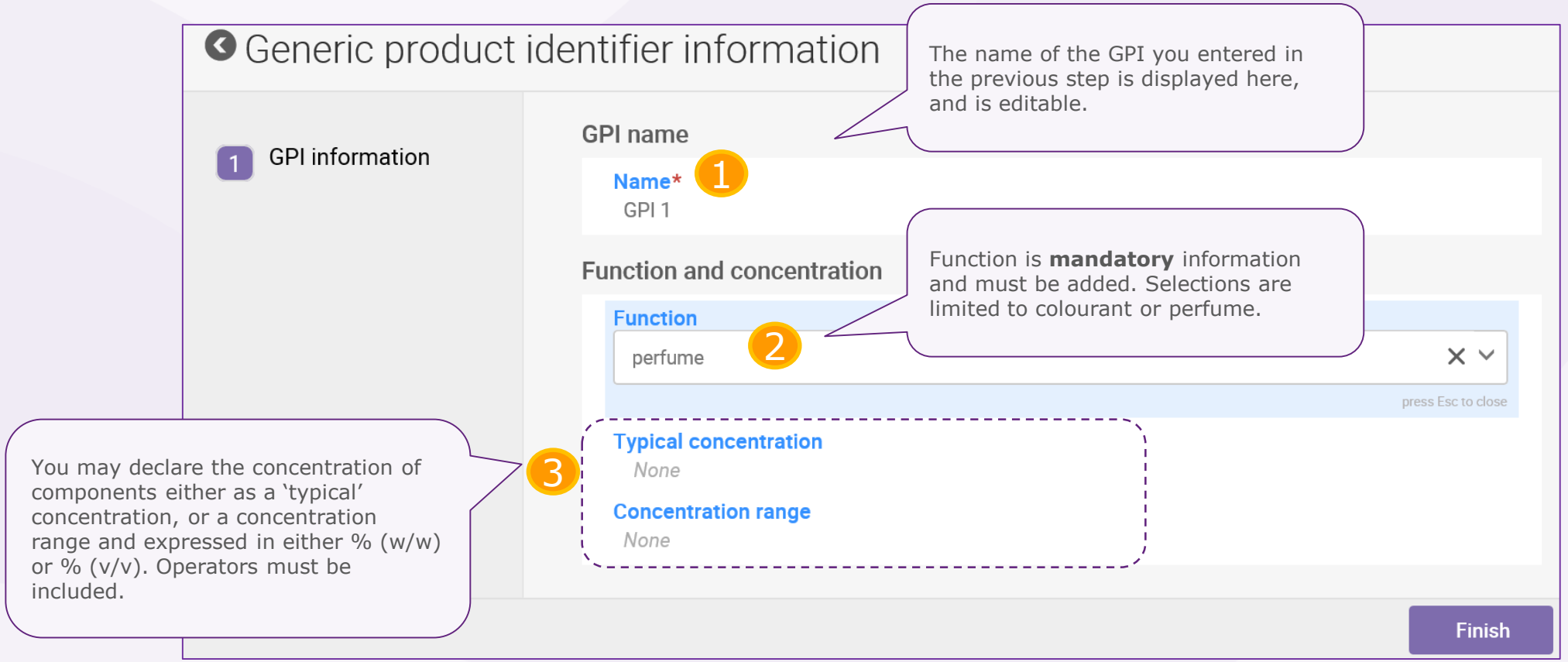
The following sub-tasks are triggered for GPI information, and classification.

4

For more information on reporting classification, you can refer to classification of the substance.

Poison centres

Sub-task ‘Generic product identifier information’ for the GPI



Poison centres

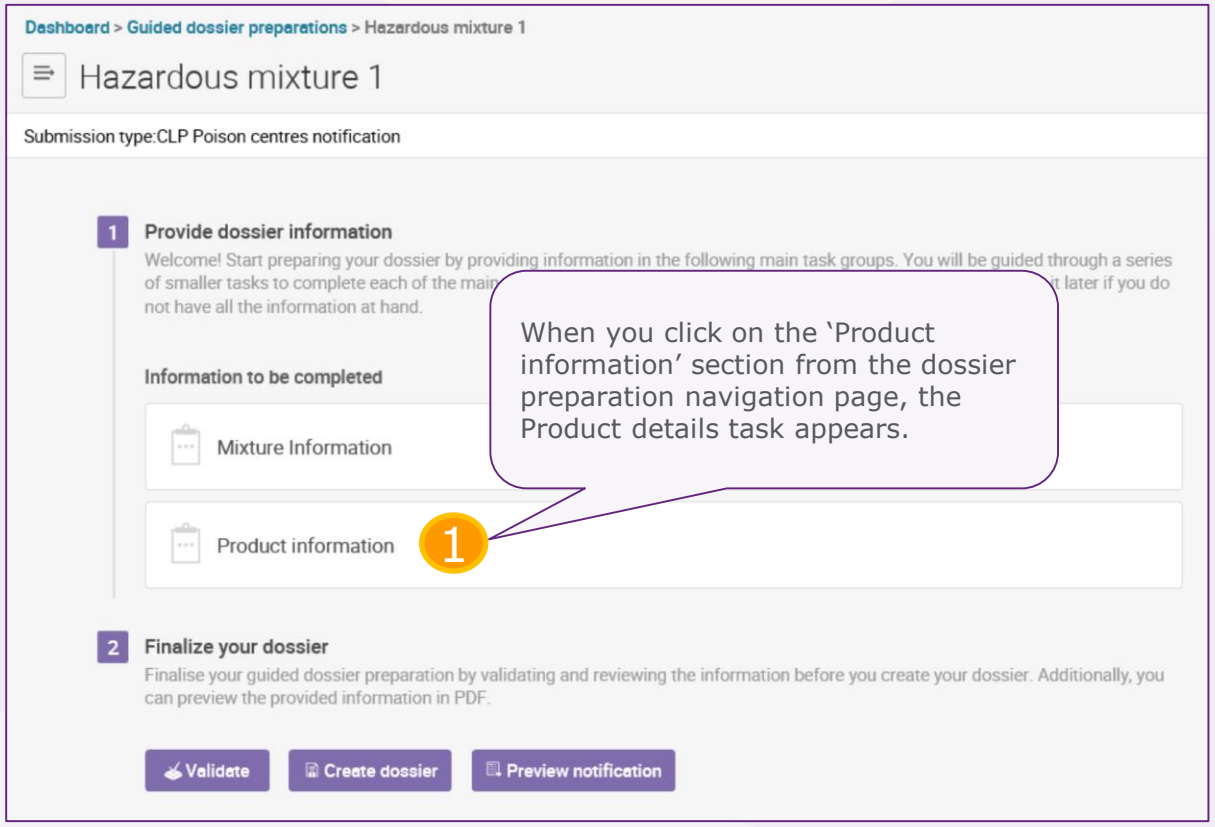
Dossier preparation: ‘Product information’

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:

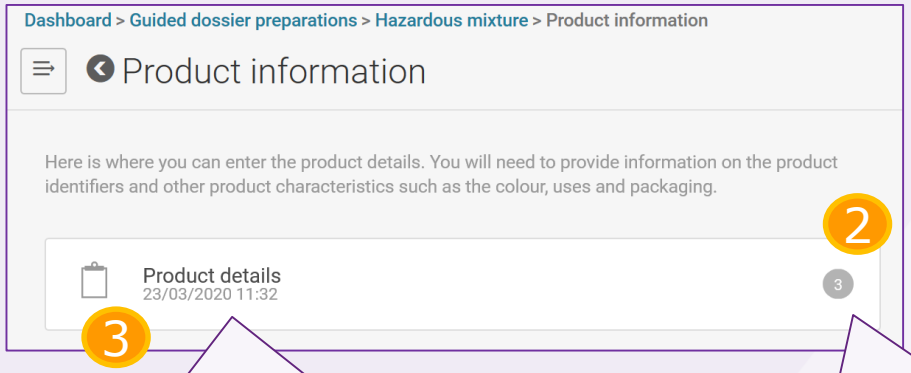
https://poisoncentres.echa.europa.eu/guidance

Poison centres

Navigating to the Product details page



When you click on the 'Product information' section from the dossier preparation navigation page, the Product details task appears.



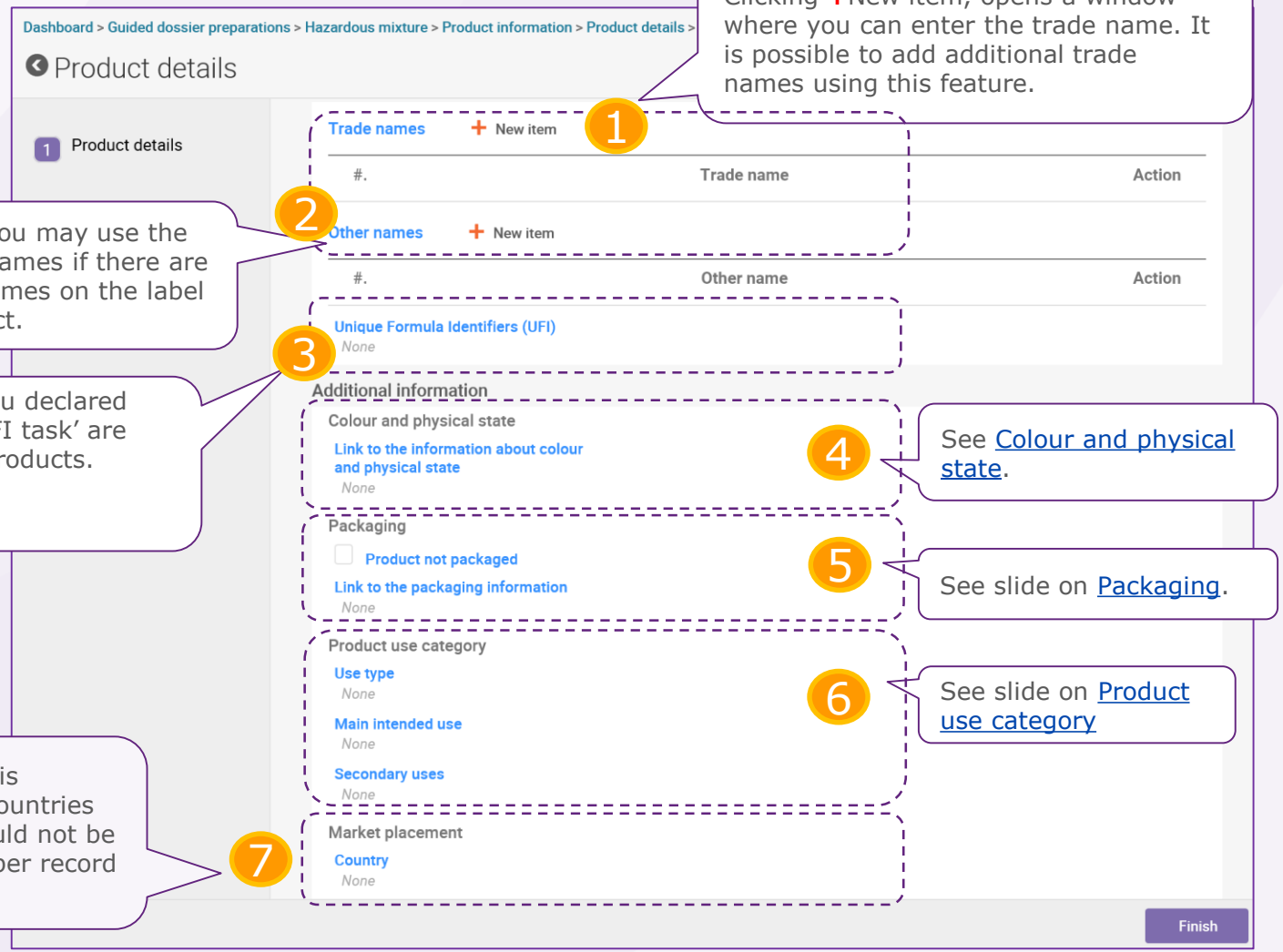
By clicking on the Product details task, you will be referred to all the product records

