Poison centre notifications

A GUIDE TO DOSSIER PREPARATION AND SUBMISSION

Version 1.3 October 2019

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 detail and link the legal entity information in order to use the tools for the preparation and submission of notifications.

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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.

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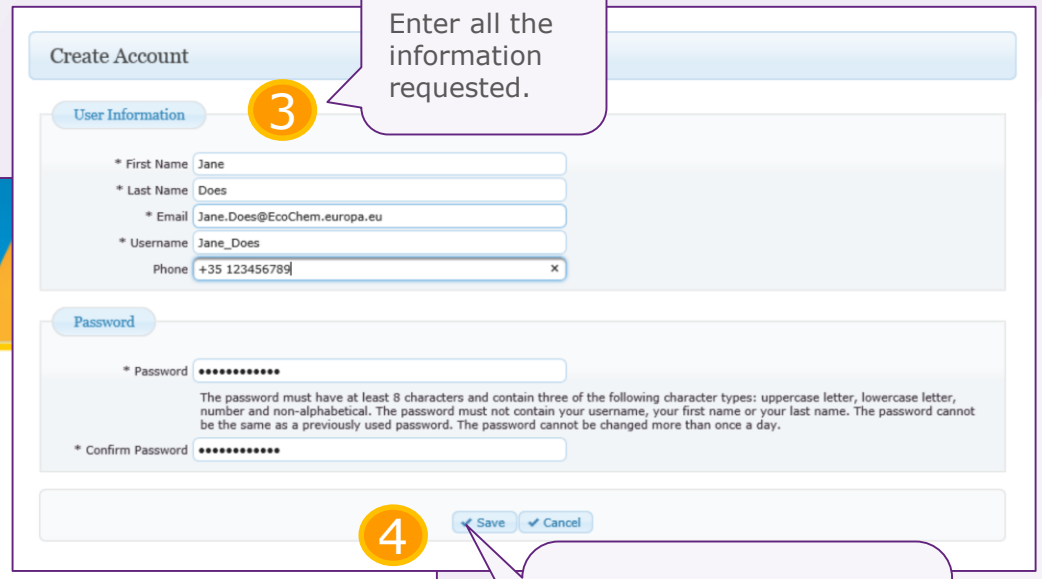

Enter all the information requested.

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

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

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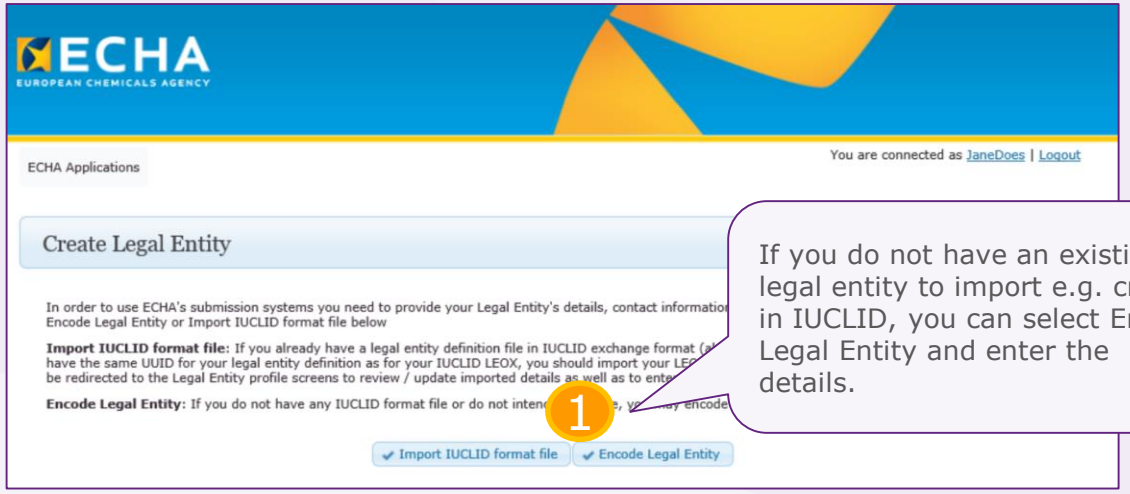
Assign the Legal Entity

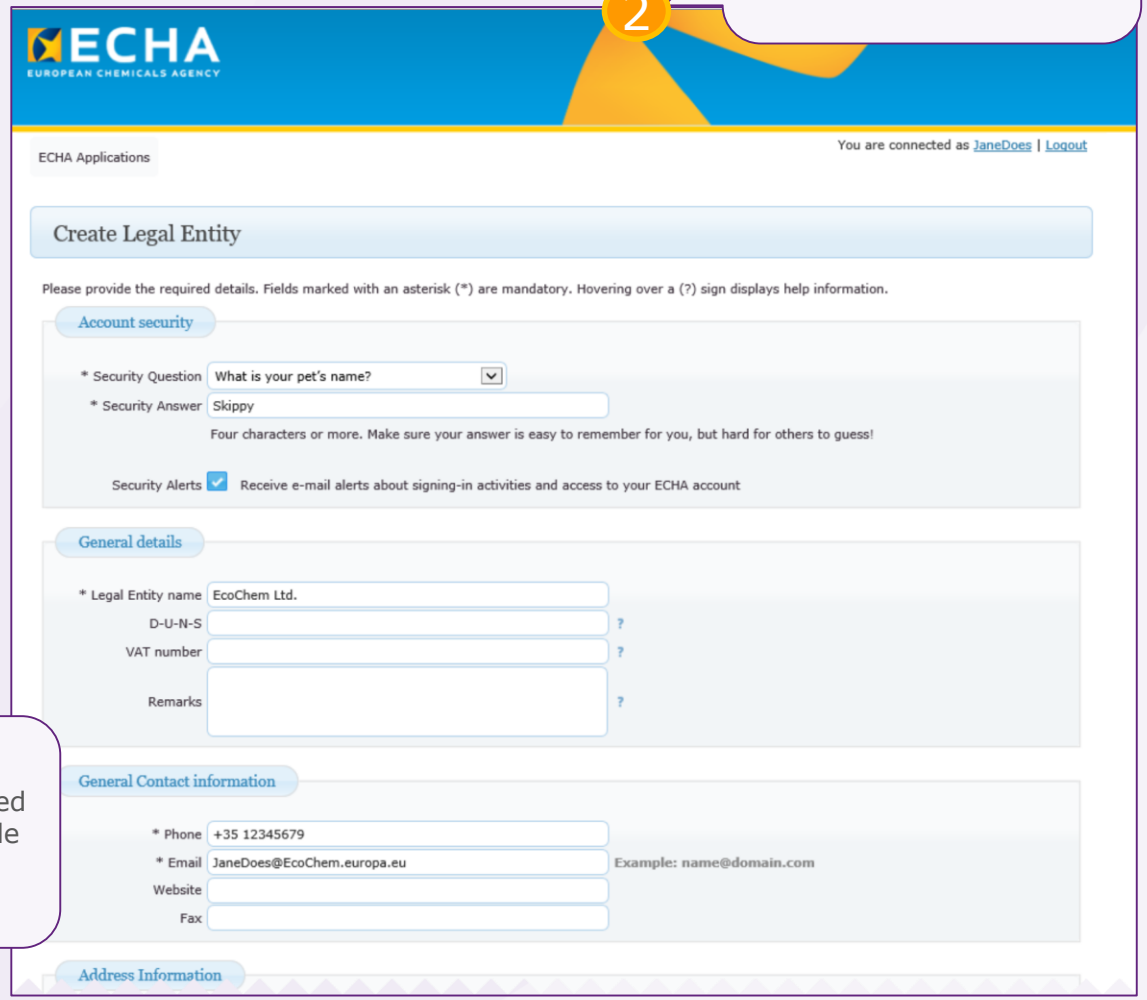
Once an ECHA Account has been created, it needs to have a legal entity (LE) assigned to it before the ECHA IT applications can be accessed.

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.



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.



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

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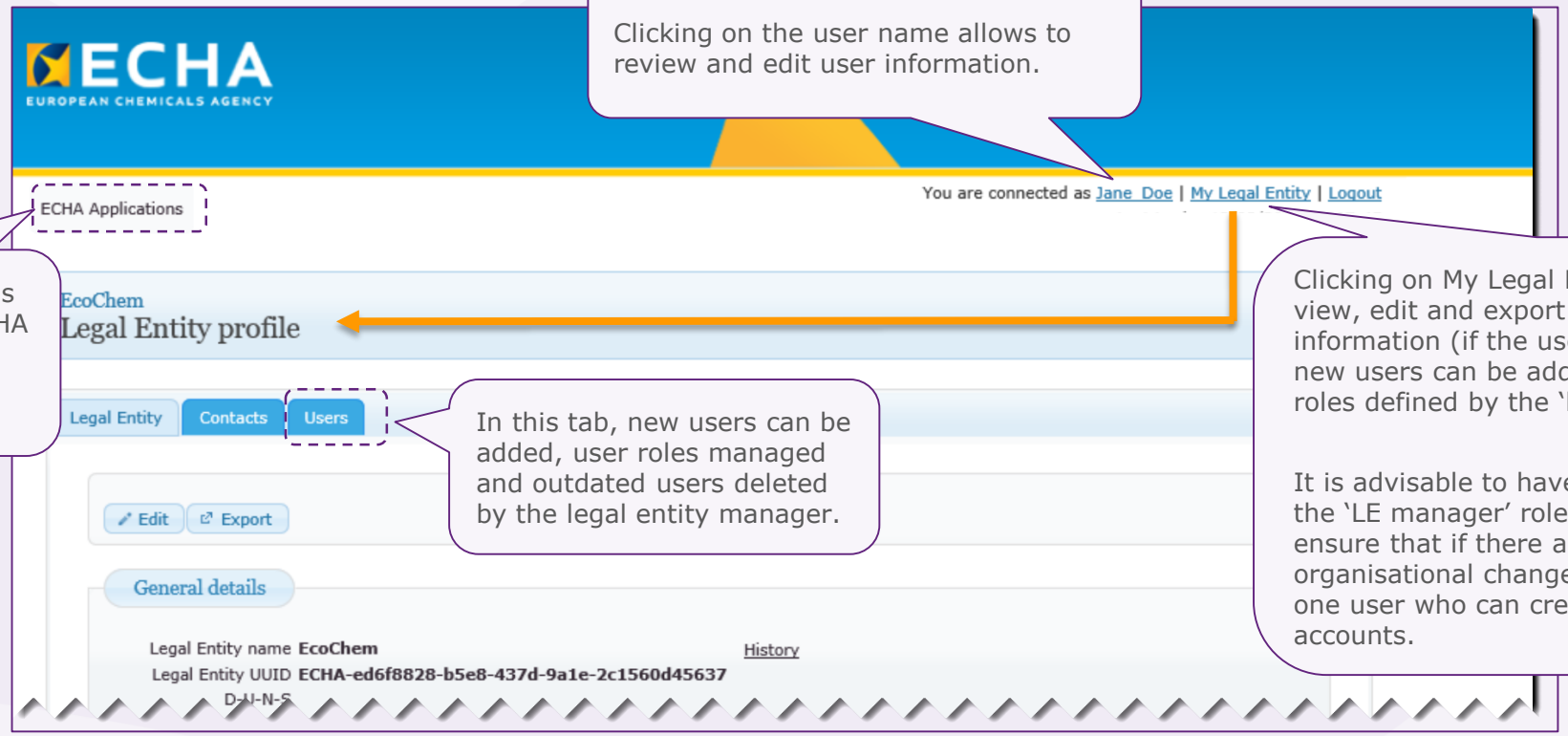
ECHA Accounts navigation



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

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

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

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'.

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.

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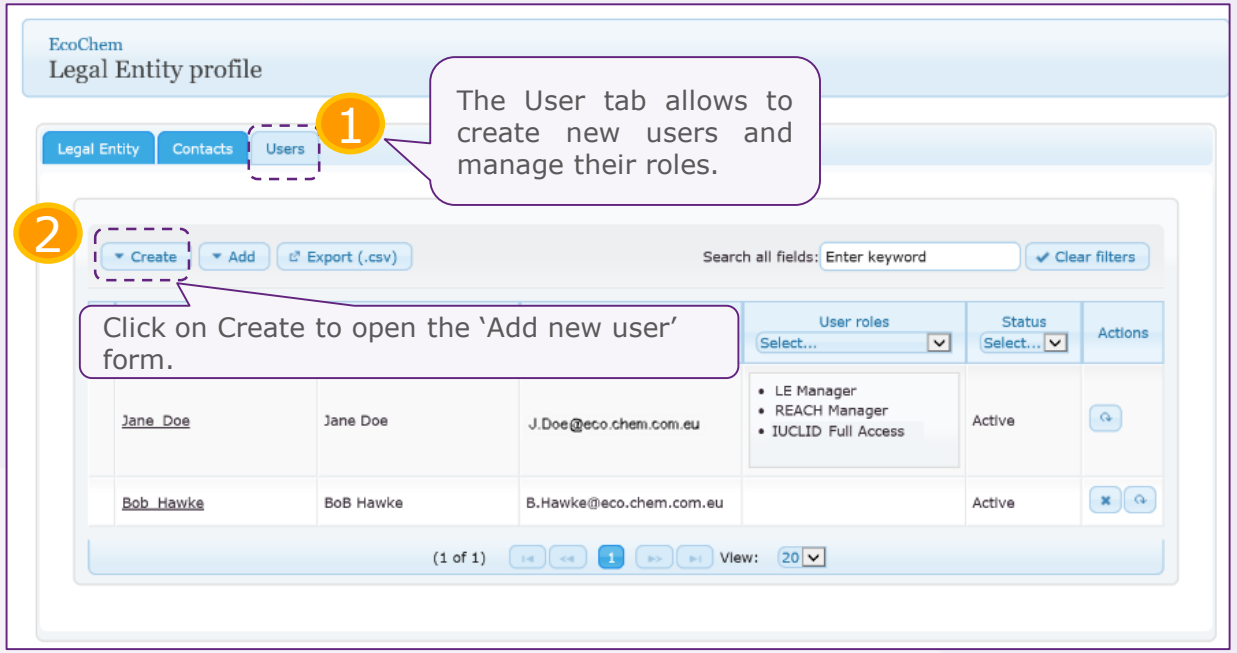
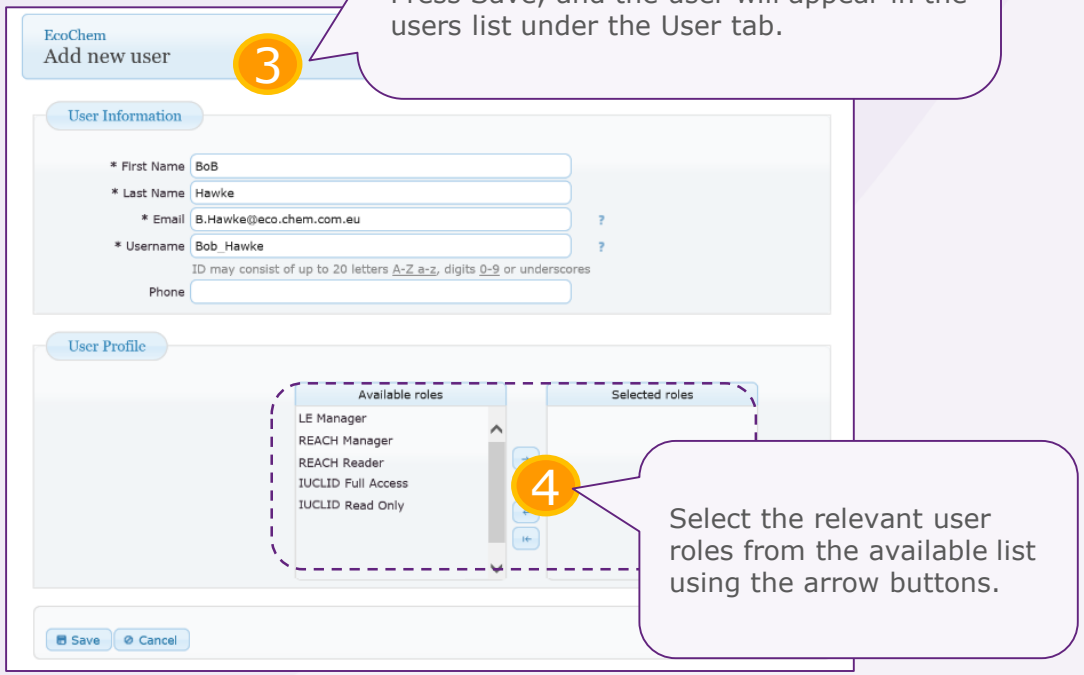
Defining the user roles

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.





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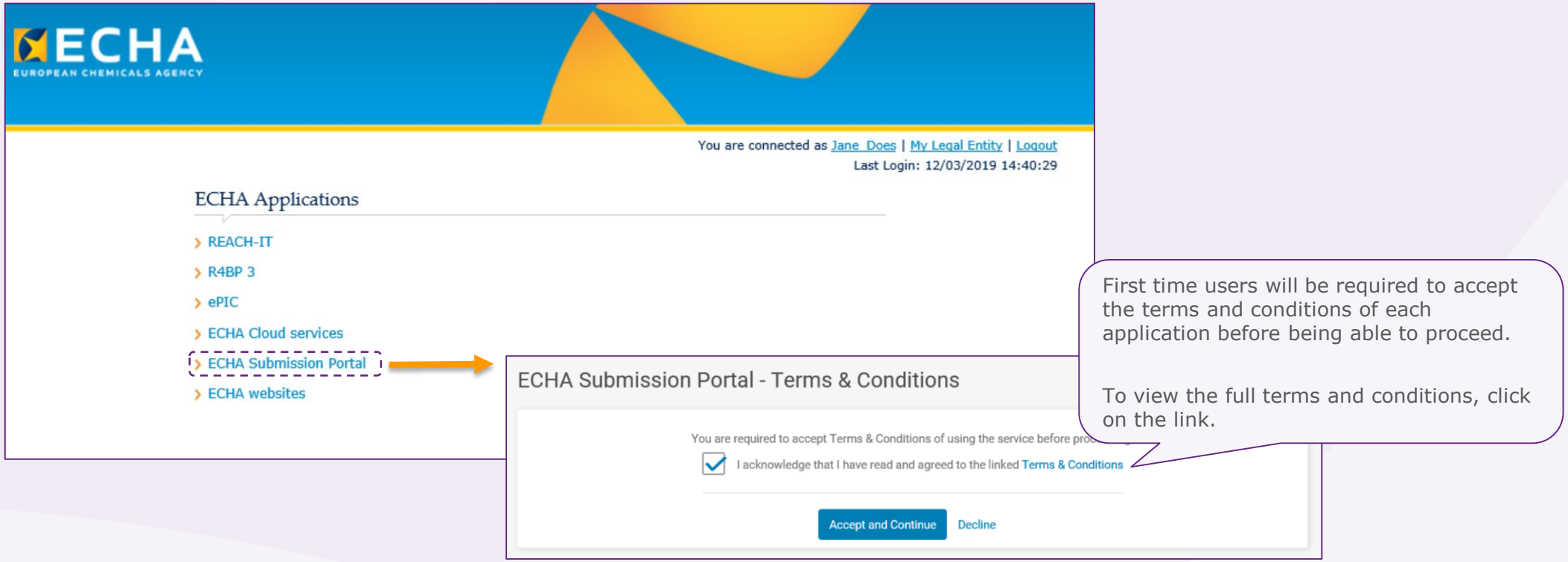
Accessing ECHA applications for the first time



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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 and searching for notifications.

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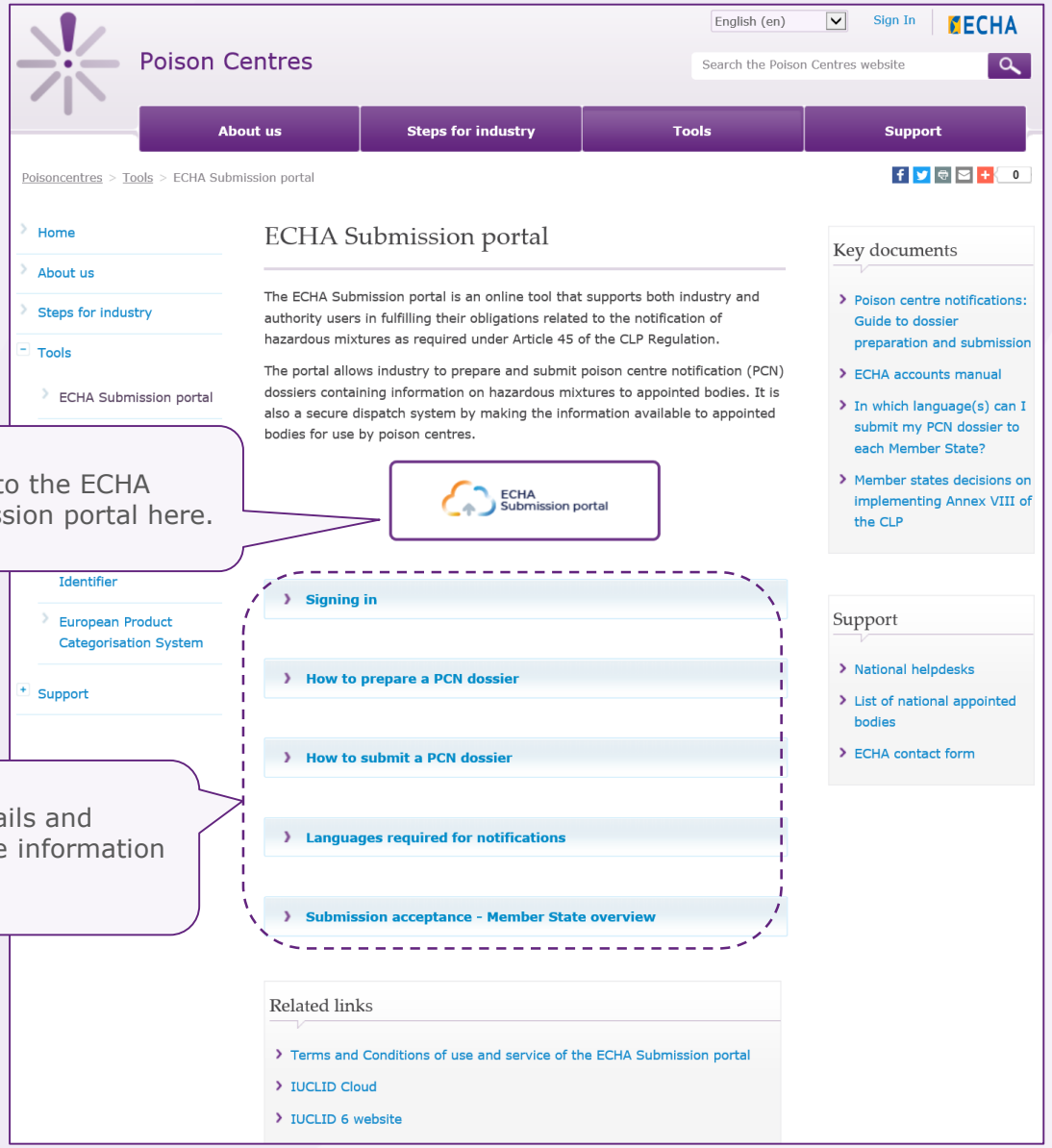
ECHA Submission portal webpage

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.



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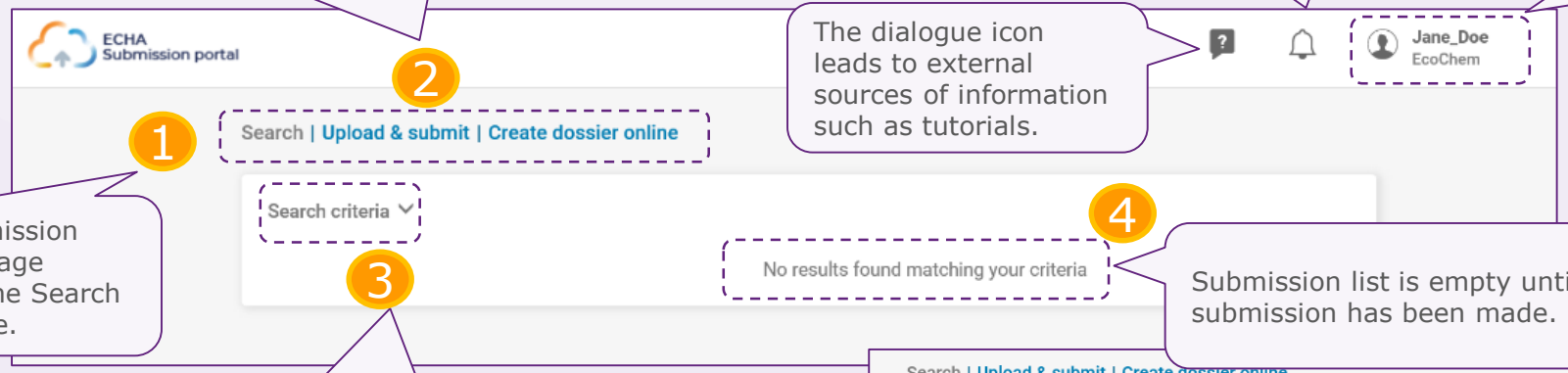
ECHA Submission portal landing page

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.

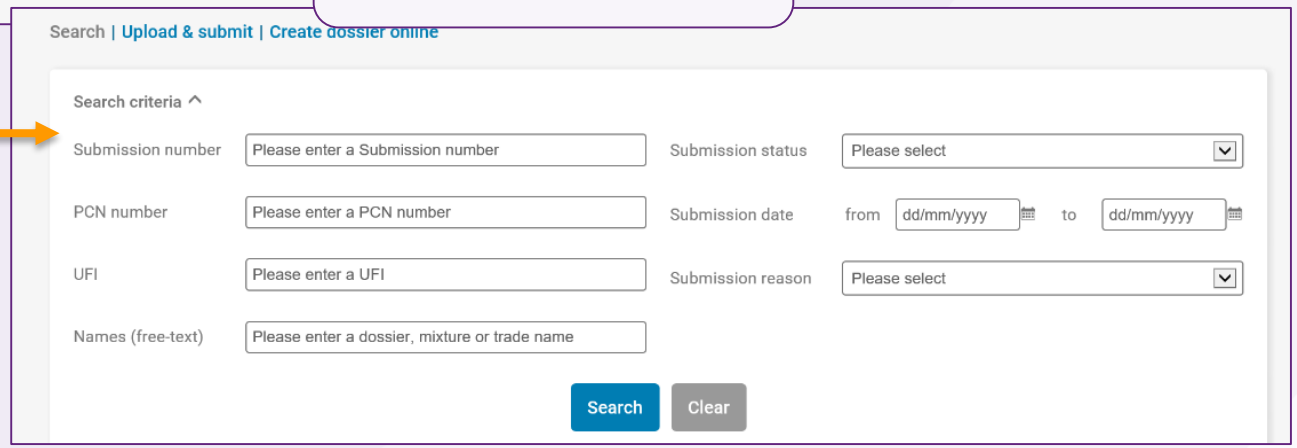
The dialogue icon leads to external sources of information such as tutorials.



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

Submission list is empty until a submission has been made.

Click here to expand or collapse the search criteria window.



