

Poison centre notifications

# PCN: a practical guide

Version 4.0 - October 2021

# ABC

## Disclaimer

This document aims to assist users in complying with their Article 45 and Annex VIII obligations under the CLP Regulation. However, users are reminded that the text of the CLP Regulation is the only authentic legal reference and that the information in this document does not constitute legal advice. Usage of the information remains under the sole responsibility of the user. The European Chemicals Agency does not accept any liability with regard to the use that may be made of the information contained in this document.

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2.0	Changes to represent the release of the latest version of the IT solution to prepare and submit poison centre notifications.	October 2020
3.0	Changes throughout the document to reflect the latest changes in IUCLID and improves all sections for clarity and general enhancement.	May 2021
4.0	Changes to represent the release of the latest version of the IT solution to prepare and submit poison centre notifications, namely the PCN format version 4.	October 2021

## PCN: a practical guide

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## 1. Introduction

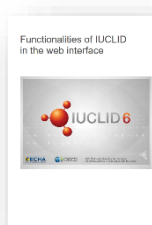
This manual gives practical guidance to support industry with their poison centre notification (PCN) obligations according to Article 45 and Annex VIII to the CLP Regulation<sup>1</sup>.

The document explains how to access ECHA's IT applications and establish third party users to work on behalf of another company. It also covers some practical issues specific to companies making poison centre notifications such as ensuring the consistency of legal entities when using various ECHA's IT tools.

Additionally, this manual looks at how to create IUCLID<sup>2</sup> 'datasets' (editable files) and build a valid dossier (non-editable file) that can be submitted to the Member States appointed bodies, for example, through the ECHA Submission portal.

Explanations of the complete functioning of IUCLID is comprehensively covered in the **IUCLID Functionalities Manual** (translations are provided)

<https://iuclid6.echa.europa.eu/documentation>



Full information requirements according to the legal text are covered in the **Guidance on Annex VIII** (translations are provided)

<https://echa.europa.eu/guidance-documents/guidance-on-clp>



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<sup>1</sup> Annex VIII to CLP Regulation [https://eur-lex.europa.eu/eli/reg\\_del/2020/1677/oj](https://eur-lex.europa.eu/eli/reg_del/2020/1677/oj)

<sup>2</sup> International Uniform Chemical Information Database - IUCLID is a key application used by industry and authorities to prepare, store and exchange data on chemicals in a harmonised format

## 2. Accessing ECHA's IT applications

You must create an ECHA Account if you want to use the available IT applications provided by ECHA e.g. ECHA Cloud Services or ECHA Submission portal for preparing or submitting your poison centre notifications.

The **ECHA Accounts manual** explains how to create, export, import and manage a legal entity in general:

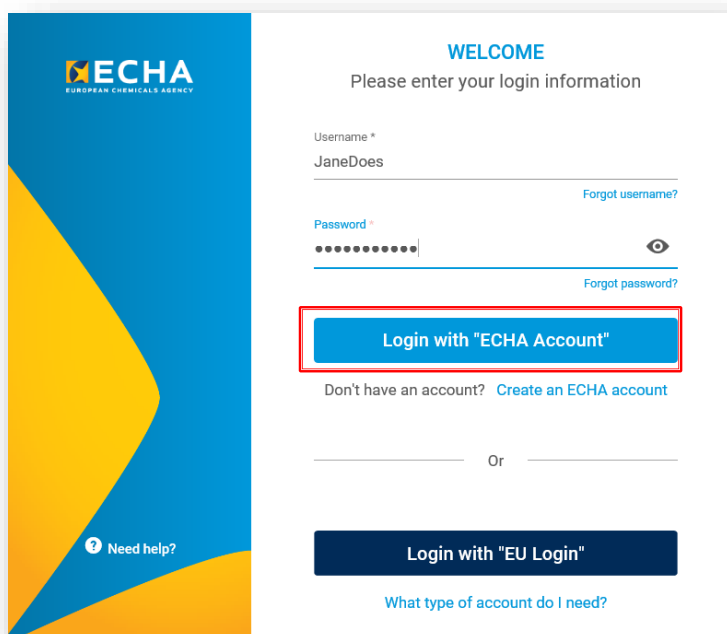
[https://www.echa.europa.eu/documents/10162/21721613/echa\\_accounts\\_en.pdf/](https://www.echa.europa.eu/documents/10162/21721613/echa_accounts_en.pdf/)



### 2.1 Step 1 - Create an ECHA Account

The 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 by creating an account first. To create an ECHA Account you will need to provide specific information about your company and verify your email address.

! It is recommended to use the latest version of **Chrome**, **Firefox** and **Microsoft Edge** to guarantee the best user experience.



**ECHA**  
EUROPEAN CHEMICALS AGENCY

**WELCOME**  
Please enter your login information

Username \*  
JaneDoes  
[Forgot username?](#)

Password \*  
●●●●●●●●  
[Forgot password?](#)

**Login with "ECHA Account"**

Don't have an account? [Create an ECHA account](#)

Or

**Login with "EU Login"**

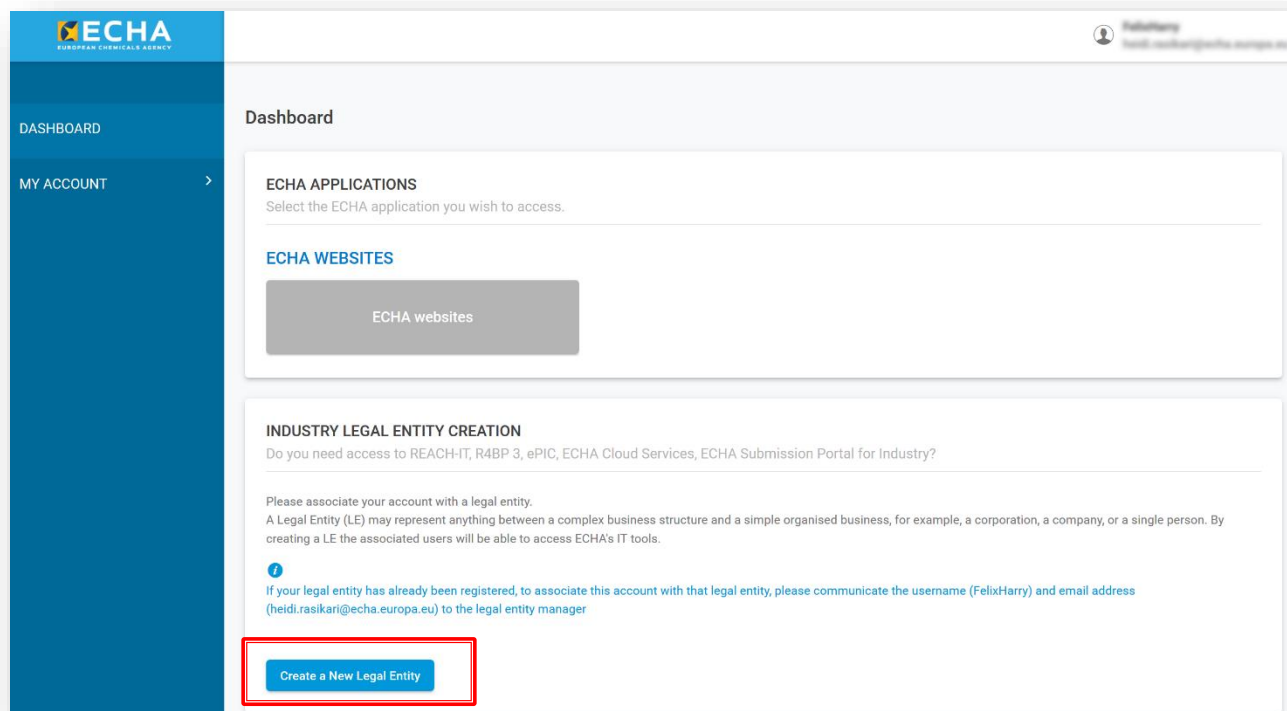
[What type of account do I need?](#)

[Need help?](#)

## 2.2 Step 2 - Assign a legal entity to the ECHA Account

Submissions made through the ECHA Submission portal are carried out by Legal Entities<sup>3</sup> which have to be defined, including contact details, prior to submission.

Once you have created an ECHA Account and you have logged in successfully, a Legal Entity must be assigned to it.



To assign the legal entity click on Create New legal Entity. You have two options:

- i) **create a new legal entity** in ECHA Accounts and enter specific information about the company (section 2.2.1).

OR

- ii) **import a pre-existing legal entity** e.g. from IUCLID desktop (section 2.2.2).



Once a legal entity has been assigned, the Industry Applications will become visible in the ECHA Accounts dashboard and the user can access the application from the available list e.g. REACH-IT, R4BP3, ePIC, ECHA Cloud services, ECHA Submission portal.

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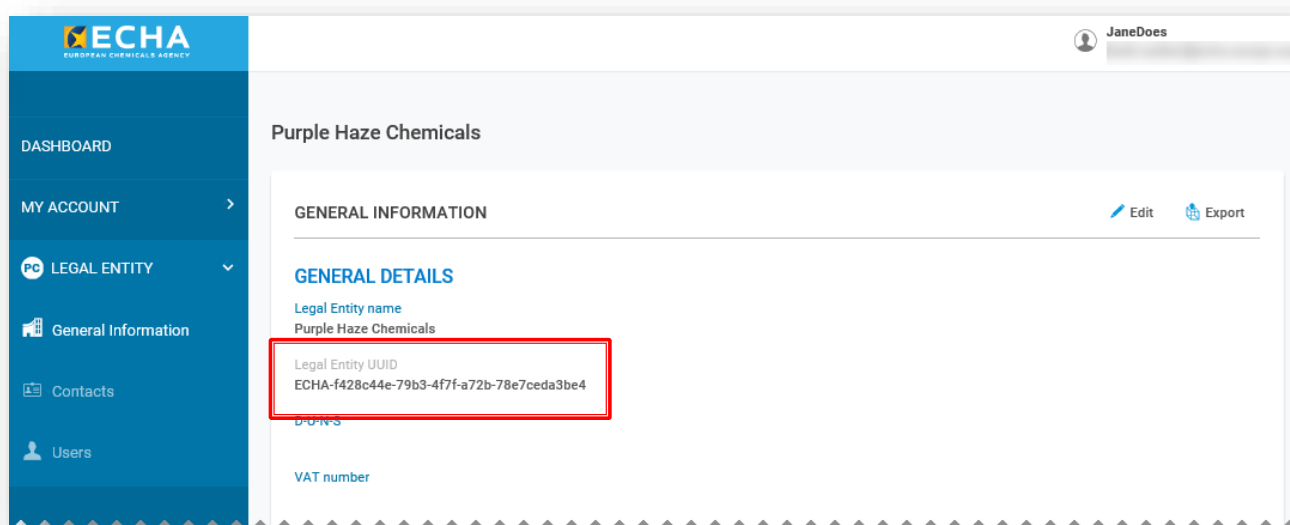
<sup>3</sup> A legal entity may represent anything between a complex business structure and a simple organised business, for example, to a corporation, a company, or a single person.

### 2.2.1 Create a new Legal Entity

Selecting create new legal entity opens a page where you need to enter information about the company, address, contact details, account security information. Upon creation, the Legal Entity is assigned an automatically generated universal unique identifier (UUID<sup>4</sup>) number so that the ECHA IT applications can explicitly identify the users and their actions.

The UUID numbers generated in ECHA Accounts contain the pre-fix 'ECHA-...'

**!** Non-EU legal entities can work in ECHA Cloud Services e.g. to prepare a notification but cannot access the ECHA Submission portal.



The screenshot displays the ECHA Cloud Services interface for a user named 'JaneDoes'. The main content area is titled 'Purple Haze Chemicals' and shows the 'GENERAL INFORMATION' section. Under 'GENERAL DETAILS', the 'Legal Entity name' is 'Purple Haze Chemicals' and the 'Legal Entity UUID' is 'ECHA-f428c44e-79b3-4f7f-a72b-78e7ceda3be4', which is highlighted with a red box. The 'VAT number' field is also visible. The left sidebar contains navigation options: DASHBOARD, MY ACCOUNT, LEGAL ENTITY (selected), General Information, Contacts, and Users.

### **!** Billing information

For certain submission processes, like submissions under REACH Regulation, the submitter has to pay a fee directly to ECHA. That's why in the registration form, you are asked to provide your billing information. However, ECHA does not charge any fee for poison centre notifications. In this context, please note that some Member States charge fees. For more information please make contact with the national authorities of the Member States where you want to place your product on the market in order to receive detailed information about that <https://poisoncentres.echa.europa.eu/appointed-bodies>

## 2.2.2 Importing a pre-existing legal entity from IUCLID

If you are a IUCLID desktop user, you will already have previously created a Legal Entity (prefix `IUC...'). Note that ECHA IT applications such as the Submission portal, will identify you by the legal entity UUID in ECHA Accounts and check it against the legal entity contained in the notification – therefore legal entities in both places must be matching.

In this case, you may prefer to either:

- i) export your legal entity from ECHA Accounts to your working instance of IUCLID, or,
- ii) export your legal entity from IUCLID to ECHA Accounts.

In the latter case, once your legal entity has been exported from IUCLID to e.g. your desktop, you can import it directly in the legal entity creation form by activating the section 'Creation method', and selecting the file for upload.

**ECHA**  
EUROPEAN CHEMICALS AGENCY

DASHBOARD  
MY ACCOUNT >

### Create Legal Entity

#### CREATE LEGAL ENTITY

In order to use ECHA's submission systems you need to provide your Legal Entity's details, contact information, users, etc. Please continue by selecting either Encode Leg...

#### ACCOUNT SECURITY

Security Question \*  
What is your pet's name?

#### ALERTS

Receive email alerts for unfamiliar signing-in activities to ECHA applications using your account

#### CREATION METHOD

If you already have a legal entity definition file in IUCLID exchange format (also known as the LEOX file format), and if you want to have the same UUID for your legal entity definition as fo... fields will be completed automatically and you will be redirected to the Legal Entity profile screens to review / update imported details as well as to enter additional details.

Import IUCLID Format File \*

Please attach an IUCLID exchange format (LEOX file format)

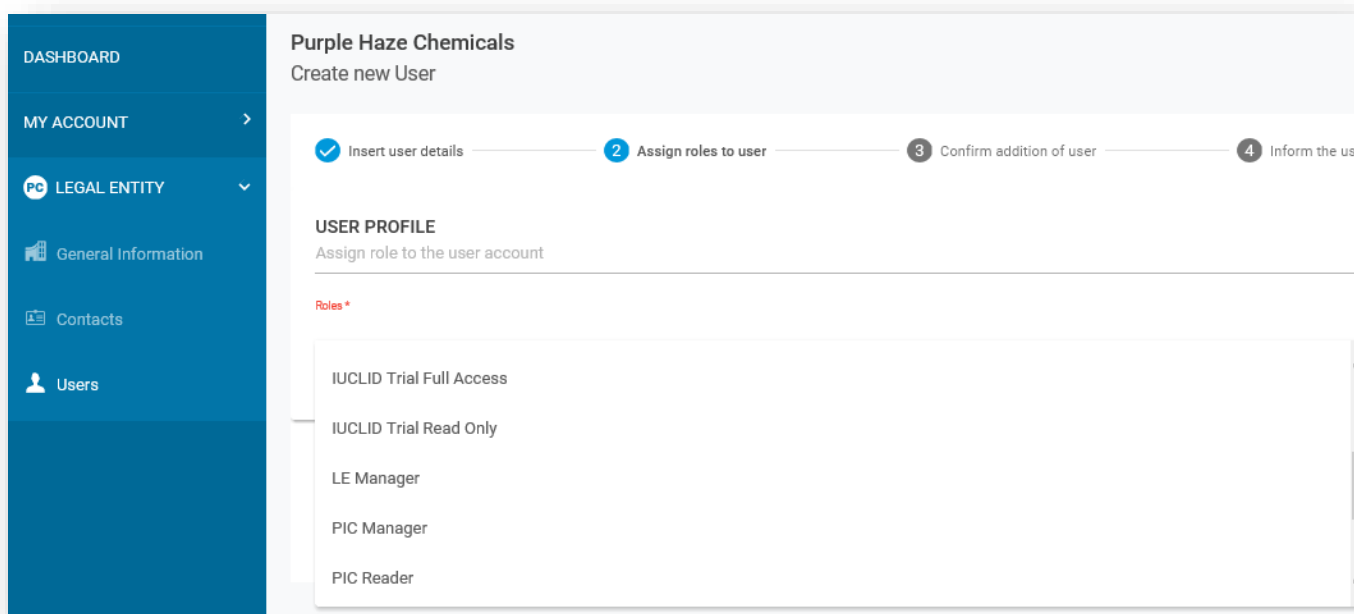
#### GENERAL DETAILS

When working from IUCLID desktop, information about the legal entity cannot be automatically synchronised with ECHA Accounts. Therefore, in cases where a company has installed IUCLID in their local systems or develops their own tool to create PCN dossiers, any legal entity changes made in ECHA Accounts will have to be replicated in those dossier preparation tools.