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.

Poison centres

Product details page



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

Optionally, you may use the field Other Names if there are additional names on the label of the product.

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

See Unique formula identifiers.

See Colour and physical state.

See slide on Packaging.

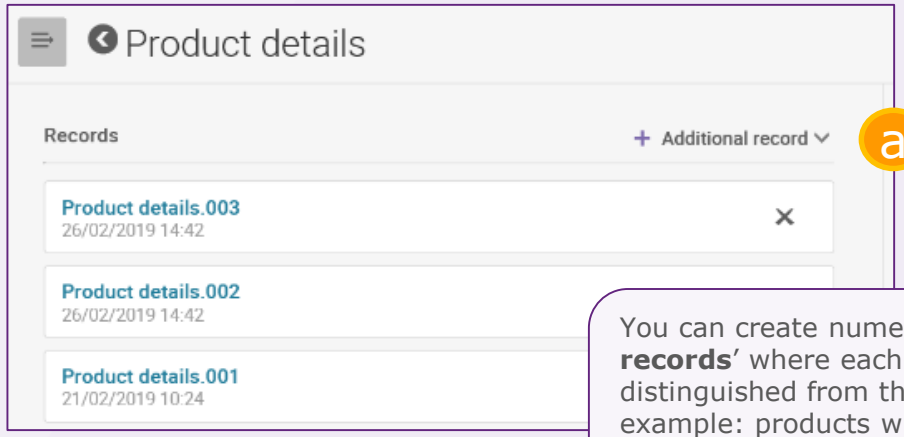
See slide on Product use category

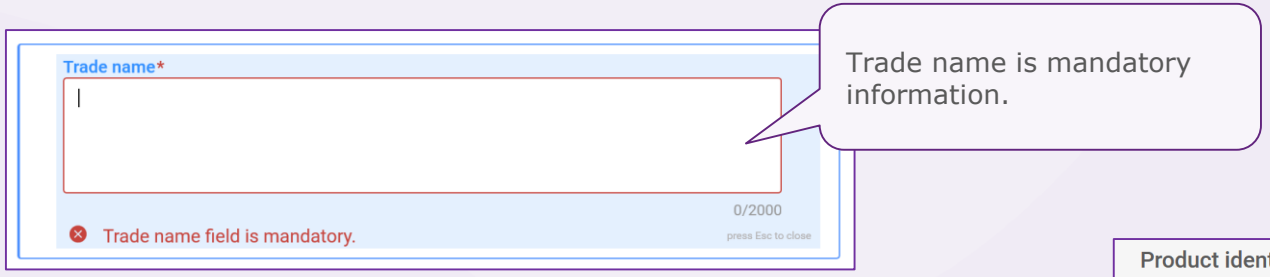
Select the countries where the product is intended to be placed on the market. Countries not indicated in the dossier header should not be selected. Note that multiple selections per record are allowed.

Poison centres

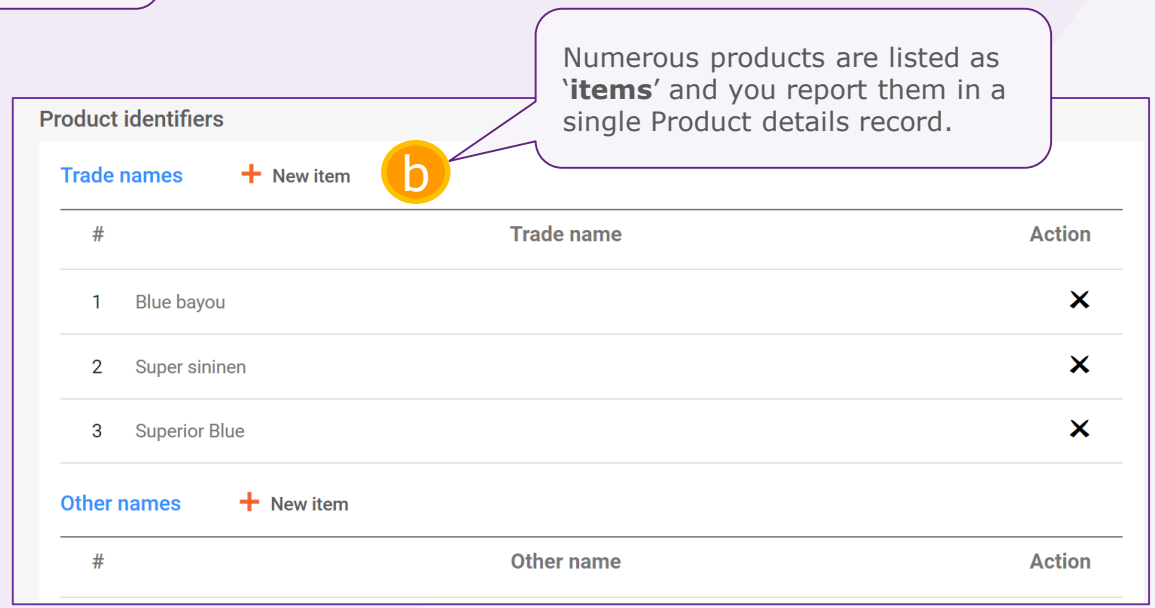
Product identifiers

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





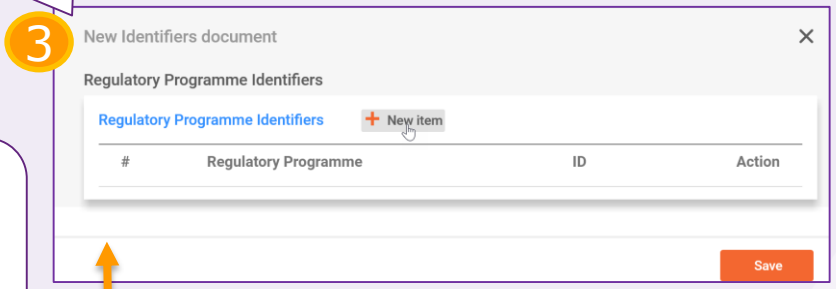
Where multiple products are concerned, the Product details record allows a very flexible configuration. In such cases, there is the possibility to manage these in a dossier in two different ways: a) and b).

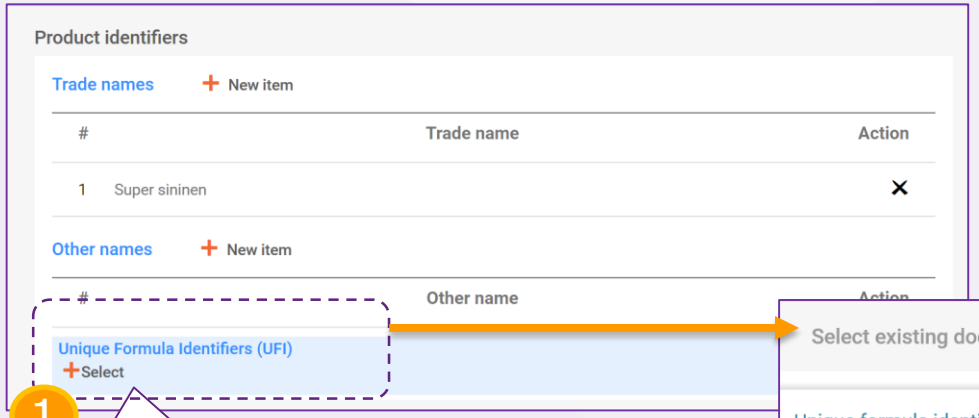


Poison centres

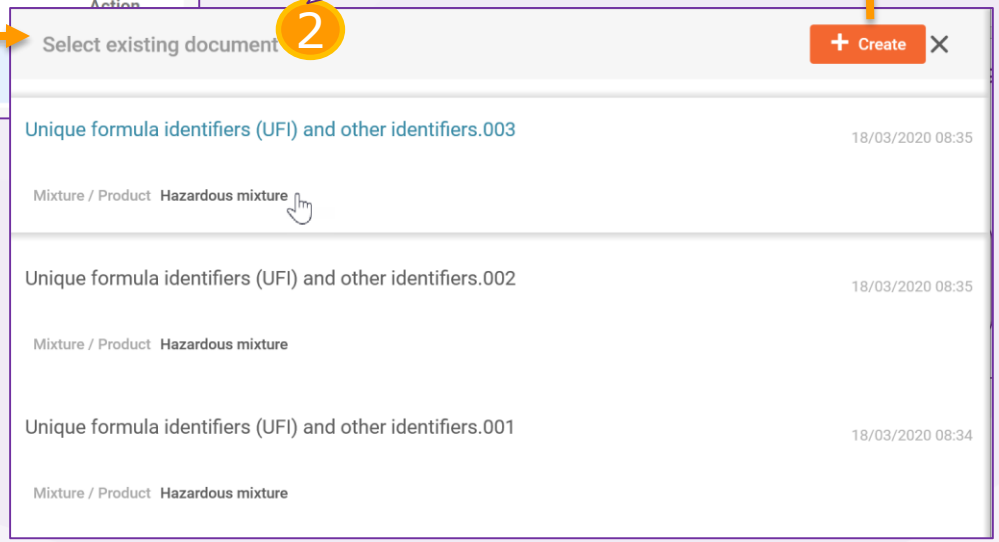
‘Unique formula identifier’

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 record.