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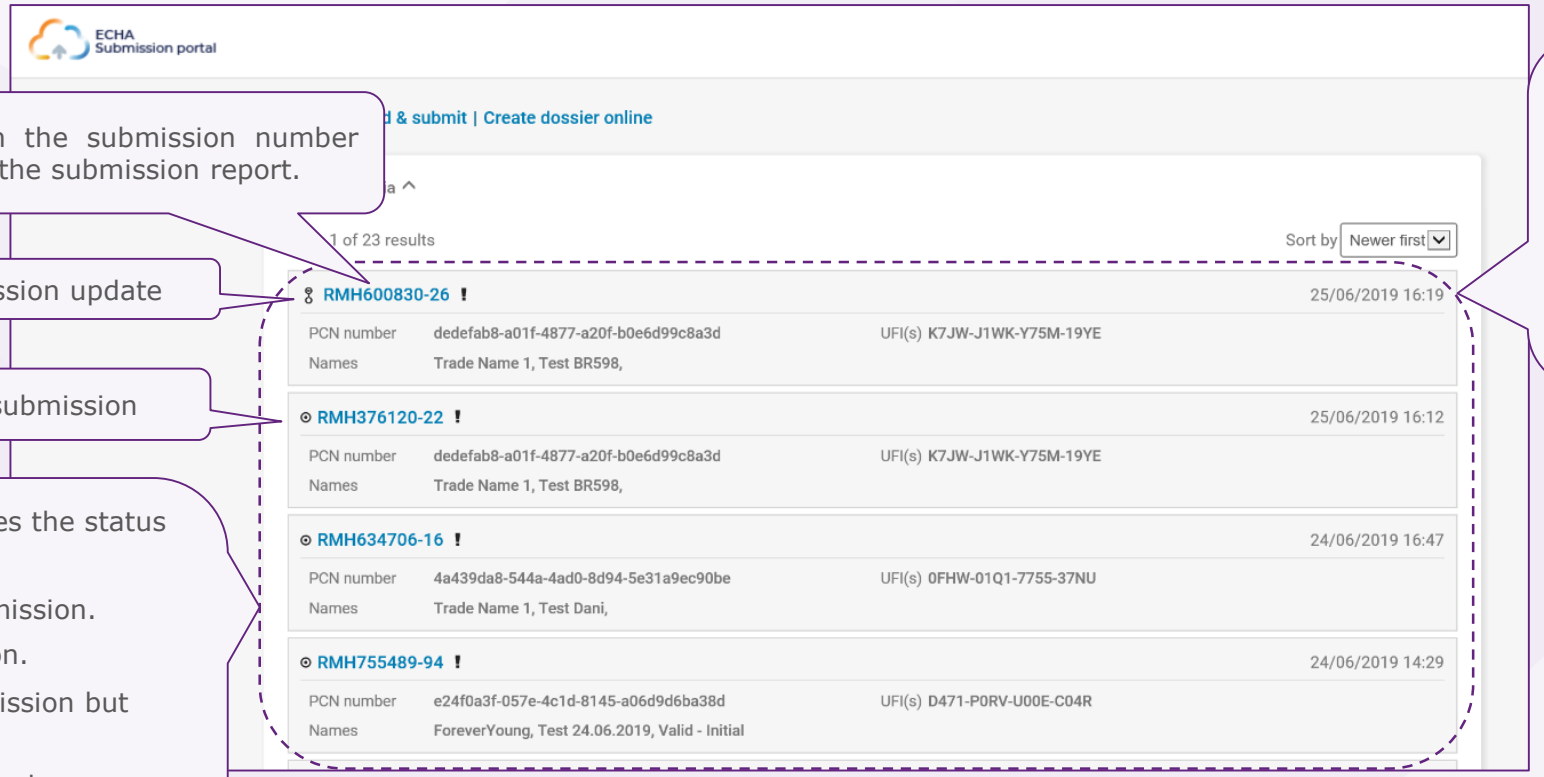
ECHA Submission portal Search page



Click on the submission number to view the submission report.

Symbol for submission update

Symbol for initial submission

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

Each submission listed indicates the status of the submission:

'✓' indicates a successful submission.

'X' 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.

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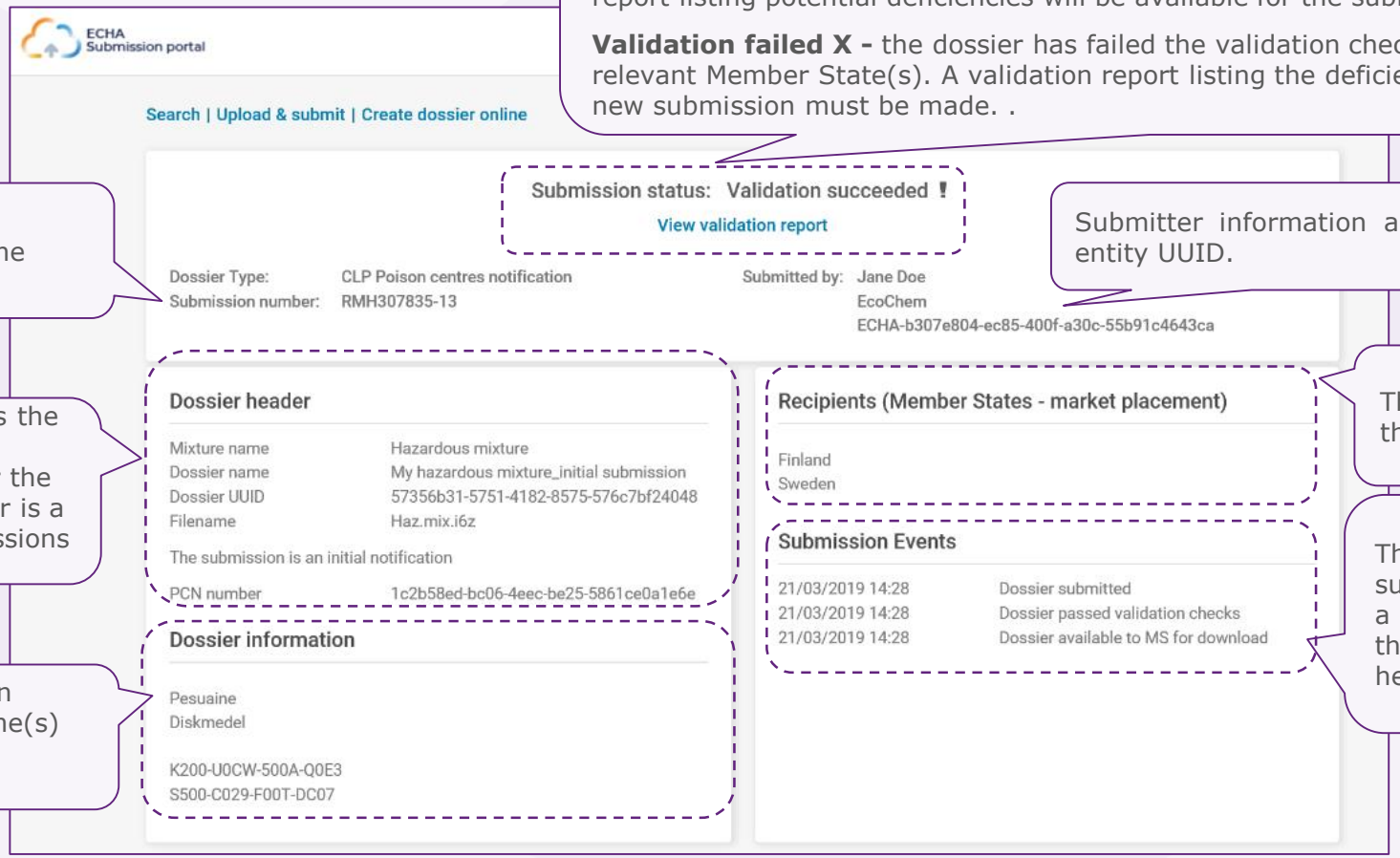
The submission report

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

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

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



The submission number is automatically assigned by the system.

Submitter information and legal entity UUID.

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

The receiving Member States for the notification are listed here.

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

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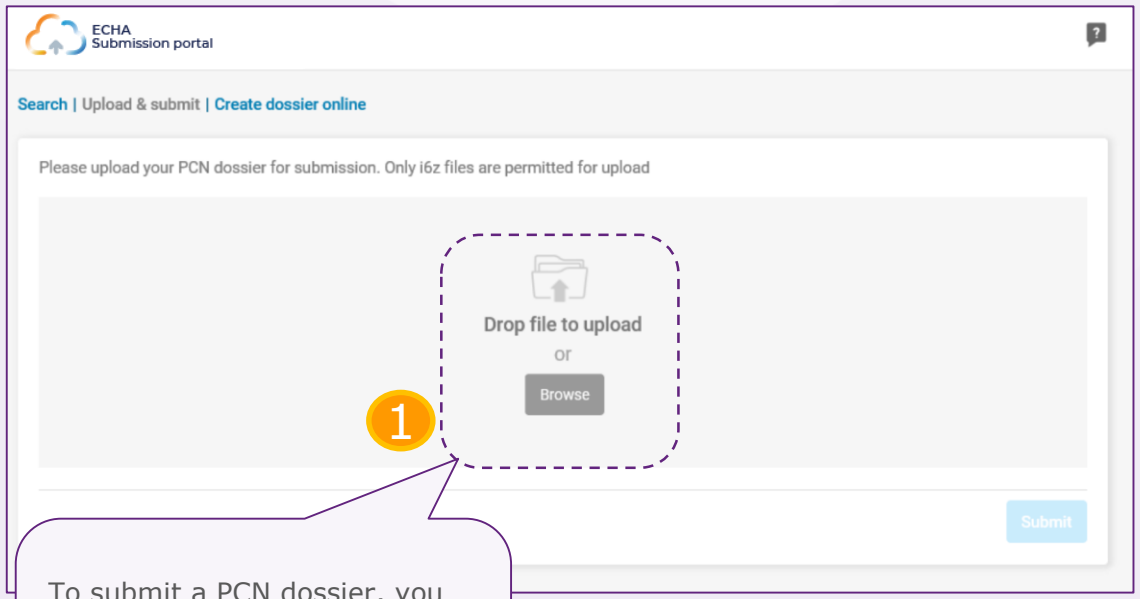
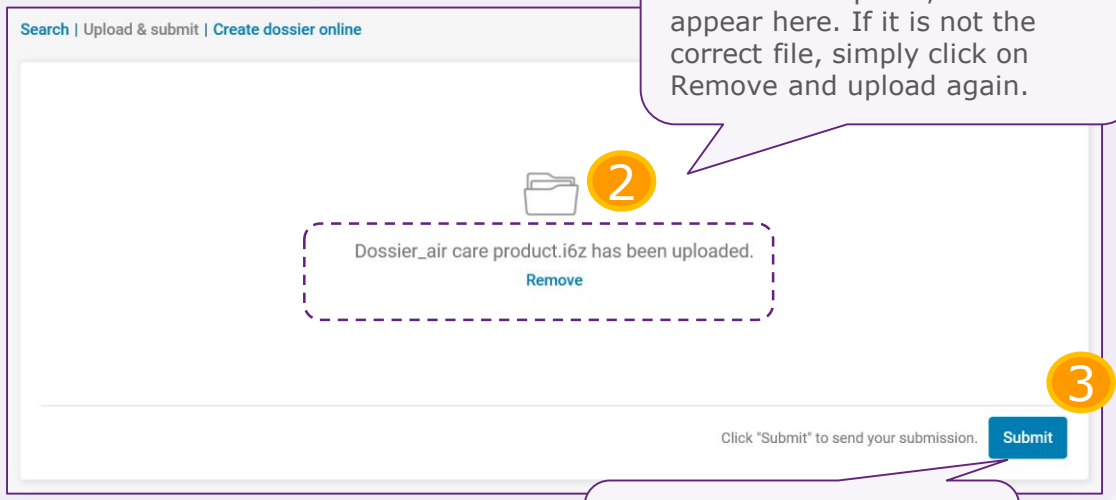
Upload and submit

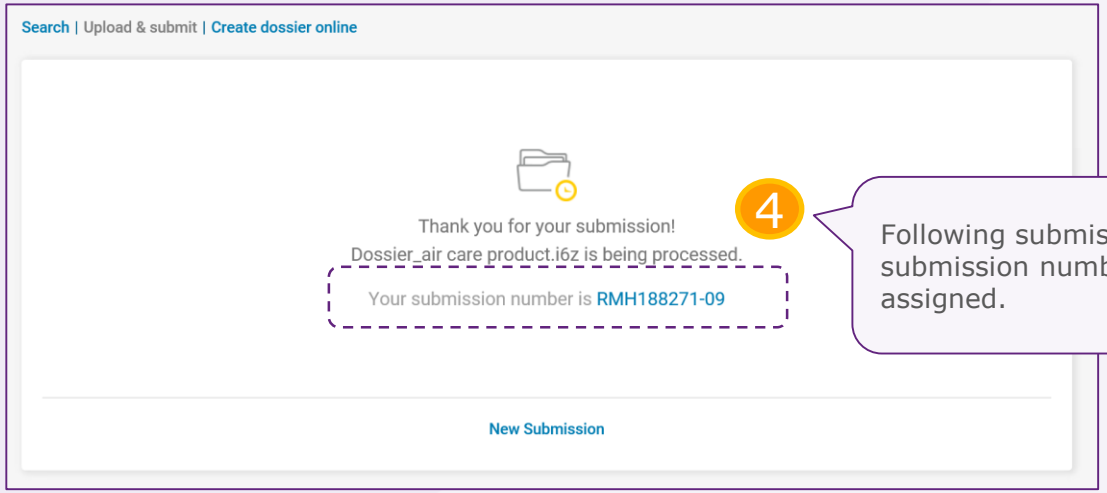


To submit a PCN dossier, you need to first upload it here by using either selecting the relevant file using the Browse or Drag and drop functionality.



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

When everything is ready, Submit the dossier!



Following submission, a submission number is assigned.

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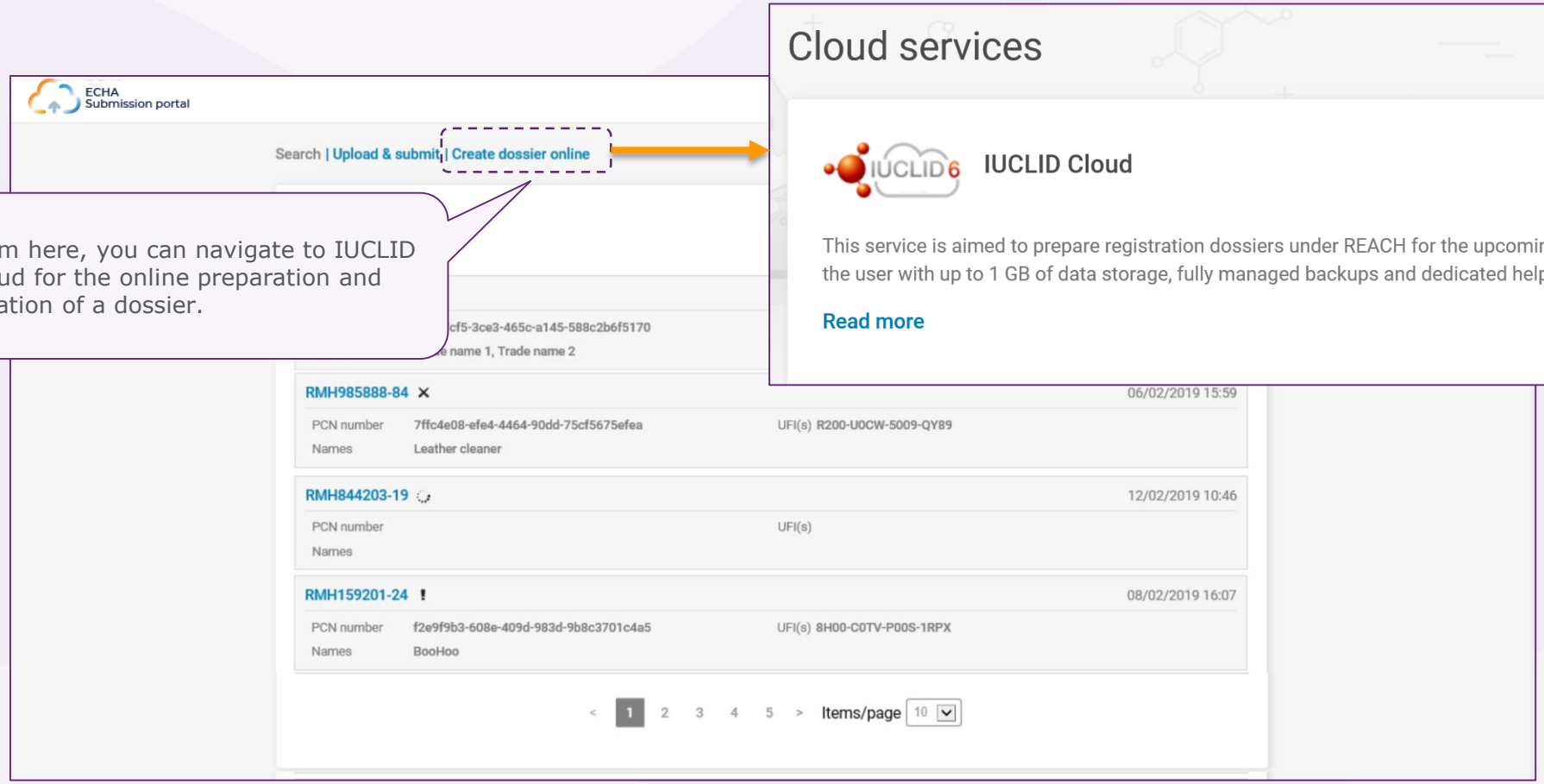
Create dossier online



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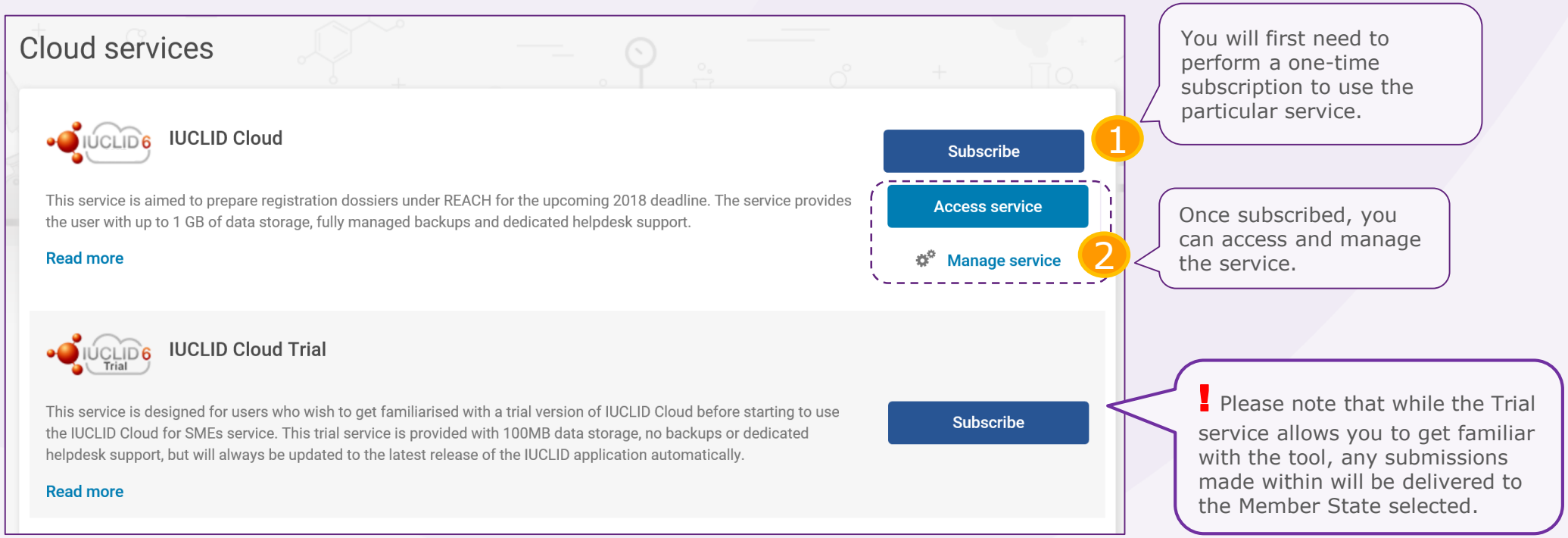
ECHA Cloud Services Dashboard

Once you have successfully logged into the system, the ECHA Cloud Services Dashboard page opens. The **IUCLID Cloud** service allows 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.



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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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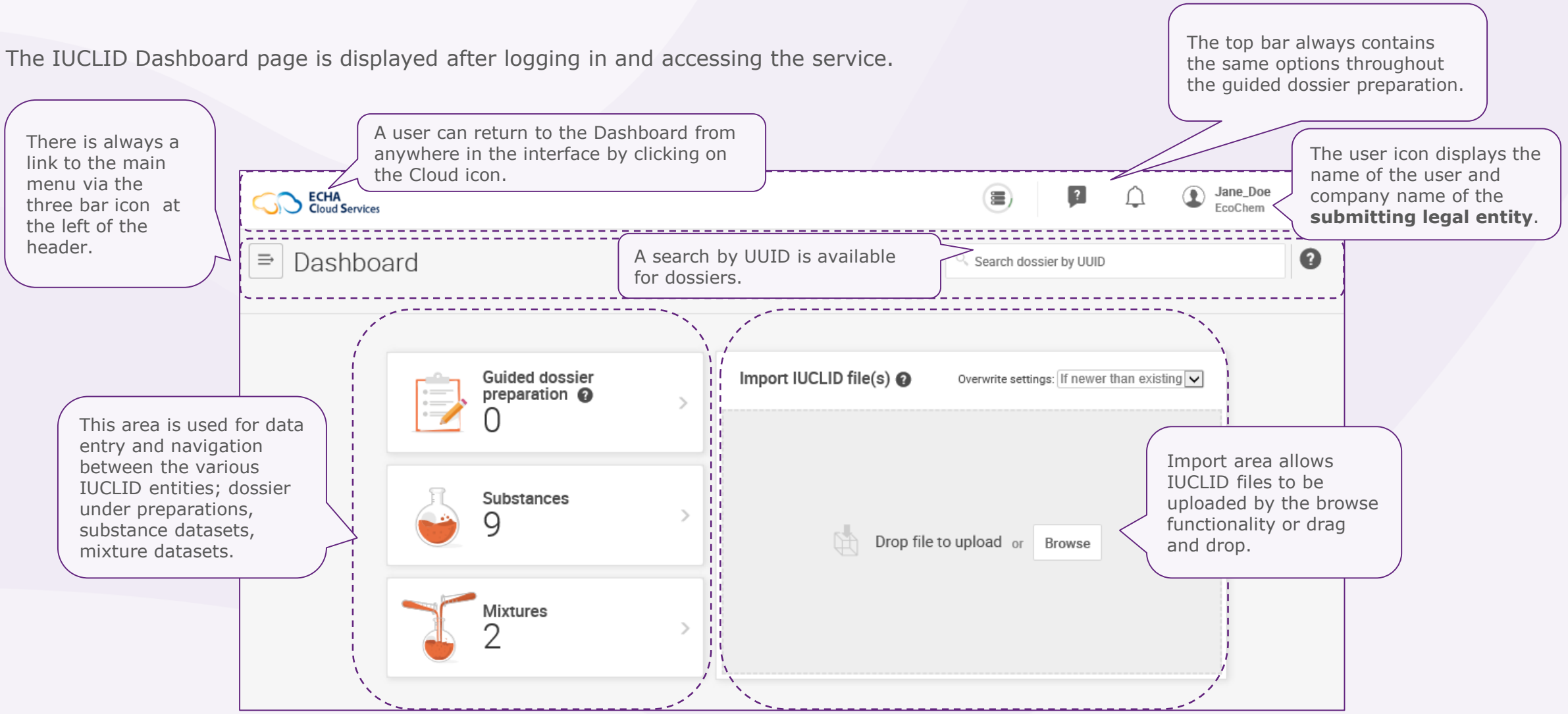
The IUCLID Dashboard for dossier preparation

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



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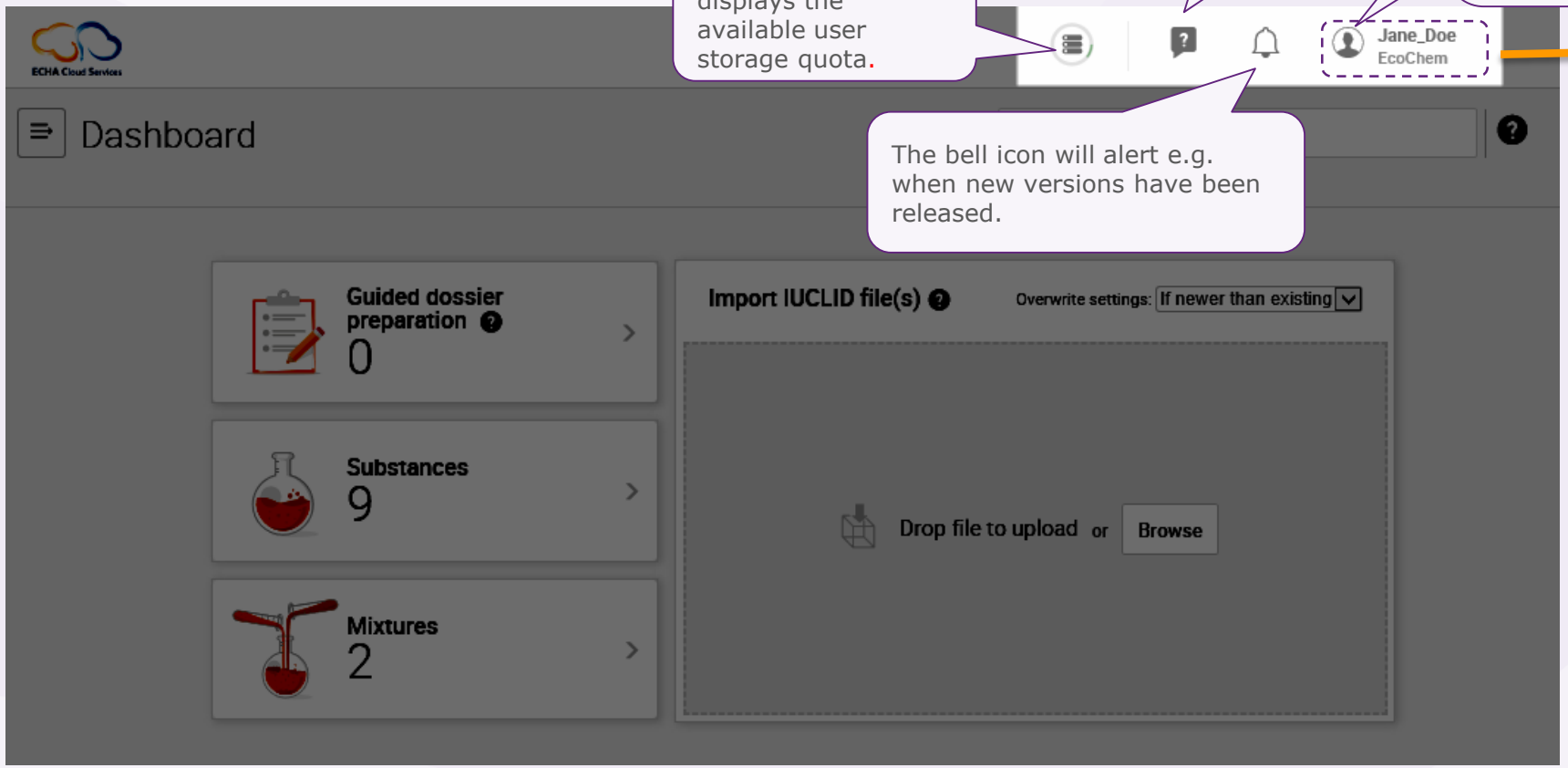
The dashboard top user bar

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 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 quota icon displays the available user storage quota.