## 2.3 Step 3 – Add users & define/manage user roles

By default, the user who created the account is the Legal Entity Manager, and additional users can also be added to the account using the 'Create New User' wizard. The user roles define the user access level within the ECHA IT applications. The specific PCN related roles include:

- **LE manager**: 'legal entity manager', can view and edit the legal entity 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.



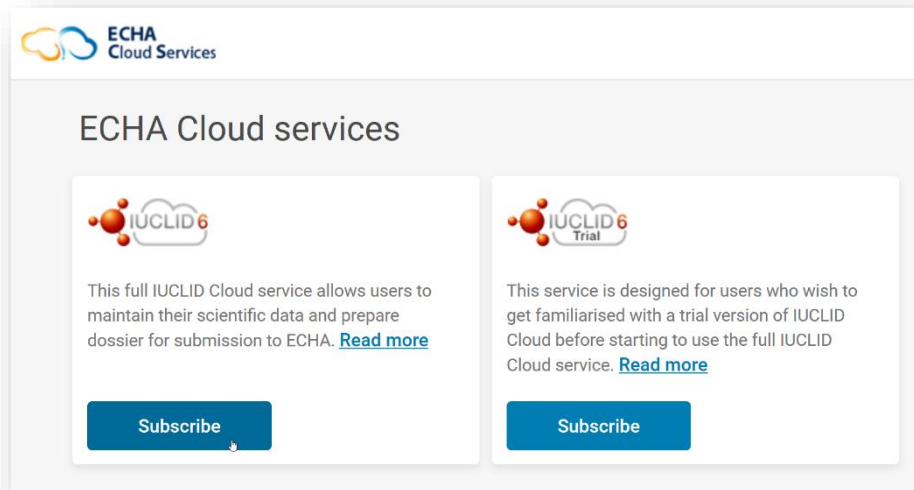
Only a user with the 'LE manager' role can edit the legal entity details – all details can be edited except for the Legal Entity UUID and the country.

Adding, modifying or deleting users, contacts and user roles is all managed in ECHA Accounts in the relevant tab under 'Legal entity profile'.

**!** It is possible for a legal entity to allow a user from another legal entity i.e. a 'third party' to work on their behalf, for example, a consultant or a non-EU company. This is possible with the '**foreign user**' functionality in ECHA Accounts. **Appendix 1** explains how to establish a foreign user using a consultant as an example

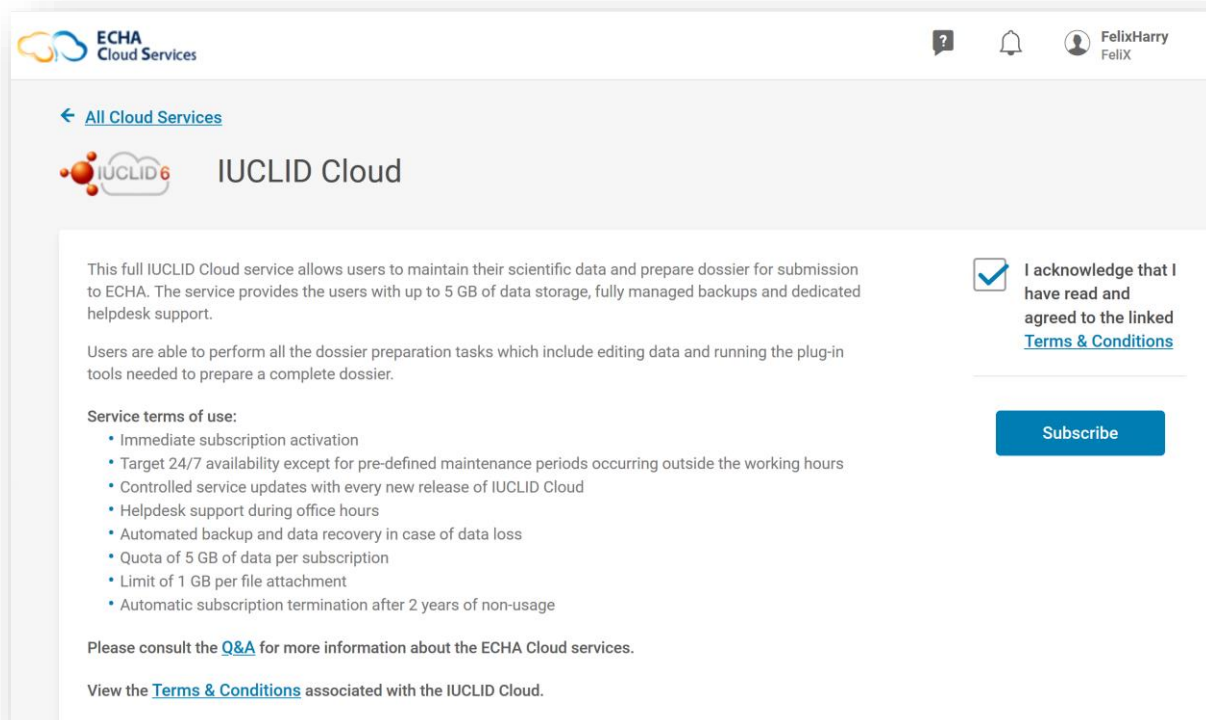
## 2.4 Step 4 - Subscribing to the Cloud services

Following the creation of an ECHA Account and legal entity, new users will need to 'Subscribe' to ECHA Cloud Services before they can begin to work in the application.



The screenshot shows the ECHA Cloud Services landing page. At the top left is the ECHA Cloud Services logo. The main heading is "ECHA Cloud services". Below this, there are two service cards. The first card is for "IUCLID 6" and describes a full service for maintaining scientific data and preparing dossiers. It includes a "Subscribe" button. The second card is for "IUCLID 6 Trial" and describes a trial version for familiarization. It also includes a "Subscribe" button. Both cards have a "Read more" link.

The IUCLID Cloud Terms and Conditions must be accepted before use.



The screenshot shows the IUCLID Cloud subscription page. At the top left is the ECHA Cloud Services logo. In the top right corner, there are icons for help, notifications, and a user profile for "FelixHarry Felix". Below the logo is a navigation link "All Cloud Services". The main heading is "IUCLID Cloud". The page contains a detailed description of the service, including its features and service terms of use. A checkbox is checked, indicating that the user has read and agreed to the linked Terms & Conditions. A "Subscribe" button is located at the bottom right of the page.

This full IUCLID Cloud service allows users to maintain their scientific data and prepare dossier for submission to ECHA. The service provides the users with up to 5 GB of data storage, fully managed backups and dedicated helpdesk support.

Users are able to perform all the dossier preparation tasks which include editing data and running the plug-in tools needed to prepare a complete dossier.

**Service terms of use:**

- Immediate subscription activation
- Target 24/7 availability except for pre-defined maintenance periods occurring outside the working hours
- Controlled service updates with every new release of IUCLID Cloud
- Helpdesk support during office hours
- Automated backup and data recovery in case of data loss
- Quota of 5 GB of data per subscription
- Limit of 1 GB per file attachment
- Automatic subscription termination after 2 years of non-usage

Please consult the [Q&A](#) for more information about the ECHA Cloud services.

View the [Terms & Conditions](#) associated with the IUCLID Cloud.

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

**Subscribe**

### 3. Ways to prepare and submit

There are several options for a company to prepare and submit poison centre notification (PCN) information depending on the company's preferences and internal systems in place.

All notifications need to adhere to the harmonised PCN format dedicated to structuring the information on hazardous mixtures classified for health or physical hazards. The format is XML-based and defined by the requirements laid out in Annex VIII to the CLP Regulation.

For the preparation and submission of information, ECHA has made available:

- Poison centre notification (PCN) format (section 3.1)
- IUCLID online and offline (section 3.2)
- System-to-system(S2S) service (section 3.3)
- ECHA Submission portal (section 3.4)

#### Additional support on the various ways to prepare and submit

Check our e-Learning page for trainings, webinars and other presentations:

<https://poisoncentres.echa.europa.eu/training-material>

#### 3.1 The Poison centre notification (PCN) format

The PCN format structures the harmonised information requirements on hazardous mixtures classified for health or physical hazards available to poison centres in cases of poisoning incidents in the EU.

The PCN format is .xml-based and is compatible with IUCLID and as such is incorporated into the PCN dossier preparation tools offered by ECHA. It is also available for companies to incorporate into their own tools for dossier preparation, for example when using the system-to-system service.

#### Additional support on the PCN format

For system-to-system users, you can download the latest version of the PCN format and related documents from the poison centre website here:

<https://poisoncentres.echa.europa.eu/poison-centres-notification-format>

## 3.2 IUCLID 6 for data preparation

This chapter looks at both the IUCLID Cloud (online) and IUCLID (offline) tools for manual preparation of poison centre notifications using the customised PCN dataset. Both tools offer the same interface and functionalities.

### 3.2.1 IUCLID Cloud & ECHA Cloud services

The ECHA Cloud services (<https://idp-industry.echa.europa.eu/idp/>) are maintained, backed-up, updated by ECHA and the data is securely stored in the Cloud. This platform features services for data preparation and data submission.

The ECHA Cloud services dashboard features data preparation services covering **IUCLID Cloud** (full service and Trial version), and submission services covering the **ECHA Submission portal** (full service and Trial version).

**IUCLID 6 Trial version** can be used for getting familiar with the tool. It is not possible to 'Proceed to submission' via the Trial version, however it is possible that any notifications created in the Trial can be accessed in the Full version and submitted from there if required.

**ECHA Submission portal trial version** layout is designed to alert users they are in the Trial version. Any dossiers for testing purposes are not forwarded to recipients indicated in the notification.

### 3.2.2 IUCLID 6 via download from IUCLID website

Offline preparation is always recommended using the latest version of IUCLID 6 which can be downloaded from the IUCLID website(<https://iuclid6.echa.europa.eu/home>).

The screenshot shows the IUCLID 6 website homepage. At the top left is the IUCLID 6 logo. To the right is a search bar with the text "Search the IUCLID 6 website". Below the logo and search bar is a navigation menu with the following items: Home, IUCLID Product, Download Software, Support, and News. Below the navigation menu, there is a "Download IUCLID" button highlighted with a red box. To the right of the button, there are several news items with dates and titles, such as "11/03/2021 - REACH Study Results refreshed", "01/02/2021 - IUCLID updated in ECHA Cloud Services", "12/01/2021 - New IUCLID YouTube Channel – Subscribe now!", "16/12/2020 - Patch available for IUCLID 6.5", and "28/10/2020 - IUCLID 6.5 is available".

Both desktop and server versions are available for the user who will need to perform their own maintenance activities.

⚠ Ensure you have the latest version of IUCLID as only the most recent version can fully accommodate the poison centre requirements and avoid unnecessary failures.

Explanations of the complete functioning of IUCLID is comprehensively covered in the **IUCLID Functionalities Manual** (translations are provided)

<https://iuclid6.echa.europa.eu/documentation>

Functionalities of IUCLID  
in the web interface



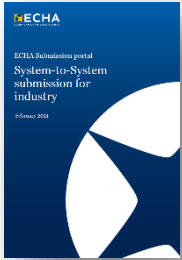


### 3.3 System-to-system service

The system-to-system (S2S) service is available to support industry who wish to prepare and submit a PCN dossier in a more automated way. Through this service, a company can create a PCN dossier directly in their own systems using the IUCLID-compatible PCN format and make a submission to the ECHA Submission portal. Dossiers are then forwarded from the portal to all the relevant Member States.

Using the system-to-system service for the first time requires a company to:

1. Request and get access to the ECHA Submission portal 'S2S' services
2. Generate the 'S2S' keys
3. Integrate their system with the ECHA Submission portal services
4. Successfully pass the connectivity and integration tests before switching to Production mode

<p>The <b>Guide to the PCN format</b> and other key documents <a href="https://poisoncentres.echa.europa.eu/poison-centres-notification-format">https://poisoncentres.echa.europa.eu/poison-centres-notification-format</a></p>	
<p>The <b>Developers Guide to the IUCLID format</b> <a href="https://poisoncentres.echa.europa.eu/poison-centres-notification-format">https://poisoncentres.echa.europa.eu/poison-centres-notification-format</a></p>	
<p><b>System-to-system integration for industry</b>, gaining access to the service, technical/practical documentation and related files <a href="https://poisoncentres.echa.europa.eu/system-to-system-service">https://poisoncentres.echa.europa.eu/system-to-system-service</a></p>	

### 3.4 ECHA Submission portal for poison centre notifications

The ECHA Submission portal is an online tool for EU based companies and can be used for the submission of poison centre notifications. Submissions made through the portal can accommodate multi-market notifications, meaning that one submission can reach multiple Member States Appointed Bodies.

! Companies are advised to refer to the 'Overview of Member States decisions on implementing Annex VIII to the CLP' key document which details to which Member duty holders can notify their mixtures through the ECHA Submission portal.

**Overview of Member States decisions in relation to Implementation of Annex VIII to the CLP Regulation (Poison Centre Notification)**

Disclaimer: The information is based on input from Member States. The declarations of Member States are indicative and subject to changes. ECHA aims at updating this document to reflect the latest status. For further information, please contact national CLP Helpdesk: [helpdesk@echa.europa.eu](mailto:helpdesk@echa.europa.eu)

Member State	Readiness of Member States to accept notifications via ECHA submission portal	Submission system options	Notification language	Fees for notifications	Placing on the market mixtures notified via ECHA submission portal
AT	Duty holders can notify their mixtures through the ECHA Submission portal	Once confirmed they are accepting, Member States will only accept via ECHA submission portal	Duty holder may choose notification language between official language of the Member State or English (includes Member States where English is official language)	No fees	Duty holder can start placing the mixture on the market immediately after confirmation in the submission report that the dossier has passed the national validation checks in the portal (without needing further approval from the Member State)
BE	Duty holders must continue to notify their mixtures according to national systems until further notice	Once confirmed they are accepting, Member States will accept notifications via the ECHA Submission portal, OR, their national submission system.	Duty holder must notify in one official language of the Member State (other than English)	Fees levied by Member State appointed body. Please contact the relevant appointed body for more details.	Duty holder can start placing the mixture on the market only after confirmation in the submission report that the dossier has been reviewed by the Member State appointed body.
DE			Duty holder must notify in multiple official languages of the Member State (other than English)	Fees under consideration. Please contact the relevant appointed body for more details.	
FR					
IT					
NL					
PT					
SE					
UK					

[https://poisoncentres.echa.europa.eu/documents/22284544/27487986/msd\\_en.pdf/](https://poisoncentres.echa.europa.eu/documents/22284544/27487986/msd_en.pdf/)

To make submissions through the ECHA Submission portal a company must:

1. Have an active ECHA account
2. Have users assigned with the correct roles and subscribed to the service
3. Be logged in to the ECHA Submission portal

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

The ECHA Submission portal dashboard landing page allows you to navigate to various functionalities of the system. In addition to CLP poison centre notifications, other notification and application types are also supported.