You can link the UFIs through selecting the correct UFI assigned to the mixture (included on the label of the related product), by clicking anywhere in the relevant information bar.

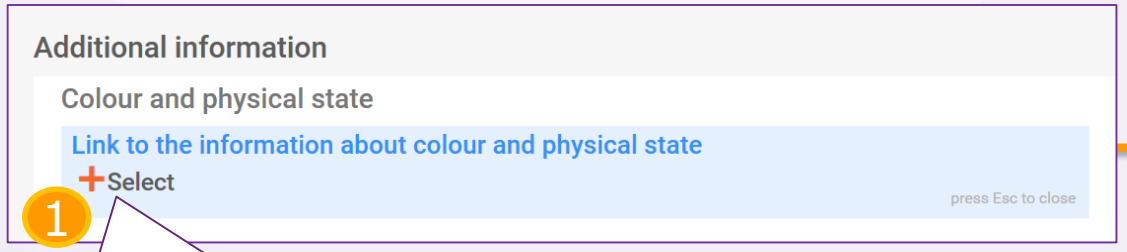


By clicking first on the UFI link (blue text), then +Select, the UFIs that you declared earlier in the Mixture information ‘UFI task’ are listed and you can link them to specific products.

Note that this linking is still required even in the simplest case; where a single UFI is declared and only one product exists.

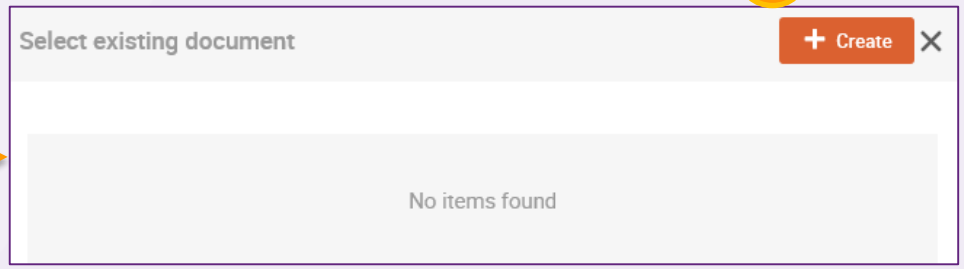
Poison centres

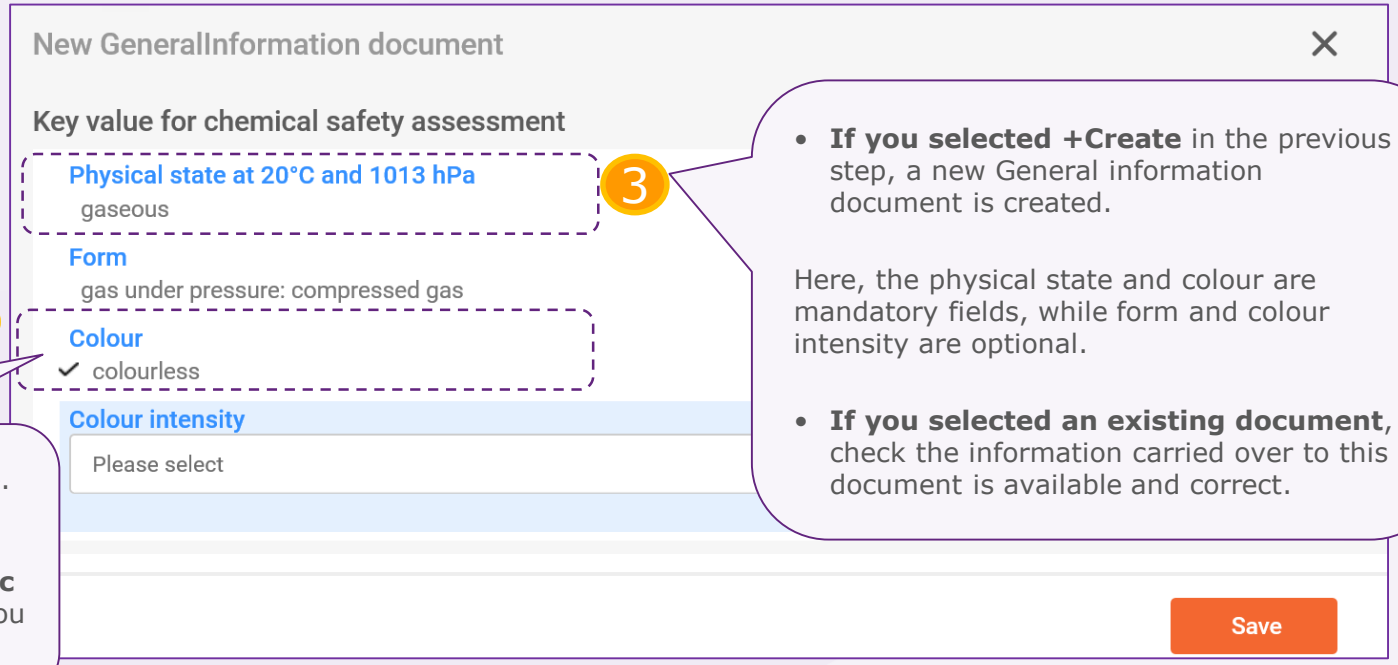
‘Colour and physical state’



To establish a link to the information about colour and physical state for the product referred to in the record, click on +Select. You can reference multiple documents here.

The system offers the option to select an existing General information document (if one exists) or create a new document.





- **If you selected +Create** in the previous step, a new General information document is created.

Here, the physical state and colour are mandatory fields, while form and colour intensity are optional.

- **If you selected an existing document**, check the information carried over to this document is available and correct.

Single or multiple colour selections (x 15 total) are available. Selecting multiple colours (for example, 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 you must additionally select all relevant colours.

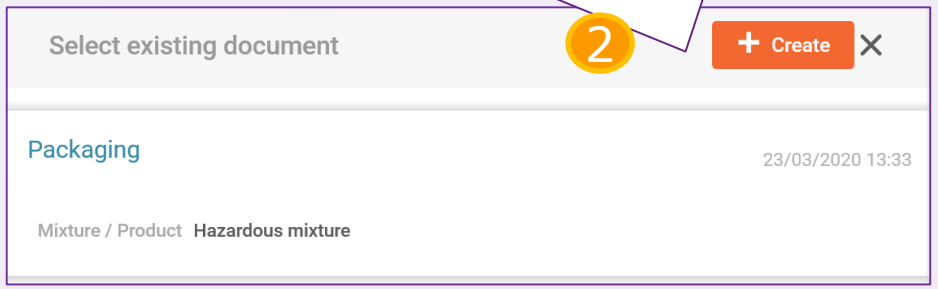
Poison centres

‘Packaging’

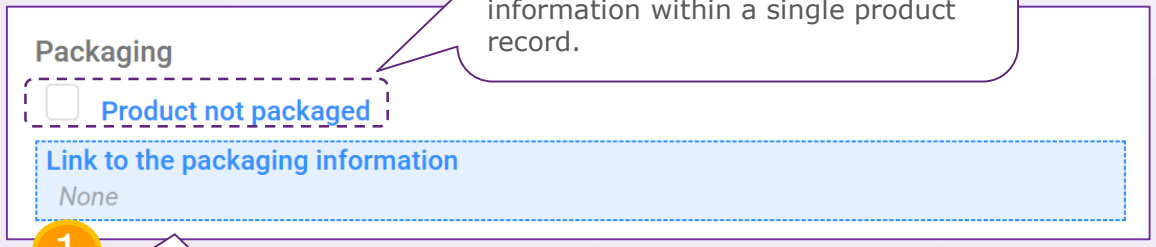
If a mixture is supplied in different types and sizes of packaging, you need to include information on all the relevant types and sizes. Note that mixtures for industrial use are not required to have packaging indicated.

You can then either select and re-use an existing document or create a new one.

To create a new document, select +Create and enter information into a new document as shown in the screenshot below (see point 3,4, & 5).



Selecting the check box Not packaged can not be used in conjunction with other packaging information within a single product record.



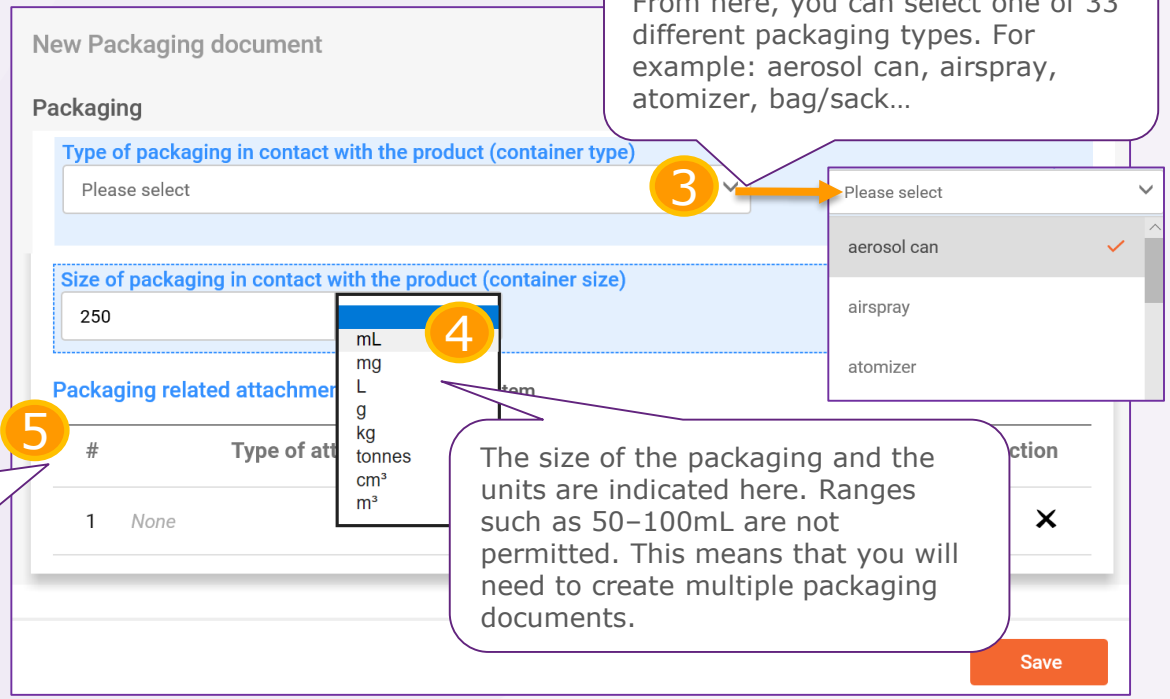
1

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

You may include here any packaging related documents such as an example label. The system accepts files such as PDF, Word or JPEG.