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



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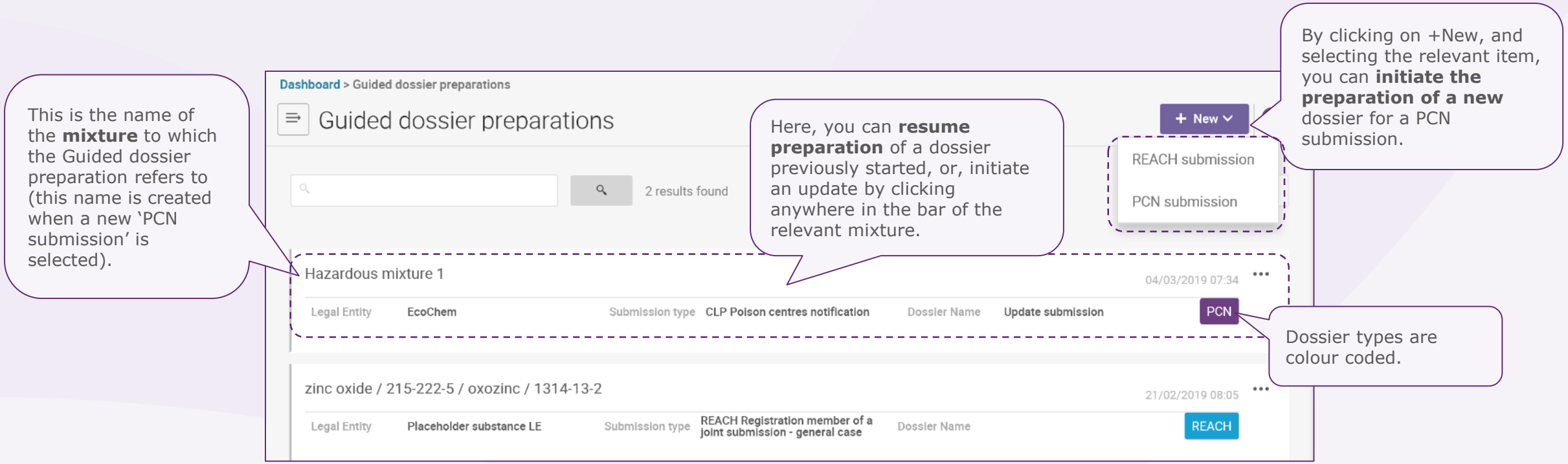
Initiating a guided dossier preparation

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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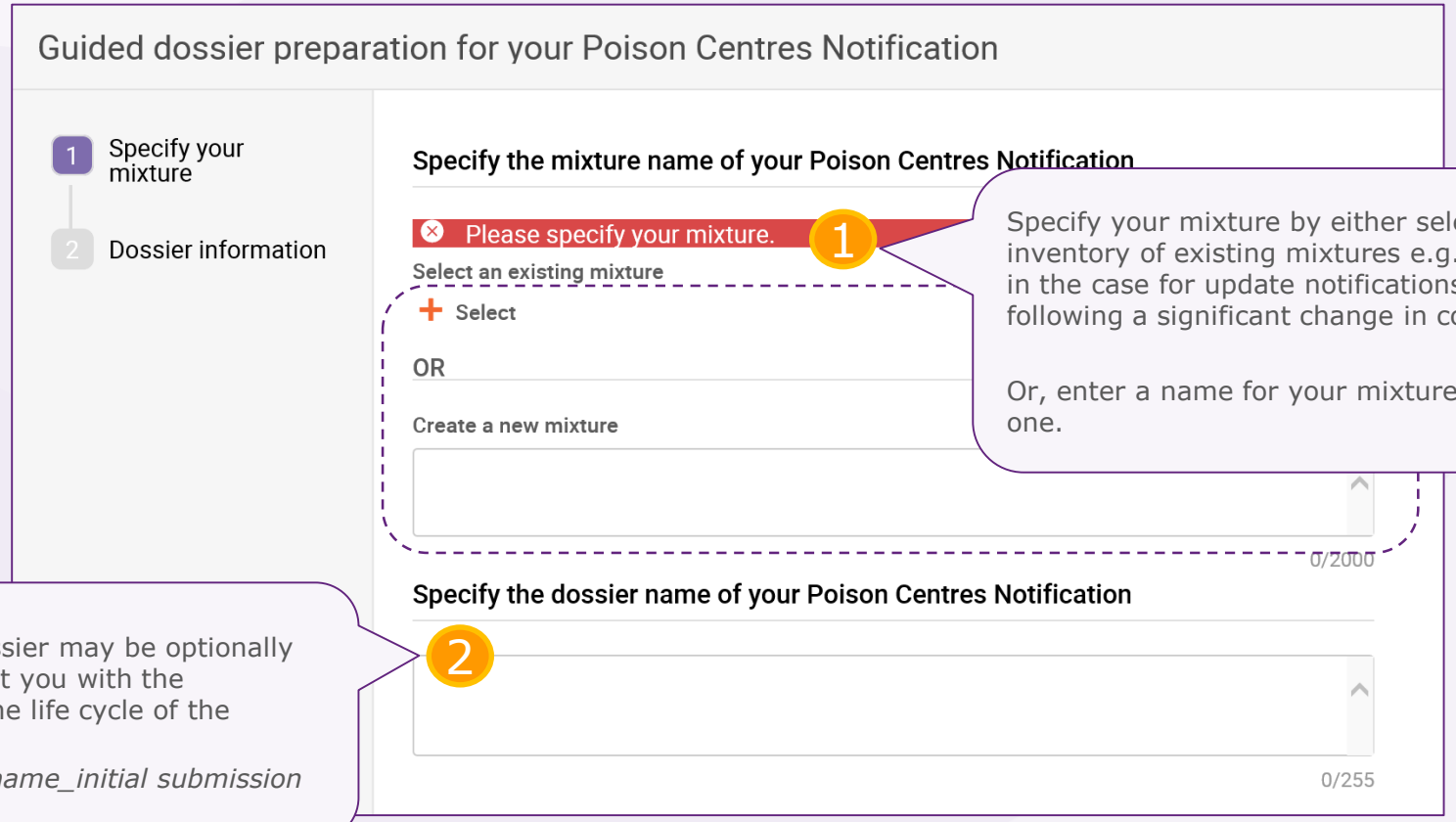
Establishing the submission context for a mixture – step 1

Once 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.



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

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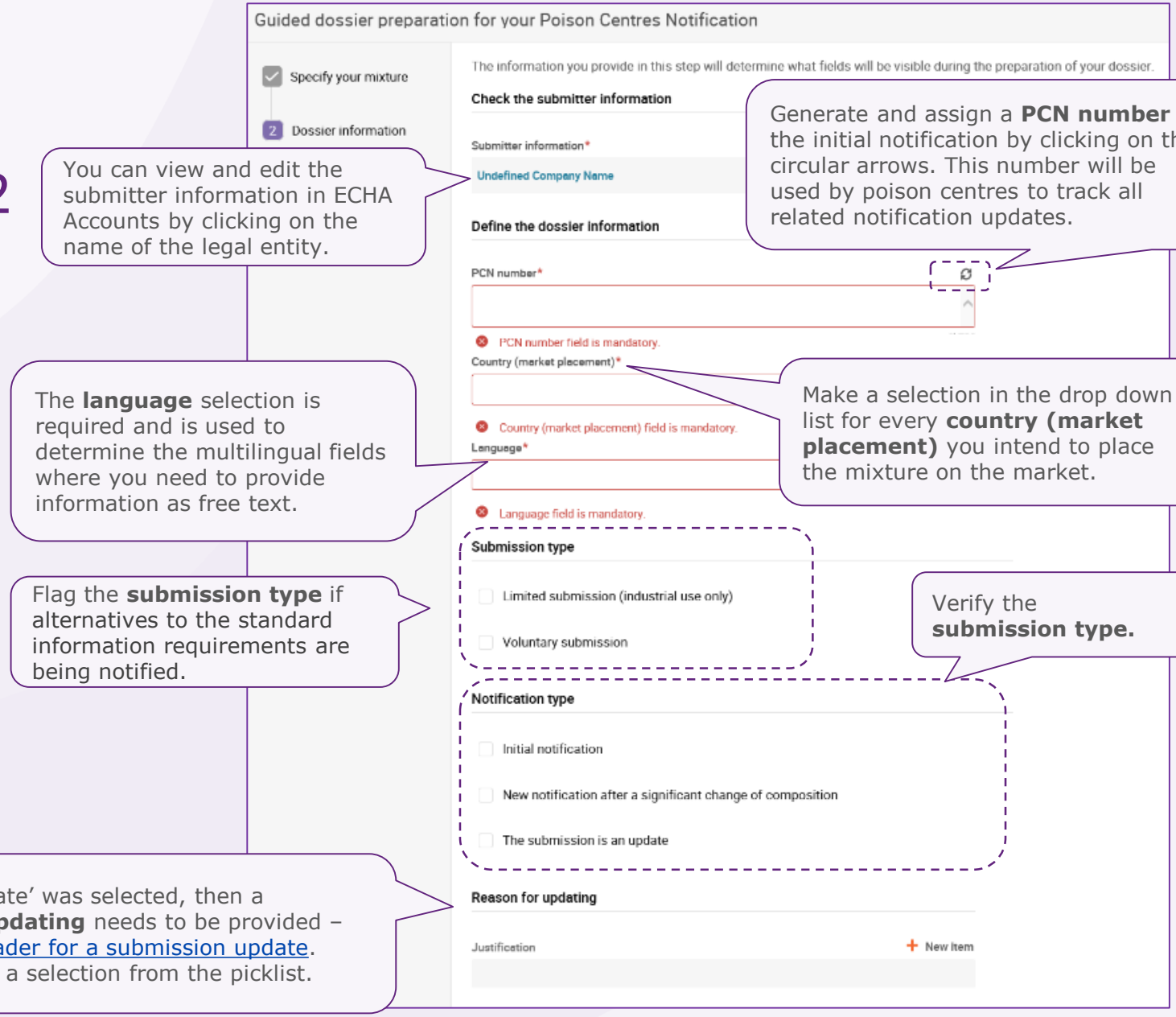
Define the dossier – step 2

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



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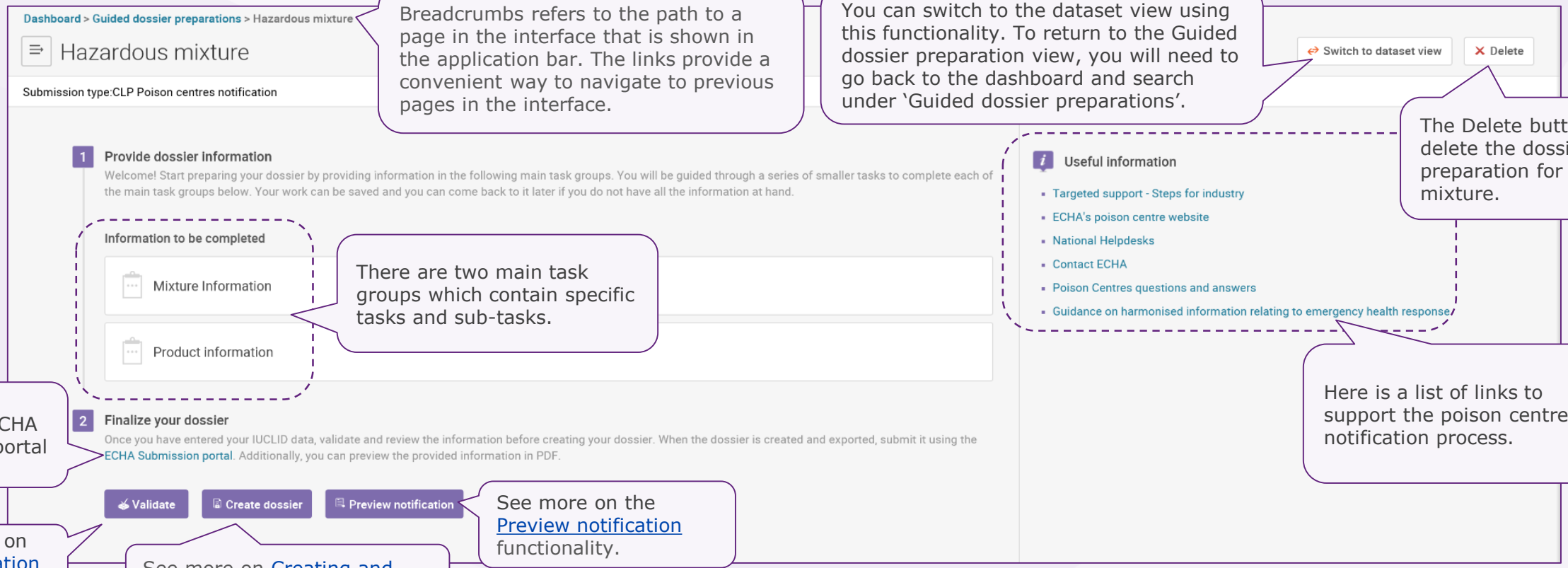
Guided dossier preparation ‘navigation page’

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.

Here is a list of links to support 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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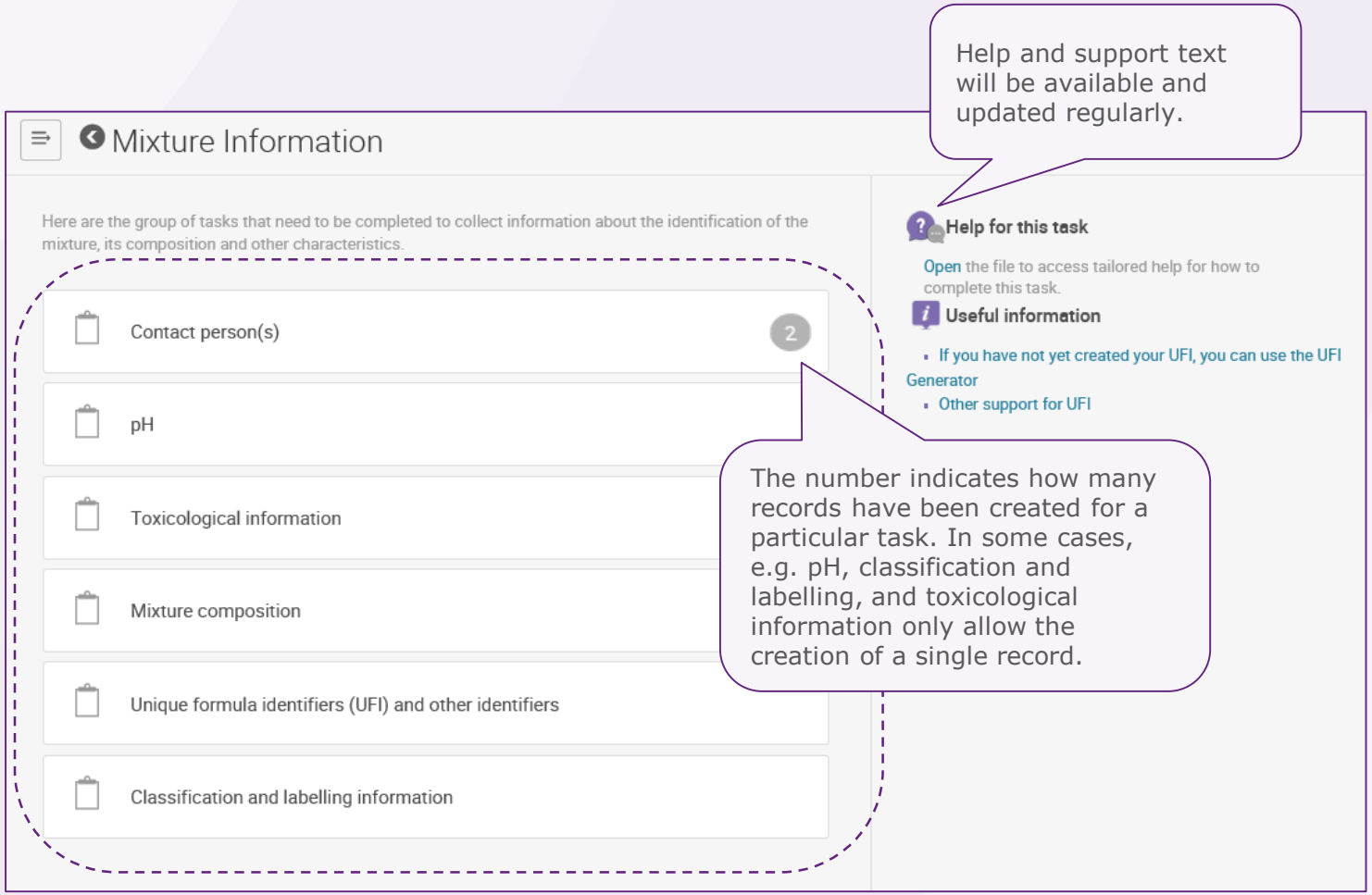
The task page

A specific task page exists for the Mixture information and the Product information. Here in the Mixture information task page 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.



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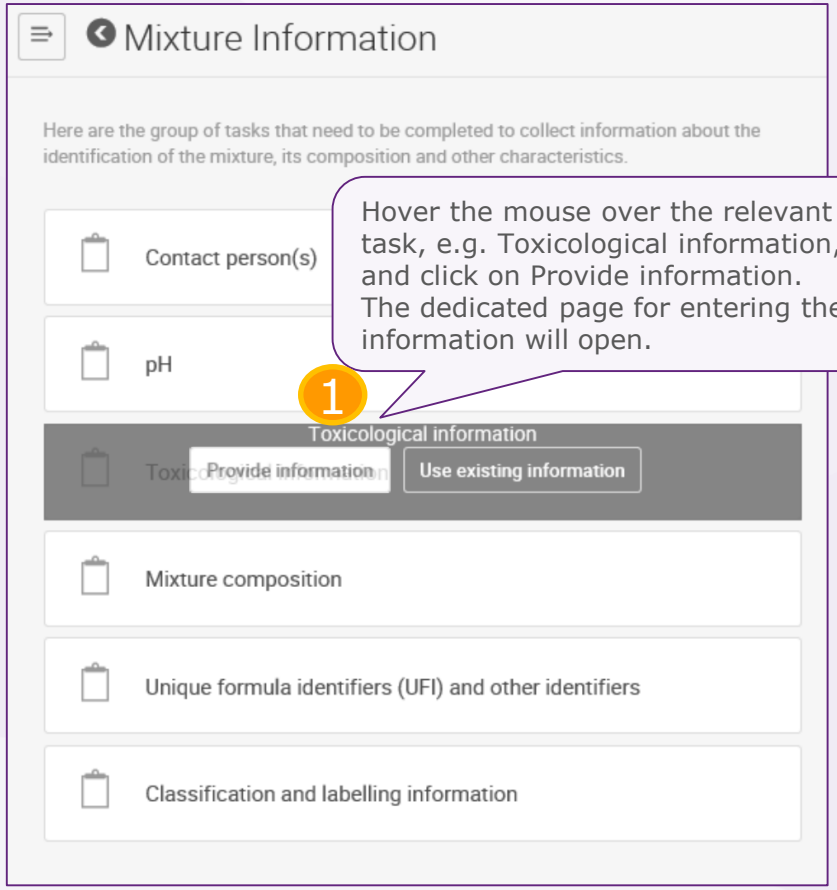
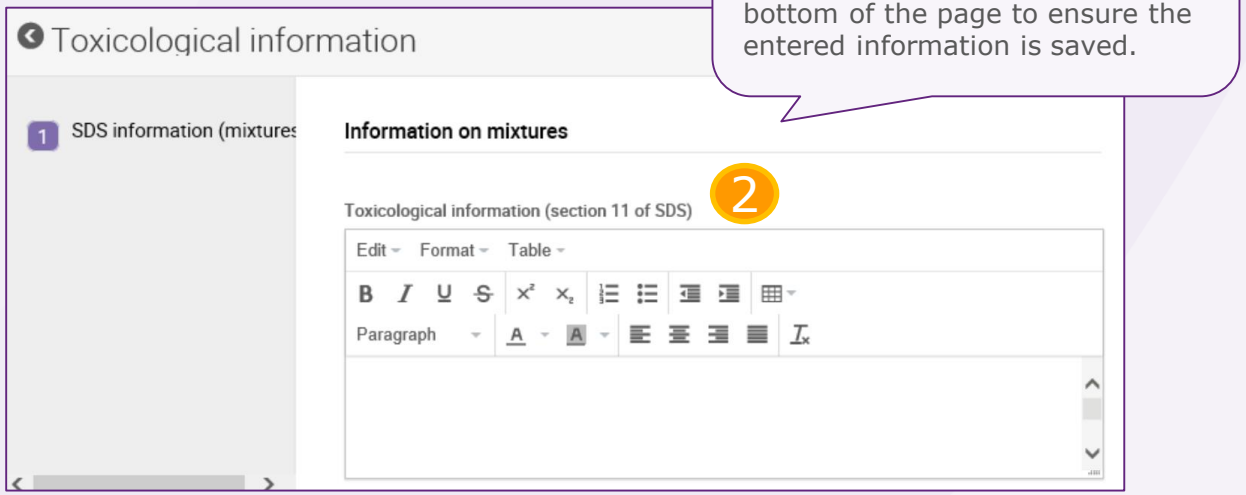
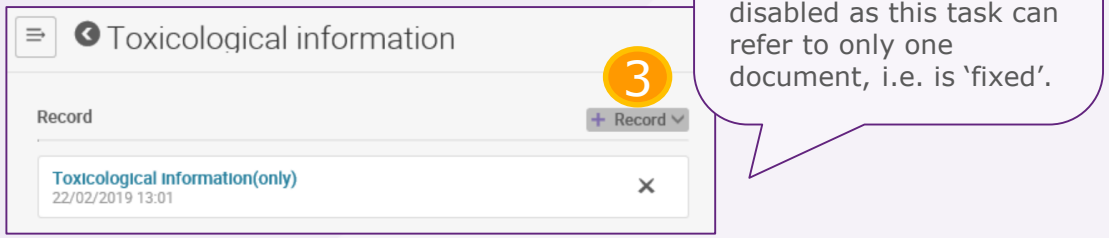
Creating a new record







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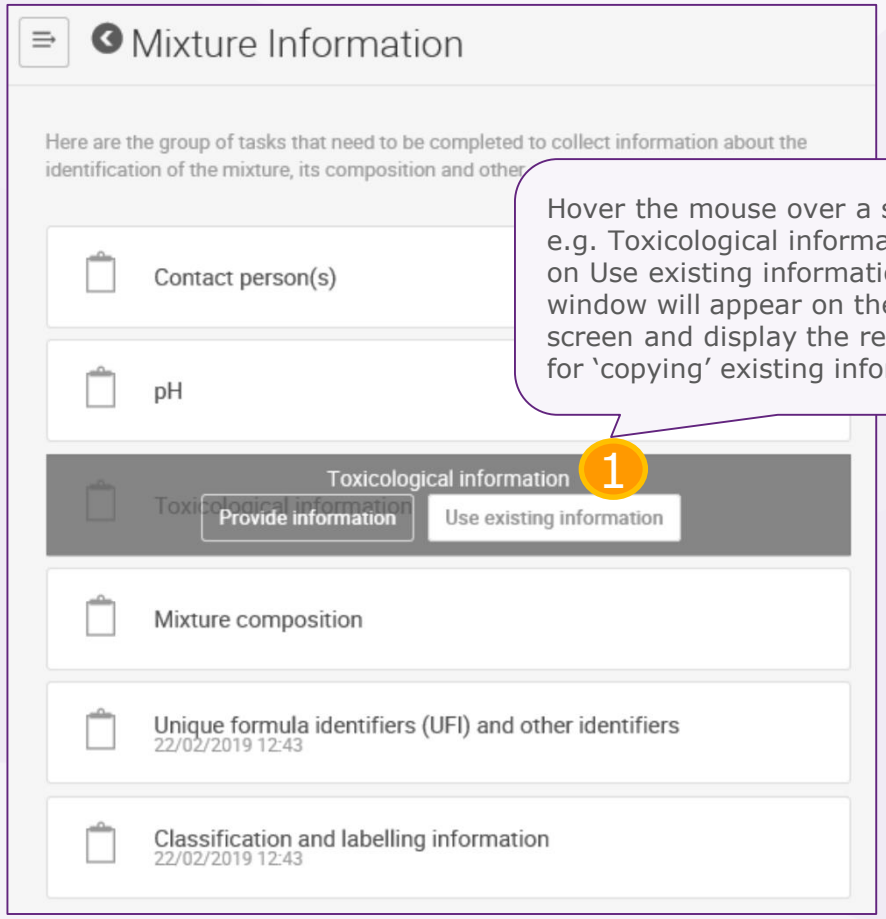
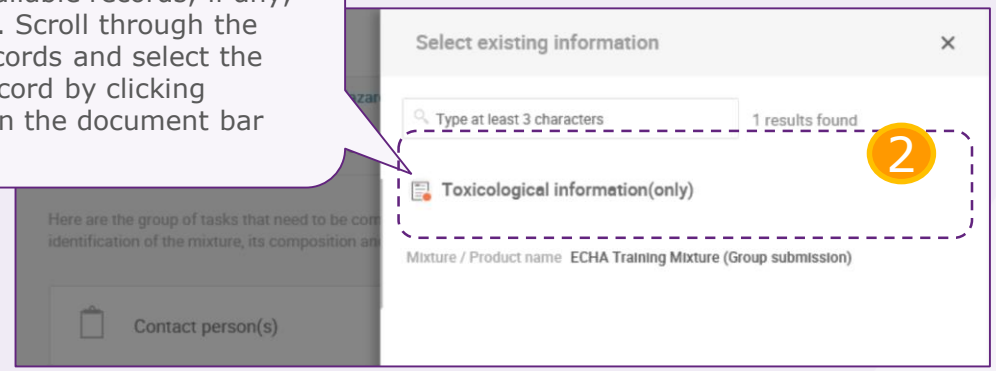
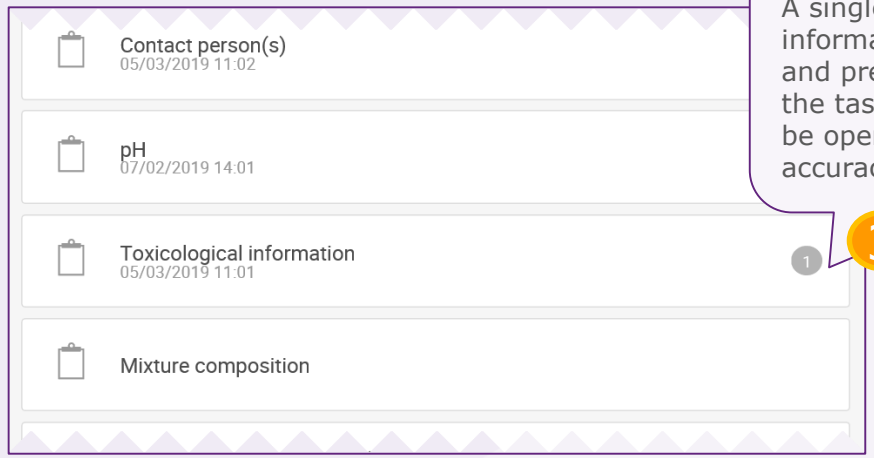
Creating a record from existing information



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.