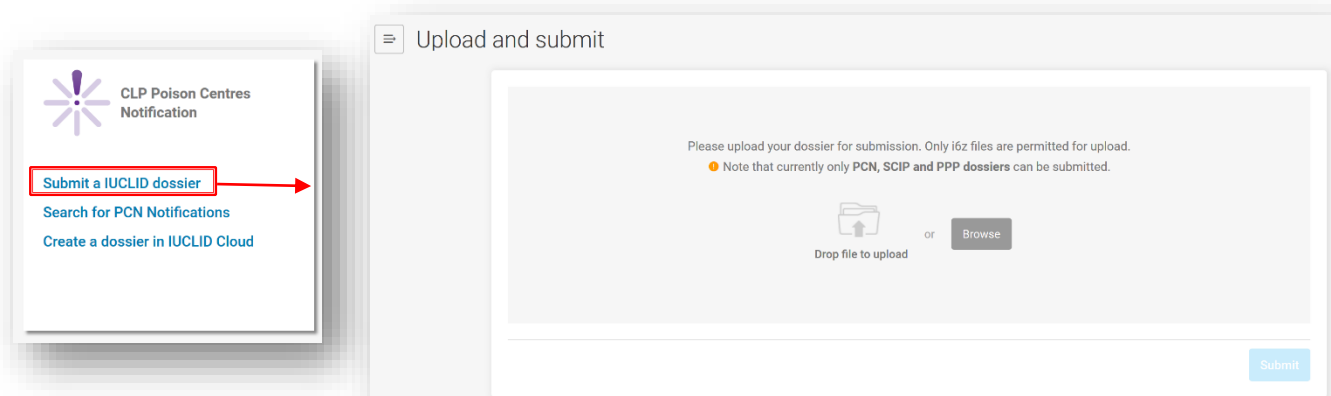
The screenshot shows the ECHA Submission portal dashboard. At the top, there is a navigation bar with the ECHA logo and the text 'ECHA Submission portal'. Below this, a 'Dashboard' header is visible. The main content area features a 'Welcome to ECHA Submission portal' message. Three primary action cards are displayed:

- CLP Poison Centres Notification:** Includes links for 'Submit a IUCLID dossier', 'Search for PCN Notifications', and 'Create a dossier in IUCLID Cloud'.
- SCIP Notification:** Includes links for 'Submit a IUCLID dossier', 'Submit a simplified SCIP Notification', 'Search for SCIP Notifications', and 'Create a dossier in IUCLID Cloud'.
- EFSA Application:** Includes links for 'Submit a IUCLID dossier', 'Search for EFSA Applications', and 'Create a dossier in IUCLID Cloud'.

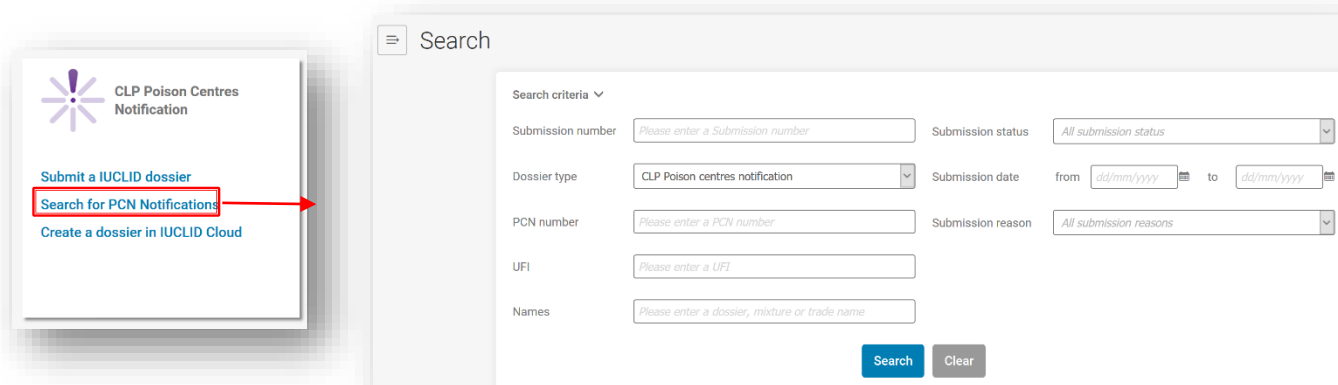
At the bottom of the dashboard, there is a search bar with a magnifying glass icon and a link labeled 'All submissions'.

For poison centre notifications, the following functionalities include:

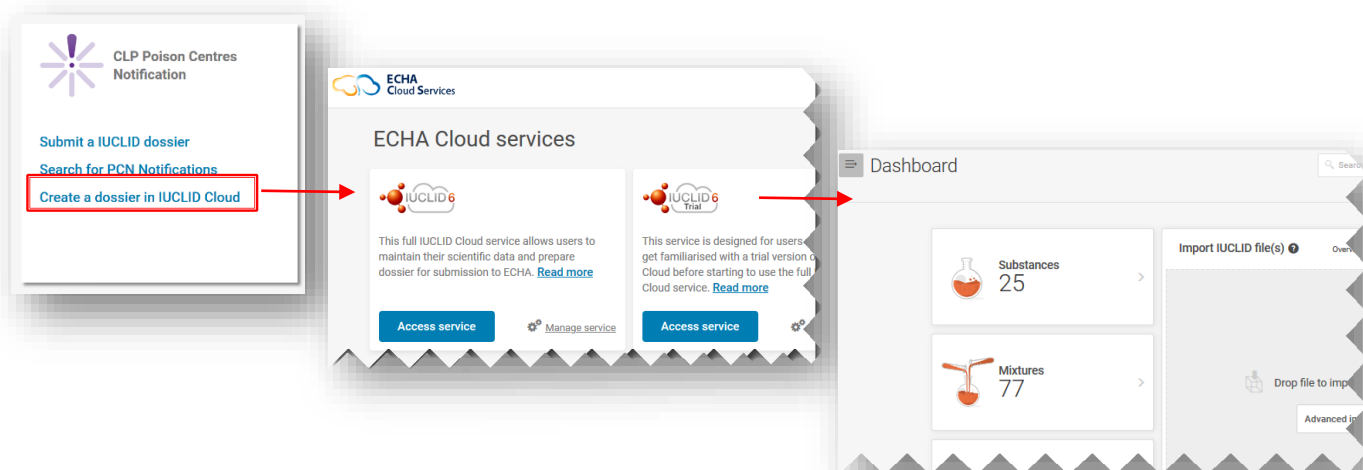
**Submit a IUCLID dossier** redirects you to the upload and submit page. (Chapter 11)



**Search for PCN notifications** redirects to the Search page of the Portal where you can search for PCN submissions - or search all submissions e.g. if you are submitting under other legislations (Chapter 11).



**Create a dossier in IUCLID Cloud** redirects you to the ECHA Cloud services where you choose from Full service or the Trial version to begin the preparation of a dossier (Chapter 4).



## 4. Creating an editable dataset in IUCLID

This chapter highlights the current IUCLID documents and their fields that have been customised for a poison centre notification.

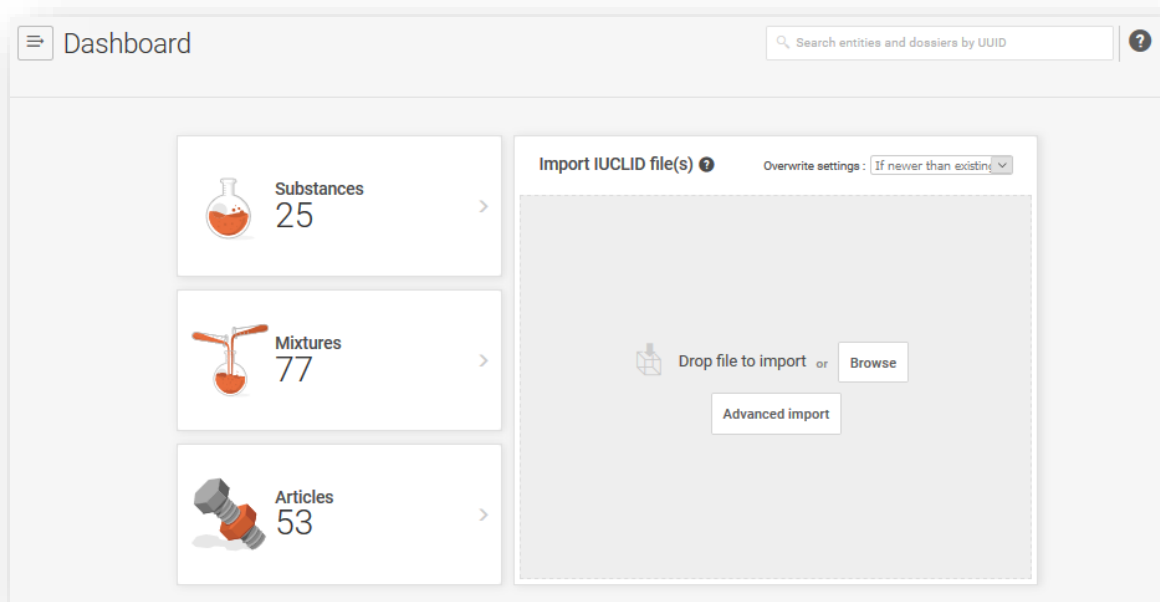
### 4.1 The IUCLID Dashboard

The IUCLID Dashboard is home to various widgets.

The '**Substances**' widget stores any substance dataset information either prepared or imported into the working environment. The number indicated on the widget refers to the number of substance datasets available.

The '**Mixtures**' widget stores information about the mixture datasets available as well as any dossiers prepared.

The '**Articles**' widget is only used for making notifications to the SCIP database, which was established under the Waste Framework Directive (WFD)<sup>5</sup>.



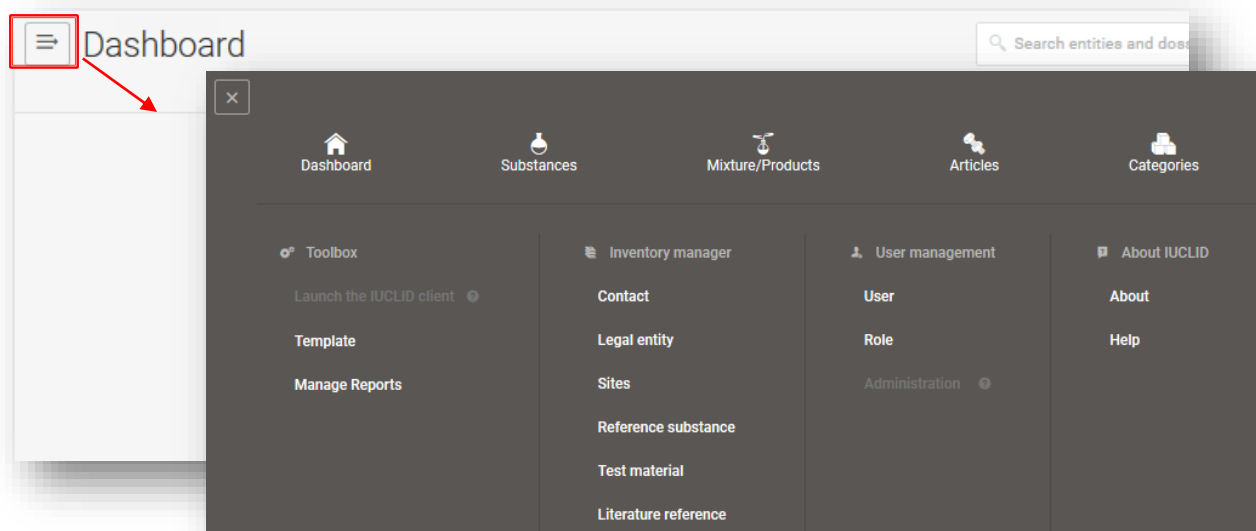
The **Import IUCLID files** area allows you import .i6z files to your working instance of IUCLID. This could include legal entity files, reference substances, or substance/mixture datasets and dossiers.

---

<sup>5</sup> This functionality is relevant only to suppliers of article containing certain substances of very high concern above 0.1% w/w. Detailed information is provided in the WFD section of ECHA website (<https://echa.europa.eu/understanding-wfd>).

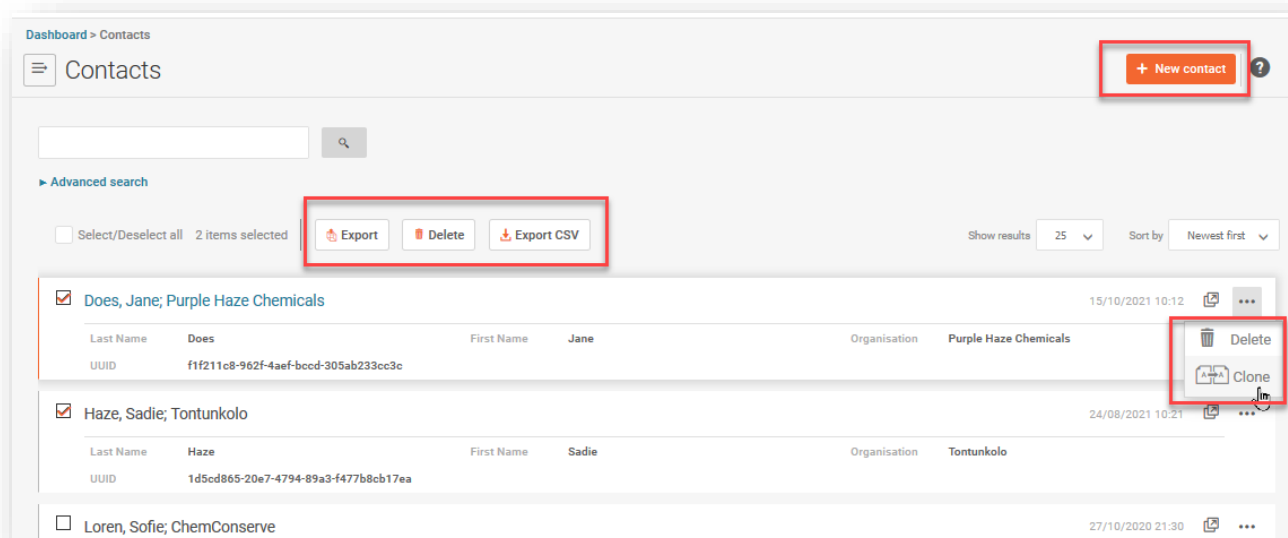
## 4.2 Managing entities outside the notification

From the menu icon on the Dashboard, you are directed to the 'Main menu'. It contains direct links to the list pages for various entities. From here you can easily manage your information, for example, on legal entities, contacts, reference substances as well as users and their roles, outside of a notification.



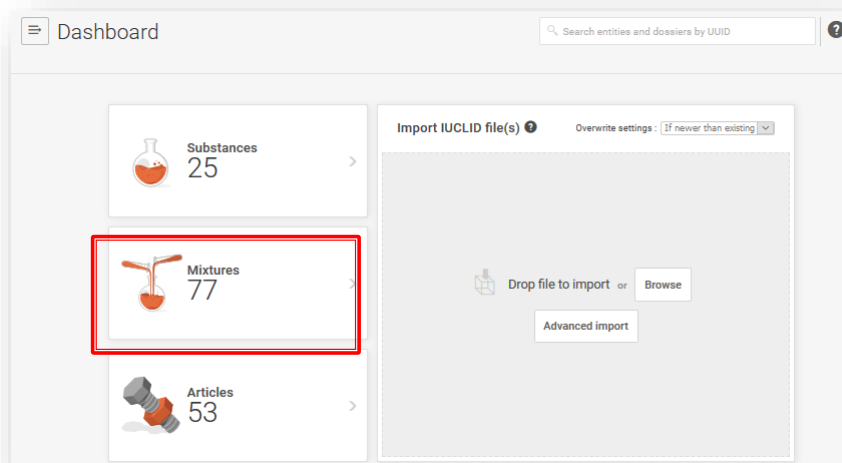
### 4.2.1 Managing Contact information

When managing Contacts outside the notification (it is possible to manage them also from within a notification), it is possible to Create new or edit existing contacts, export selected contacts and clone them as well.