5

From here, you can select one of 33 different packaging types. For example: aerosol can, airspray, atomizer, bag/sack…



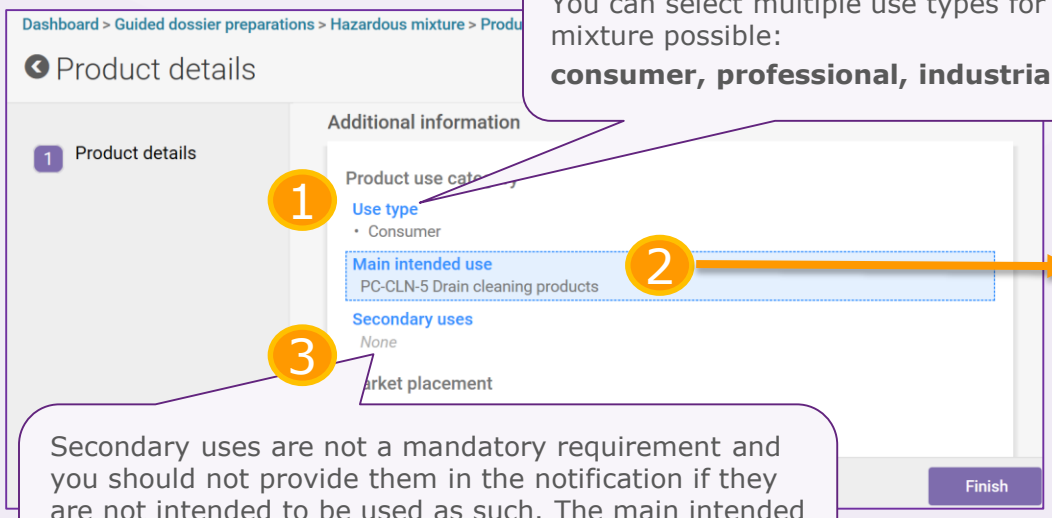
The size of the packaging and the units are indicated here. Ranges such as 50–100mL are not permitted. This means that you will need to create multiple packaging documents.

Poison centres

‘Product use’

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.

You can select multiple use types for the mixture possible:
consumer, professional, industrial.

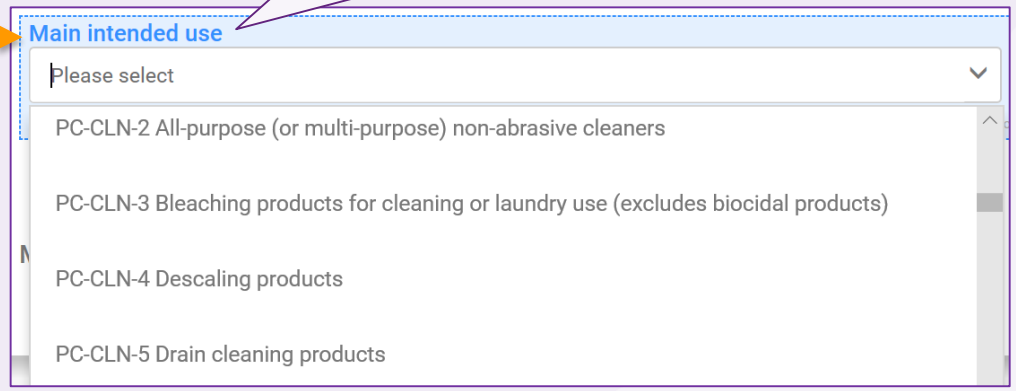


Secondary uses are not a mandatory requirement and you should not provide them in the notification if they are not intended to be used as such. The main intended use categories are, however, available to make secondary use selections if needed. The maximum number recommended is three.

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

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

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



Poison centres

Validate information, create dossier and preview notification

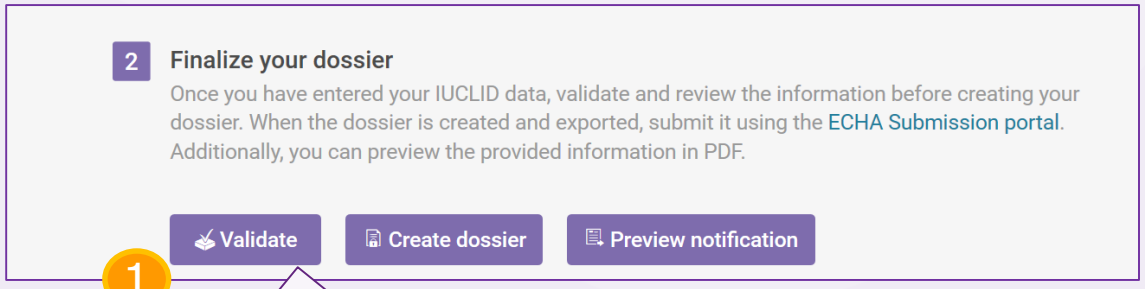
An explanation of the functionalities to finalise the dossier preparation process; validate, create a dossier, and preview notification.

Poison centres

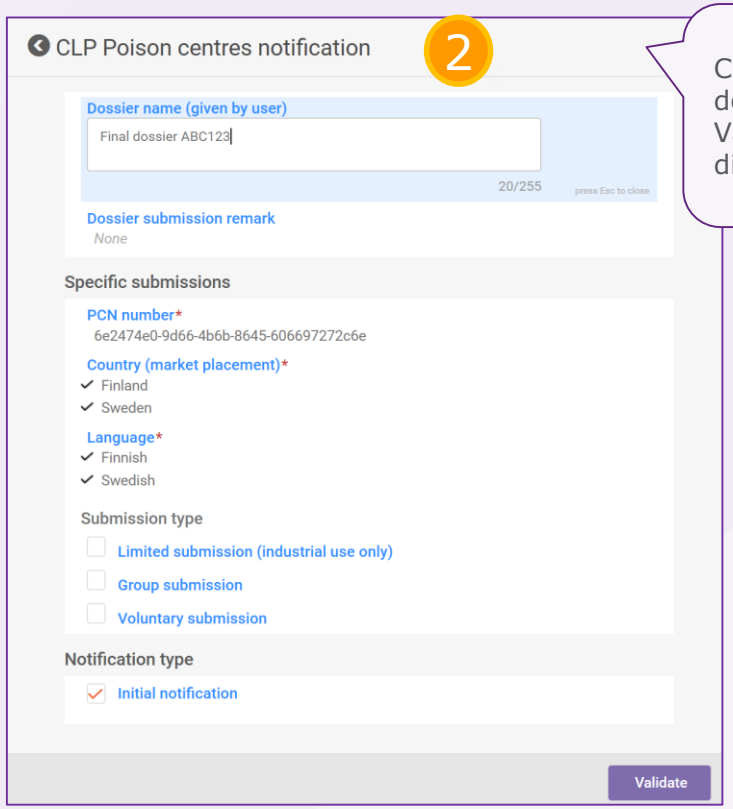
The validation assistant

The validation assistant carries out checks according to a set of pre-defined rules to verify that you have provided the information 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



Clicking Validate will display the Dossier header page for final review.

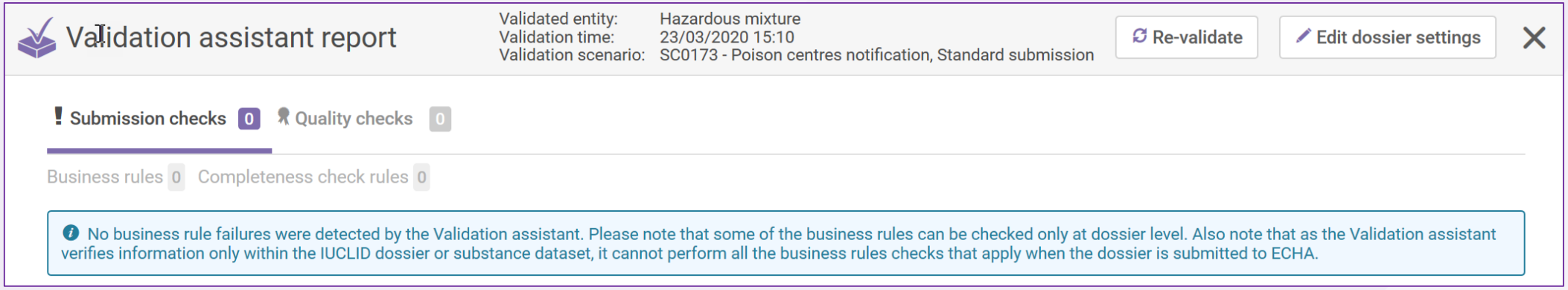


Click on Validate again from the dossier header page and the Validation report will be displayed.

Poison centres

The validation report - passing

When no rules are triggered, the validation assistant will not issue a validation report. Instead, it will provide a note to highlight that additional checks are performed in the system upon submission.



Poison centres

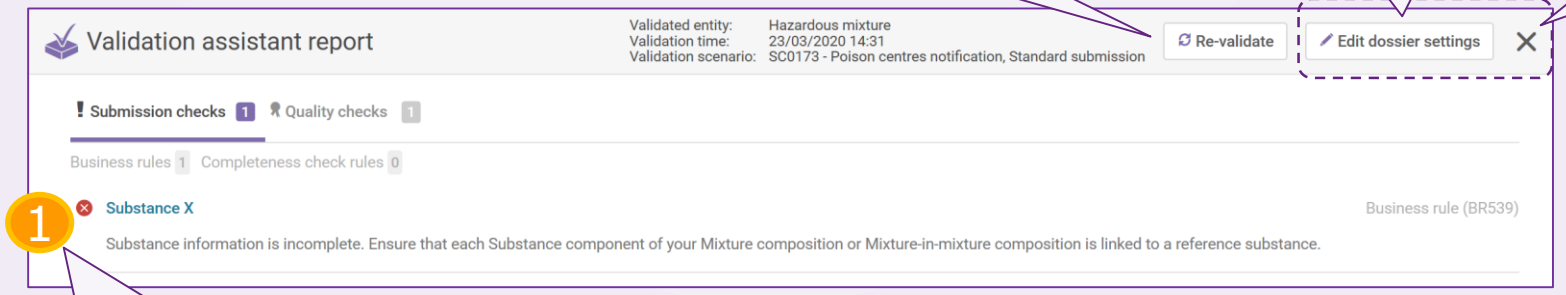
The validation report - failure

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

It is possible to re-validate any new change.