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.





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.

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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

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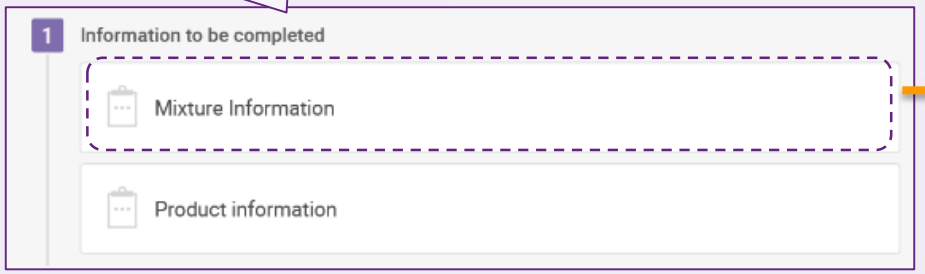
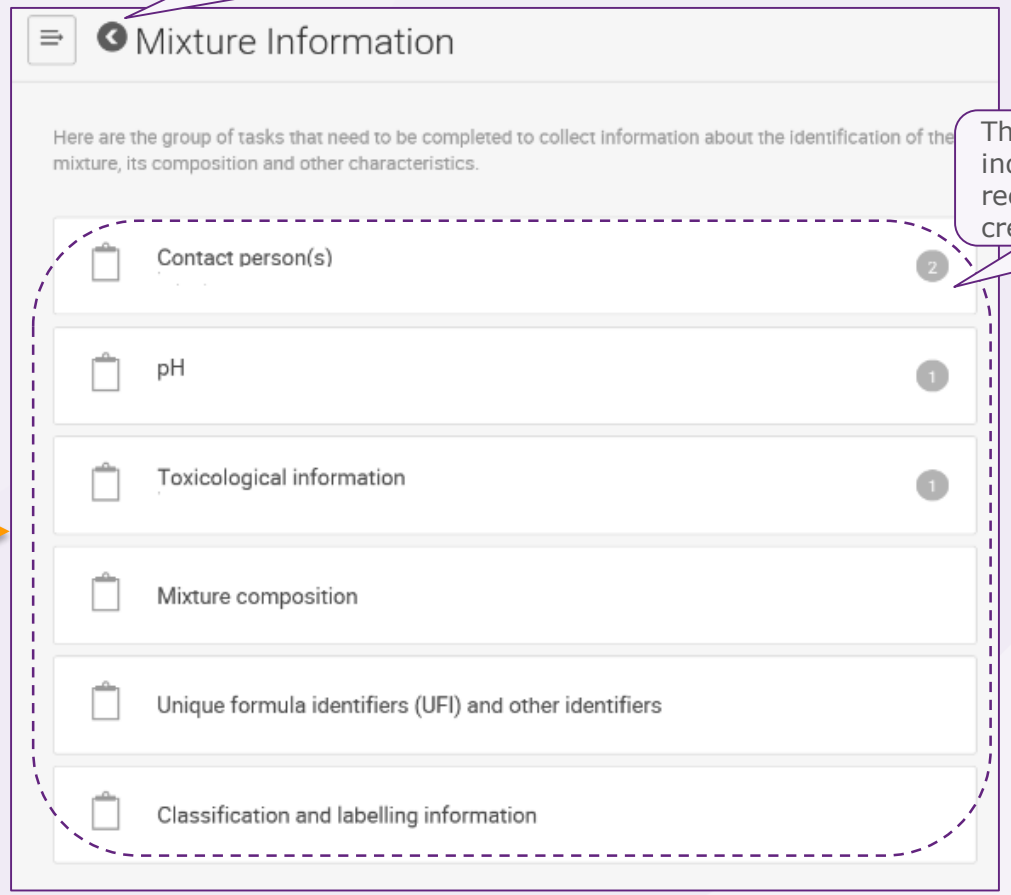
Mixture information task page

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.

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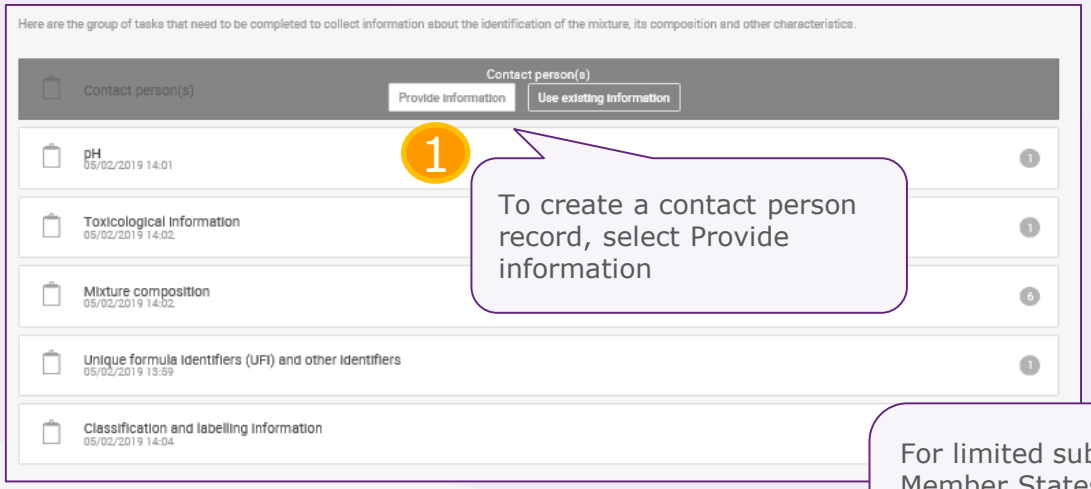
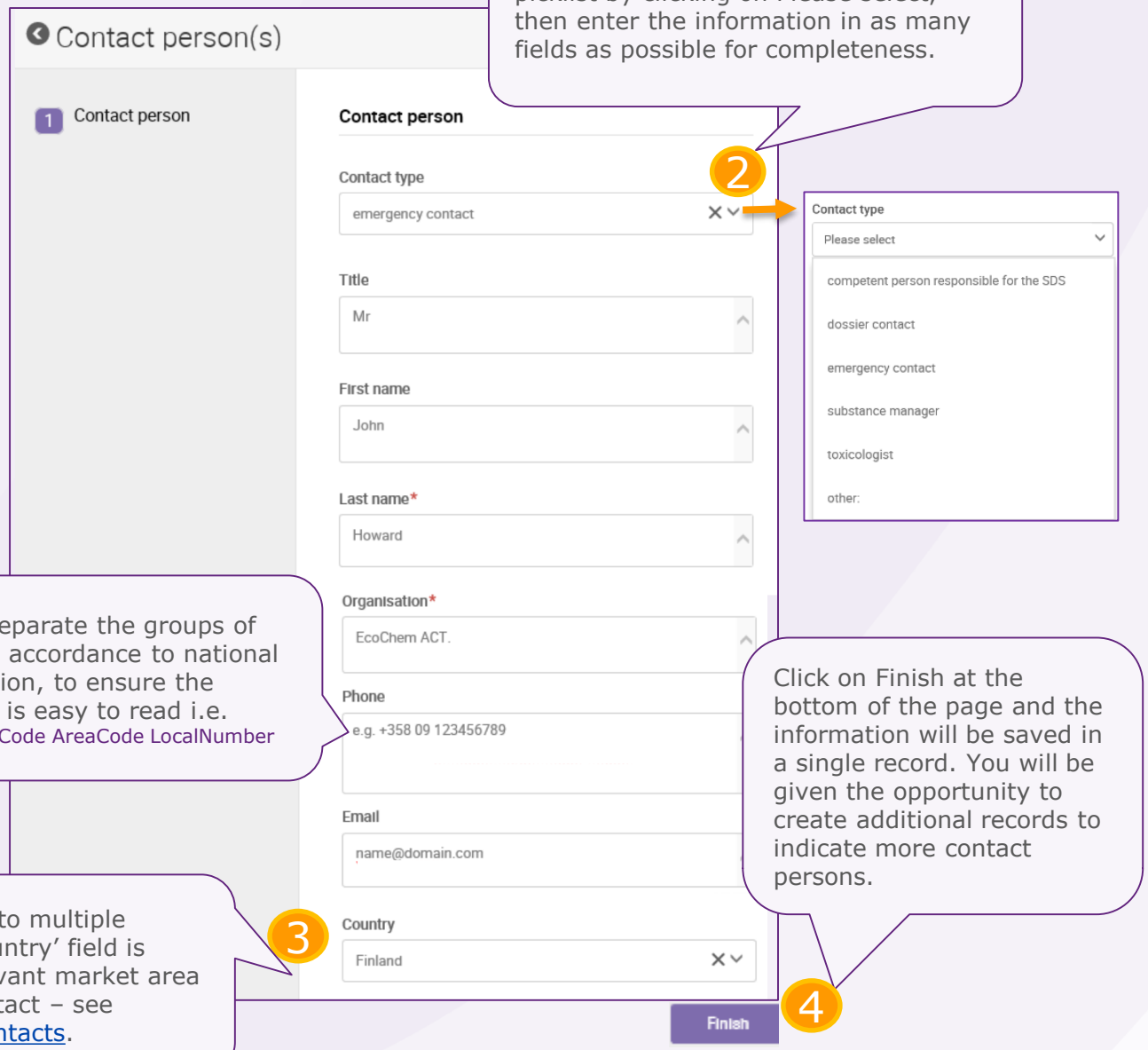
The ‘Contact person(s)’ task

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.



1 To create a contact person record, select Provide information



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

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

3 For limited submissions to multiple Member States, the ‘Country’ field is used to identify the relevant market area for each emergency contact – see Providing emergency contacts.

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.

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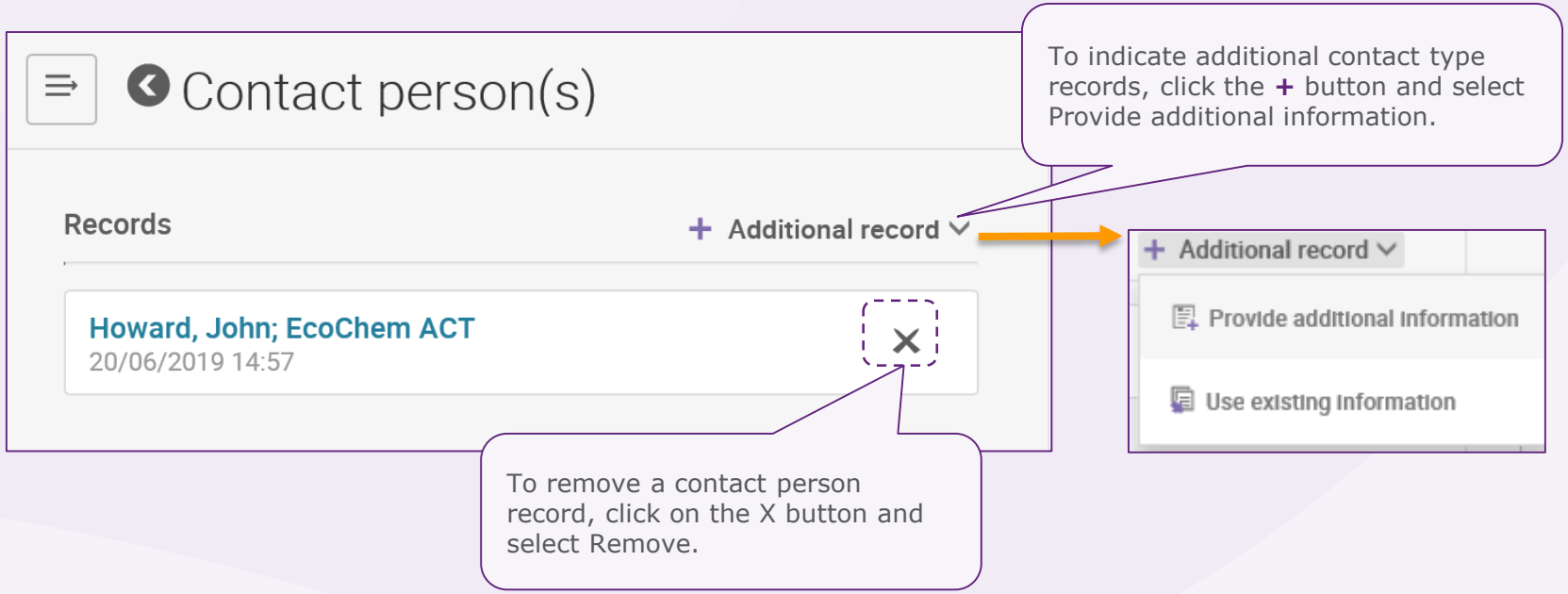
Providing emergency contacts

! 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.

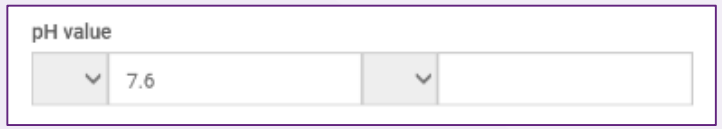


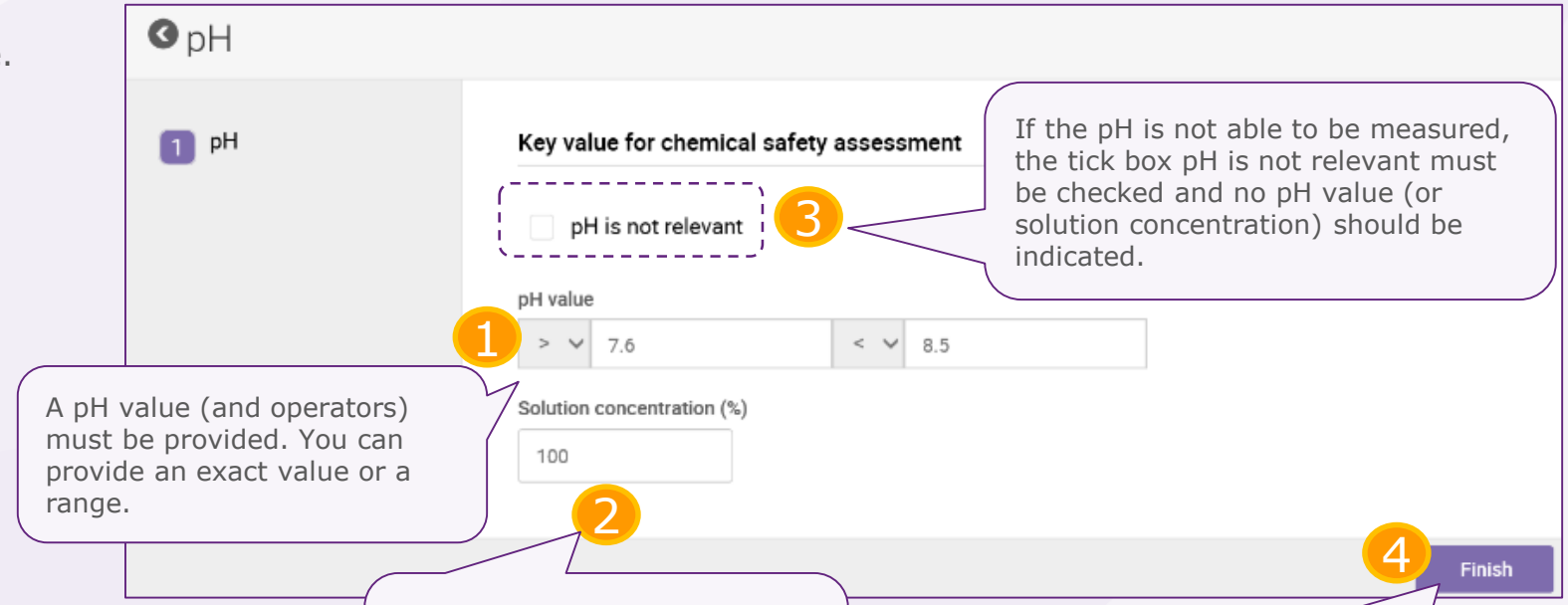
Poison centres

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 e.g.:





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

Poison centres

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.

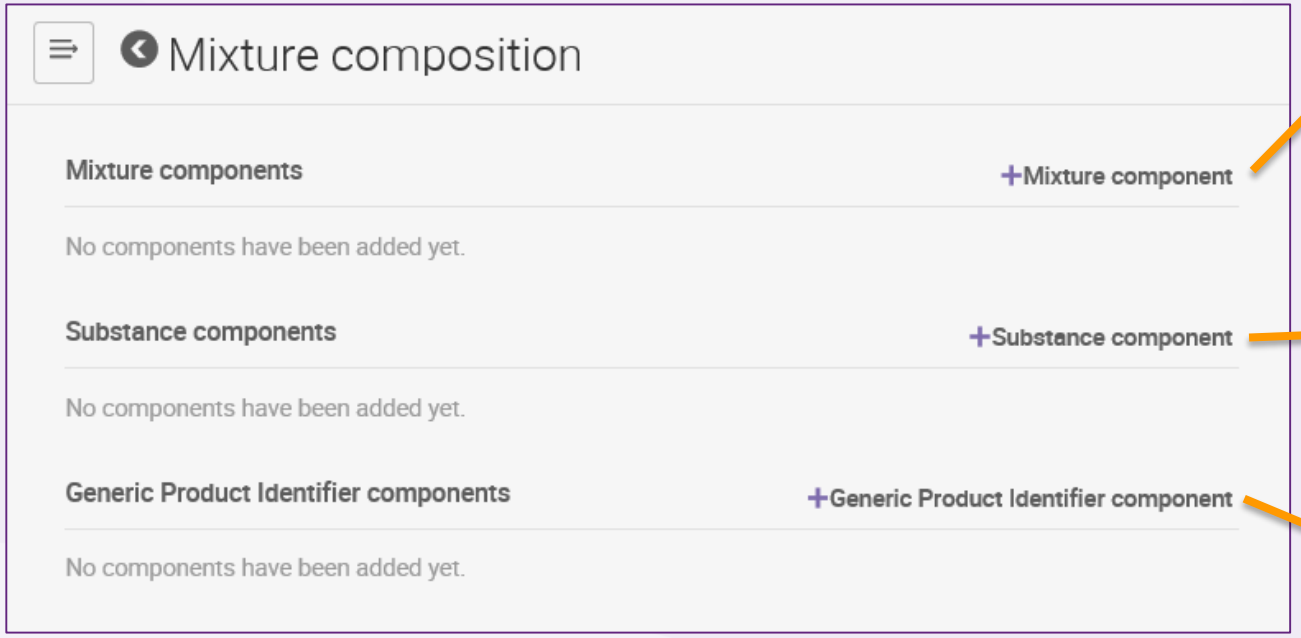
It must be ensured that the information entered here is ‘stand alone’ information and does not e.g. contain cross-references to other sections of the SDS.

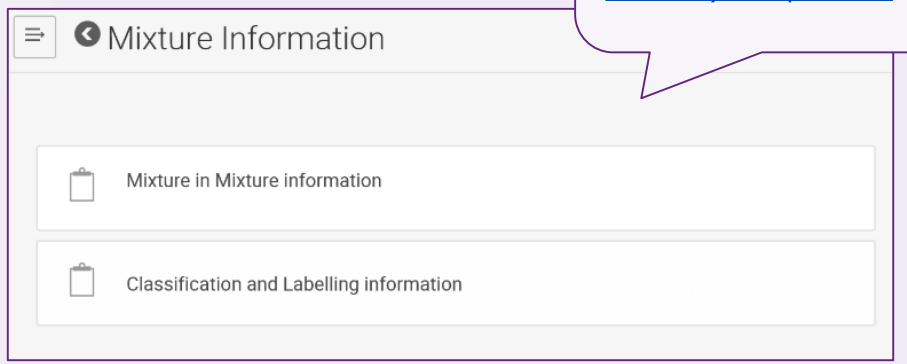
! If your mixture/product is related to a **multi-component** product, then all relevant information should be included in the toxicological information field.

Poison centres

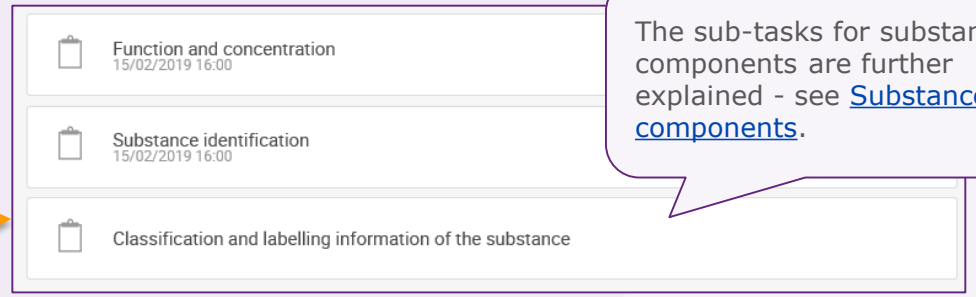
The ‘Mixture composition’ task

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).

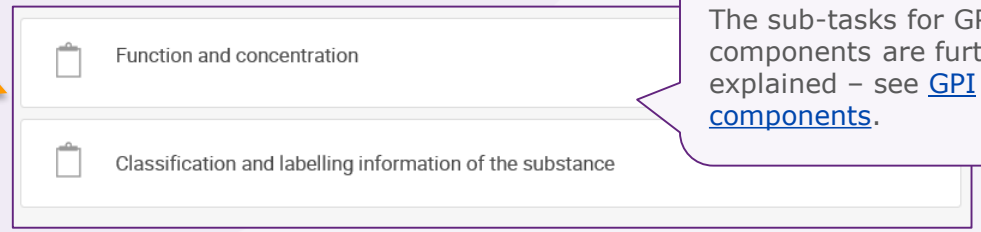




The sub-tasks for mixture components are further explained - see Mixture (in mixture) components.



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

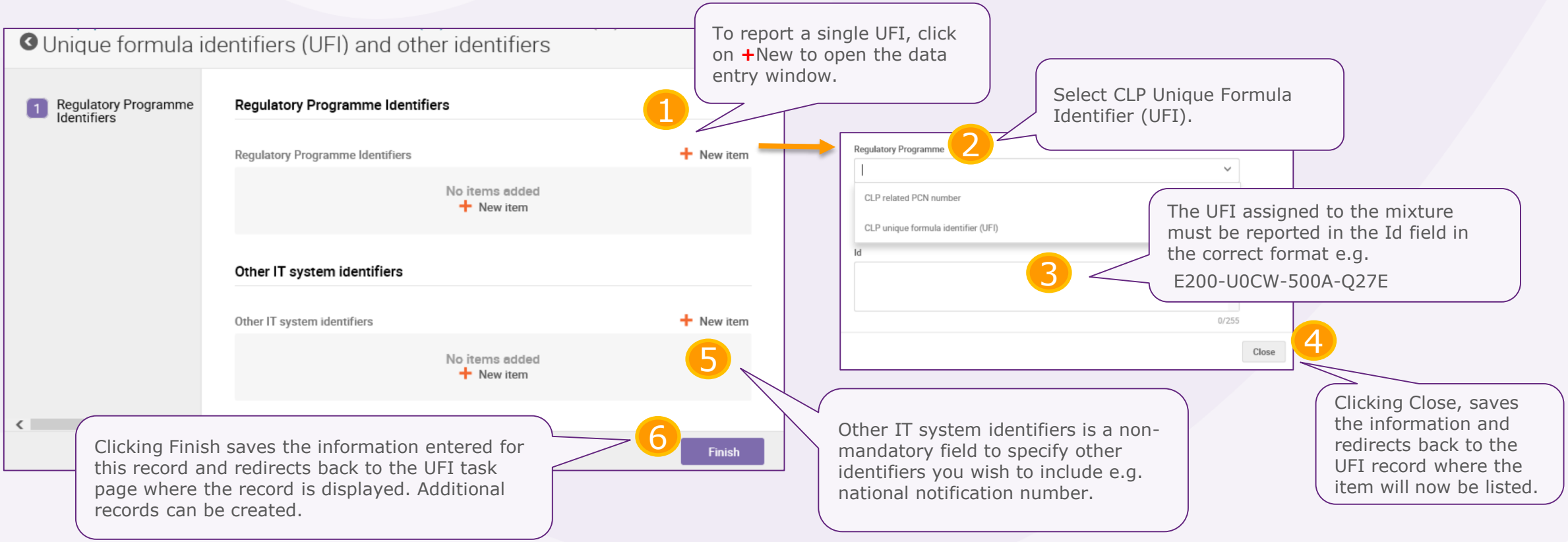


The sub-tasks for GPI components are further explained – see GPI components.

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.



Poison centres

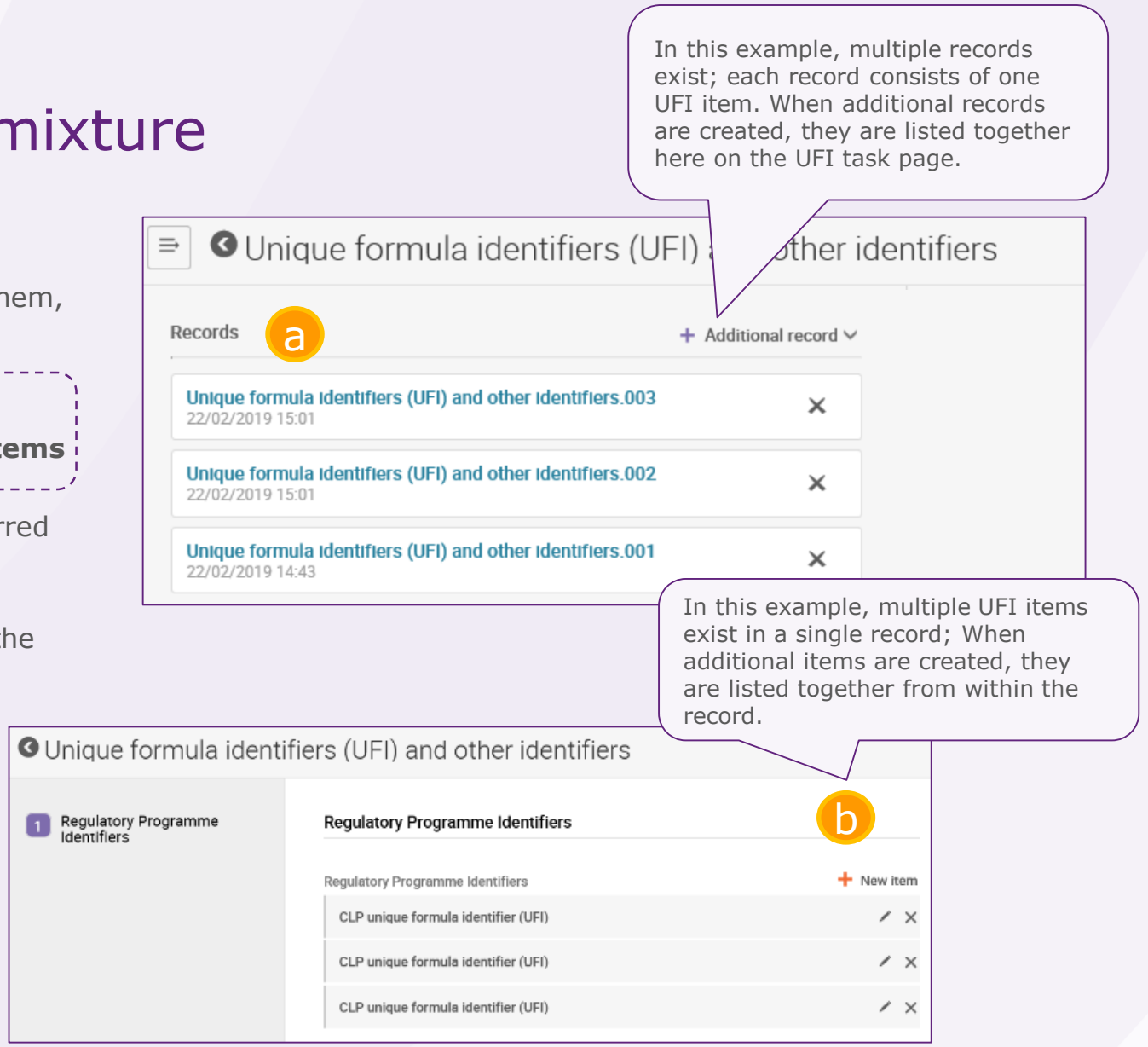
Reporting multiple UFIs for the mixture

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.