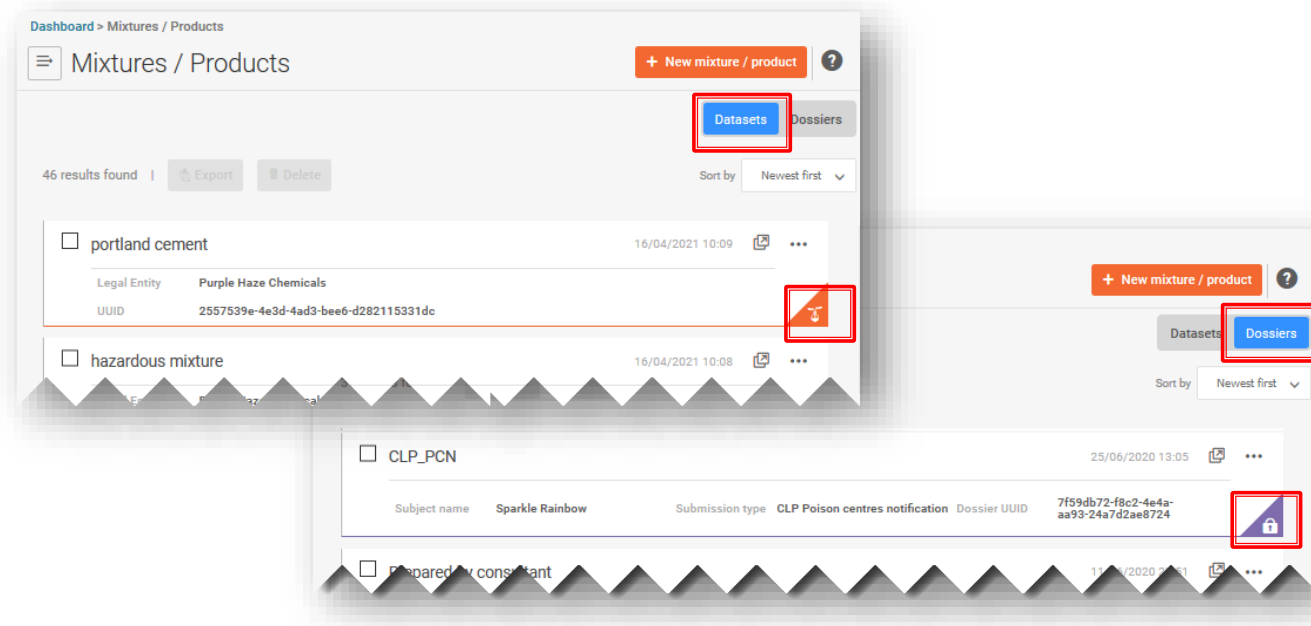


### 4.3 Steps to prepare an initial mixture/product dataset via the 'Mixtures' widget

This section will explore the general principles for creating a dossier customised for poison centre notifications, field by field. To enter the IUCLID section for mixture datasets, we begin by clicking on 'Mixtures'

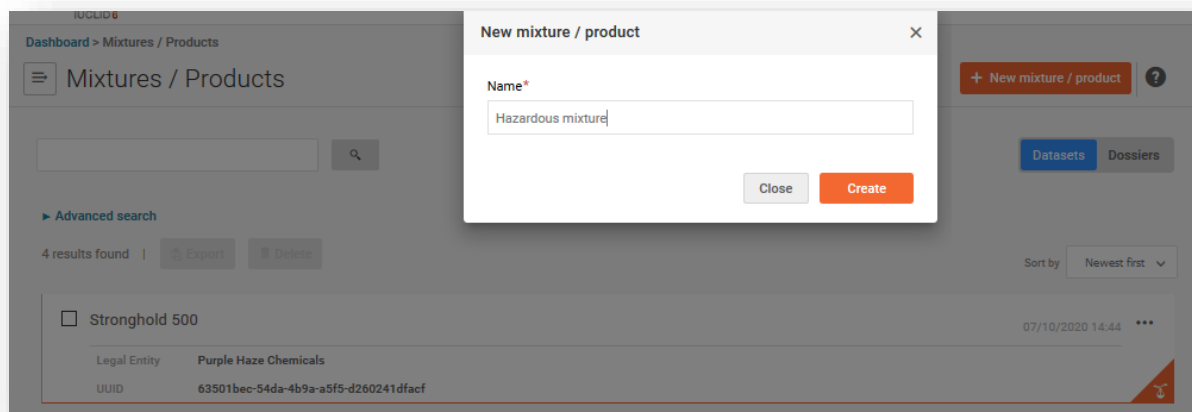


Upon redirection from the Mixtures widget, the Mixtures/Products landing page opens. It will list all datasets under preparation (orange mixture symbol) or you can switch to view all dossiers that have been previously created (purple lock symbol).



### 4.3.1 Create a 'New mixture/product' dataset

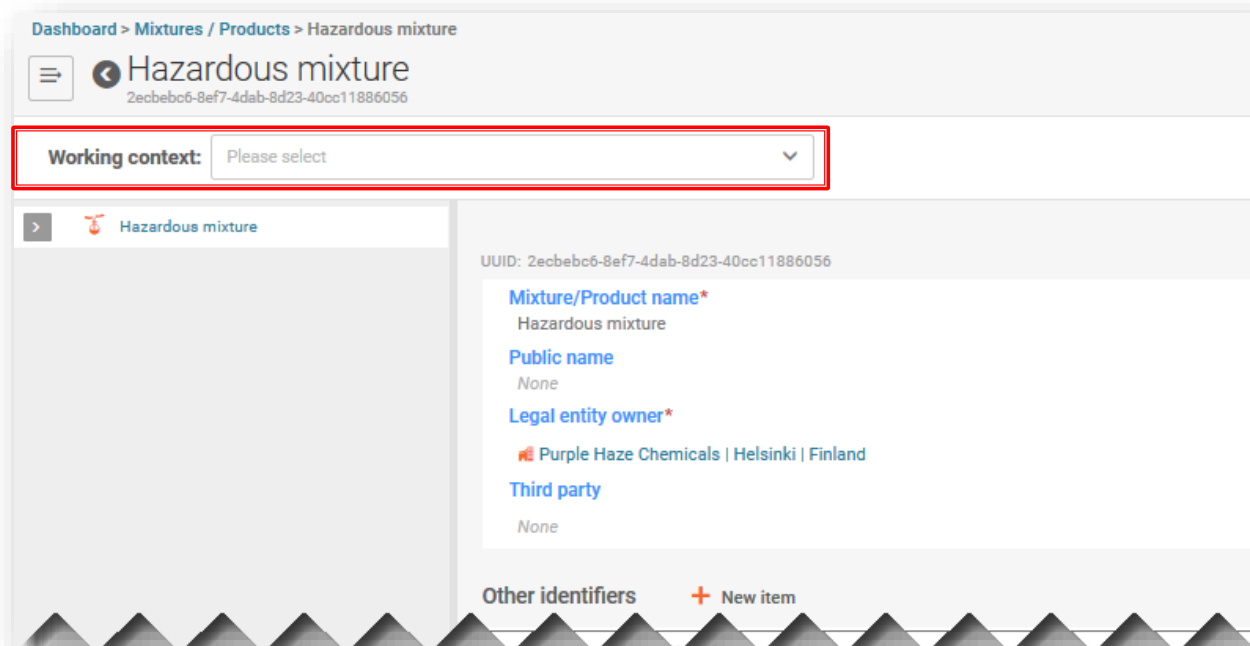
The '+Create new mixture/product' button starts the creation process of a new mixture/product dataset. To complete the process, you need to enter a name for the mixture and press 'Create'.



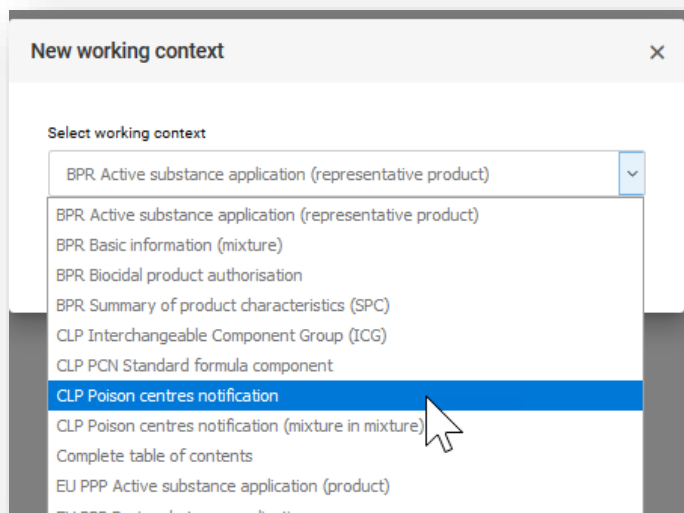
! The mixture dataset is identified by its name given when the dataset is created. Any identifier can be used. It is however suggested to select an identifier which is commonly used for that mixture within the company. This can be for instance an internal name or a formulation identifier. If necessary, this name can be changed.

### 4.3.2 Set the working context

Once the mixture dataset has been created, it can be opened and the working context needs to be selected first. Making a selection from the working context customises the dataset view so that only the relevant fields are visible according to the selection.



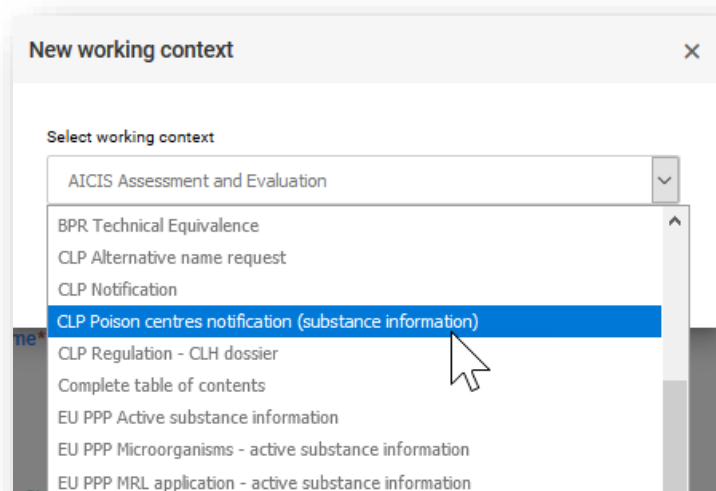
The selection '**CLP Poison centre notification**' is used to prepare a poison centre notification.




Other selections relevant to poison centre notifications are available but not generally required to be used if creating component datasets directly in the composition document of the final mixture. More information on how to create these datasets are discussed in later sections of this document:

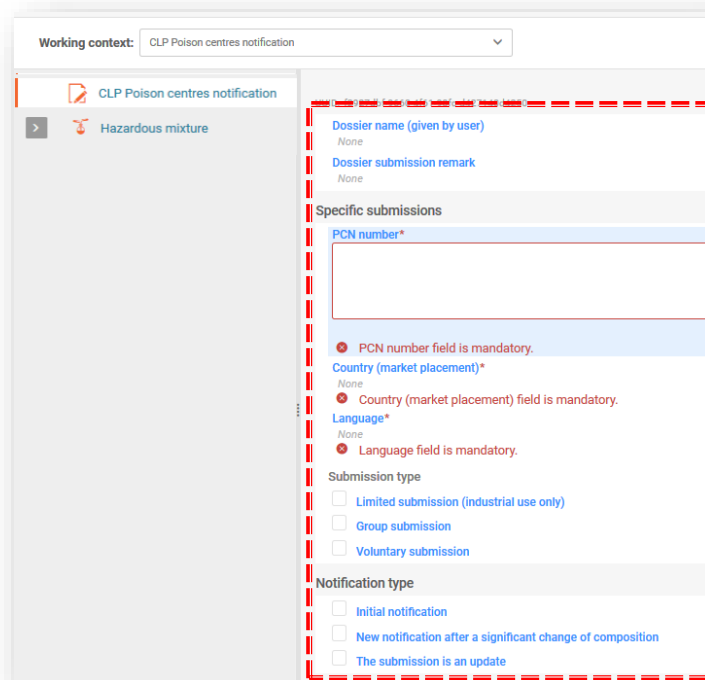
- CLP Interchangeable Component Group (ICG) - (Chapter 5)
- CLP PCN Standard formula component (SF) - (Chapter 5)
- CLP Poison centre notification (mixture in mixture) - (Chapter 4.8)

Similarly, a working context for PCN Substance information is also listed working in the 'Substances' widget. Again, it is not necessary to make this selection when adding substance components in the final mixture composition document (section 4.7).



### 4.3.3 Open and complete the dossier header

Open the dossier header by clicking on the hyperlinked title '  CLP Poison centre notification' as seen in the left hand side of the navigation tree – note that some sections of the dossier header are mandatory to provide at this stage, while others are not. Each section is further explained below.



**Dossier name & Dossier submission** remarks are fields in the dossier header, where you may wish to enter the name of the dossier you are preparing, or if you wish provide any remarks about the submission for your own records.

**PCN number** i.e. a poison centre notification number, is required information and can be generated and assigned by opening the field and using the auto-generate button depicted by two circular arrows. The PCN number refers to an initial notification (or a new notification after a significant change of composition) 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 using one of the UUID generators available online, e.g. <https://www.uuidgenerator.net/>

**Country (market placement) and language selections** must include all the market areas where the mixture will be placed on the market. In addition, all the relevant languages required for each market area must be indicated as well. The allowed languages as specified by each Member State can be found from the Overview of Member States' Decisions on Implementing Annex VIII to the CLP <https://poisoncentres.echa.europa.eu/appointed-bodies>

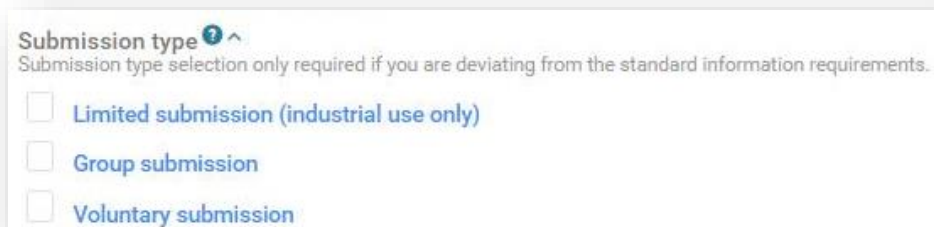


Indicating the **languages** prior to data preparation is necessary as it creates the multilingual fields required for any free text fields which must be provided in all relevant languages e.g. for the toxicological information.

It is also important to consider which are the **market areas** effectively relevant where notifications should be submitted. Following successful submission, market areas cannot be deleted in an update but can always be added, if needed. Note, this applies even in case of ceasing the market in a specific country (see section 4.9.2).


#### 4.3.3.1 Explaining when to use limited, group or voluntary submission types

**Submission type** is by default, set for standard submission type requirement. Therefore, it is not required to make a selection for the Submission type unless you are deviating from the standard information requirements.



The screenshot shows a form titled "Submission type" with a help icon and a dropdown arrow. Below the title is a note: "Submission type selection only required if you are deviating from the standard information requirements." There are three radio button options: "Limited submission (industrial use only)", "Group submission", and "Voluntary submission".


**Limited Submission (industrial use only)** are available for hazardous mixtures placed on the market for industrial use only.

 Note that the use of the mixture downstream should be taken into account. If, for example, the mixture is used in the formulation of a mixture intended for consumer or professional use, this option cannot be selected. Nevertheless, this option applies to mixtures included in a final mixture intended for professional or consumer uses that are outside the scope of Article 45 and Annex VIII ("mixtures with an end use not subject to notification").

A **group submission** (further described in Chapter 8) is available for the creation of a dossier containing information for several mixtures provided:

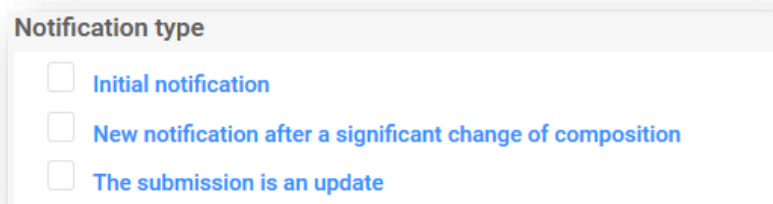
- all mixtures contain the same composition except for certain perfumes under specific conditions;
- reported concentrations/ranges for each of the components is the same (except certain perfumes);
- all mixtures in the group have the same classification for health and physical hazards

**Voluntary submission** is available for non-duty holders or mixtures outside the scope of Article 45 and Annex VIII.

 The submitter of a voluntary submission is always responsible for the notification. Voluntary submissions should also be maintained, for example if there is a need to update any information.

### 4.3.3.1 Explaining the notification types

**Notification type** must be provided, e.g. initial, update or new notification after a significant change in composition. The selection here, sets the framework for the dossier and rules that will be used to validate the information using the Validation assistant.




Notification type


- Initial notification
- New notification after a significant change of composition
- The submission is an update

**Initial notification** is the very first submission made for a mixture/product. An initial submission must be successful before an update can be accepted.