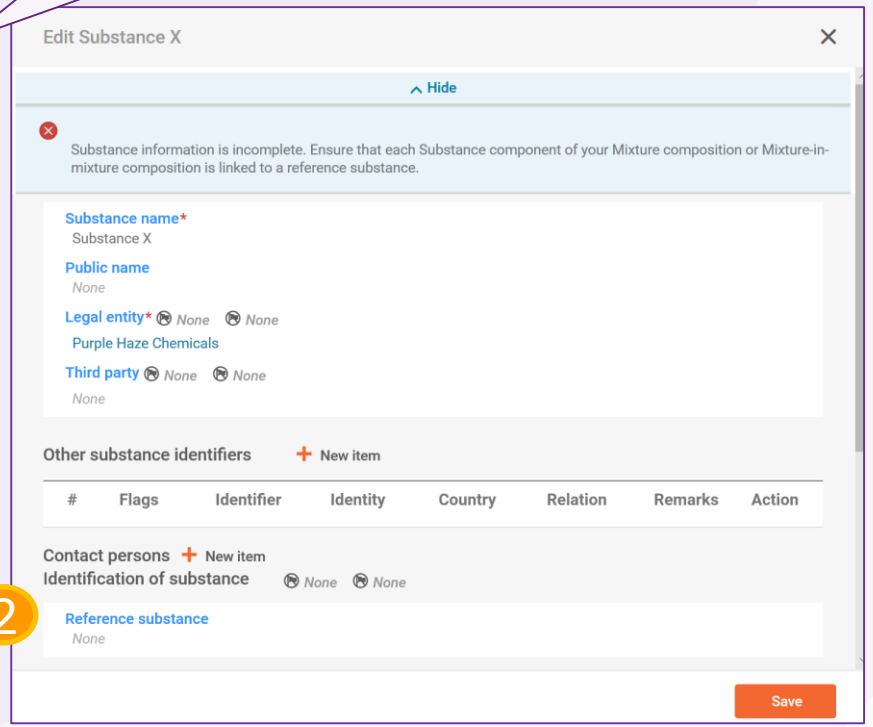
'Edit dossier settings' redirects to the Dossier Header page.

The 'X' directs backs to the Dashboard



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

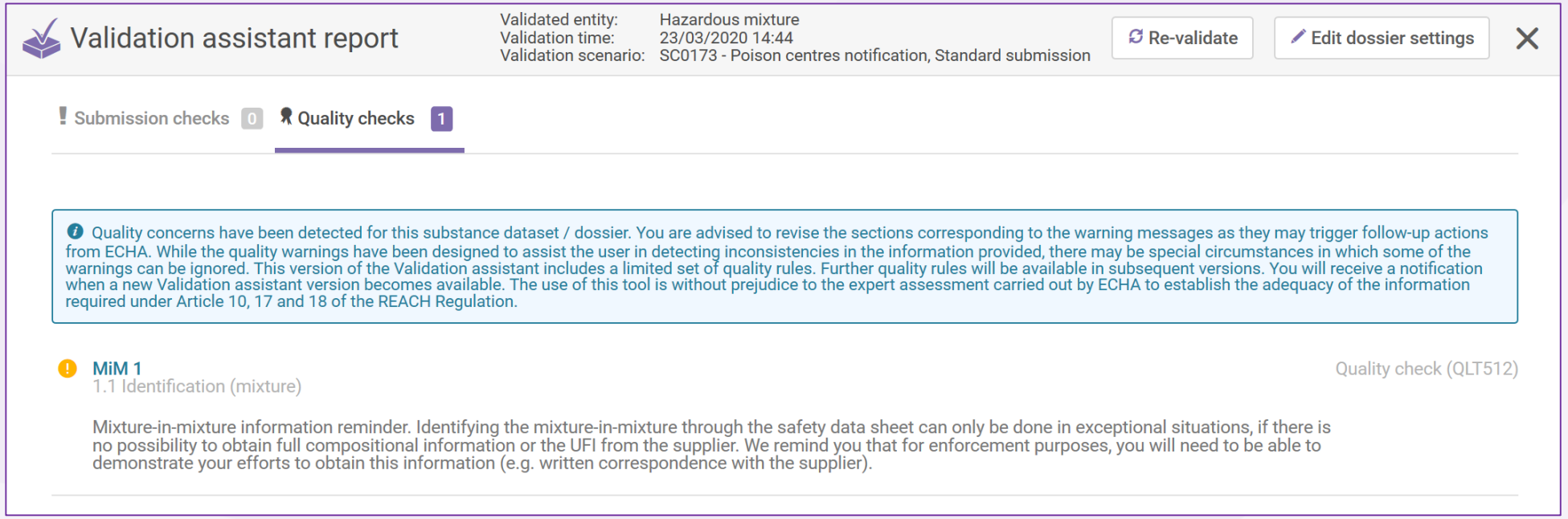
Make any required changes where relevant and save before re-validating.



Poison centres

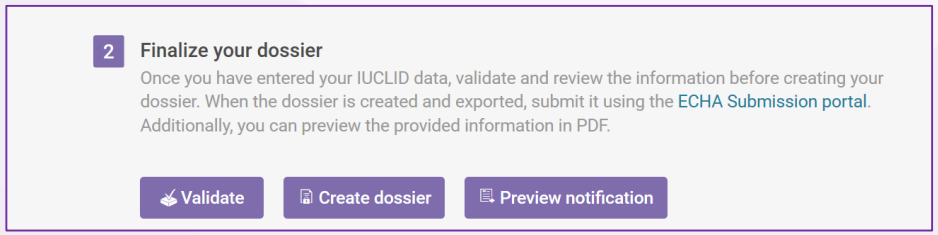
The validation report – warnings listed

A quality rule (QLT) warns or reminds you, the notifier, of common shortcomings and inconsistencies. Quality rules will not lead to the failure of the submission, but can result in further clarification requests from Member State(s) at a later stage.

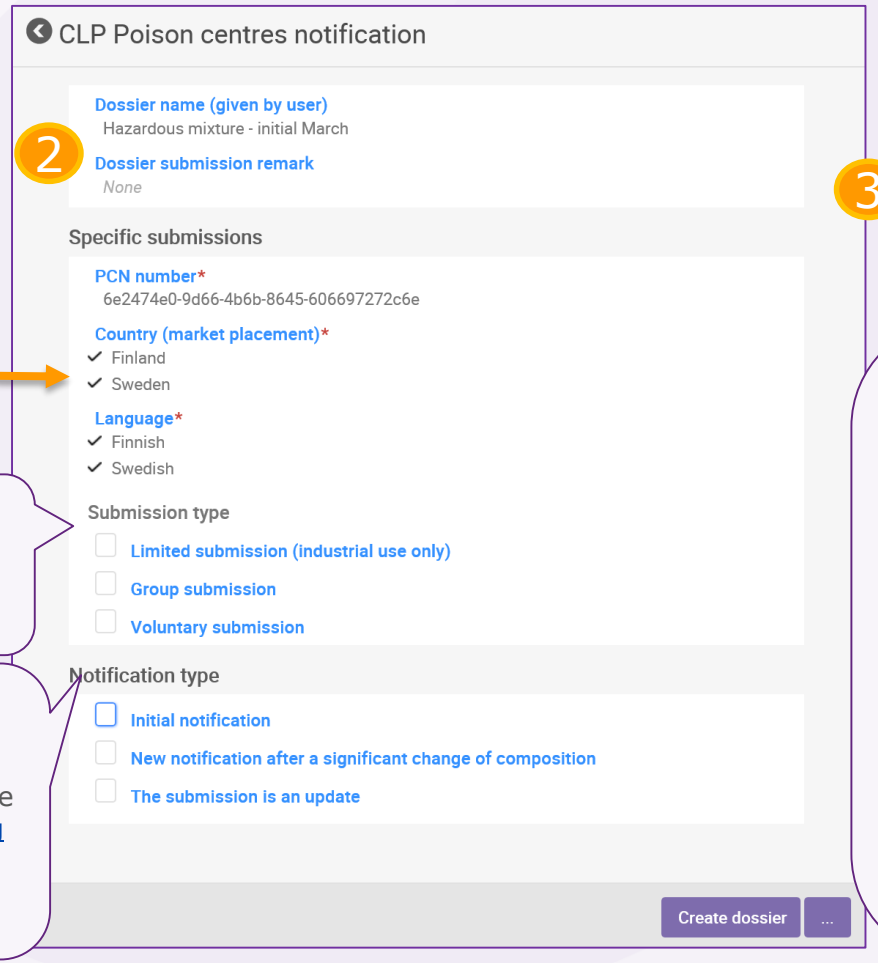


Poison centres

Creating and submitting (or exporting) the dossier



1 Clicking 'Create dossier' will display the Dossier header page.

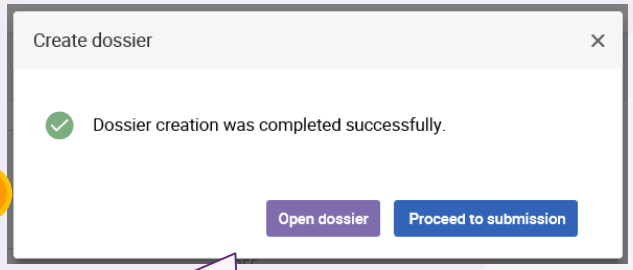


2

Flag the **submission type** if you are notifying alternatives to the standard information requirements.

Flag the **notification type**. If you select 'The submission is an **update**', then you need to provide a reason or justification for updating. See Updating the dossier header for a submission update.

3



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.