Poison centres

The ‘Classification and labelling’ task – step 1

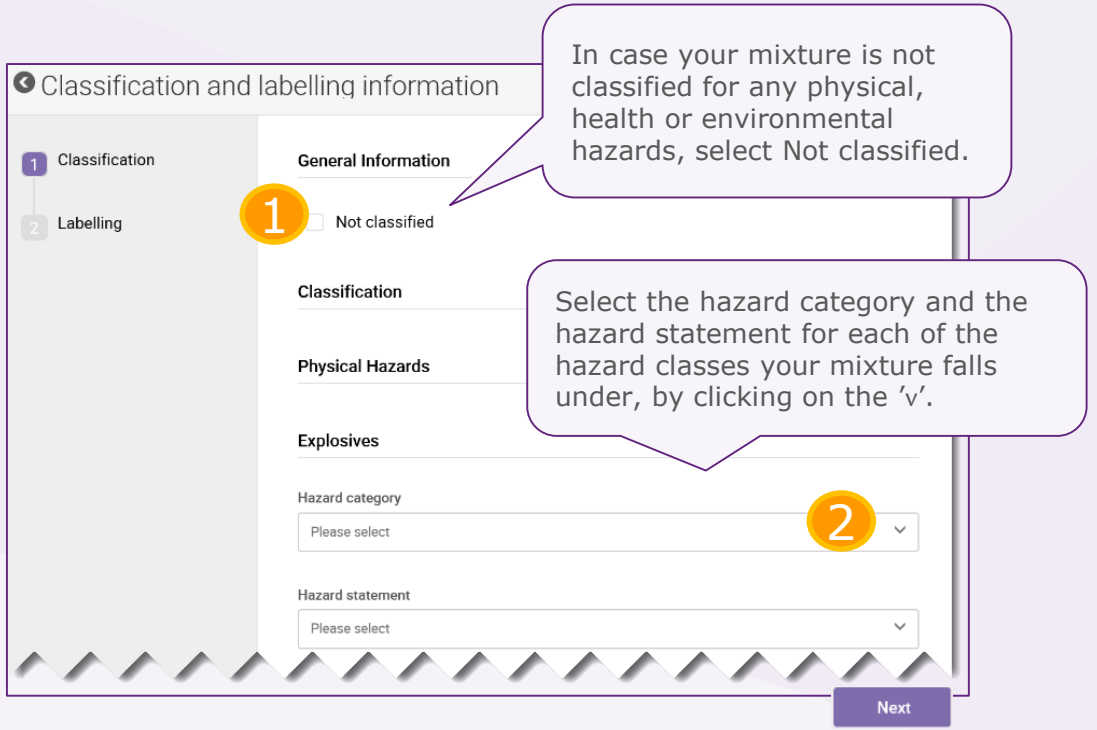
Only a single classification and labelling record can exist for a mixture for a standard submission. Environmental hazards may be included, but are not mandatory to indicate.

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

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

1 **Classify your mixture** by providing:

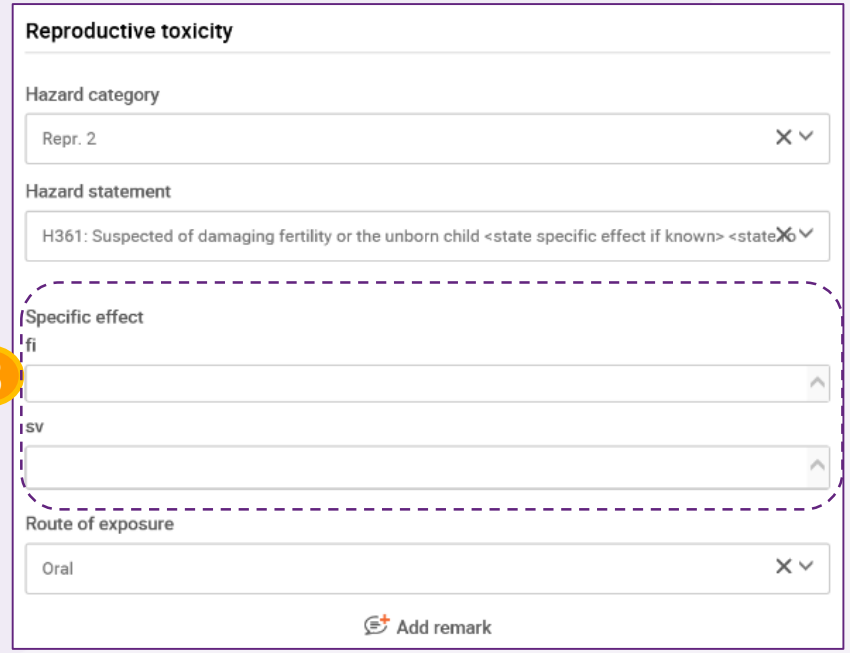
- Hazard category
- Hazard statements
- Any relevant additional information



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.**



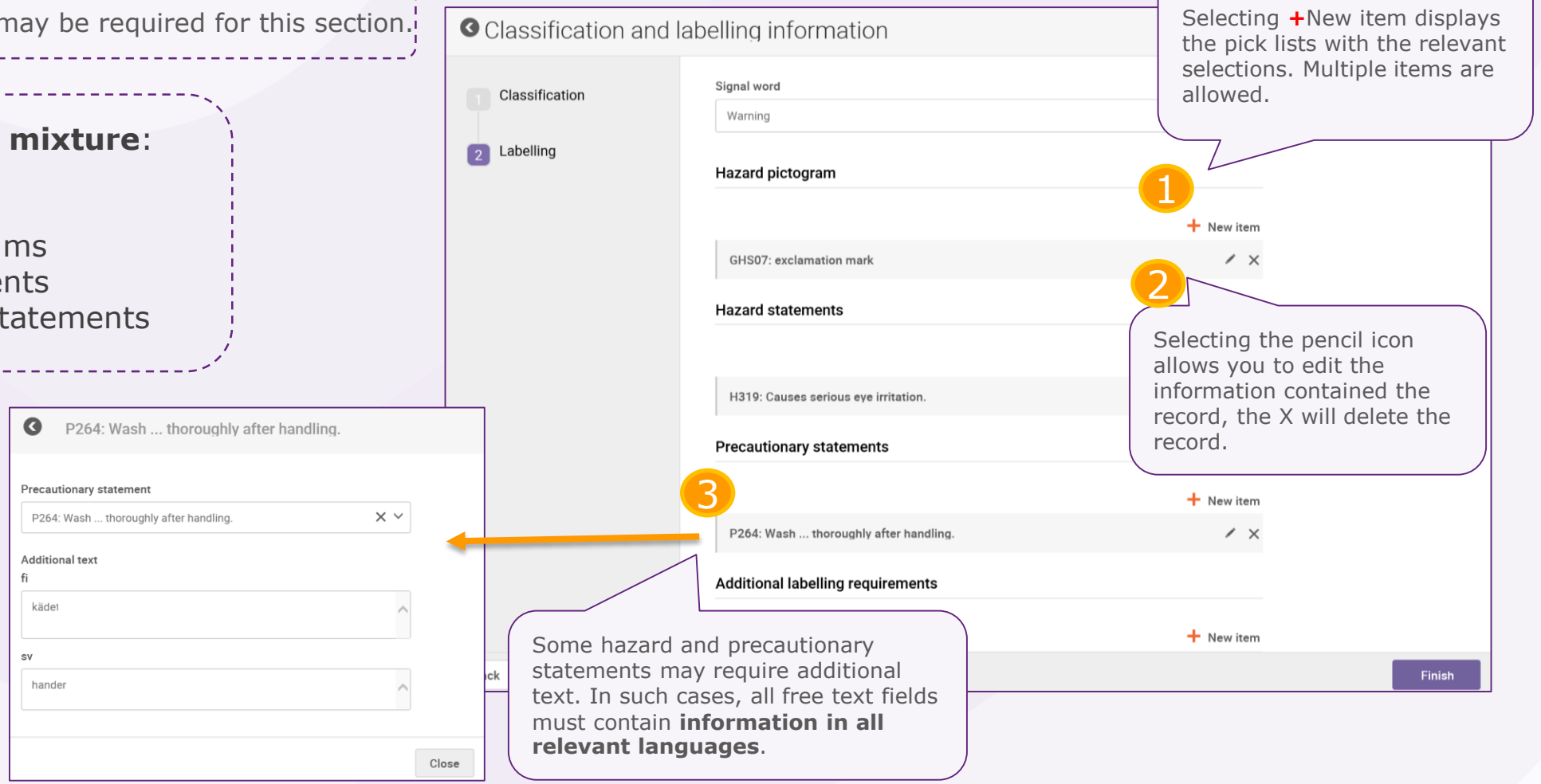
Poison centres

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



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:

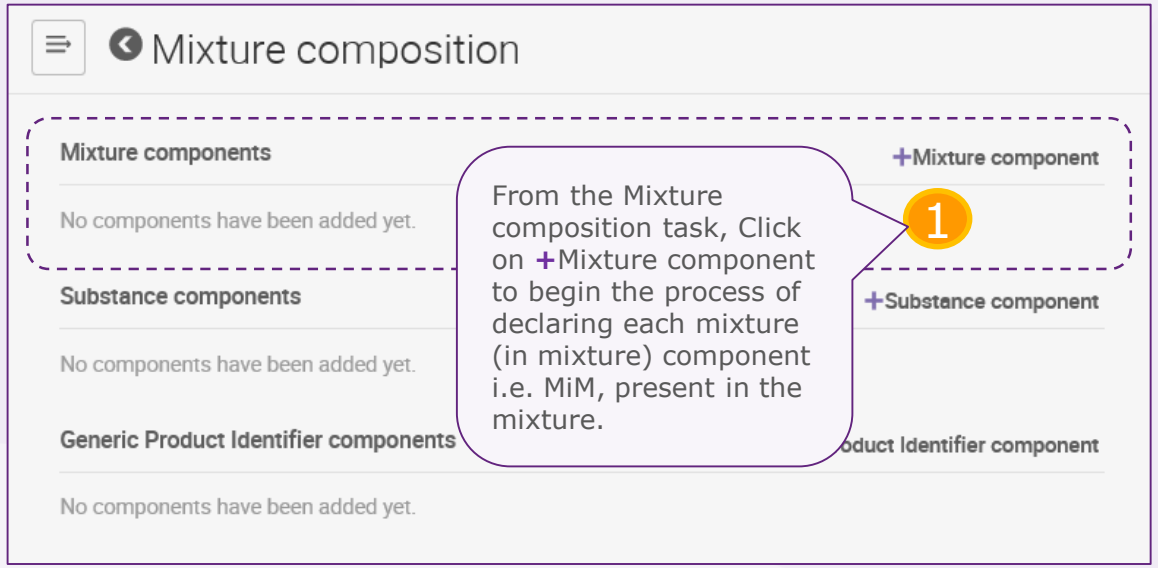
https://poisoncentres.echa.europa.eu/guidance

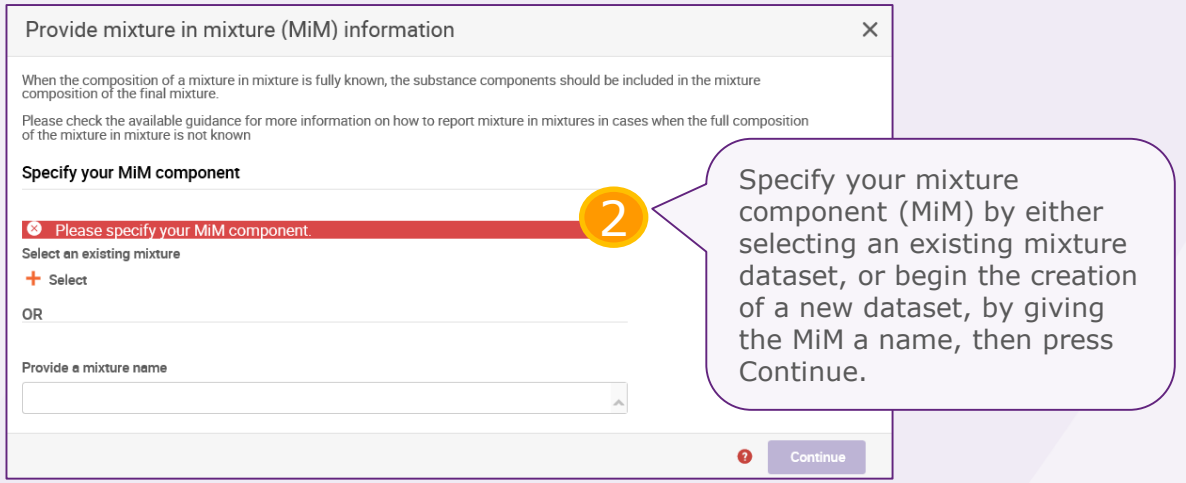
Poison centres

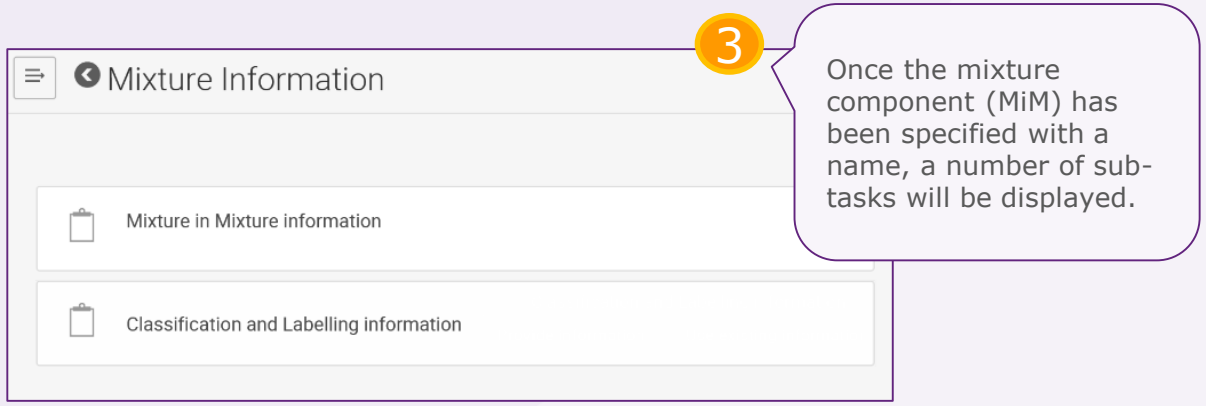
Mixture (in mixture) components

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.

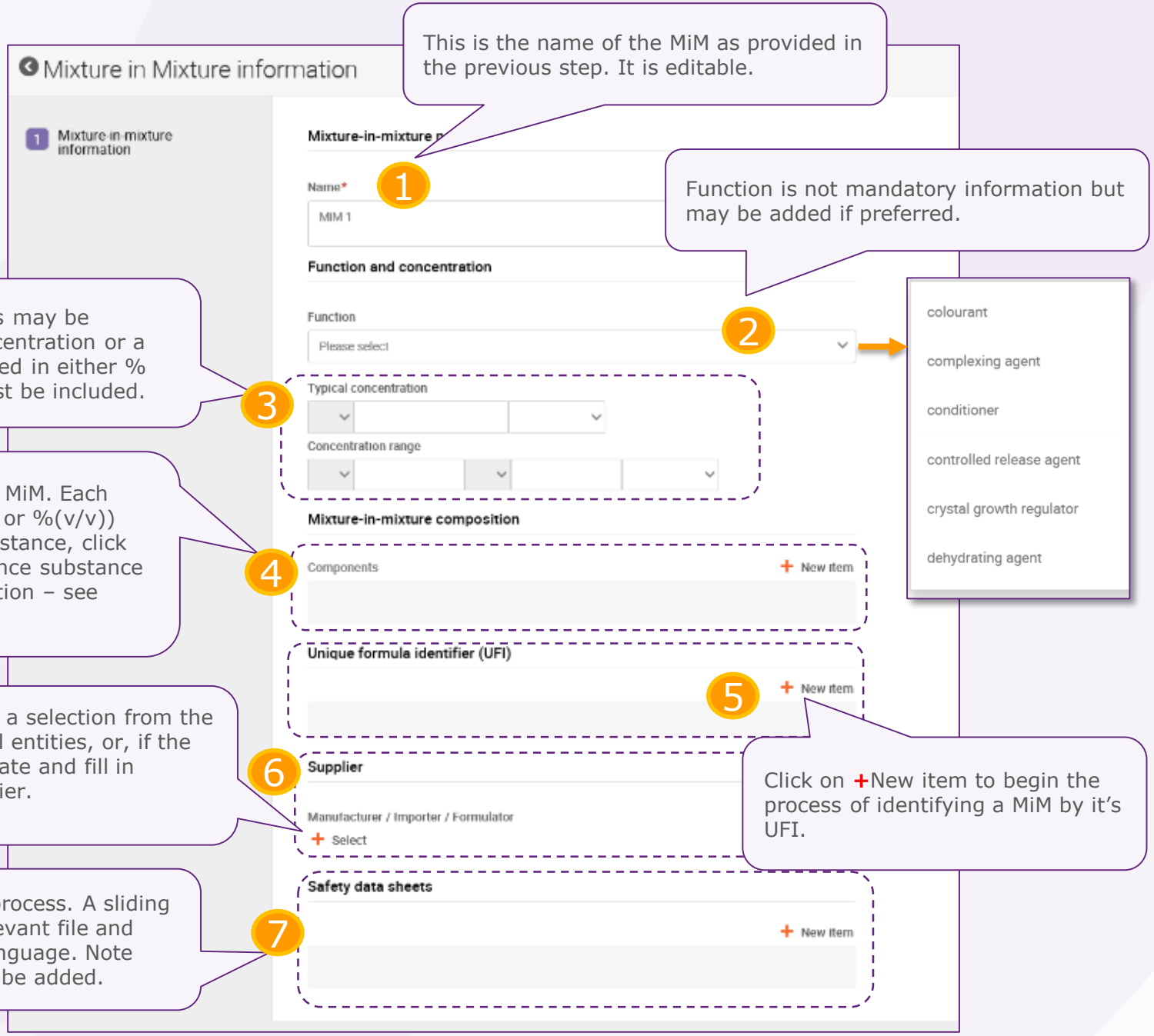






Poison centres

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 may be added if preferred.

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 wondow, 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 of identifying a MiM by it’s UFI.

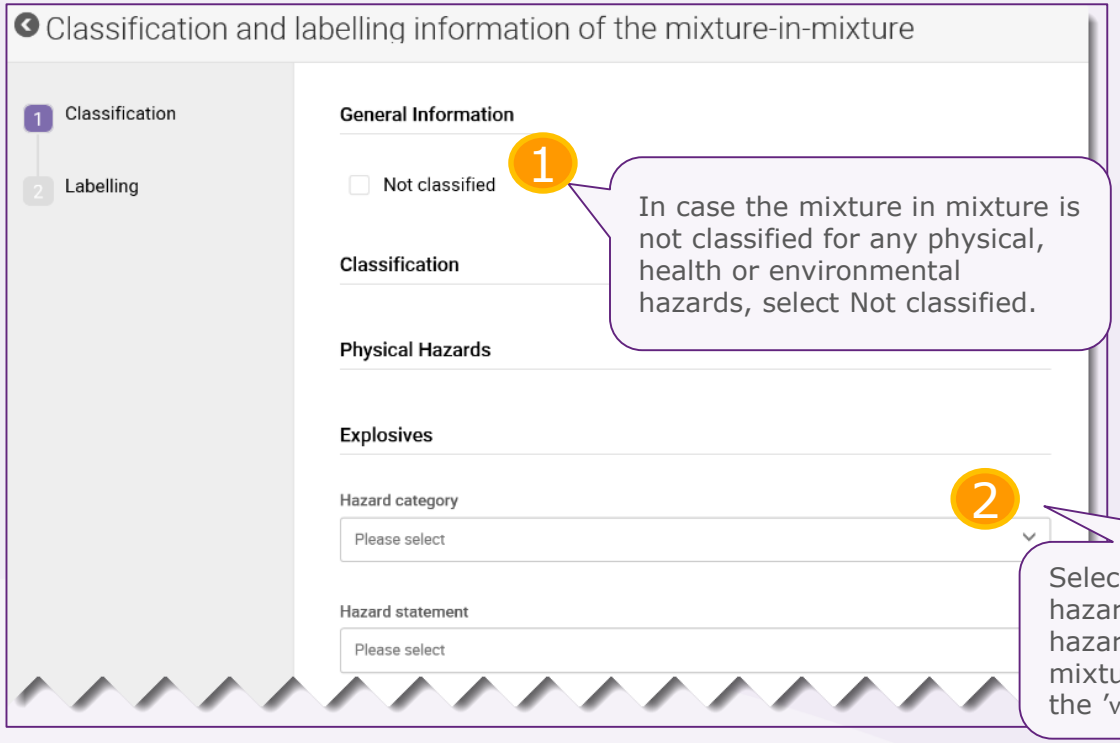
Click on +New item to begin the process. A sliding window will open – upload the relevant file and select the relevant country and language. Note that multiple SDSs i.e. items, can be added.

Poison centres

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.



1

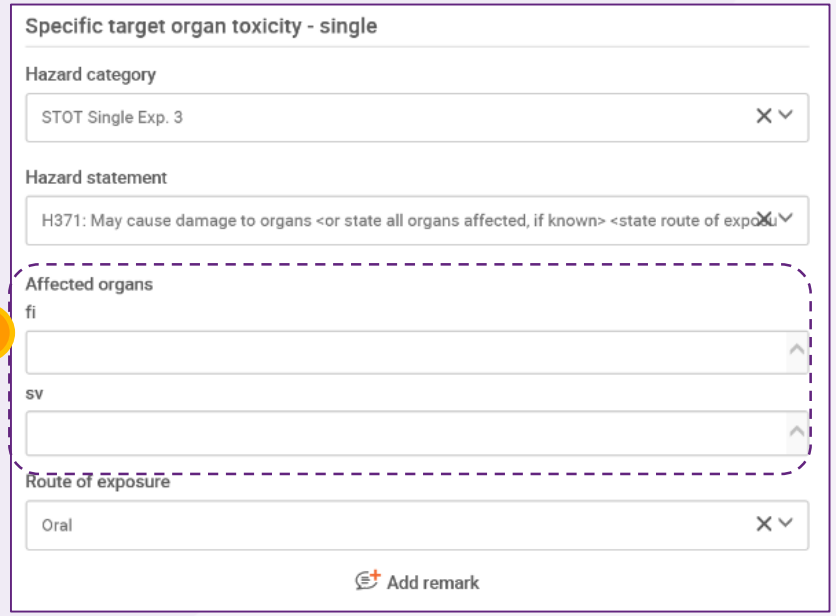
In case the mixture in mixture is not classified for any physical, health or environmental hazards, select Not classified.

2

Select the hazard category and the hazard statement for each of the hazard classes your mixture in 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.**

3



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:

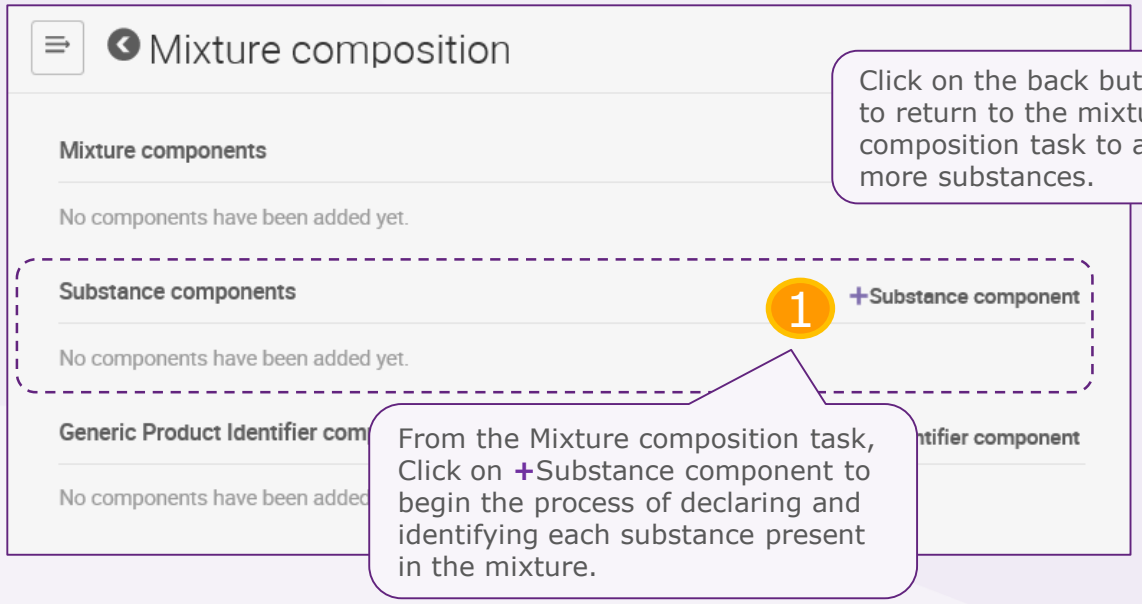
https://poisoncentres.echa.europa.eu/guidance

Poison centres

Substance components

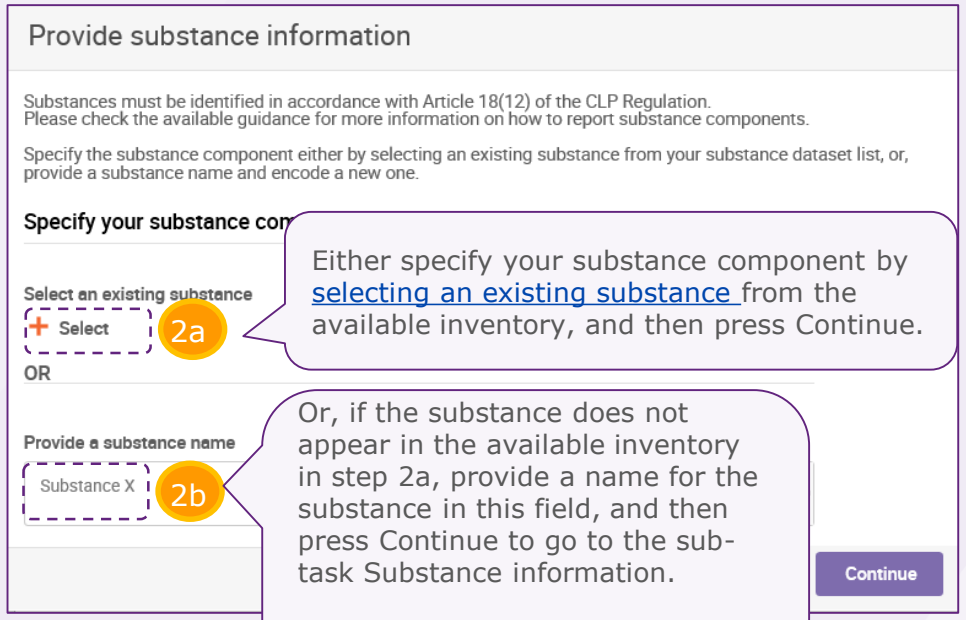
A substance component requires a record that contains information about function and concentration, it's identity and it's classification. Each substance component is linked to a **Reference Substance**.