**New notification after a significant change of composition** is expected for a notified mixture when a change in the composition has occurred outside the set limits indicated in Annex VIII to CLP. This leads *de facto* to two different mixtures on the market; the two sets of information (referring to the original and new composition) remain relevant (both products may remain on the market for potentially a long time). The previous submission and the 'new' notification remain linked via the 'related' PCN number – see section 11.2.

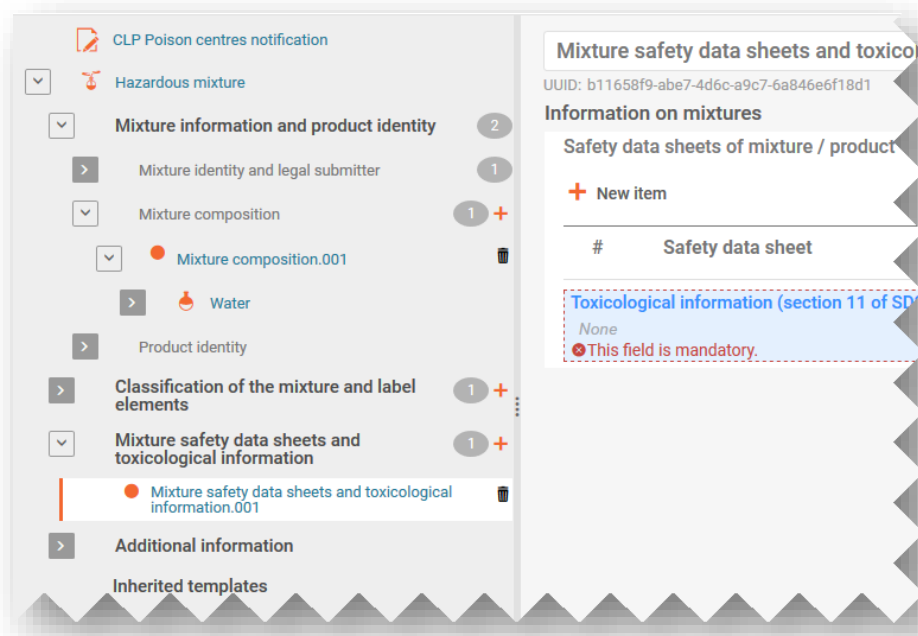
**The submission is an update** is selected if there is a need to update information that currently exists in the database. An updated submission is where the mixture composition remains the same. Both previous and updated submissions remain potentially relevant for the poison centres and appointed bodies - see section 11.1.

 Do not select 'update' if you need to resubmit following a validation rule failure and there is no prior successful 'initial' submission. This will trigger a validation rule BR568.










	BR568	The PCN number provided in the dossier header for submission updates cannot change and must be the same as that of a valid initial submission. Please note that if there is no successful submission yet for this PCN number then the submission should still be indicated to be 'Initial notification' / 'New notification after a significant change of composition' depending your specific case.
---	-------	--

### 4.3.4 General navigation and functionalities for data entry

The navigation tree, featured on the left-hand side of the page, allows easy movement between the dossier header and the customised sections created for the poison centre notification mixture dataset. Documents need to be created for each of the sections - in this guide the word "document" is used to indicate a set of information that can be entered in the PCN format. **The navigation tree allows you to** navigate in the dataset using the collapsible/expandable arrows.

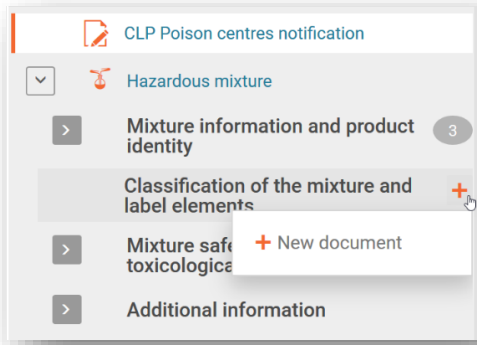


Each of the created sections and documents are expandable and can be managed by additional features.

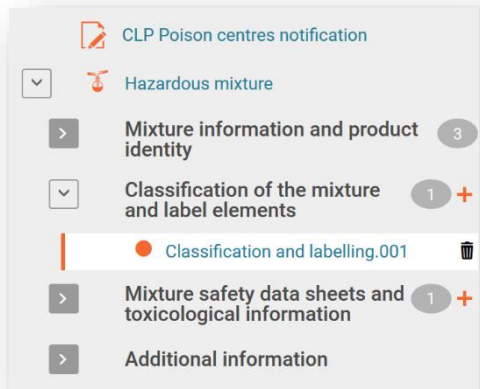
Function	Symbol
Collapses a section	
Expands a section	
Adds a New document	
IUCLID document	
Number corresponds to the amount of IUCLID documents per section	
Trash-can deletes unwanted documents	
Substance	
Mixture/product	
Dossier header	

#### 4.3.4.1 Entering information into a new document

Information can be entered into a dedicated document type by clicking on the orange '+' and selecting create 'New document'.

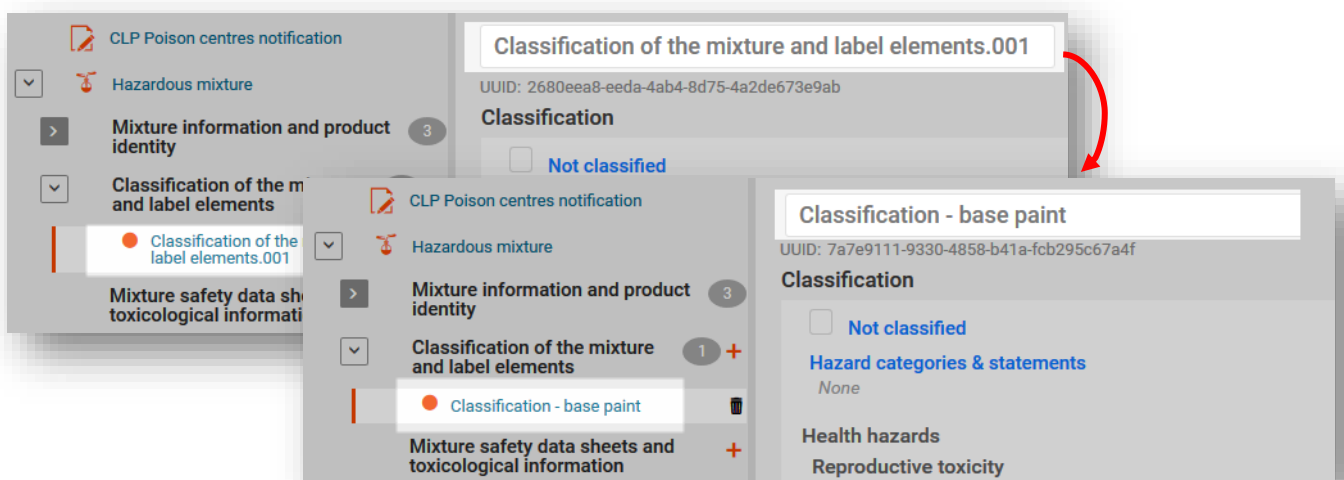


When a specific IUCLID document has been created it is represented by an orange circle and given a default name and number and a specific document UUID. The name of the document can be edited to suit.



#### 4.3.4.2 Re-naming documents

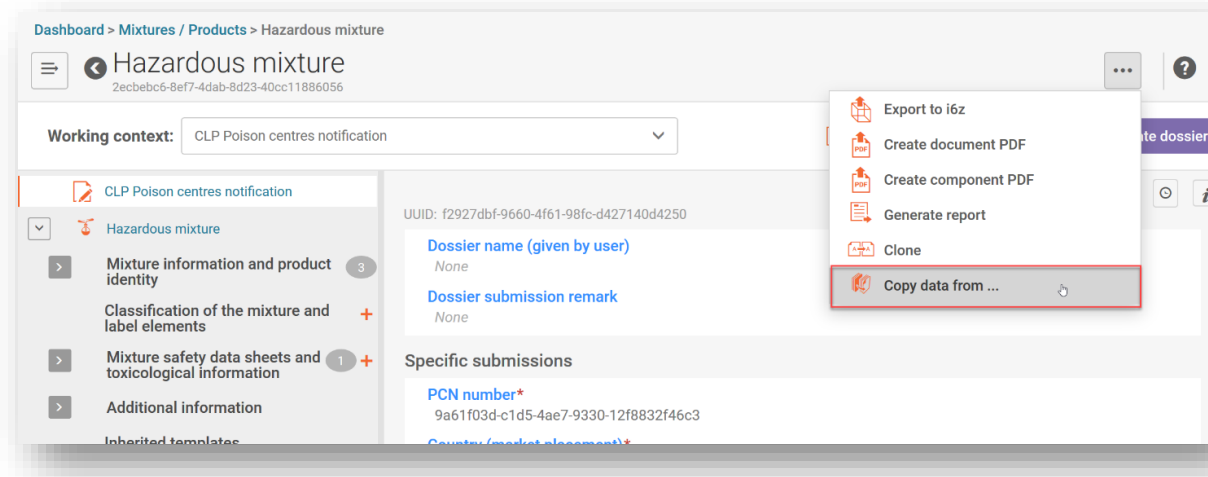
When a record is created, a name (and UUID number) is automatically created e.g. [name of record].001. It is possible to rename the records according to the needs of the user – this helps to better locate the record, for example, when using the 'Copy from existing' functionality. Once the document has been renamed, it is necessary to save the changes.



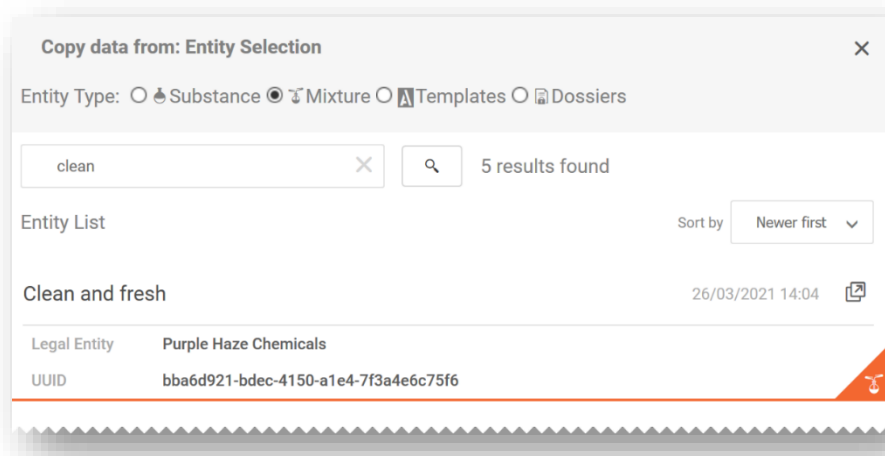
### 4.3.4.3 Copying data from existing documents

If you have previously created information records and datasets for other mixtures, they will be available for re-use in new datasets.

Working within a dataset you wish to include previously prepared information, click on the three dots '...' (ellipsis) in the top right-hand corner will open a list of functionalities including the 'Copy data from ...'

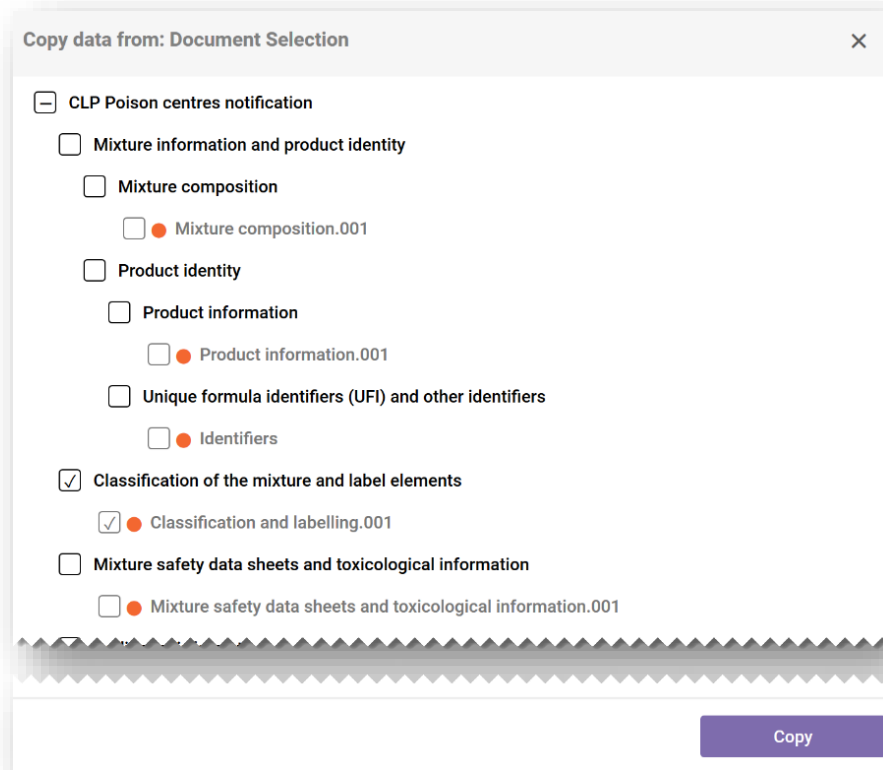


A list of available datasets to select information is automatically presented. The entity type is set by default to Mixture dataset, but it is possible to select also Dossier. You may wish to use the search function to assist locating your source information and making your selection faster.

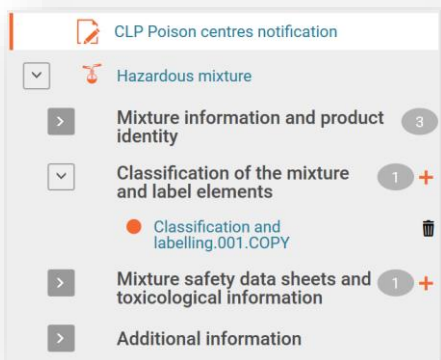


**!** You **can bulk copy data from a dossier** to a new created dataset by selecting the Entity type 'Dossier' and selecting the information you would like copied.

Once you select the source document from which to copy information from, you can copy all sections (note the dossier header information cannot be copied over) or further refine which sections you would like to copy.



After you Copy the specified information, the copied document will appear as [*original name of the record*].COPY which can always be renamed if preferred.

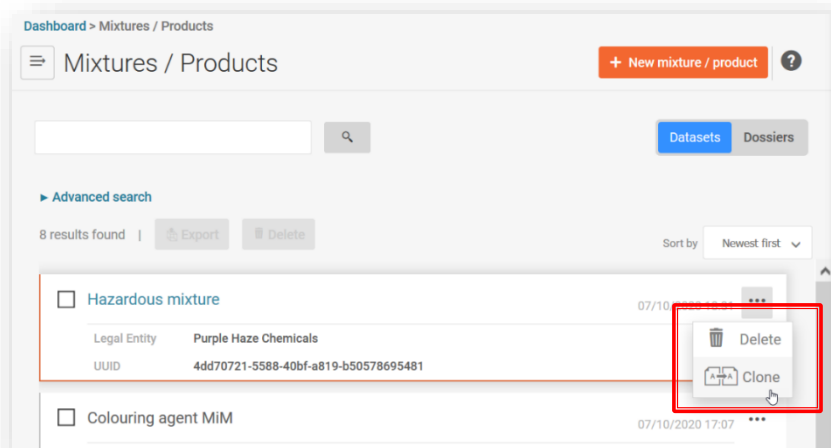


#### 4.3.4.4 Using the 'cloning' functionality

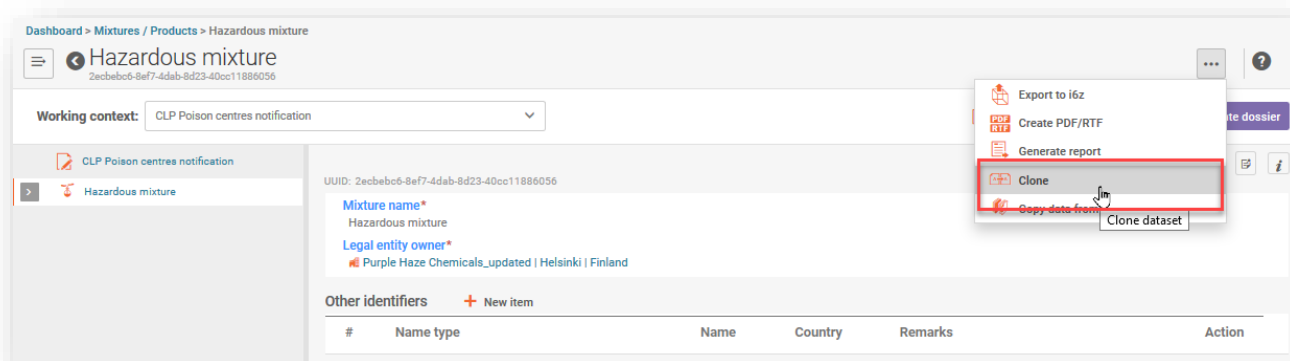
The 'clone' functionality is available to facilitate e.g. the preparation of update dossiers by cloning a mixture dataset and build a new dossier from that. In this way, you do not need to re-enter all the information related to the mixture, such as composition, toxicological information or product information.