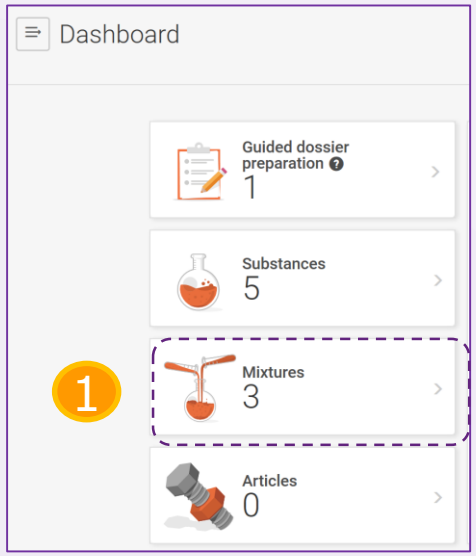
Note, clicking **Proceed to submission** automatically uploads the dossier to the ECHA Submission porta. However, you will still need to use the Submit functionality – see Upload and submit.

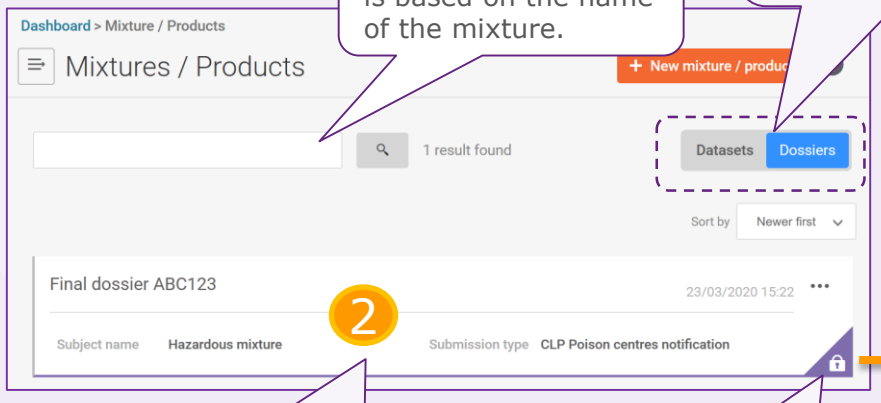
Alternatively, you can export the dossier locally by clicking **Open dossier**, clicking '…' in the top left corner and selecting Export to i6z. Give the dossier a meaningful name to help you with dossier management.

Poison centres

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.



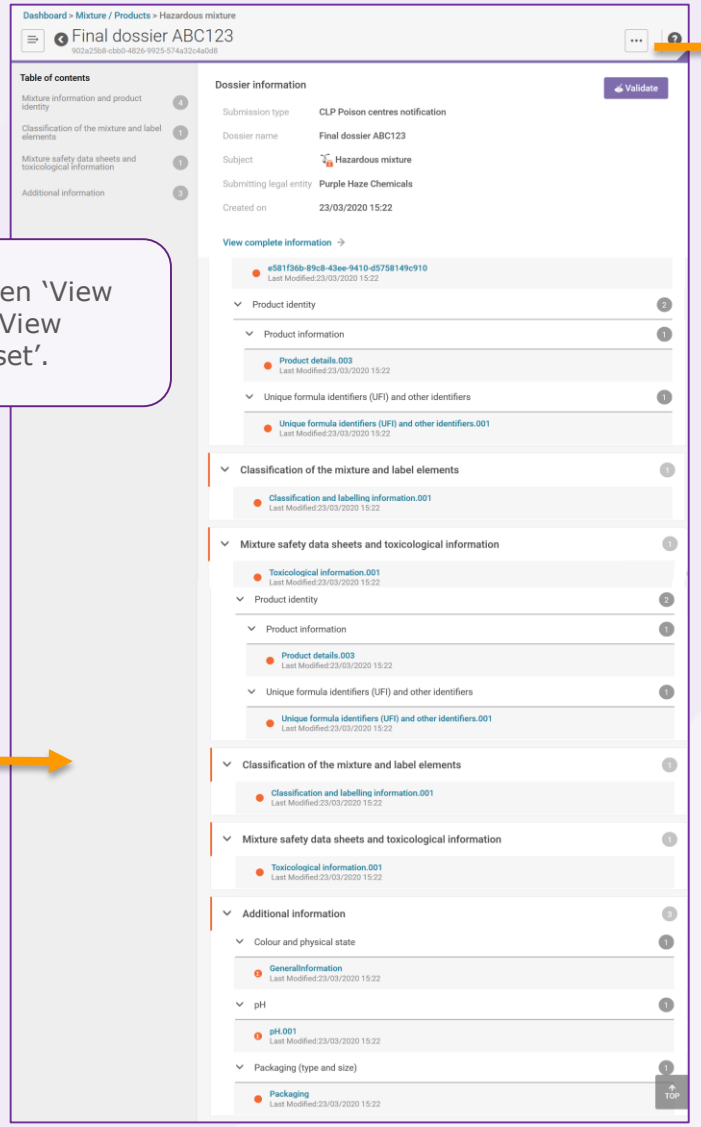


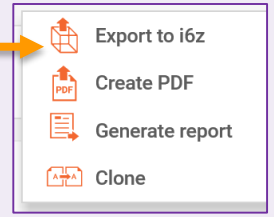
The search function is based on the name of the mixture.

Toggle between 'View dossier' and 'View mixture dataset'.

Clicking on the name of the selected dossier, redirects to the View Dossier mode.

In View Dossier mode, the lock symbol means a dossier file.





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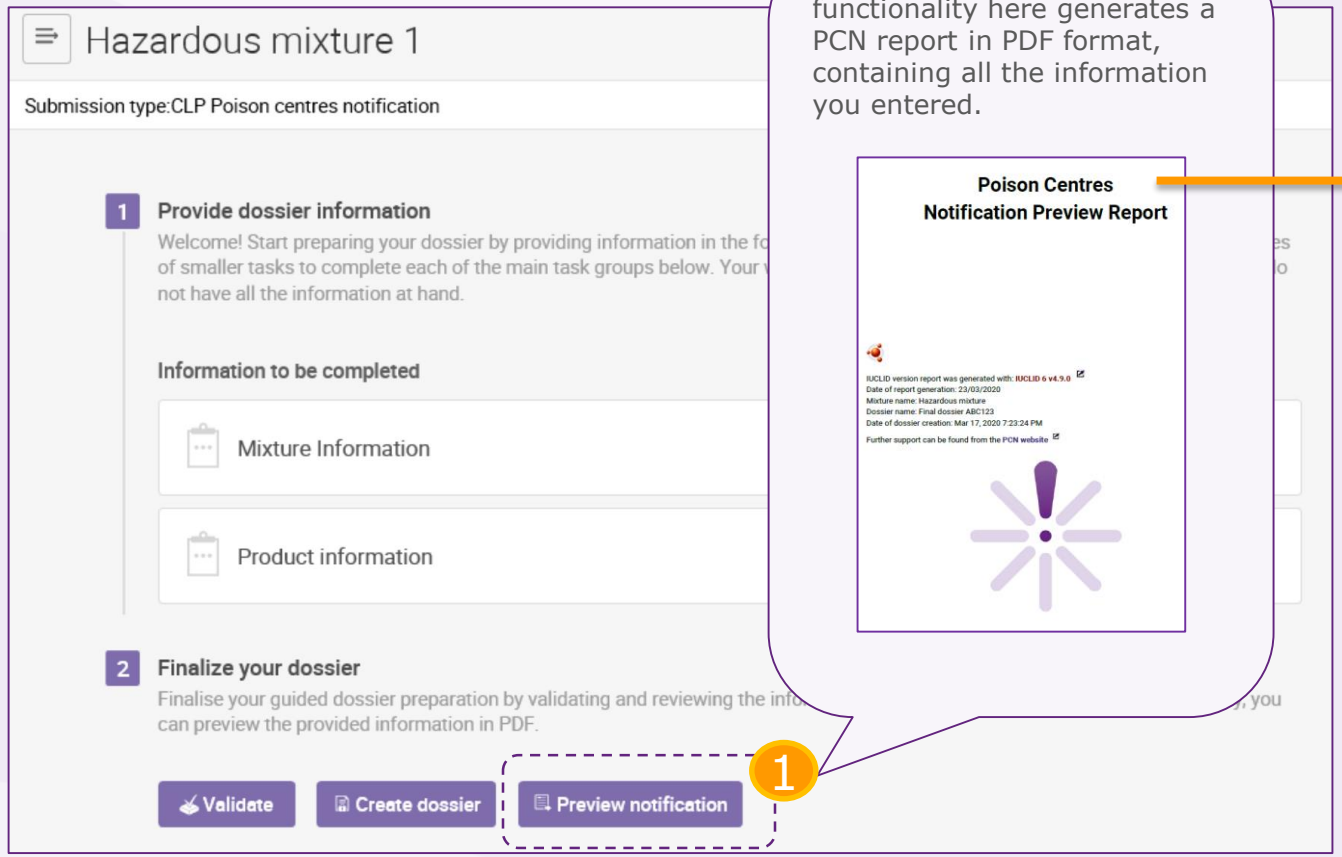
Preview notification

You can open or save the PCN preview report contents.



The Preview notification functionality here generates a PCN report in PDF format, containing all the information you entered.

2

1. PCN Preview Report

1.1. Dossier information

Dossier name: Final dossier ABC123	
Dossier UUID	80cde36c-efe2-4eda-b5d3-387905f21e45/0
PCN number in dossier header	6e2474e0-9d66-4b6b-8645-606697272c6e
Country (market placement)	Finland [FI] ; Sweden [SE]
Language	Finnish [fi] ; Swedish [sv]
Type of submission	Initial notification
Reason for updating	

1.2. Submitter information

Submitting legal entity	
Legal Entity name: Purple Haze Chemicals Phone: +358432343 E-mail: PHC@chemicals.eu	Address 1: 15 Violet st Address 2: Postal code: 12324 Town: Lilac Country: Finland [FI]

1.3. Mixture information

Mixture name: Hazardous mixture

pH	
pH is relevant	pH value: 7.6 Solution concentration (%): 100
No contact information provided	
UFI and other identifiers	
CLP unique formula identifier (UFI)	T4QV-70S1-V004-K1Y7
CLP unique formula identifier (UFI)	E7QV-R0FF-500M-7DJ9
CLP unique formula identifier (UFI)	N9QV-804U-G003-WR4C

1.4. Mixture composition

Substance components
Substance name: Ethyl acetate **Identifiers:** Reference substance name: ethyl acetate

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Updating dossier information

An explanation on how to prepare for a dossier update.