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



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

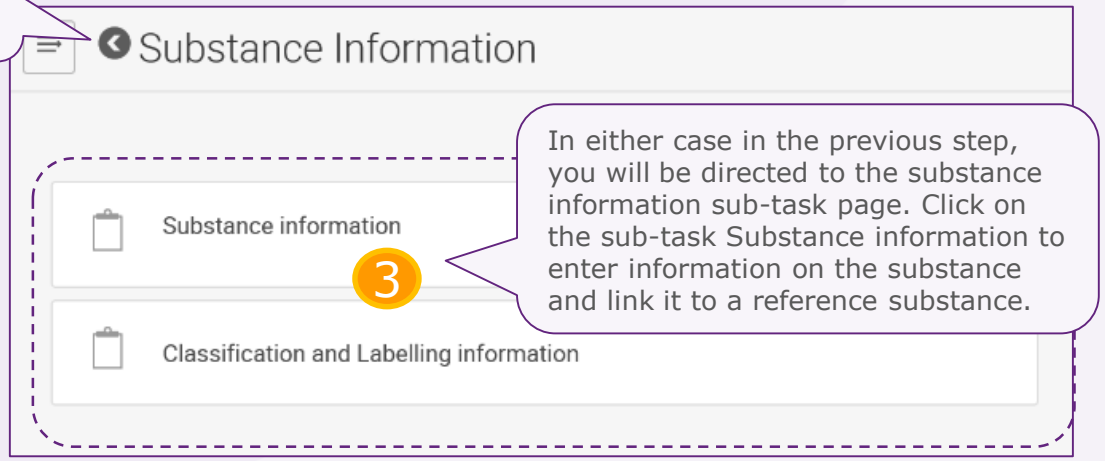
Click on the back button '<' to return to the mixture composition task to add more substances.



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

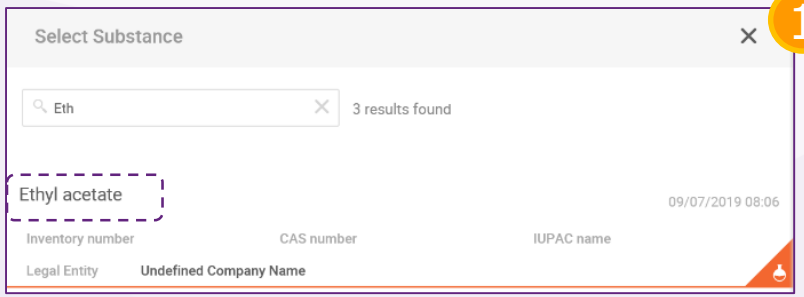
Note that the name you provide here is only for the label of the record.



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.

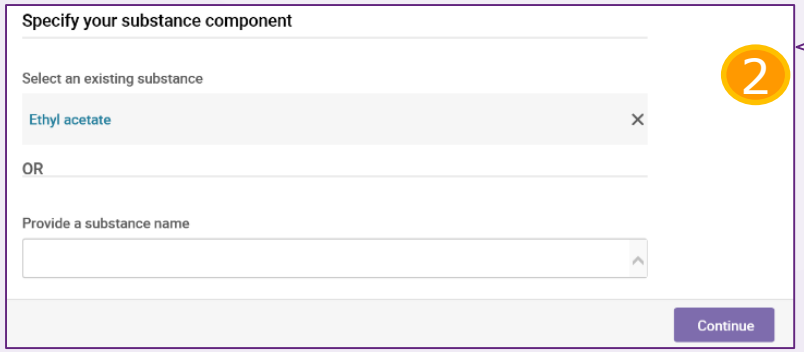
Poison centres

Selecting an existing substance



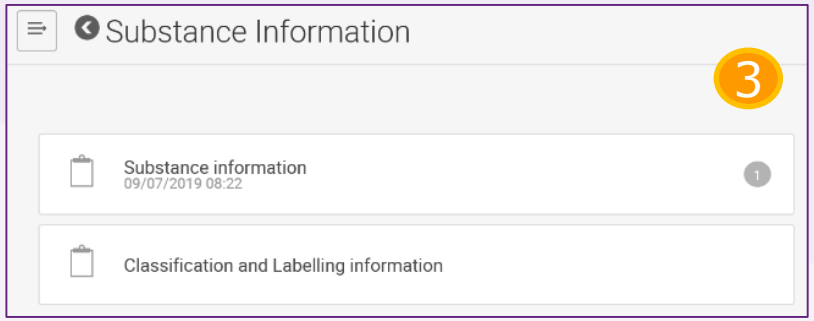
1

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



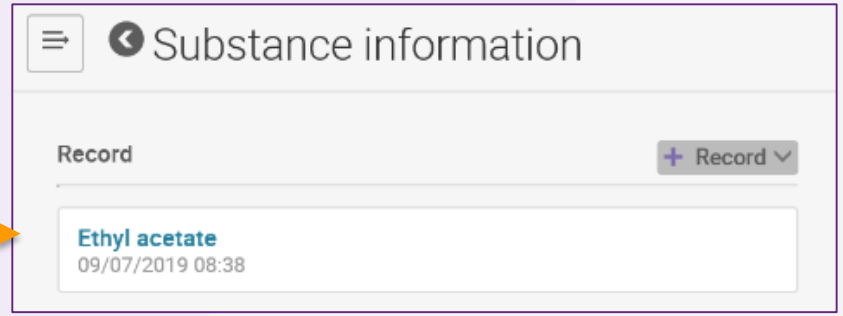
2

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

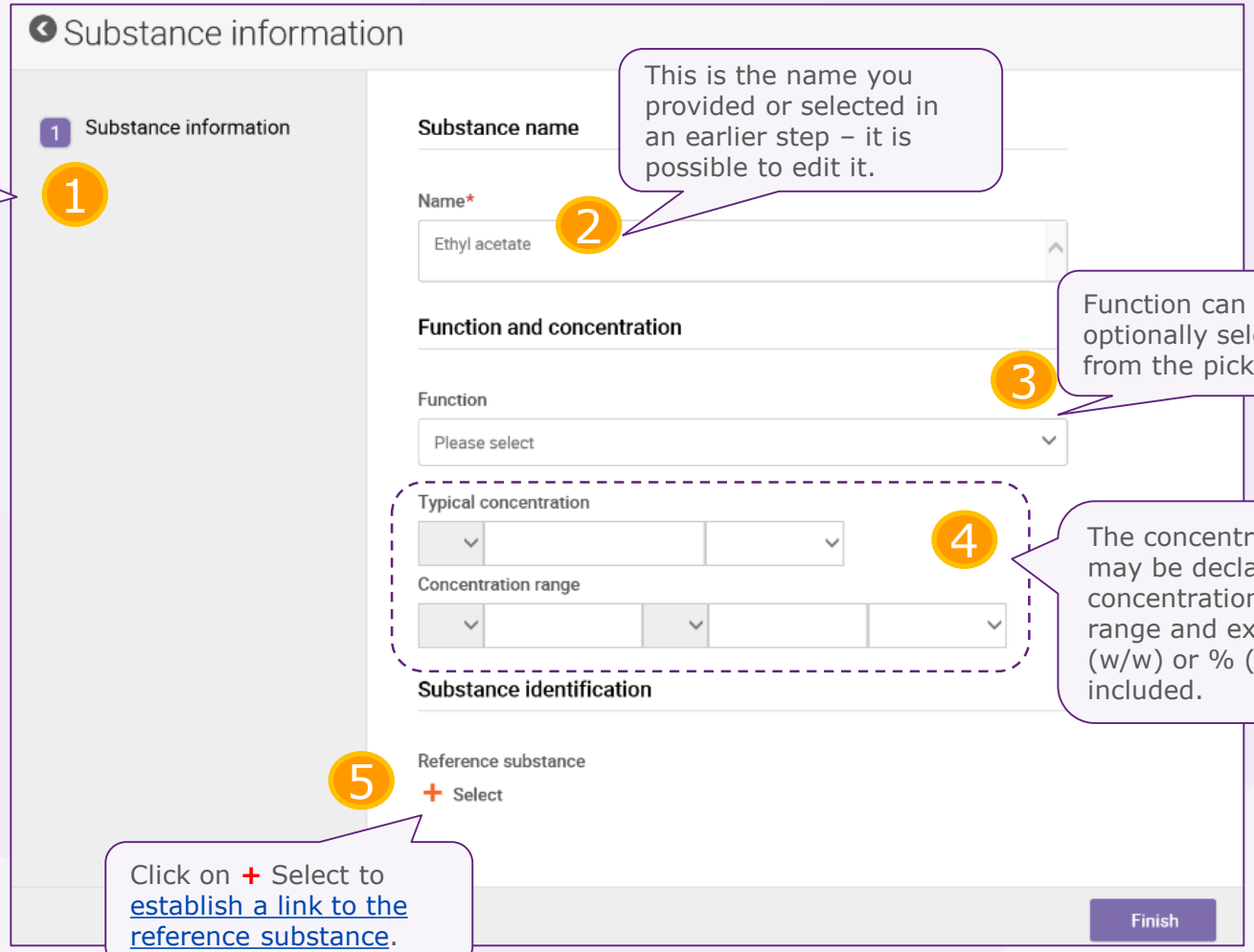
The sub-tasks for the substance are now displayed. Click on Substance information and open the substance record by clicking on it's name, in this example, Ethyl acetate.



Poison centres

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.



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.

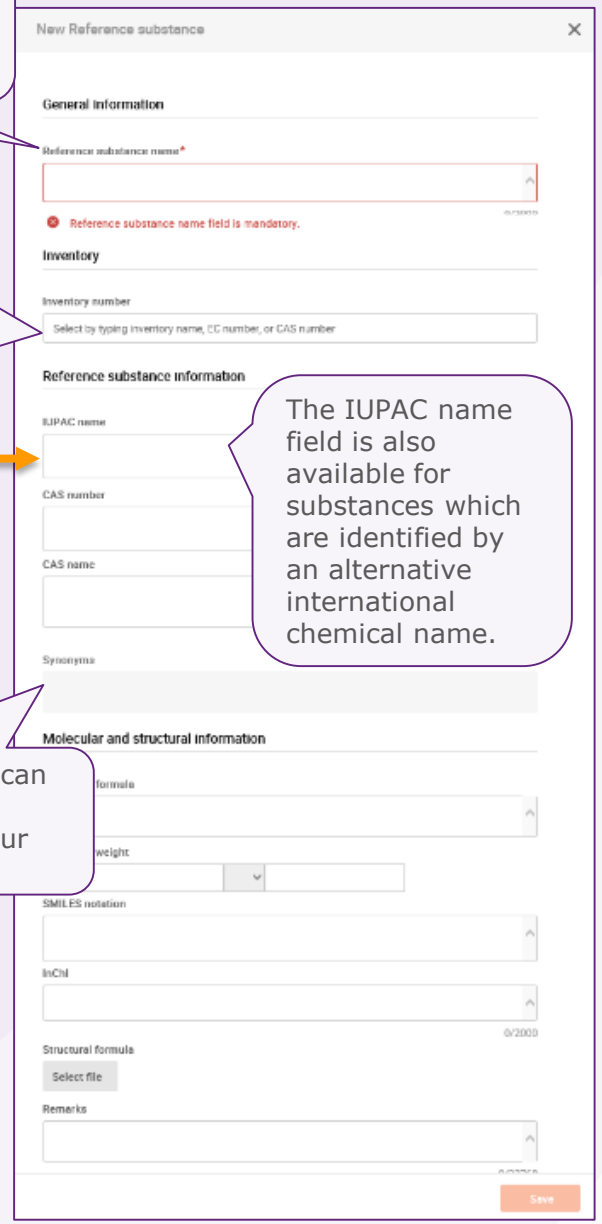
The concentration of components may be declared either as a ‘typical’ concentration or a concentration range and expressed in either % (w/w) or % (v/v). Operators must be included.

Click on + Select to establish a link to the reference substance.

Poison centres

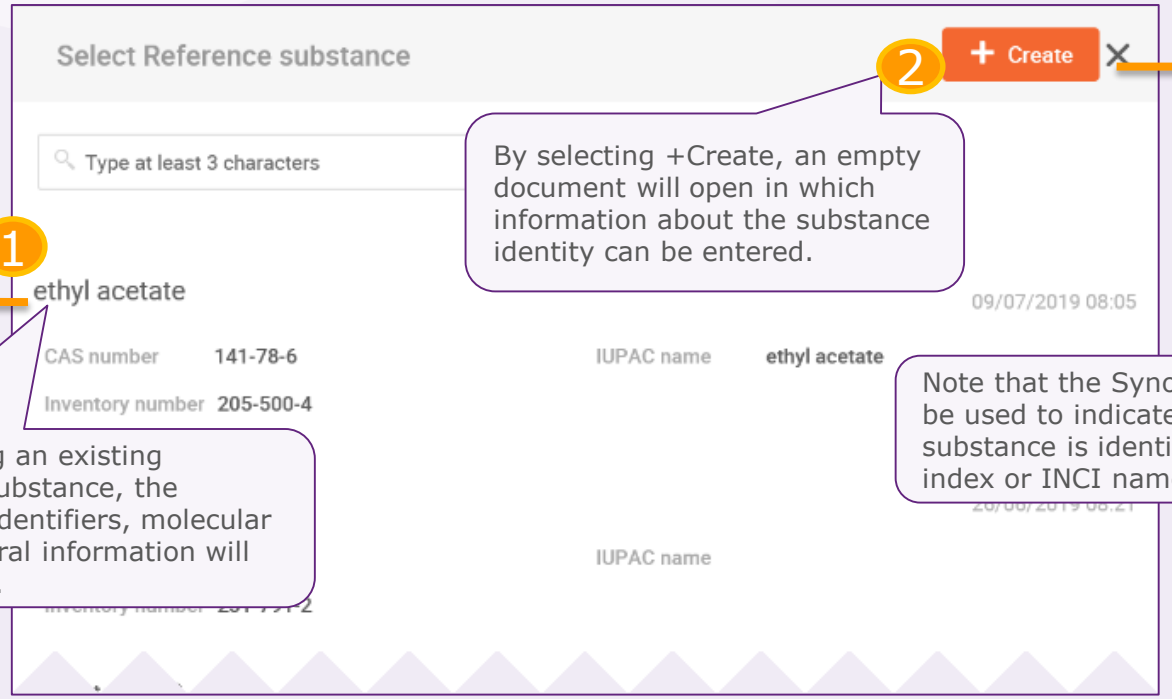
Establishing a link to a reference substance

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

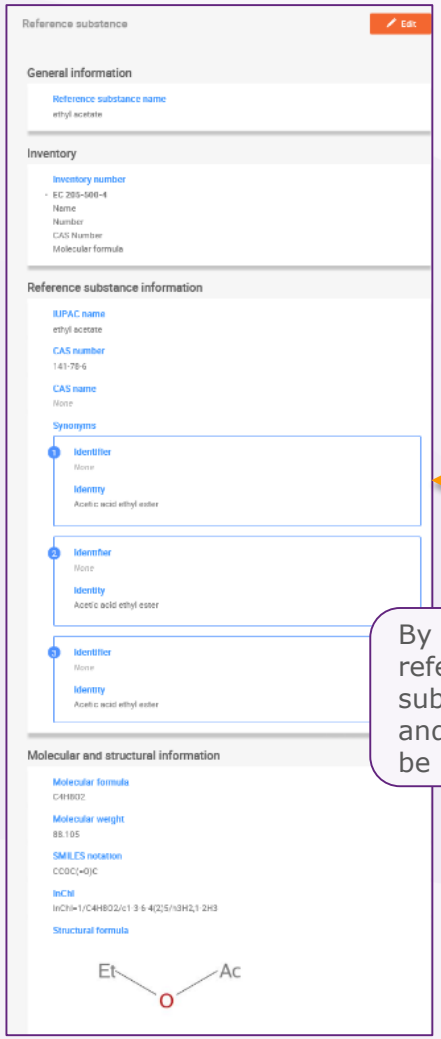


It is possible to link the reference substance to the EC inventory by entering the name, EC number or CAS number.

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



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.

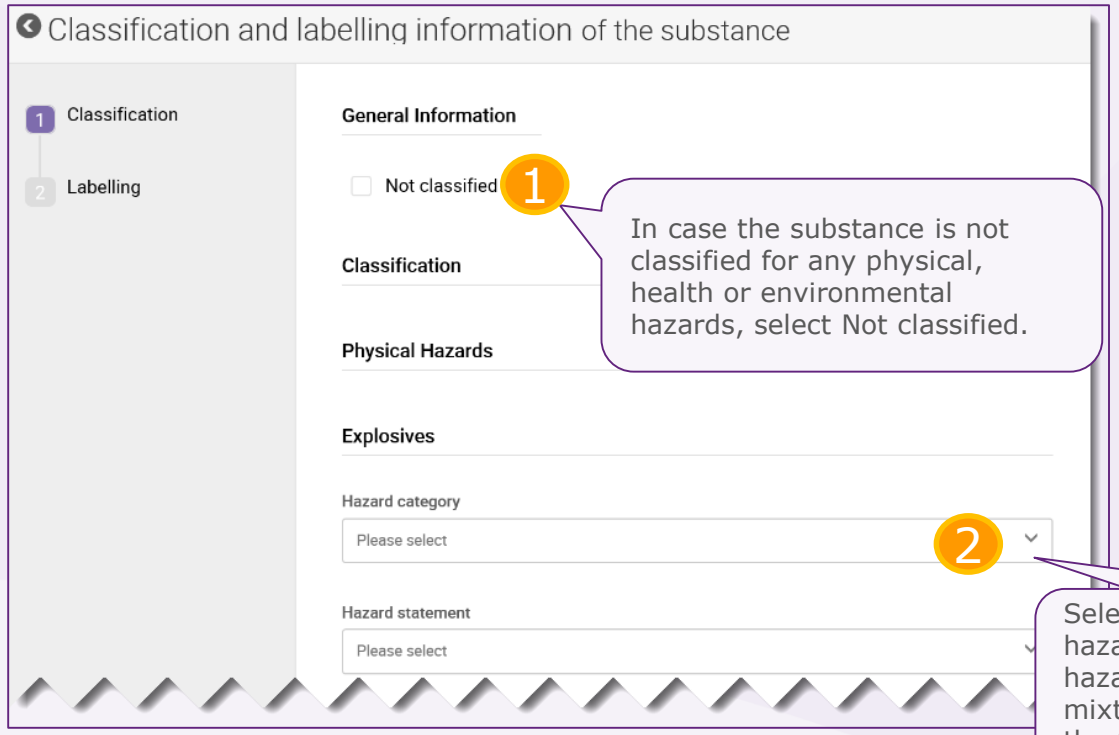
Note that the Synonyms field can be used to indicate if the substance is identified by colour index or INCI name.

Poison centres

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.

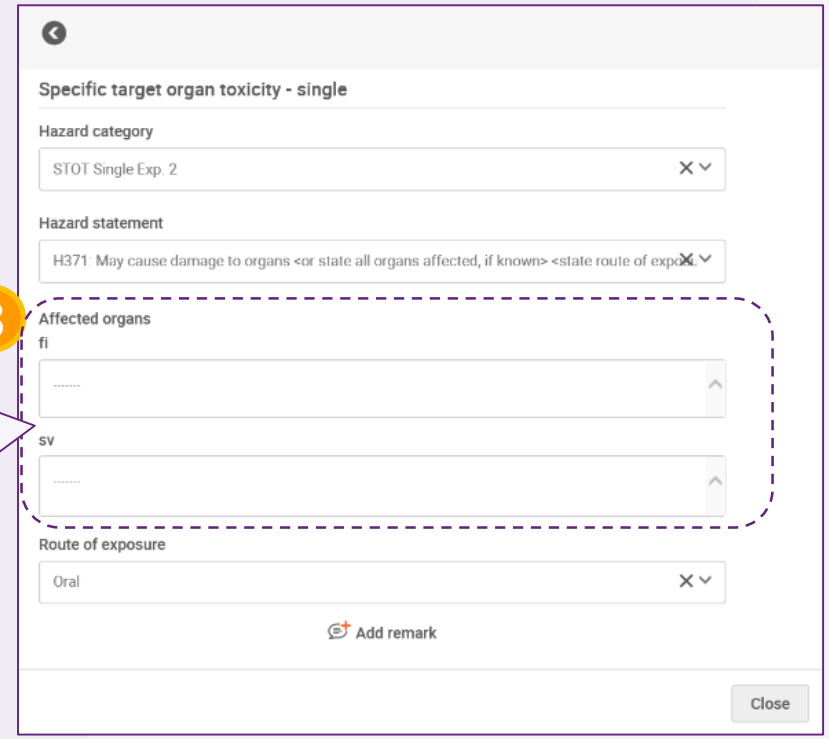
! Note that **multilingual text** may be required for this section.



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 in 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**.



Poison centres

Reporting generic product identifier components

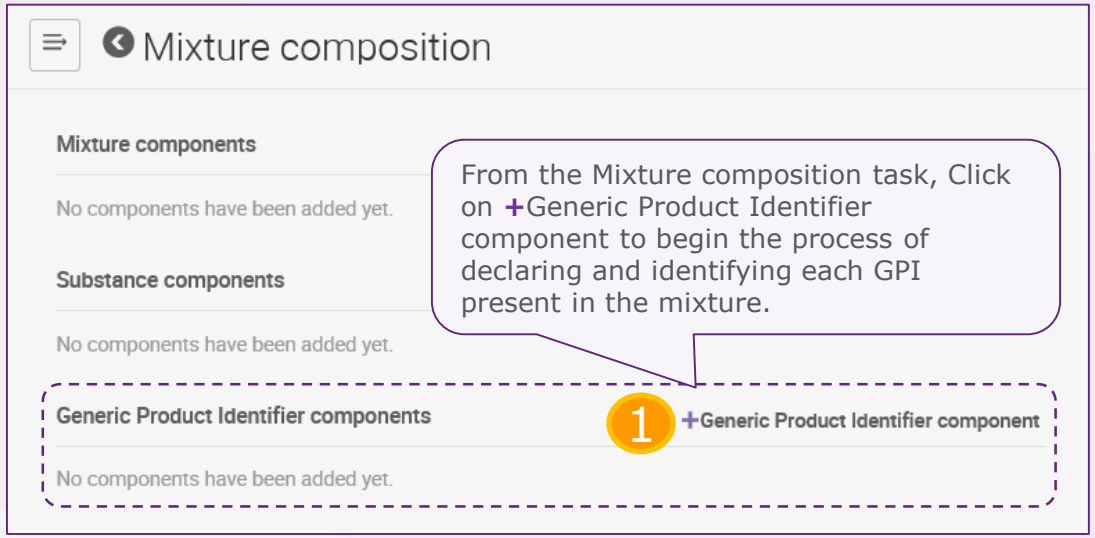
An overview of how to use IUCLID to complete the sub-tasks for generic product identifier (GPI) components. Full details on the information requirements can be found from the *Guidance on harmonised information relating to emergency health response* at:

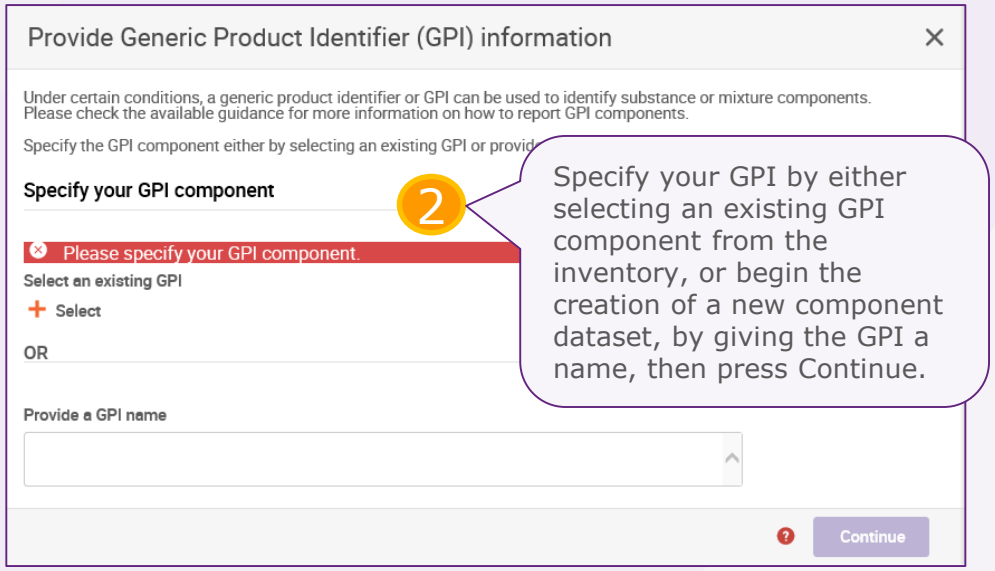
https://poisoncentres.echa.europa.eu/guidance

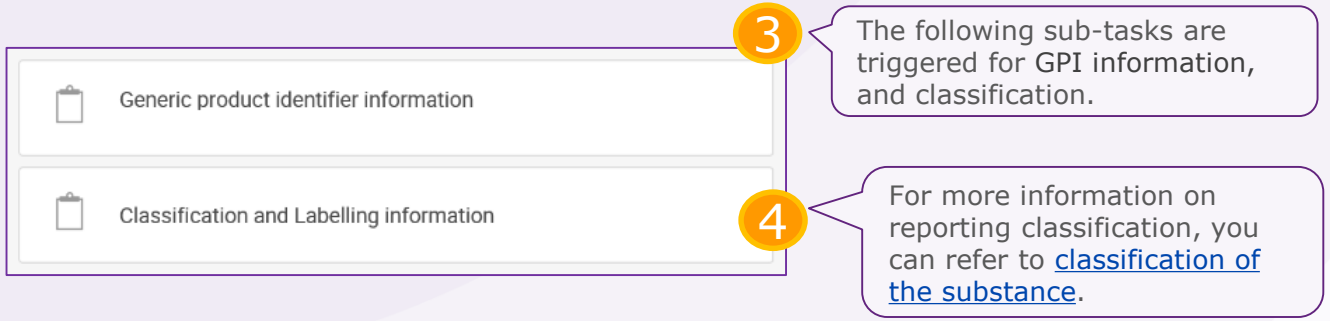
Poison centres

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.