**Note** that the **working context** is not cloned therefore you will need to re-set the working context and enter the information in the **Dossier Header**.

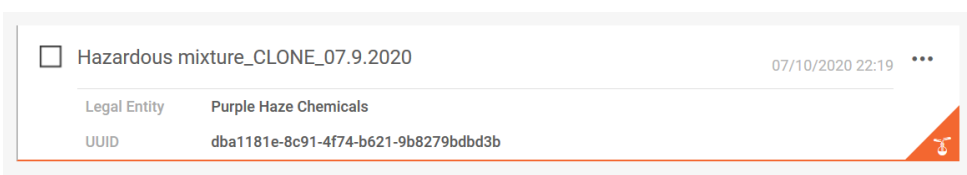
You can Clone a dataset either from the list of Mixture datasets - Click on the ellipsis '...' of the dataset you wish to replicate and select 'Clone'.



Alternatively, you can open the dataset and create a clone by clicking on the three dots '...' (ellipsis) in the top right-hand corner. This opens a list of functionalities including 'Clone'.



Once the dataset has been cloned, it will appear in the list of mixture datasets named as mixture '\_CLONE\_[date]' which you can edit, then open and further edit specific sections in the notification before creating a dossier.



## 5. Preparing a PCN - section by section

### 5.1 Mixture identity and legal submitter

The following IUCLID documents comprise the mixture information and legal entity plus any contact persons for the dossier.

#### 5.1.1 Mixture/product name

This is the name of the mixture you entered when you created the 'New mixture/product' dataset. It does not necessarily need to be the trade name of your product, though can be. This field is editable.

Dashboard > Mixtures / Products > Hazardous mixture

Hazardous mixture  
2ecbebc6-8ef7-4dab-8d23-40cc11886056

Working context: CLP Poison centres notification

CLP Poison centres notification

Hazardous mixture

Mixture information and product identity 3

Mixture identity and legal submitter 1

Hazardous mixture

Purple Haze Chemicals

Mixture composition 1 +

Product identity 1

Classification of the mixture and label elements 1 +

UUID: 2ecbebc6-8ef7-4dab-8d23-40cc11886056

Mixture name\*  
Hazardous mixture

Legal entity owner\*  
Purple Haze Chemicals | Helsinki | Finland

Other identifiers + New item

#	Name type	Name	Country
---	-----------	------	---------

Contact persons + New item

#### 5.1.2 Legal submitter

Opening the legal entity document displays the legal entity name and UUID. This is the legal entity that is checked against the logged in user of the ECHA Submission portal and is considered the duty holder.

CLP Poison centres notification

Hazardous mixture

Mixture information and product identity 3

Mixture identity and legal submitter 1

Hazardous mixture

Purple Haze Chemicals

UUID: ECHA-f428c44e-79b3-4f7f-a72b-78e7ceda3be4

General information

Legal entity name\*  
Purple Haze Chemicals

Legal entity type  
None

Remarks  
None



The legal entity UUID specified at the mixture level must be consistent with the legal entity in the ECHA Submission portal upon submission.

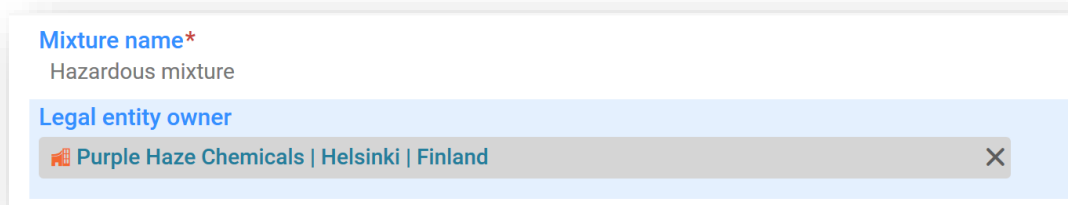
### 5.1.2.1 How to change the legal submitter

In the Mixture identity section, the legal entity details can be changed to a different legal entity if needed. To remove a legal entity, click on the hyperlinked name of the legal entity under 'Legal entity owner'.



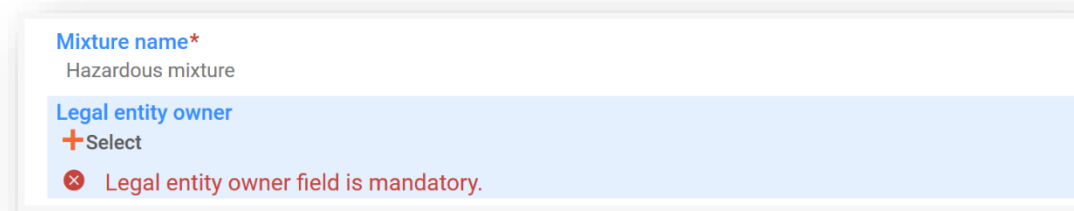
The screenshot shows a sidebar on the left with navigation items: 'CLP Poison centres notification', 'Hazardous mixture', 'Mixture information and product identity' (with a '3' badge), and 'Mixture identity and legal submitter' (with a '1' badge). The main content area displays 'UUID: 2ecbebc6-8ef7-4dab-8d23-40cc11886056'. Below this, the 'Mixture name\*' is 'Hazardous mixture'. The 'Legal entity owner\*' field is highlighted with a red box and contains 'Purple Haze Chemicals | Helsinki | Finland'.

Click on the 'X' to remove the current legal entity assigned.



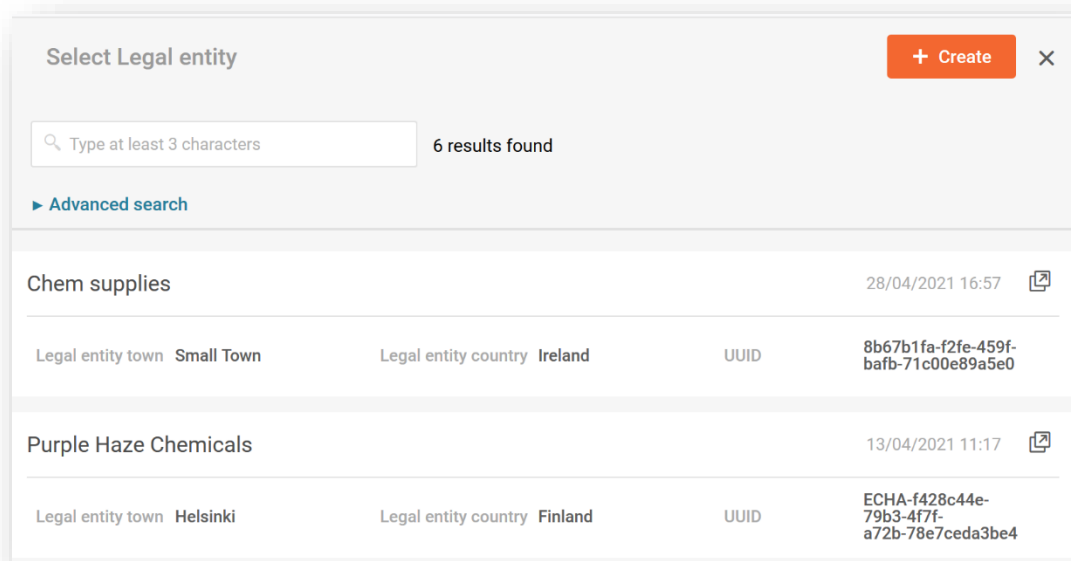
The screenshot shows the 'Legal entity owner' field with a red 'X' button to the right of the current entity name 'Purple Haze Chemicals | Helsinki | Finland'.

Click on 'Select' to open the available legal entities listings.



The screenshot shows the 'Legal entity owner' field with a '+ Select' button. Below the field, there is a red error message: 'Legal entity owner field is mandatory.'

Make a selection from the available legal entities listed in your working instance. If it is not there, then the legal entity owner details will need to be imported e.g. from ECHA Accounts.

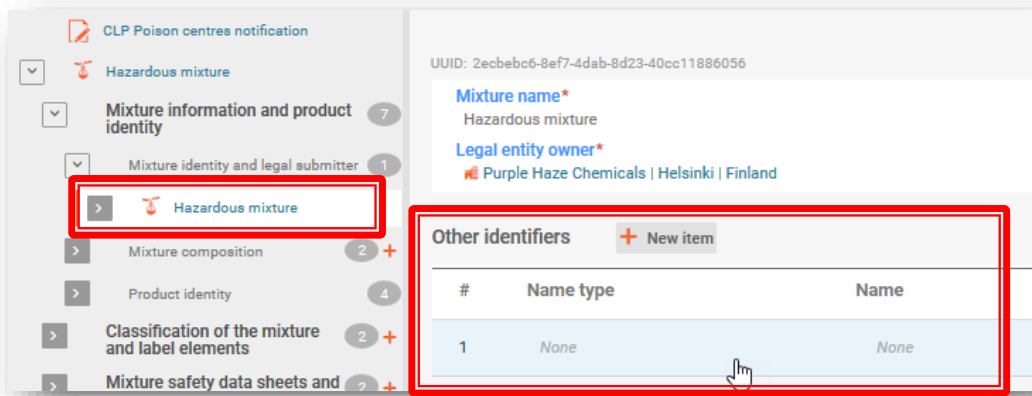


The screenshot shows the 'Select Legal entity' dialog. It has a search bar with the placeholder 'Type at least 3 characters' and '6 results found'. Below the search bar, there is a link for 'Advanced search'. The results are listed in a table:

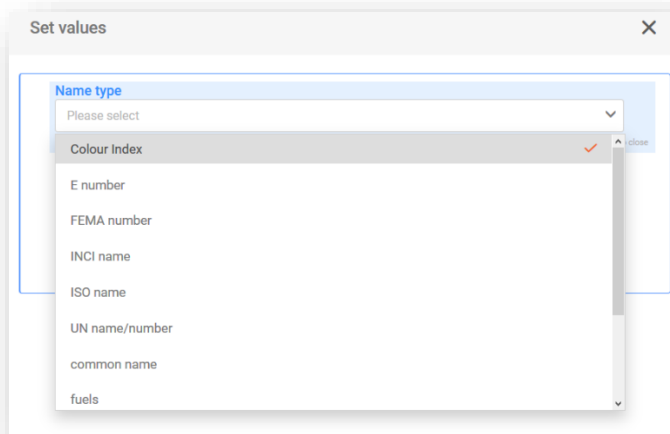
Entity Name	Legal entity town	Legal entity country	UUID	Date
Chem supplies	Small Town	Ireland	8b67b1fa-f2fe-459f-bafb-71c00e89a5e0	28/04/2021 16:57
Purple Haze Chemicals	Helsinki	Finland	ECHA-f428c44e-79b3-4f7f-a72b-78e7ceda3be4	13/04/2021 11:17

### 5.1.3 Other identifiers

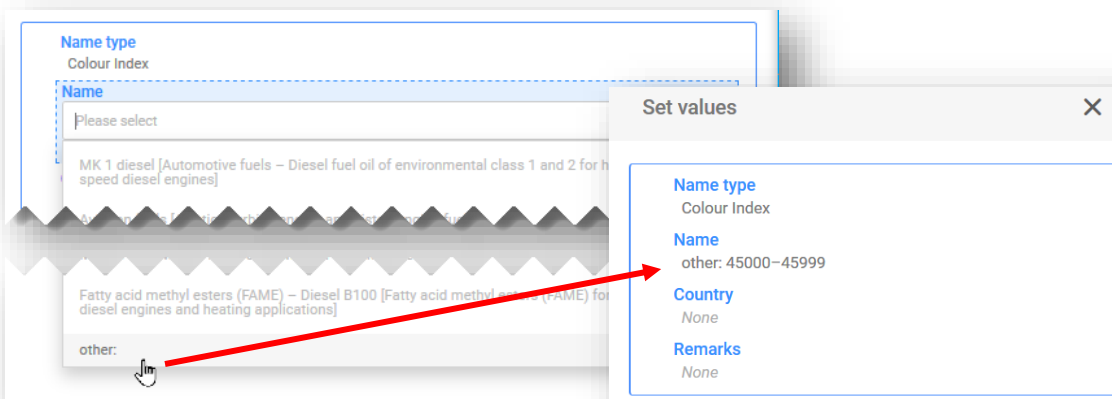
Can be used to add additional information about the mixture.



Add a +New item and make a selection from the Name type picklist (e.g. Colour index). Then add the specific information to the Name field – either by selecting a specific name from the picklist (for fuels and stand formulas only) or by selecting 'Other'



If 'Other' is selected from the Name field, further information can be provided in the free text field.



### 5.1.4 Contact person

A Contact person(s) is used to record the person's role and contact, for example, an Emergency contact in the case of a limited submission, or a Contact point if the submitter is not in possession of further information relevant for emergency health response.

Click on New item and either select an already created contact or create a new one.

Contact persons + New item

1 Person  
+ Select  
press Esc to close

2 Person  
Haze, Sadie; Tontunkolo | Haze | Sadie | Tontunkolo | Finland

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.

Create new Contact

Contact person

Contact type  
None

First name  
None

Last name\*  
None  
⊗ Last name field is mandatory.

Organisation\*  
None  
⊗ Organisation field is mandatory.

Phone  
None

Email  
None

Country  
None

Contact type  
Please select

competent person responsible for the SDS

dossier contact

emergency contact

substance manager

toxicologist

other:

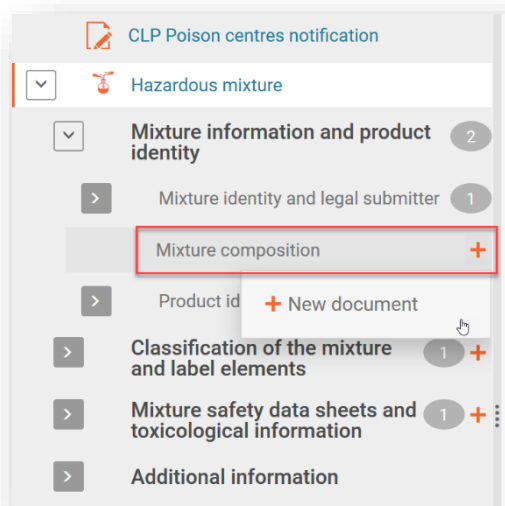


In case of **limited submissions**, the contact type '**Emergency contact**' has to be selected.

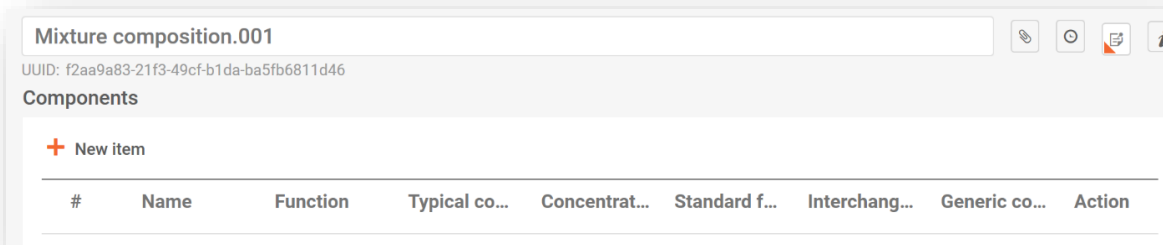
Further, if the mixture is placed on the market in a **single market area**, then you must provide only one emergency contact record containing this information. If the submission is for **multiple market areas**, then you need to provide multiple Contact person(s) records. Each record will contain the 'Emergency contact' person information for each country, specified in the 'Country' field, even if the same details are applicable for all the countries.