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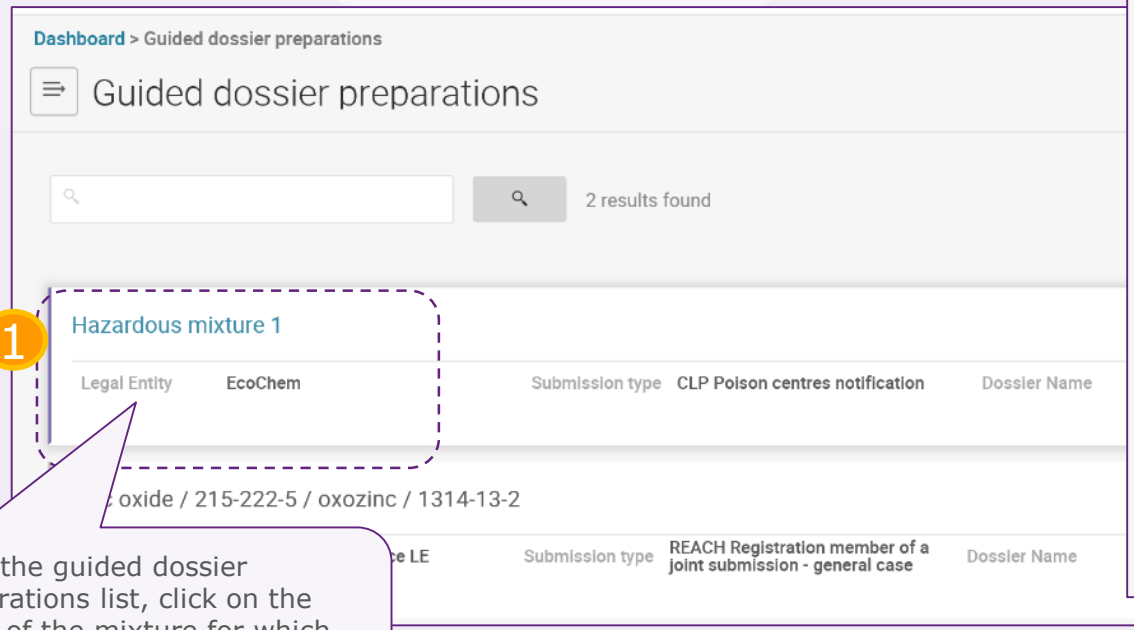
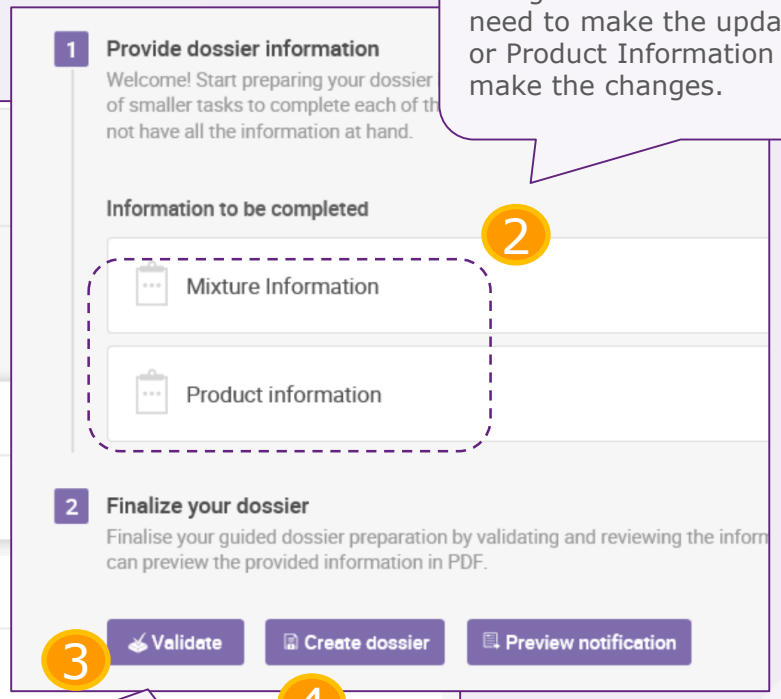
Updating dossier information

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



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



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

When you have made all the necessary changes to the notification, click on Validate.

Note: some validation checks can only be performed following the submission process, particularly in the case of updates.

When you click on Create dossier, the dossier header page will be displayed. Note that the information can be edited where relevant. See also: Updating the dossier header for submission update.

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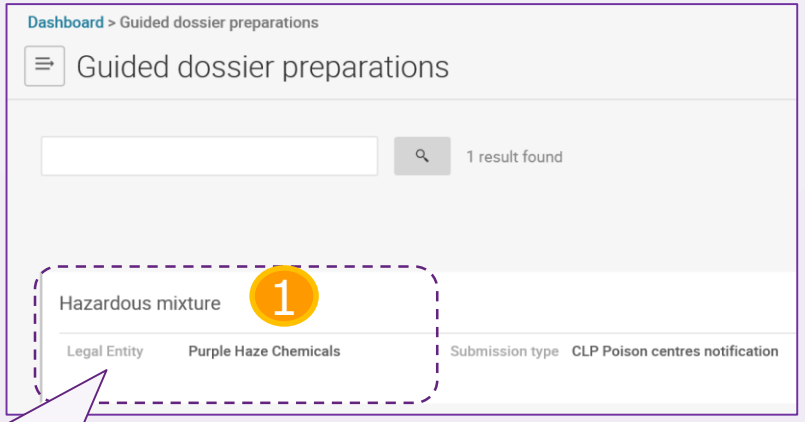
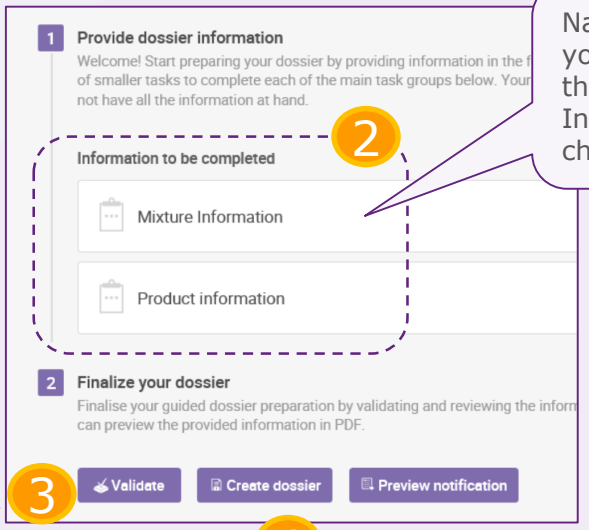
Updating dossier information – clone a dossier

Once you have created a dossier, it is possible to update that data and create an updated dossier from the Guided dossier preparations list. You can also use the 'Clone' functionality – see Cloning a mixture dataset.



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



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

When you have made all the necessary changes to the notification, click on Validate.

Note: that some validation checks can only be performed following the submission process, particularly in the case of updates.

Click on Create dossier to edit the dossier header page. See Updating the dossier header for submission update.

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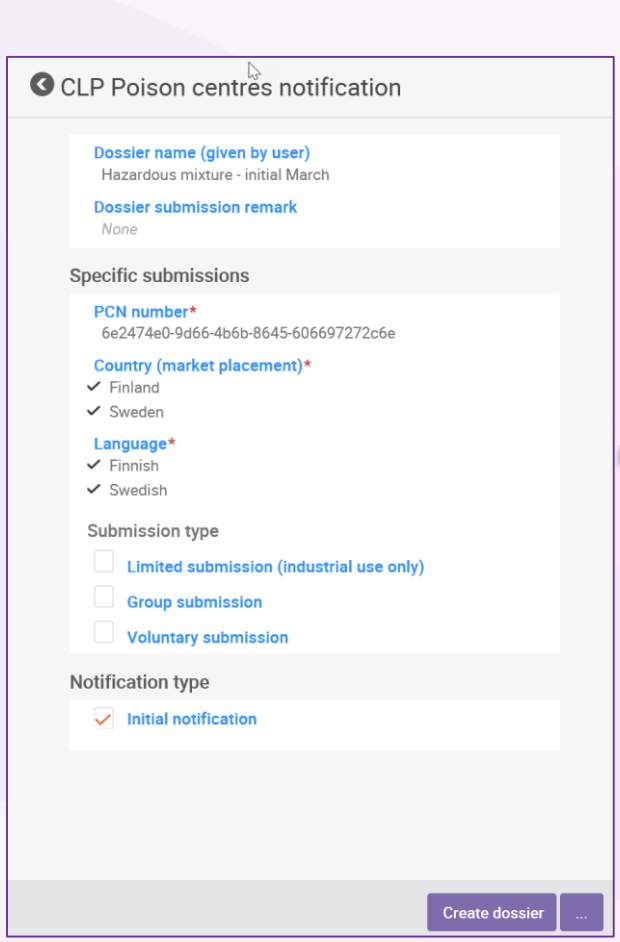
Updating the dossier header for a submission update

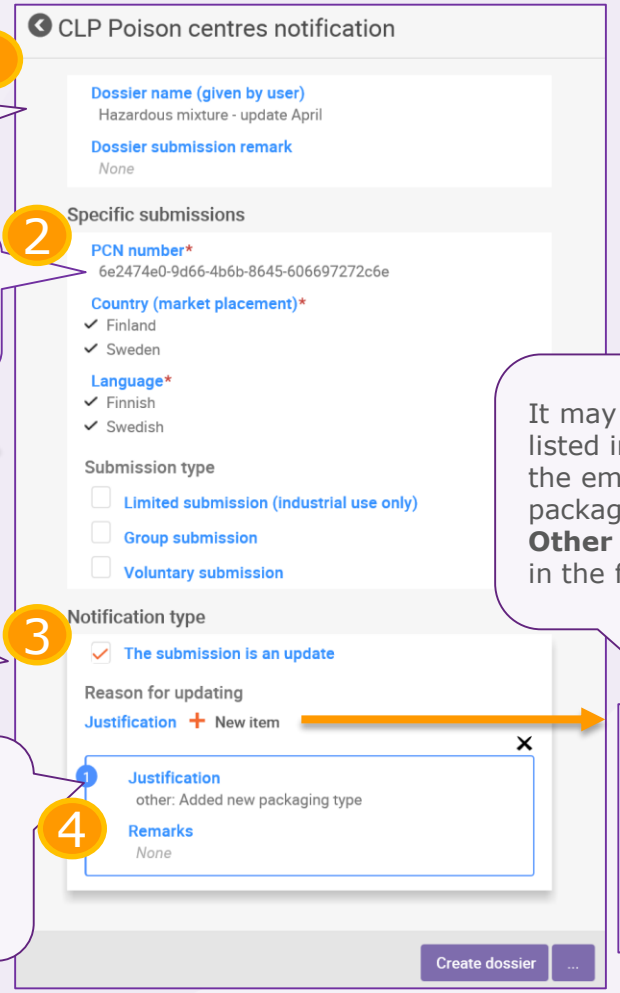


You should give the dossier a new and meaningful name.