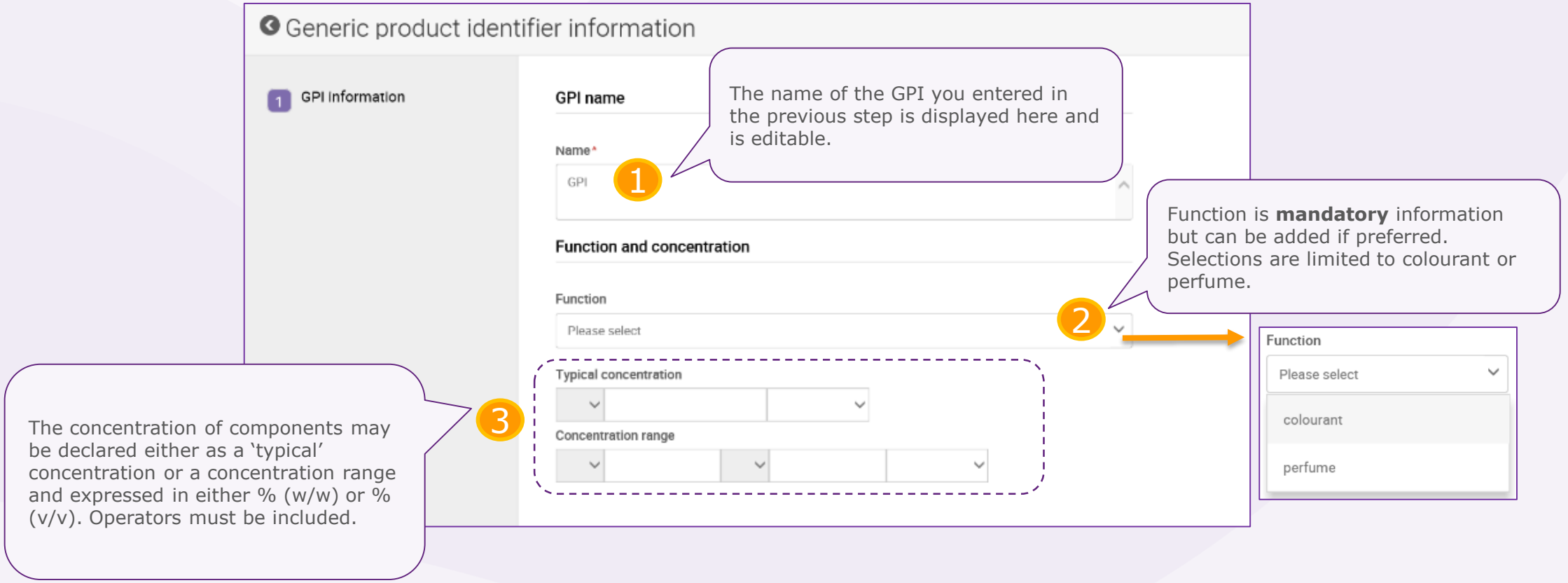






Poison centres

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



Poison centres

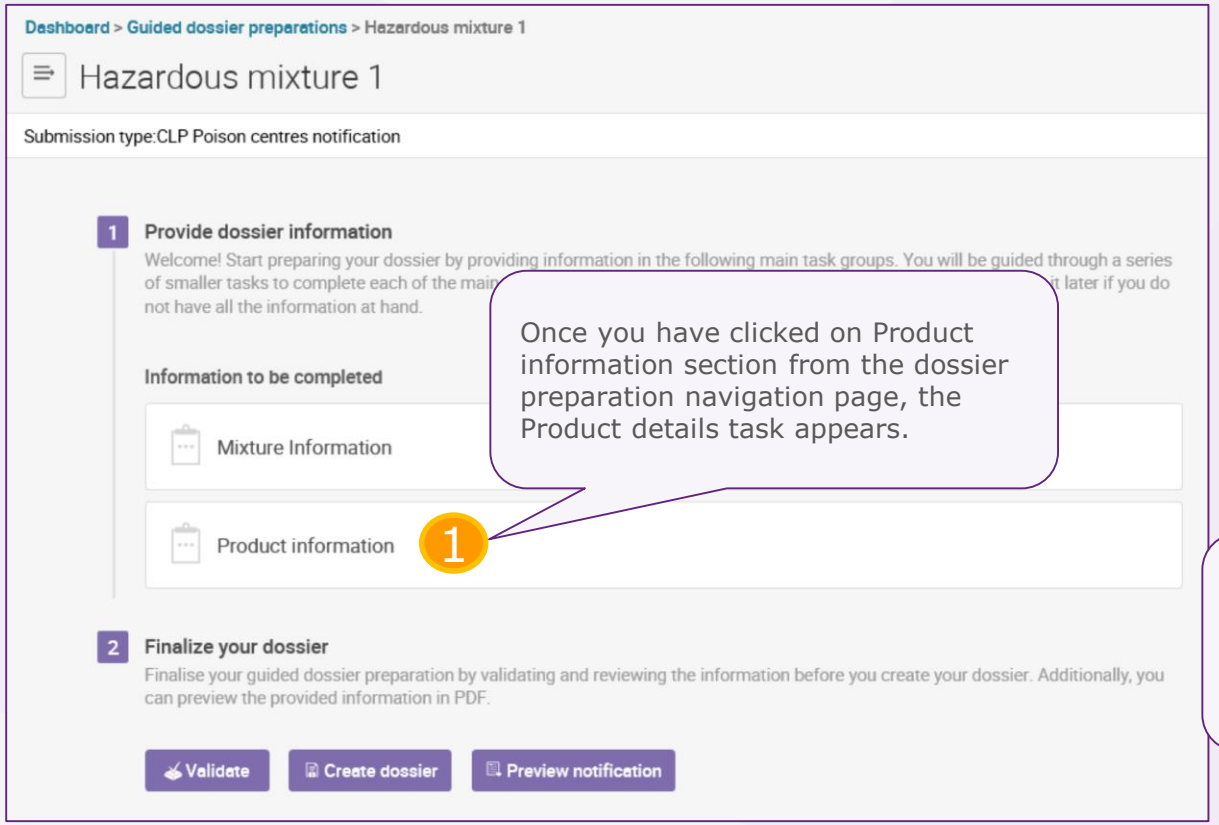
Dossier preparation: ‘Product information’

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:

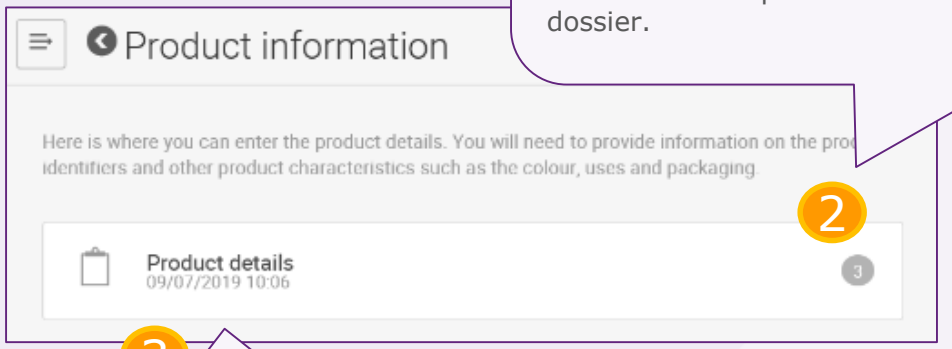
https://poisoncentres.echa.europa.eu/guidance

Poison centres

Navigating to the Product details page



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



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

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

Poison centres

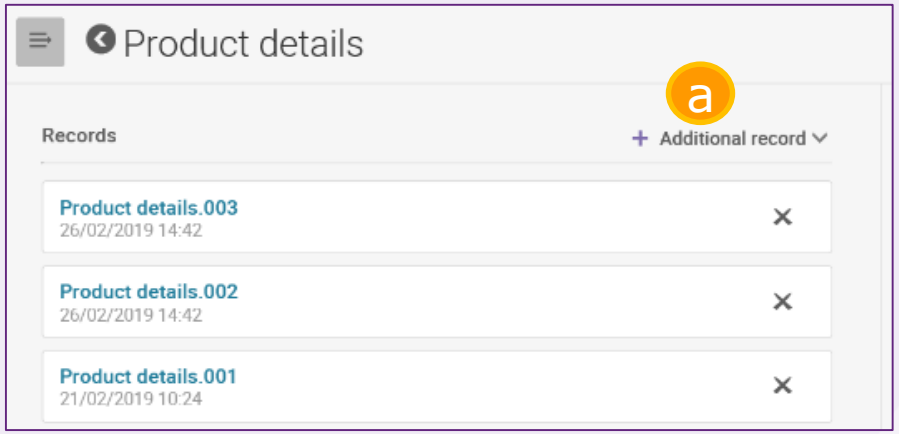
Reporting multiple products

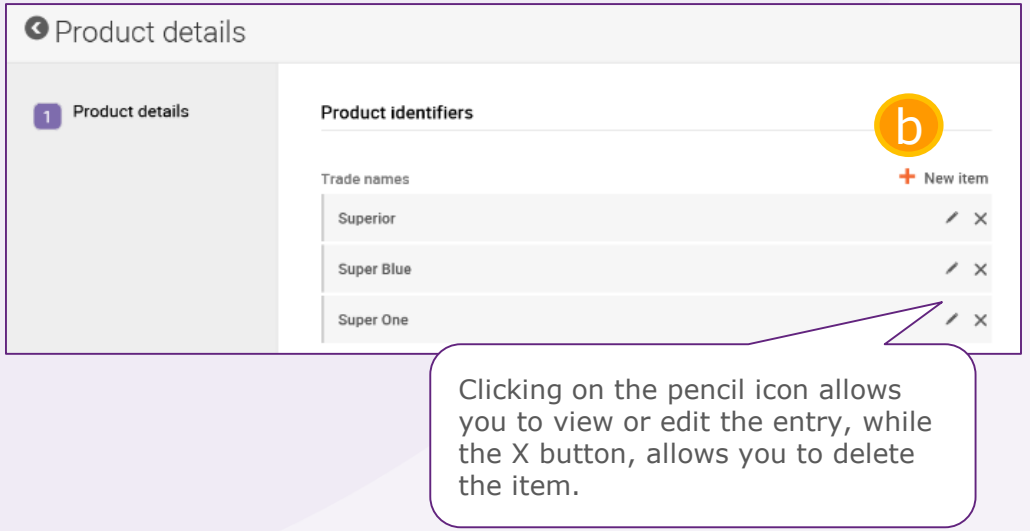
Reporting a single product with a single trade name and UFI is the most straightforward way to include product information in a notification i.e. a single Product details record referring to one product under one trade name, and one UFI.

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.



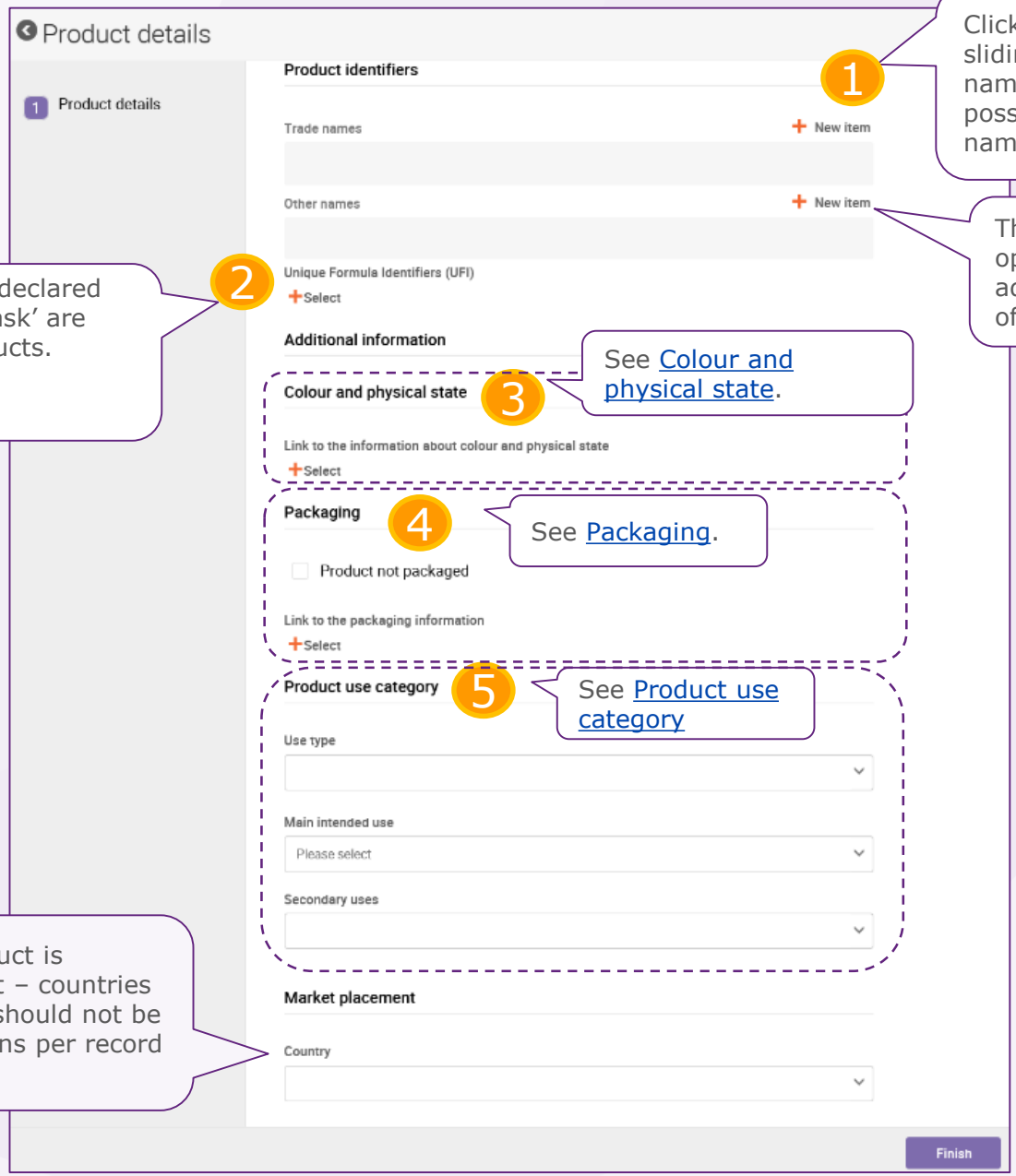


Poison centres

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.



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.

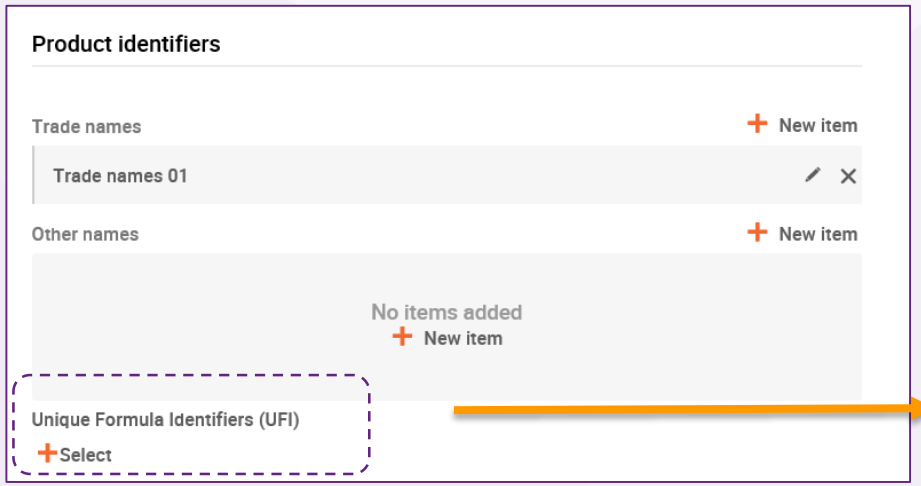
See Packaging.

See Product use category

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.

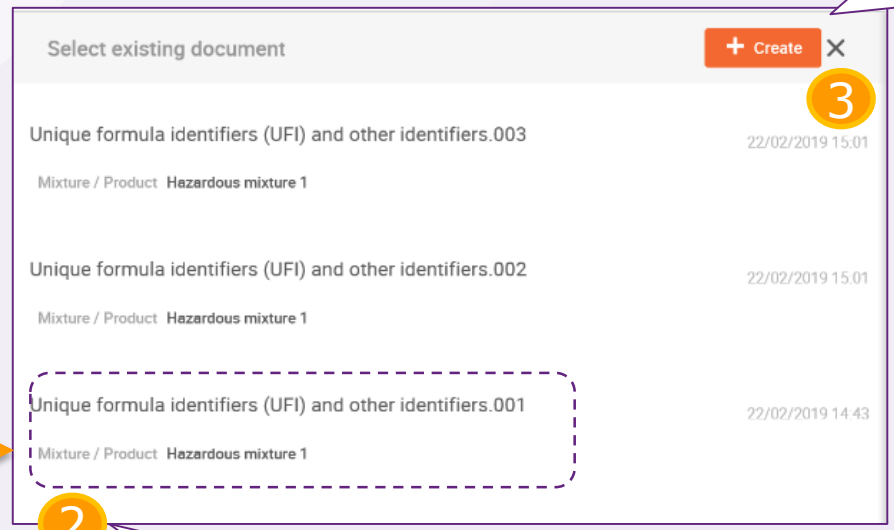
Poison centres

‘Unique formula identifier’



1

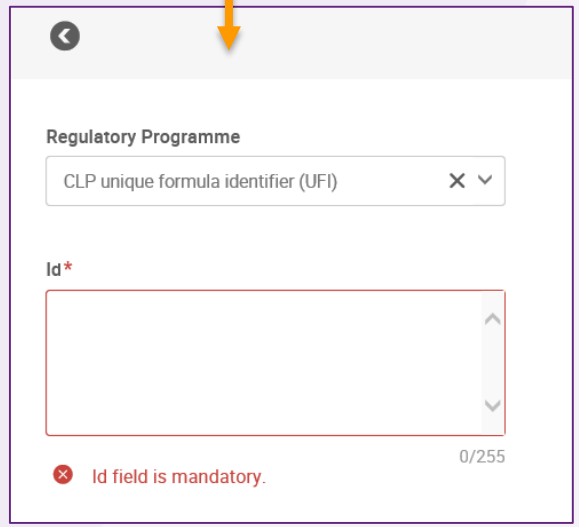
By clicking +Select, the UFIs that were declared earlier in the Mixture information ‘UFI task’ are listed and can be linked to specific products. Note that this linking is still required even in the simplest case where a single UFI is declared and only one product exists.



2

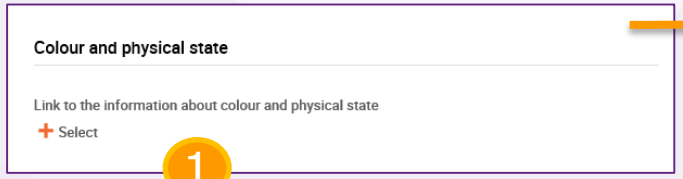
The linking of UFIs is done through selecting the correct UFI assigned to the mixture and on the label of the related product, by clicking anywhere in the relevant information bar.

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.

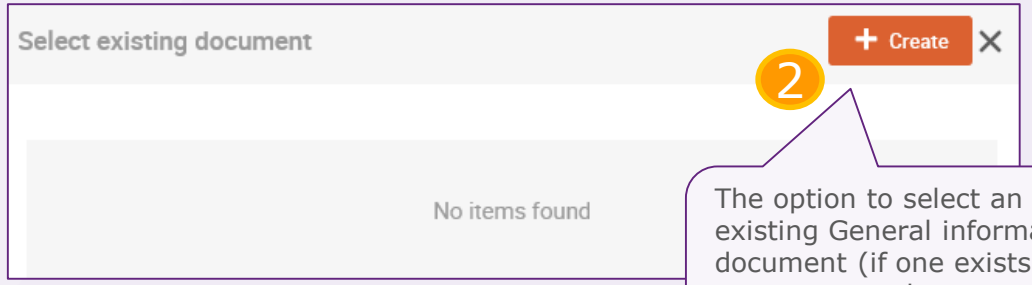


Poison centres

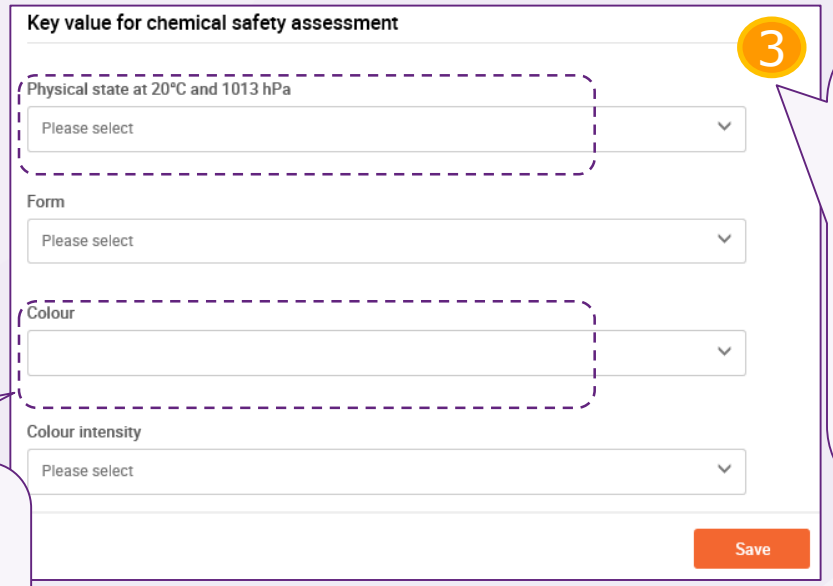
‘Colour and physical state’



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



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



If you selected +Create in the previous step, a new General information document is created. Here, the physical state and colour are mandatory fields, while form and colour intensity are optional.

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

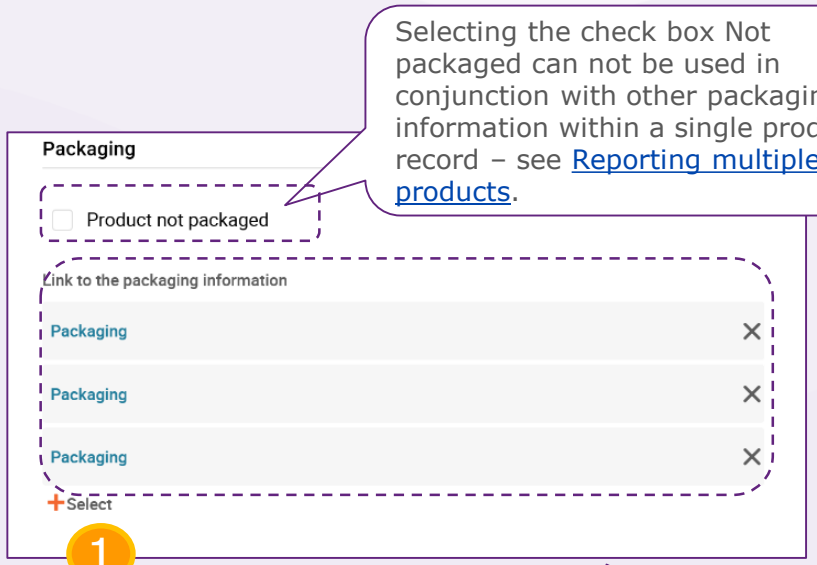
Single or multiple colour selections (x 15 total) are available. Selecting multiple colours, e.g. white and yellow, means that the product comes in white or yellow variations.

An additional colour selection ‘**Mixtures containing generic product identifiers ‘colouring agents’** is available, and all relevant colours must be additionally selected.

Poison centres

‘Packaging’

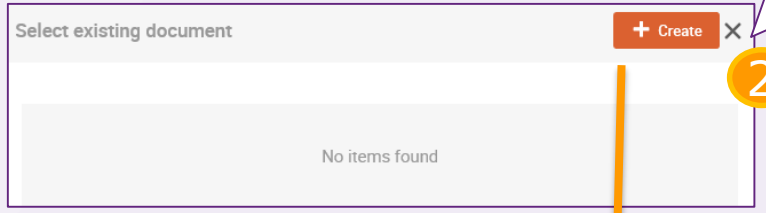
If a mixture is supplied in different types and sizes of packaging, information on all the relevant types and sizes placed has to be included. Note that mixtures for industrial use are not required to have packaging indicated.



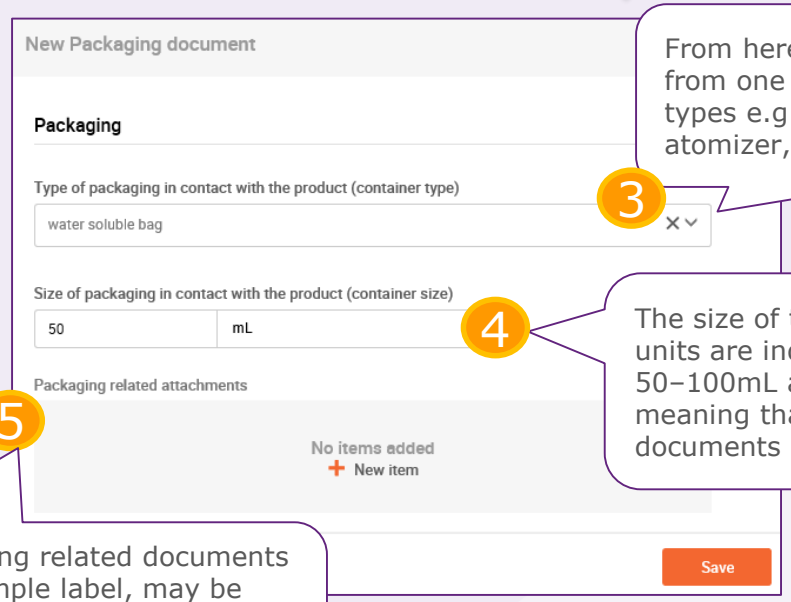
Selecting the check box Not packaged can not be used in conjunction with other packaging information within a single product record – see Reporting multiple products.

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

Multiple packaging documents for a product are displayed here.



Select +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.

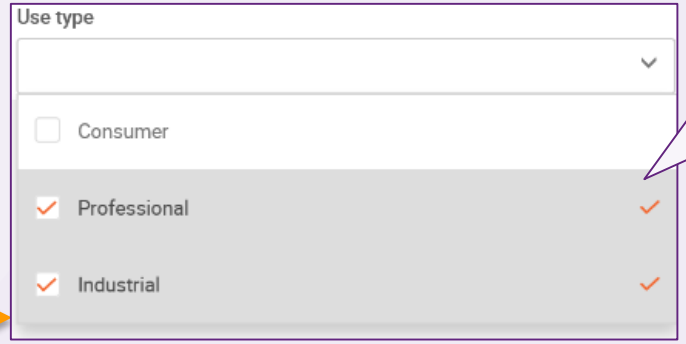
Any packaging related documents e.g. an example label, may be included here. Files accepted include, but are not limited to pdf, word, jpeg.

Poison centres

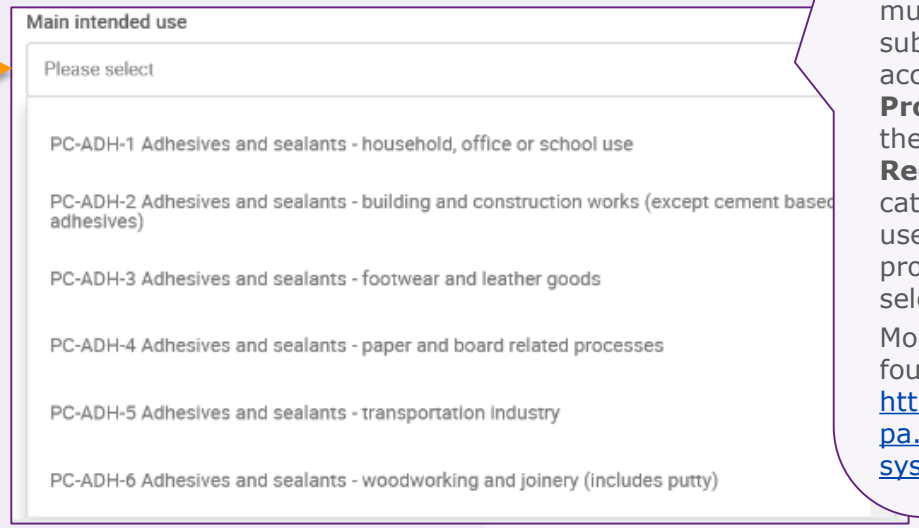
‘Product use category’

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.