## 5.2 Mixture composition document

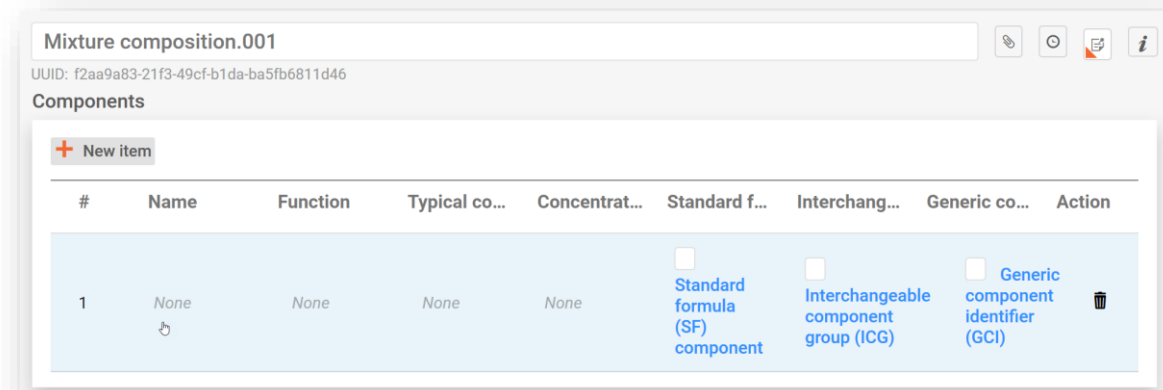
The mixture composition document contains the list of all the components of the mixture. To enter each components information in the mixture composition document, a New document must be created first.



Once you create the mixture composition document a Components section is created where you add the individual substances or mixture in mixture components (or interchangeable component groups), by selecting New item.



An empty component item is created and can be opened and completed by clicking on the item (shaded in blue).



A 'Set values' box opens and specific values must be entered for each component.

**Name:** The name of the component. You need to first select if the type of component i.e. is it a substance or mixture (i.e. mixture in mixture) component. Making a selection requires that you then continue to identify the component.

**Function:** The function is only mandatory to include if you are indicating a GCI (generic component identifier) component. In these cases, a selection must be made between perfumes or colourants. In any other case, the information can be voluntarily provided.

**Typical concentration/range:** The concentration of components can be declared either as a 'typical' concentration (i.e. exact concentration), or a 'concentration range' and expressed in either % (w/w) or % (v/v). Operators (>, <, ≤, ≥) must be included for reporting ranges.



Note that units should be reported in the same way for the concentration of all components.

## Declaring concentrations

Declaring concentrations must be in accordance with the allowed limits detailed in Annex VIII, unless specific provisions apply. Information on the allowed ranges and working examples can be found here:

<https://poisoncentres.echa.europa.eu/components-of-major-concern>

### Declaring concentrations under Annex VIII to CLP Regulation



Annex VIII to the CLP Regulation has provisions on the information provided on the concentration of mixture components (substances or mixture in mixtures). Different provisions apply to hazardous components considered of major concern and to other hazardous components and components not classified as hazardous. The distinction is defined in section 3.4 of Part B of Annex VIII. The submitter is required to provide the concentration or concentration range of each component according to the hazard class.

#### Suggested reading

3 Annex VIII to the CLP on hazardous information relating to emergency health response

Components of major concern Other hazardous and non-hazardous components Changes in composition and the effect on the LFD



Only where components fit specific conditions outlined in Annex VIII to the CLP Regulation should these component types be flagged. See Chapter 6 for more information:

**Standard formula (SF) component**

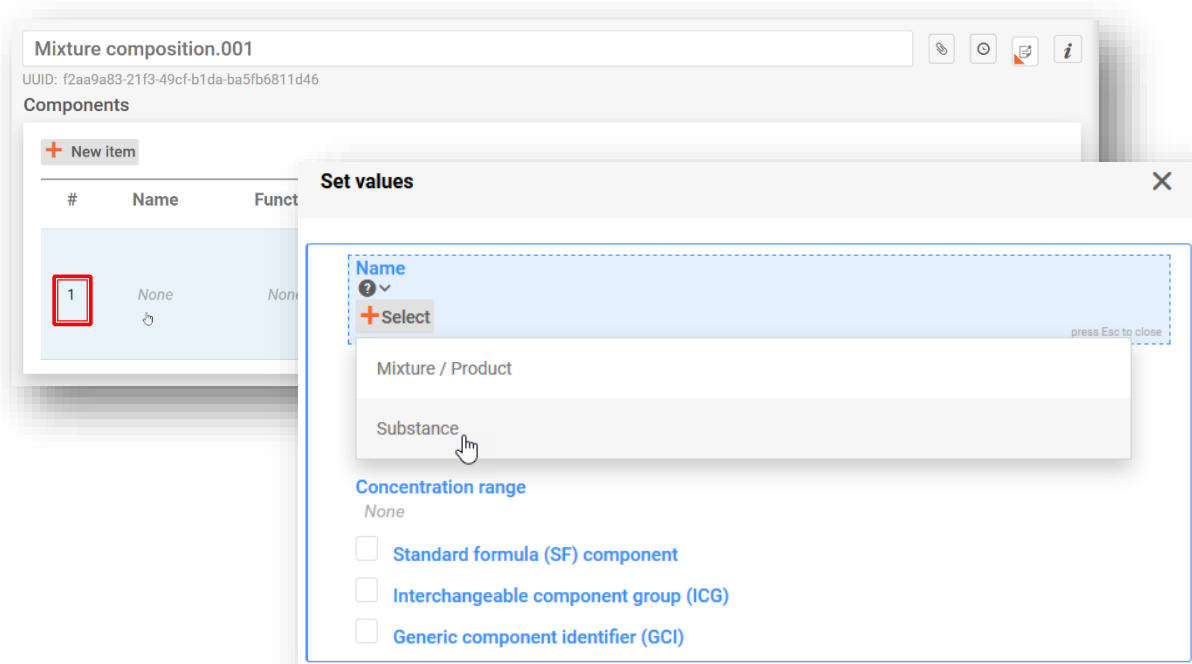
**Interchangeable component group (ICG)**

**Generic component identifier (GCI)**

## 5.3 Adding a substance component

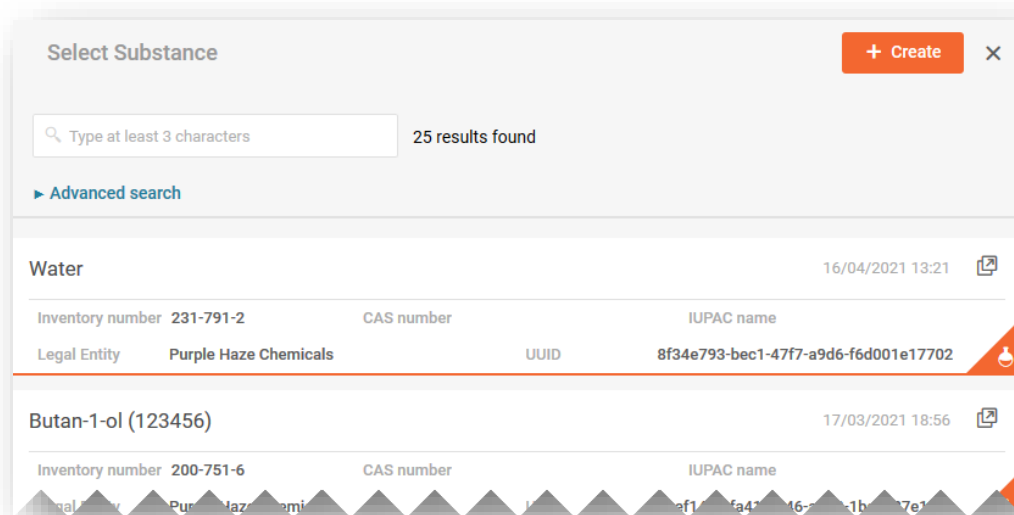
Creating a substance dataset is required for each substance component of the final mixture that will be placed on the market. In addition, substance datasets will also be required for all the substance components of any mixture in mixtures reported.

From the (main) Mixture composition document, you need to first create a New item. The generated field for the component is numbered. Clicking on the field (shaded blue) opens the Set values box where you select 'Substance' in the Name field.



The substance can be included in one of two ways, either by:

- selecting a previously prepared substance dataset from the list, OR,
- +Create a new substance dataset



- i) Selecting a substance from the list automatically fills the name section with what was provided in the Substance dataset, plus is linked to all other information included in that dataset.




- ii) Creating a substance dataset requires entering information manually for the:

**Reference Substance:** The reference substance information is required for substance components (with the exception of generic component identifiers) – here you will also need to either select a reference substance from the Reference Substance list if available or if not, you can either download and import them directly into your working environment, or create your own.

**Legal entity:** Note that the legal entity is mandatory to create the IUCLID dataset, however, this is not mandatory for PCN purposes and no checks concerning this information are carried out. Your own Legal Entity is automatically pre-populated but can be edited e.g. to an undefined legal entity.

**Substance name:** The substance name is a free text field and is not language specific. Therefore, it is at the discretion of the notifier to decide on the most appropriate language for all recipients. Names in additional languages can be included in the Reference substance document under 'Synonyms'.

 Where more than one name exists for a substance component, these should not be included all in this field. Additional names should be included in the reference substance document under 'Synonyms' – see section 5.3.2

#	Identifier	Identity	Country	Remarks	Action
+ New item					

### 5.3.1 Downloading a reference substance from the IUCLID website

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. While you can create reference substance documents during dossier preparation, 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>).



Note that the set of reference substances available for download is not maintained and errors and inconsistencies can exist. It is the responsibility of the user to verify the information used in the notification.

From the reference substance page of the IUCLID website, begin by searching for the substance using an EC or other product identifier. From the results list, select Download and save the file locally (.i6z format) to a more meaningful name.

Search for and download Reference substances

EC Num	CAS Num	EC Name	IUPAC Name
<input type="text" value="200-659-6"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Molecular Formula			
<input type="text"/>			
<input type="button" value="Search"/> <input type="button" value="Reset"/>			

EC Num	CAS Num	EC Name	IUPAC Name	Molecular Formula	Link to i6z file
200-659-6	67-56-1	methanol	methanol	CH4O	<input type="button" value="Download"/>

To import the reference substance from the Cloud Dashboard, select Browse, and locate the file that you have previously saved e.g. on your desktop.

Dashboard

Substances 25

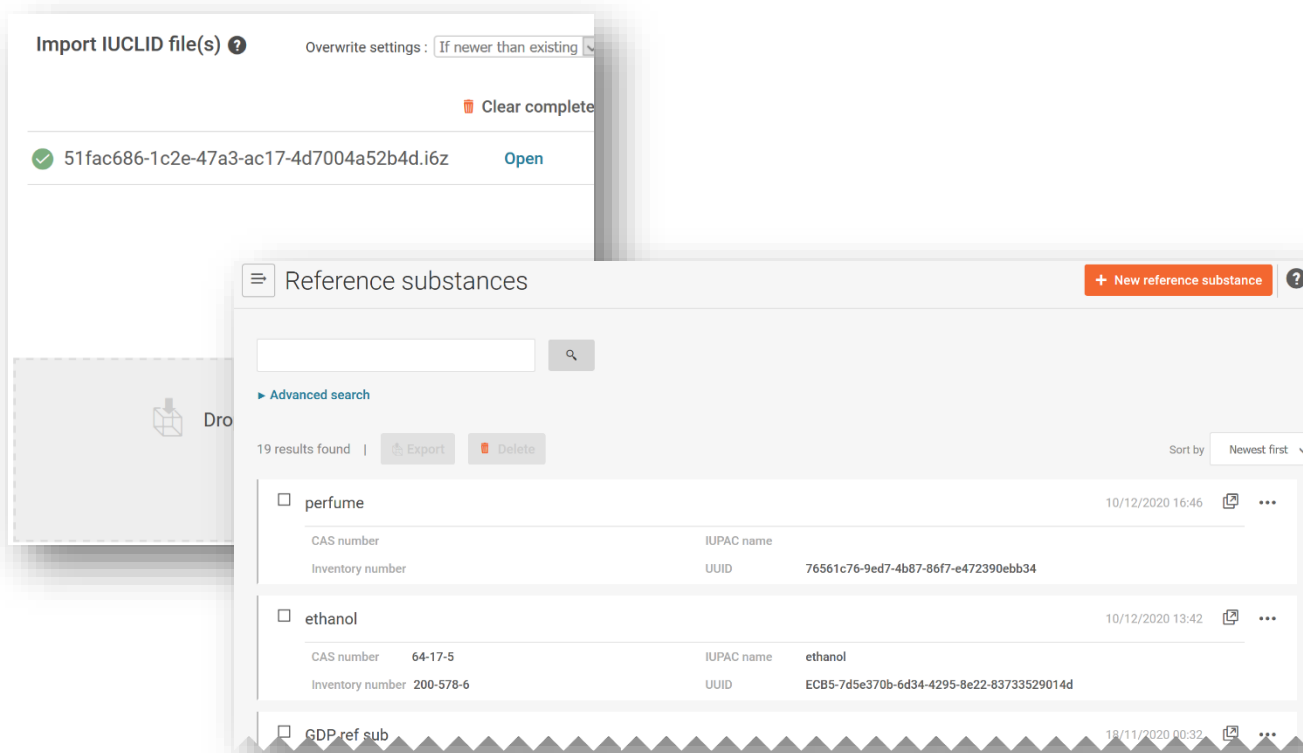
Mixtures 78

Articles 53

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

Drop file to import or

Once the reference substance file has been successfully imported, it will be available to use in your reference substance repository list containing the information to identify the substance.



### 5.3.2 Creating and linking a reference substance

Linking a substance dataset to a reference substance can be done either a) from your repository of reference substances or b) create a new one. To create a new one, a minimum of information must be provided:

1. A reference substance name
2. The reference substance must have at least one of the following identifiers reported: **EC number**, **CAS number**, **IUPAC name**, **international chemical name**, **Colour index** or **INCI** name. Please note that **international chemical name** should be reported in IUPAC name field.

**Polymers** are considered to be substances and need to be identified in the same way as any other component, i.e. you have to provide a name and an identification number as described in Article 18(2) of CLP. Where no EC, CAS or IUPAC details are available, you can report the known name in the 'IUPAC name' field in the Reference Substance document.

When you Create a new reference substance, the reference substance form is opened, and you can enter the relevant information.




The EC inventory is not an exhaustive list. If the substance is not found in the EC inventory, you will need to enter the substance identity information manually.

Create new Reference Substance

**General information**

Reference substance name\*  
None  
Reference substance name field is mandatory.

**Inventory**


Inventory number  None

**Reference substance information**

IUPAC name  
None

CAS number  
None

CAS name  
None


Synonyms  New item

#	Identifier	Identiv	Remarks	Action

**Molecular and structural information**

Molecular formula  
None

Inventory

Inventory number 

231-79

EC / 231-790-7 / trans-4-methylcyclohexanol / 7731-29-5 / C7H14O

EC / 231-791-2 / water / 7732-18-5 / H2O

EC / 231-792-8 / estra-1,3,5(10)-triene-3,17β-diol diheptanoate / 7732-97-0 / C32H48O4

EC / 231-793-3 / zinc sulphate / 7733-02-0 / H2O4S.Zn

EC / 231-794-9 / hexadecane-1,16-diol / 7735-42-4 / C16H34O2

EC / 231-795-4 / 1,1'-oxybis[2-chloroethanol] / 7737-02-2 / C4H8Cl2O3


The Reference substance '**Synonyms**' field can be used e.g. to include additional languages or to include other names such as common names.