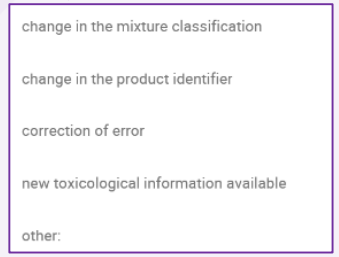
The PCN number remains the same in the update dossiers.

You must untick the tick box 'Initial submission' and select 'The submission is an update'.

In the 'Reason for updating field', click on +New item and make a selection from the available picklist. Multiple reasons for updating are allowed.



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.



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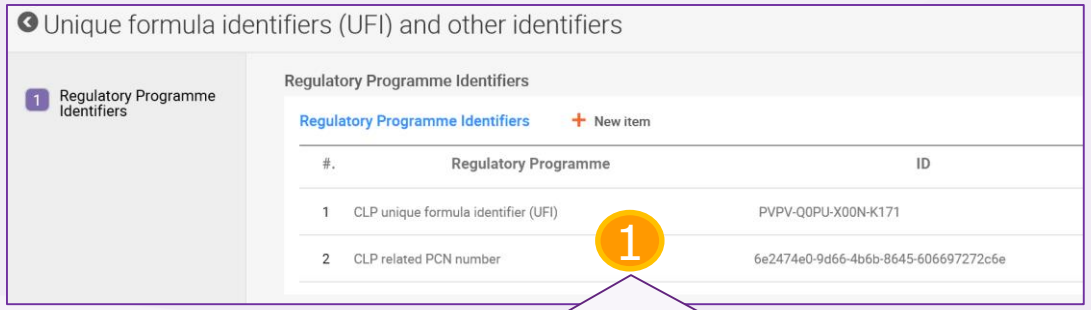
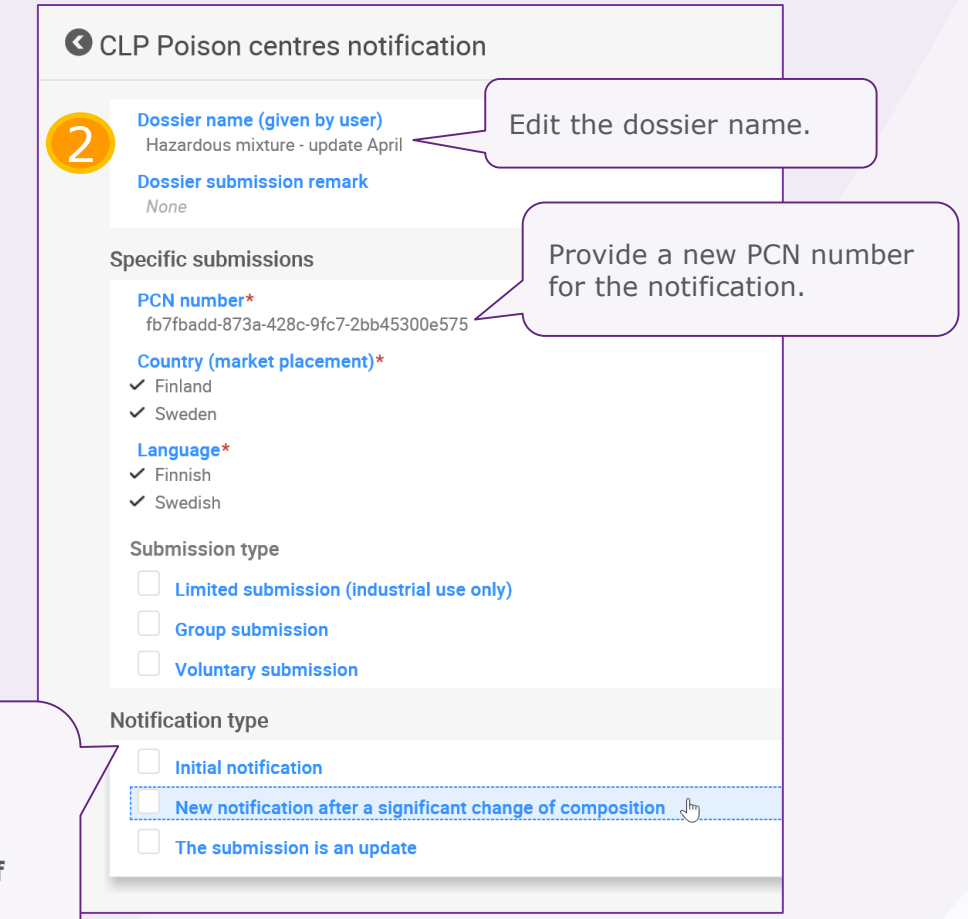
Updating the dossier header when the mixture significantly changes in composition

When the mixture composition changes beyond the allowable limits defined in Annex VIII to CLP, by default, this will lead to two chemically different 'products' on the market. In this case, you must make a notification for the new composition (containing a new PCN number), meaning 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 you must assign a new UFI, declared in the notification and included on the product. These identifiers are included in the UFI and other identifiers section in the Mixture task



Check that a new UFI is included in the notification – see UFI and other identifiers task. You must also indicate the PCN number from the previous related submission – this becomes the related PCN number.



You must select the notification type '**New notification after a significant change of composition**'.

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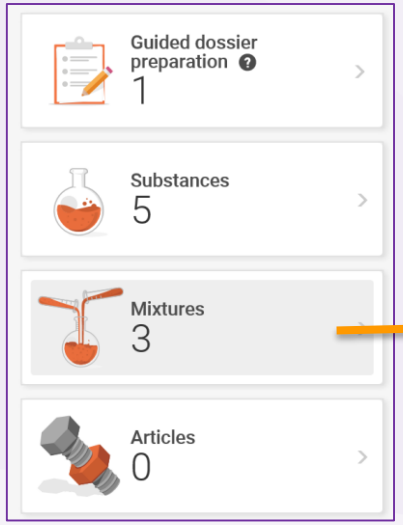
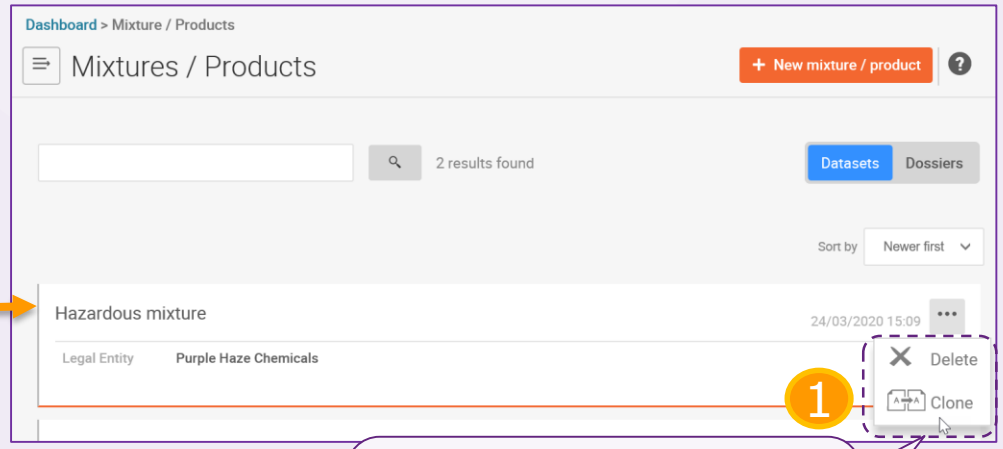
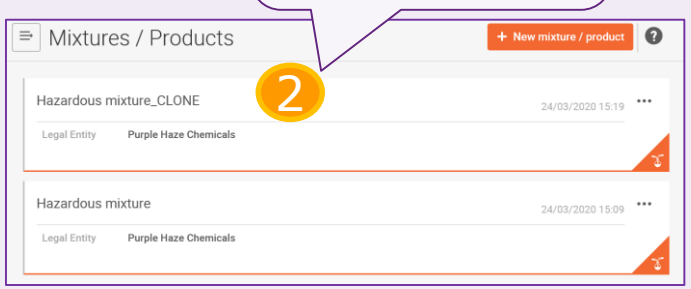
Cloning a mixture dataset

The ‘clone’ functionality is available to facilitate the preparation of update dossiers by cloning a mixture dataset and build a new dossier on that. In this way, you do not need to re-enter all the information related to the mixture, such as composition, toxicological information or product information.

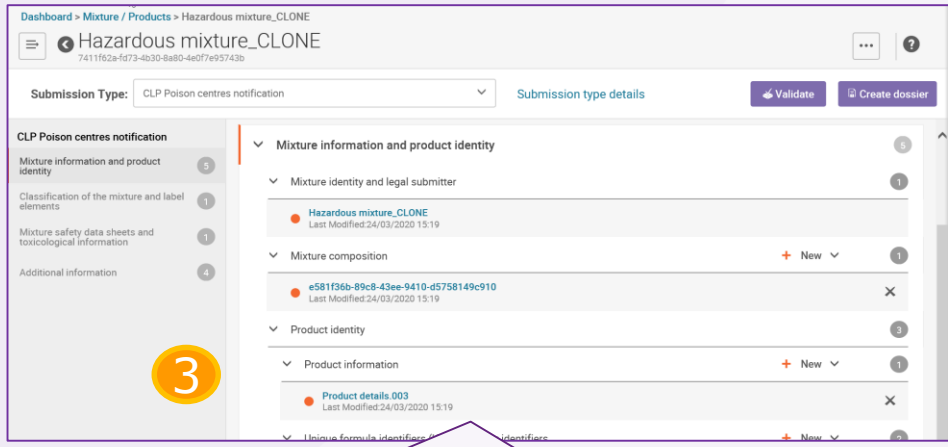




From the Mixture dataset view, locate the dataset you wish to clone. Click on ‘…’ and select ‘Clone’.



The cloned mixture dataset will be saved in the dataset list.



The information can be edited in the dataset view.