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.



Selection of multiple use types for the mixture is possible.



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

Poison centres

Validate information, create dossier and preview notification

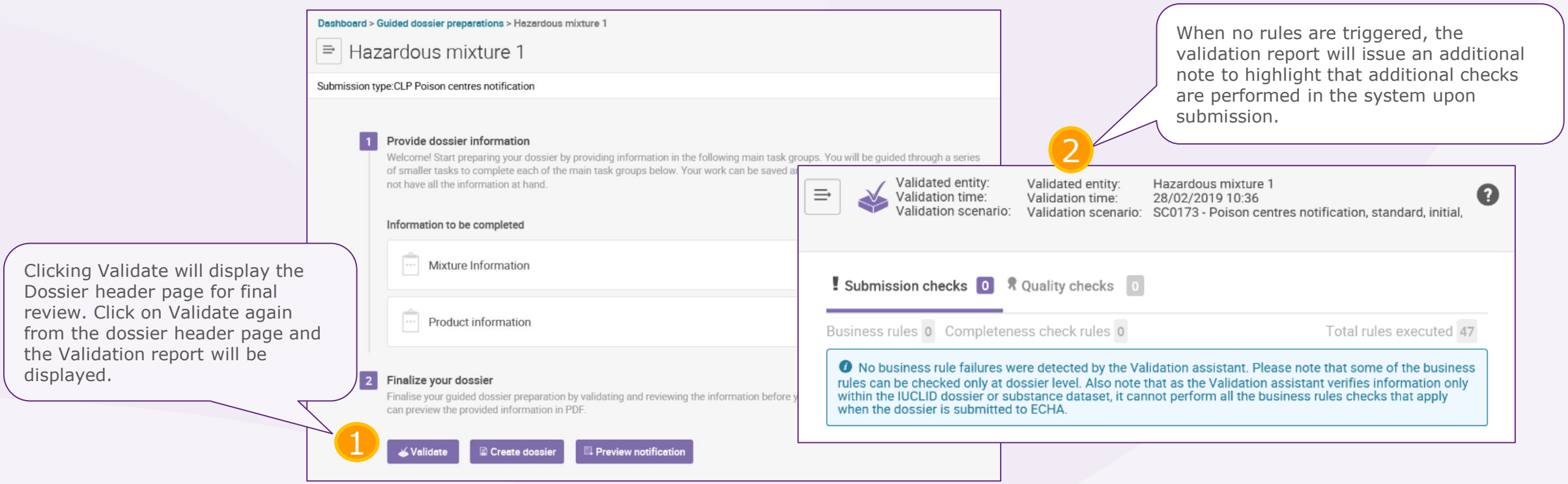
An explanation of the functionalities to finalise the dossier preparation process; validate, create a dossier, and preview notification.

Poison centres

The validation assistant

The validation assistant carries out checks according to a set of pre-defined rules to verify that 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.

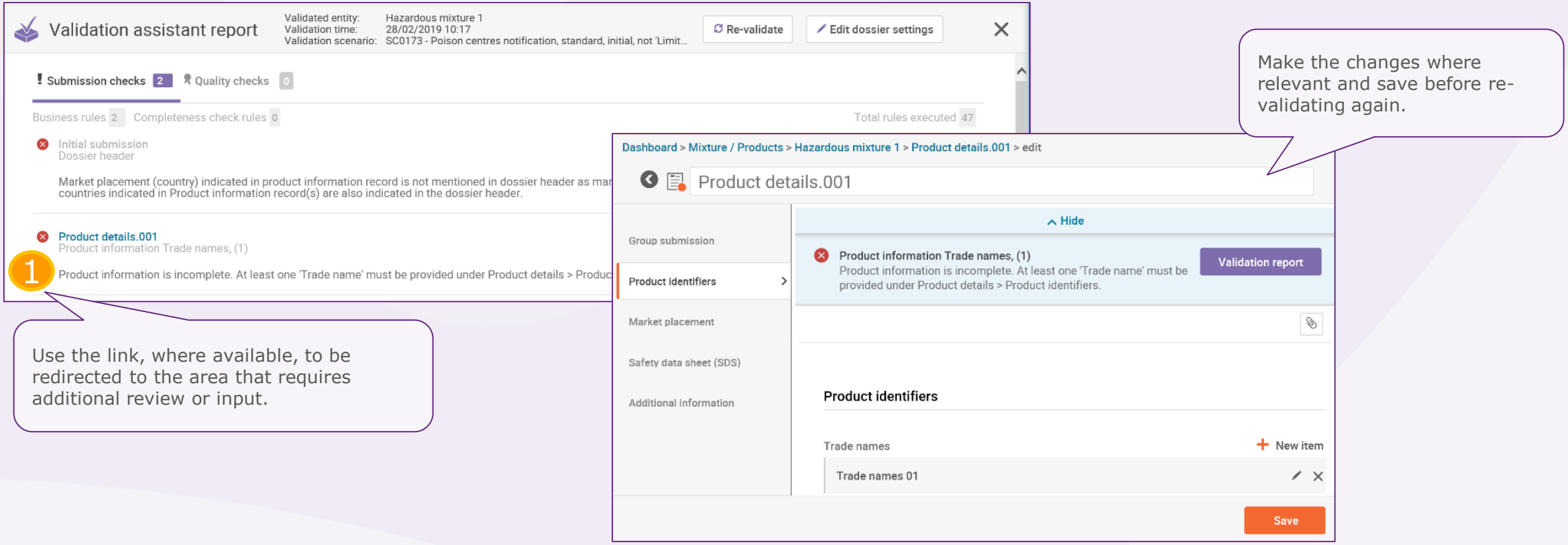
The outcome of the validation is a report, which lists the rules (if any) for which the validation assistant was triggered. For a list of the rules, you may refer to the Annex available at: https://poisoncentres.echa.europa.eu/poison-centres-notification-format



Poison centres

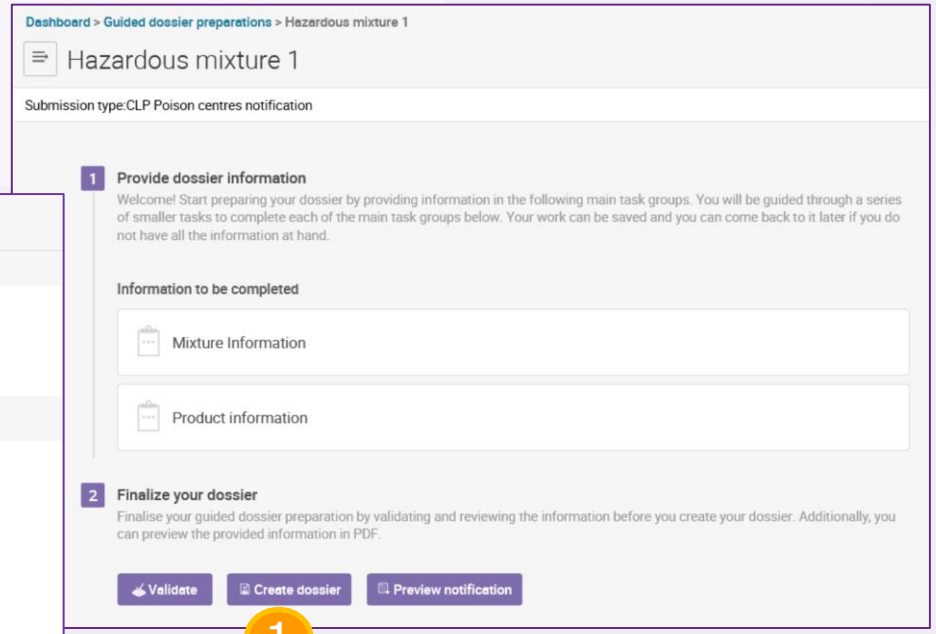
The validation report

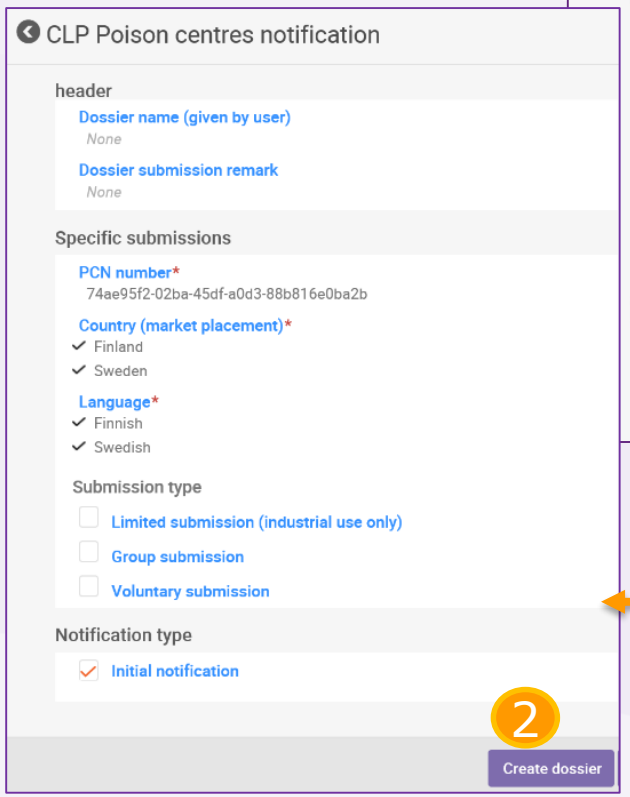
When rules are triggered, the validation report will listing the submission checks as failures or warnings.



Poison centres

Creating and submitting (or exporting) the dossier



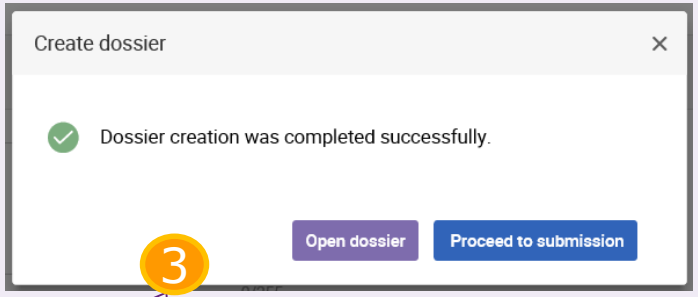


1

2

Clicking Create dossier will display the Dossier header page for final review.

Click on Create dossier again from the dossier header page.



3

4

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.

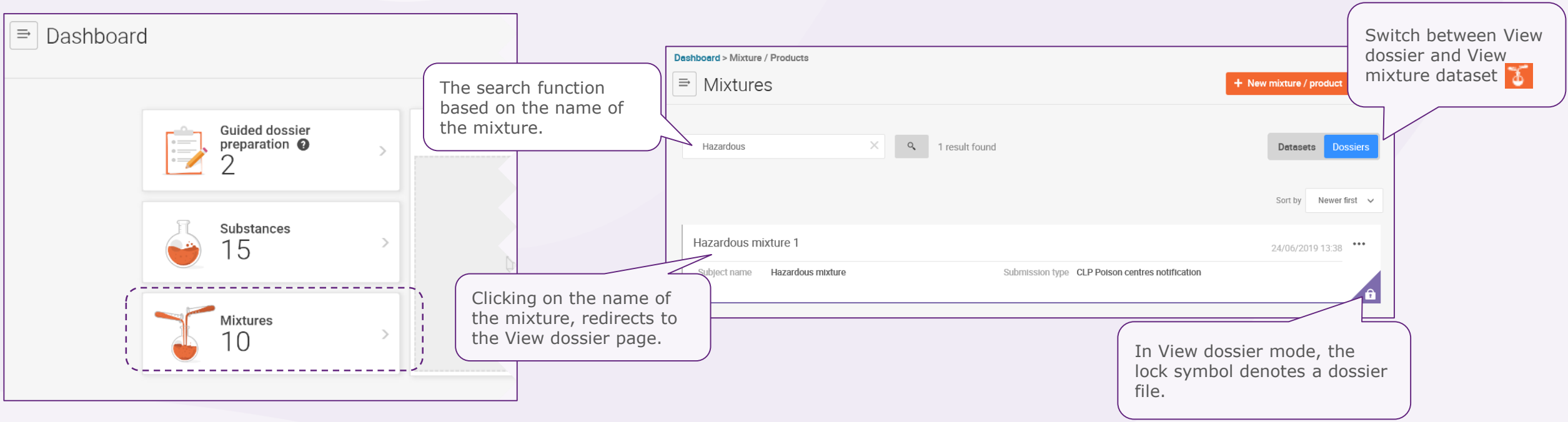
Note, clicking **Proceed to submission** automatically uploads the dossier to the ECHA Submission portal – you will still need to use the Submit functionality – see Upload and submit.

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.

Poison centres

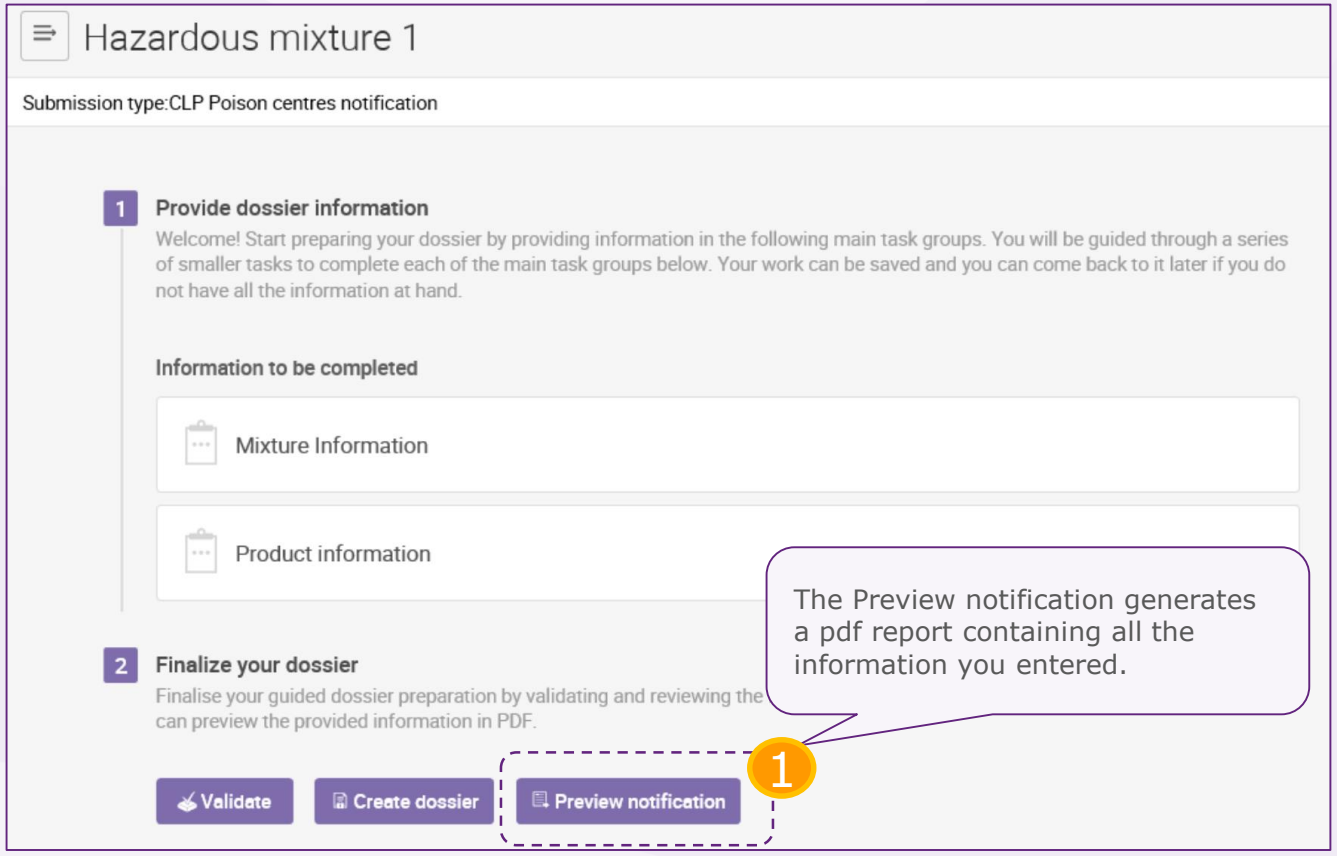
Locating the dossier

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.



Poison centres

Preview notification



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

2

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

Poison centres

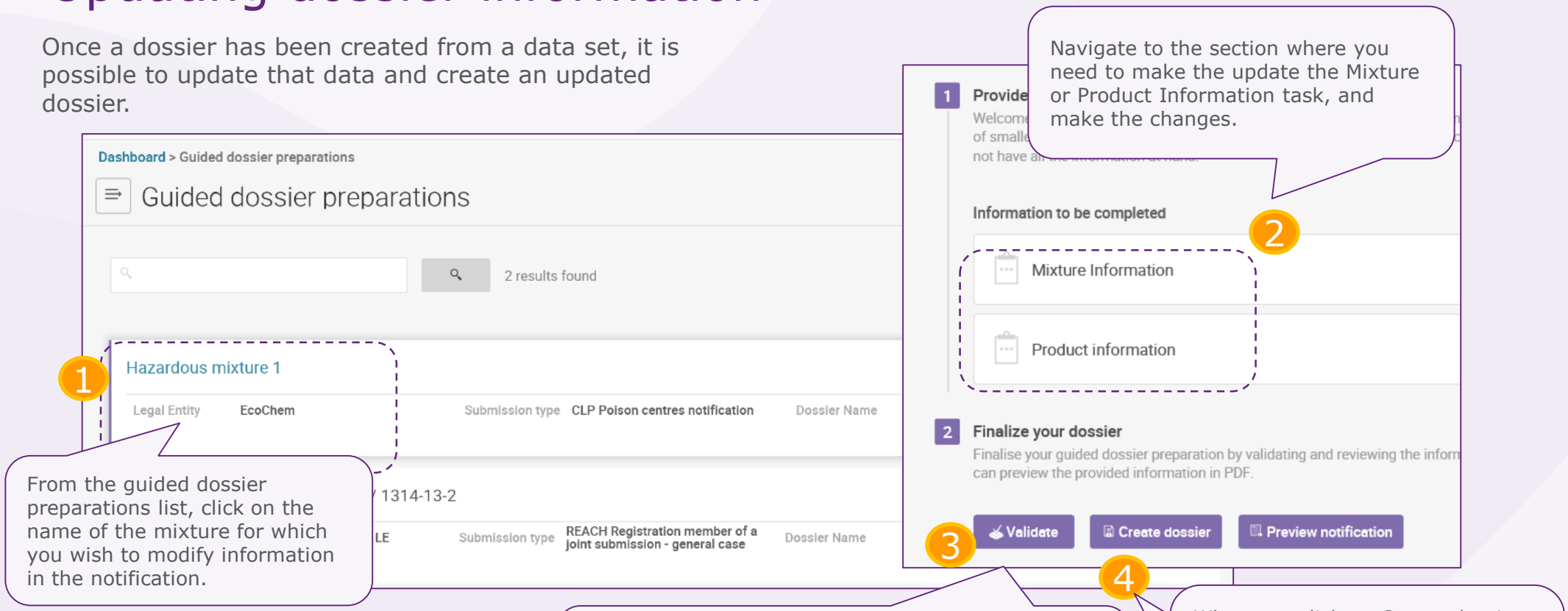
Updating dossier information

An explanation on how to prepare for a dossier update.

Poison centres

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.



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

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

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

Poison centres

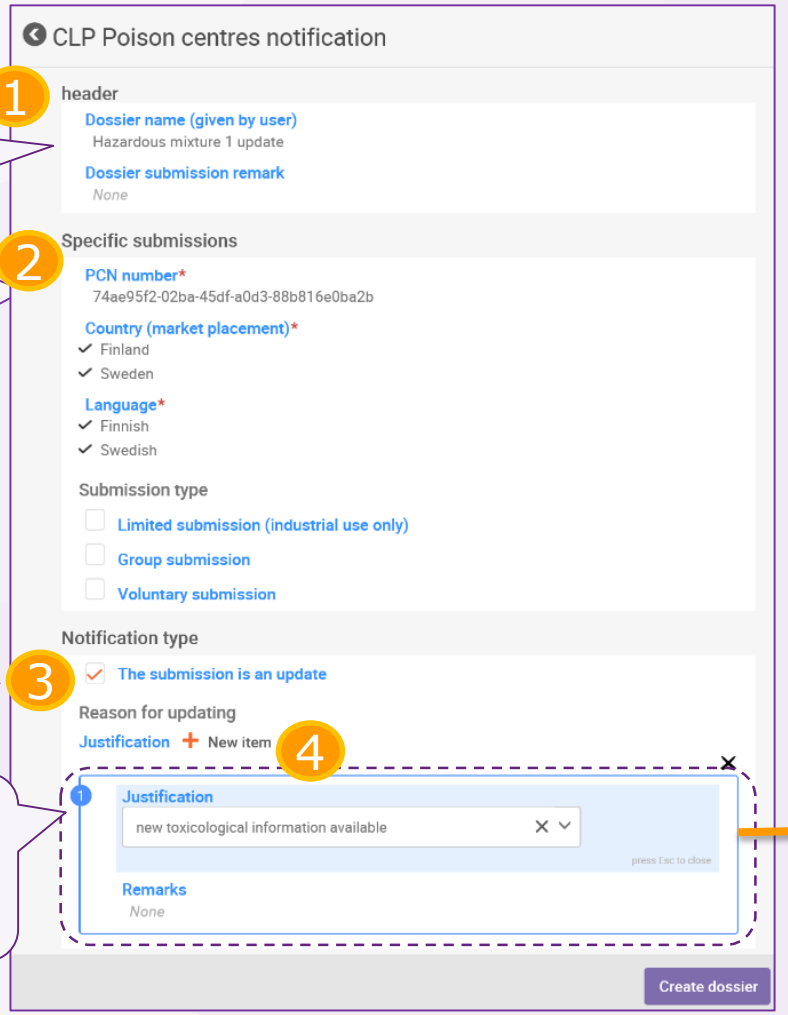
Updating the dossier header for a submission update

The dossier should be given a new and meaningful name.

The PCN number remains the same in the update dossiers.

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

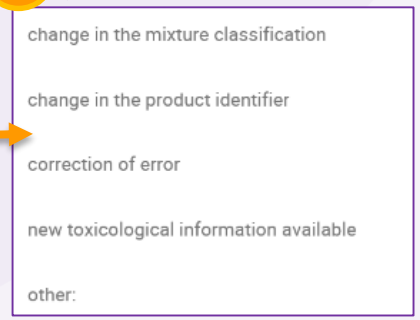
In the Reason for updating field, click on +New item and make a selection from the available picklist. Multiple reasons for updating are allowed.



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.

Click on Create dossier to finalise the process.

5

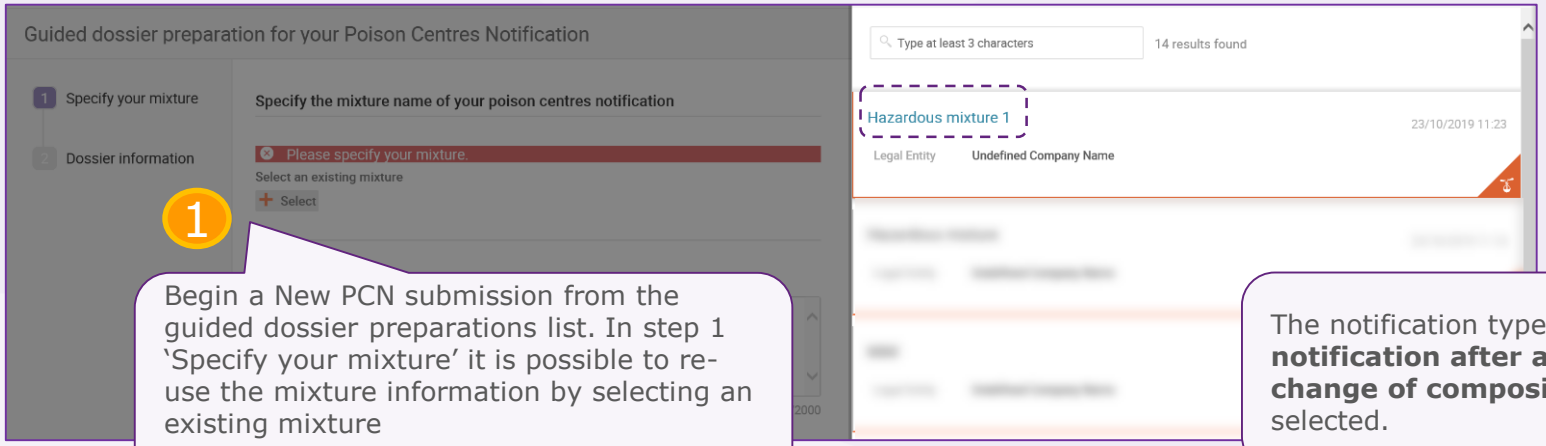


Poison centres

Updating the dossier header when the mixture significantly changes in composition

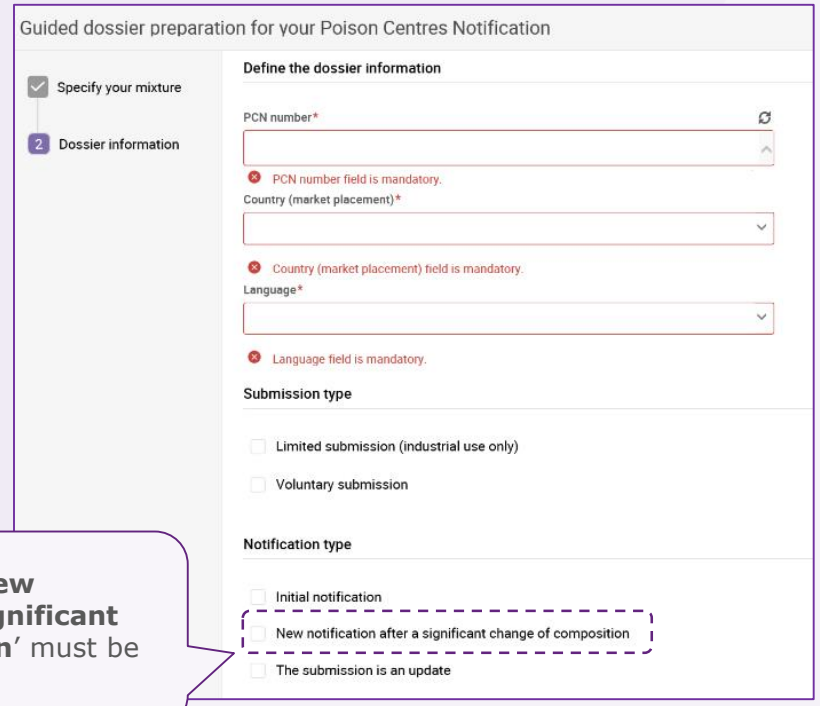
When the mixture composition changes beyond the allowable limits defined in Annex VIII to the Classification and Labelling Regulation, by default, this will lead to two different 'products' on the market. In this case, a notification for the new composition must be made (containing a new PCN number)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



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

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.



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