**Reference substance information**

IUPAC name  
None

CAS number  
None

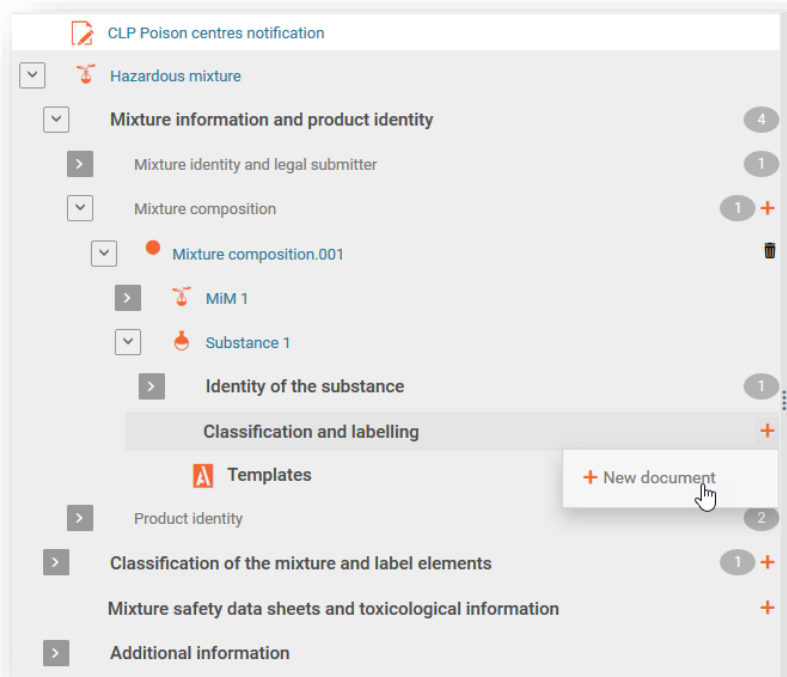
CAS name  
None

Synonyms  New item

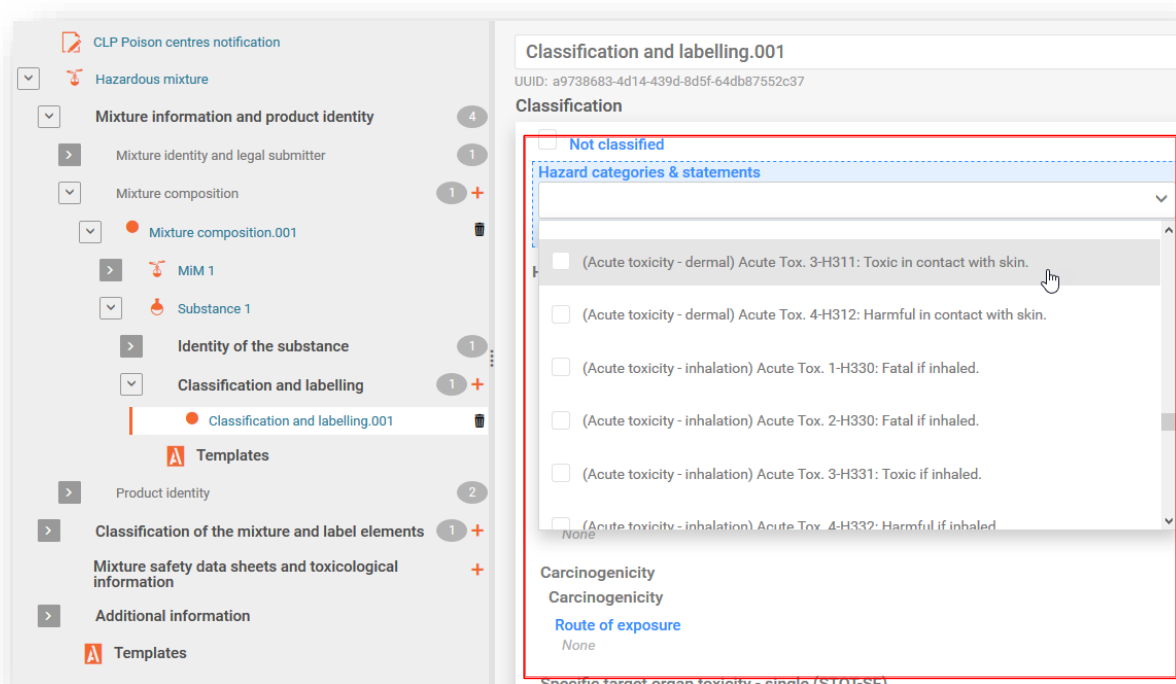
#	Identifier	Identiv	Remarks	Action
1	other: Finnish	Vettä	None	
2	other: Swedish	Vatten	None	

### 5.3.3 Classification (and labelling) of the substance

A new classification and labelling document must be included for the substance. A new document can be created, or one can be copied from an existing source (see section 4.3.4.3).



The new document must have the classification of the substance indicated by making a selection from the 'Hazard categories and statements' picklist. Specific concentration limits and M-factors, if applicable, can also be indicated in the specific fields. If it is not classified for any physical, health or environmental hazards, select 'Not classified'. This selection freezes the classification fields. Additional hazard classes may also be entered in this section.



The labelling information related to substance components is not necessary but may be easily included using the 'Calculate' function. This function calculates the information based on the classification information entered in the previous step.



It is the responsibility of the submitter to verify the results of the Calculate function in the labelling section. The information can be edited if necessary.

The screenshot shows the 'Labelling' section of the software. On the left, a sidebar lists various categories with expandable options. The main panel is titled 'Labelling' and includes a 'Calculate' button. Below this, the 'Signal word' is set to 'Danger'. Under 'Hazard pictogram', three icons are displayed: GHS02: flame, GHS07: exclamation mark, and GHS09: environment. The 'Hazard statements' section contains two entries: 'H242: Heating may cause a fire.' and 'H302: Harmful if swallowed.', each with an 'Additional text' field set to 'None'.

## 5.4 Adding a mixture-in-mixture component

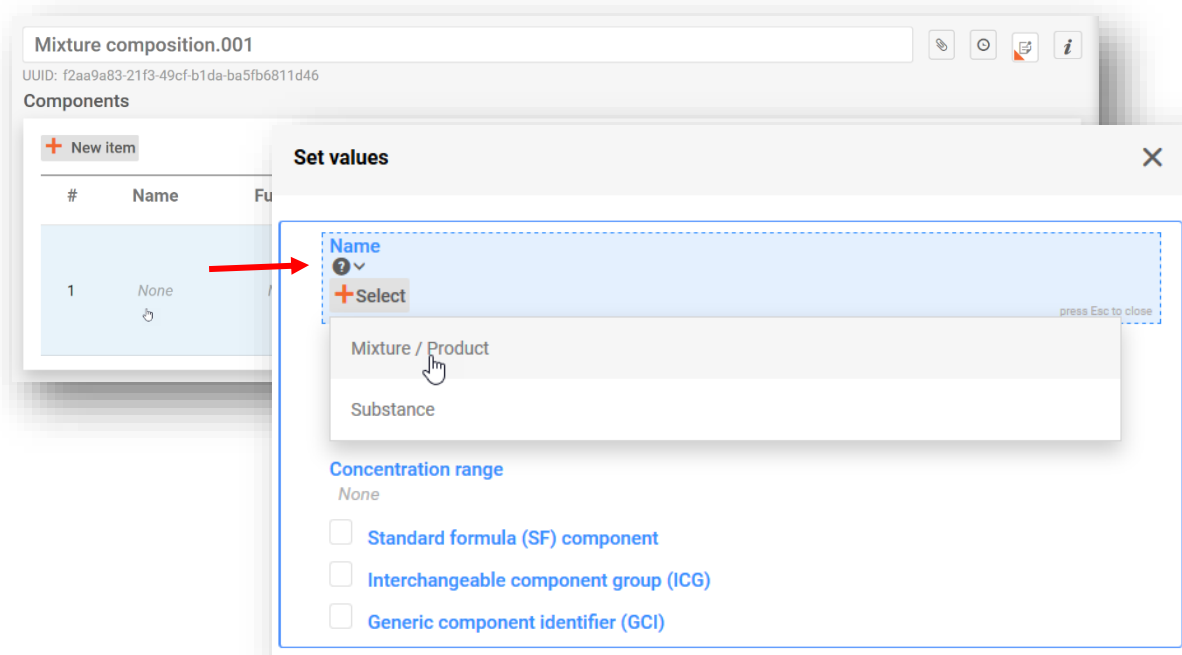
### 5.4.1 Specifying the mixture and concentration

Creating a mixture dataset is required for each mixture-in-mixture (MiM) component that is included in the final mixture that will be placed on the market. If reporting the known substances of the MiM, specific substance datasets are required, each to be identified with their respective identifier and linked to a reference substance.



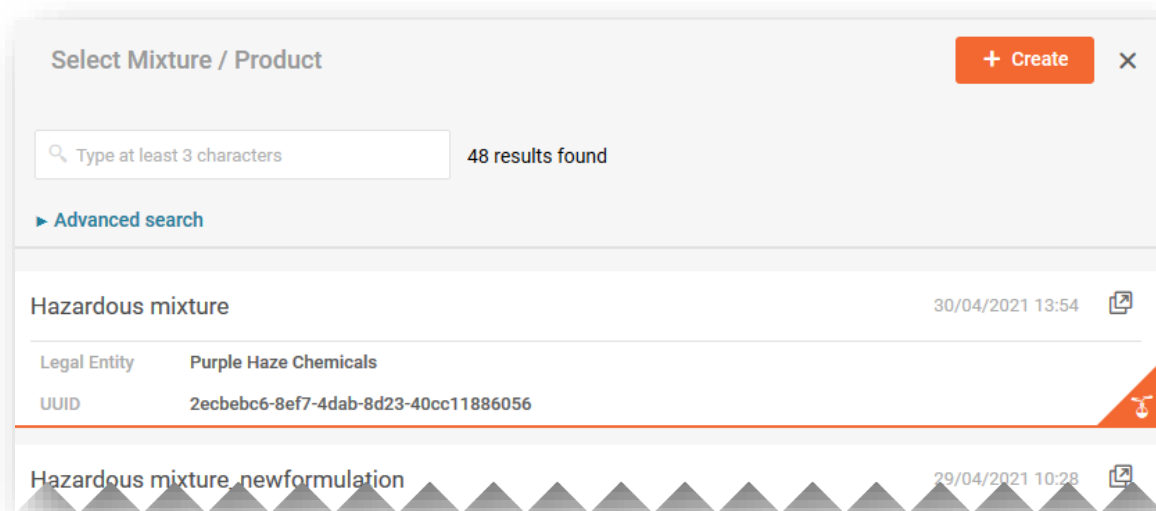
If all the substances in the mixture component (i.e. the MiM) are known, they need to be reported individually, as for all other substances i.e. it should not be included as a MiM. In this case any same substances have to be merged and reported only once.

From the (main) Mixture composition document, you need to first create a New item. Clicking on the field (shaded blue) opens the Set values box where you select 'Substance' in the Name field.



The Mixture (in mixture) can be specified in one of two ways, either by:

- selecting a previously prepared mixture dataset from the list, OR,
- +Create a new Mixture dataset




**Selecting a mixture dataset** from the list automatically populates the Set fields box with the name of the mixture in mixture and its associated information.



When **creating a mixture dataset**, you need to enter information manually for the mixture.

**Mixture name:** The mixture name is a free text field and should include the name of the mixture as received by the supplier.

 Where more than one name exists for a mixture component, these should not all be included in this field.


**Legal entity owner:** Note that the legal entity is mandatory to create the IUCLID dataset, however, this is not mandatory for PCN purposes and no checks concerning this information are carried out. Currently a Legal Entity selection must be made e.g. it could be your own legal entity.

#	Name type	Name	Country	Remarks	Action
---	-----------	------	---------	---------	--------

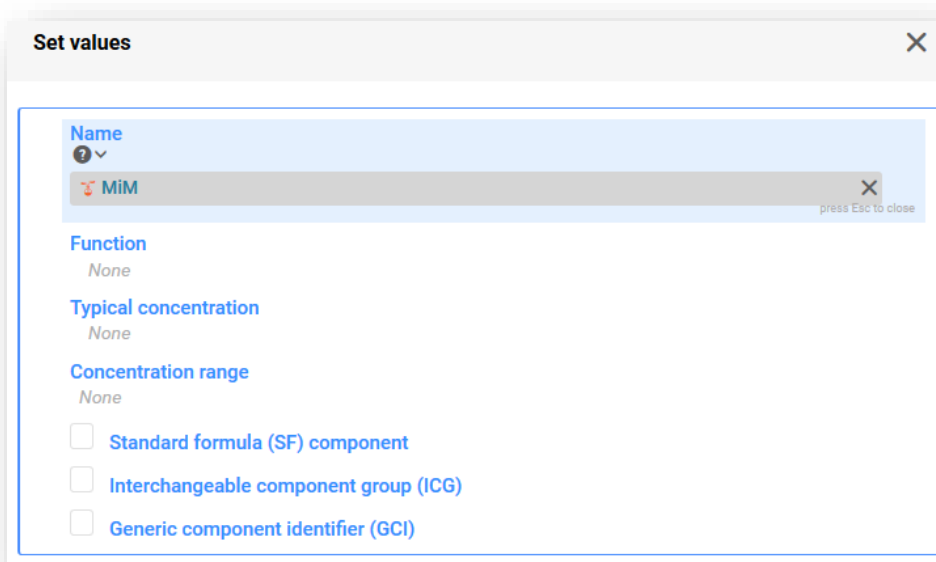
Once the mixture name has been provided and saved, the Set values box need to be completed as for substances:


**Function:** The function is only mandatory to include if you are indicating a GCI (generic component identifier) component. In these cases, a selection must be made between perfumes or colourants. In any case, the information can be voluntarily provided.

**Typical concentration/range:** The concentration of components can be declared either as a 'typical' concentration (i.e. exact concentration), or a 'concentration range' and expressed in either % (w/w) or % (v/v). Enter the relevant information either if the MiM component conforms to either 100% of the final mixture, or only a part of the final mixture. Operators (>, <, ≤, ≥) must be included for reporting ranges – note ca. is not permitted.

 Note that units should be reported in the same way for the concentration of all components.

Declaring concentrations for hazardous and non-hazardous components must be in accordance with the allowed limits detailed in Annex VIII (unless specific provisions apply). You can find more information about these ranges, including working examples <https://poisoncentres.echa.europa.eu/components-of-major-concern>



 Only where components fit specific conditions outlined in Annex VIII to the CLP Regulation should these component types be indicated. See Chapter 5 for more information:

**Standard formula (SF) component**

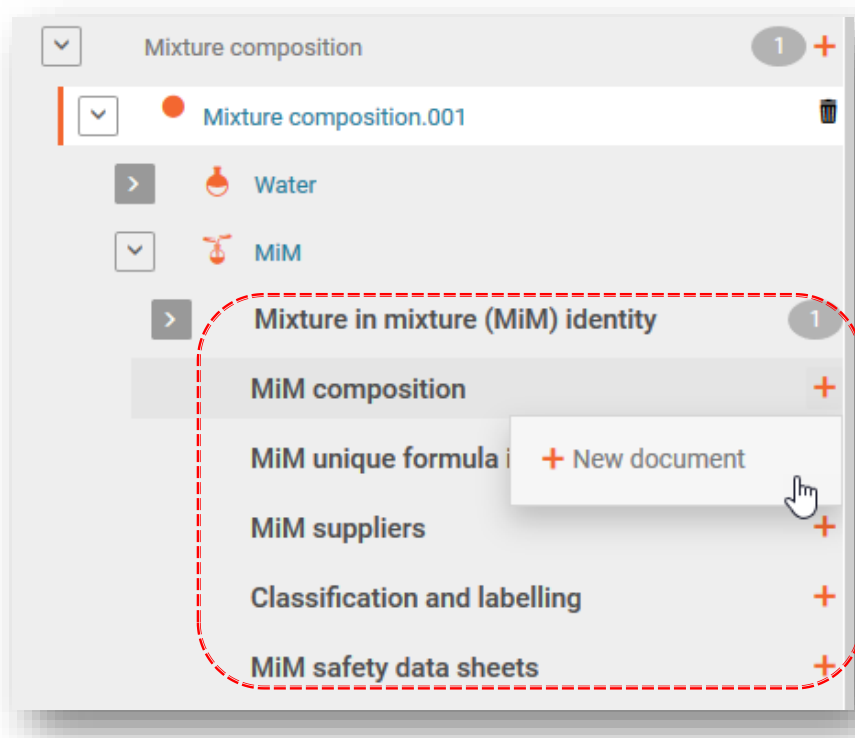
**Interchangeable component group (ICG)**

**Generic component identifier (GCI)**

### 5.4.2 Completing information about the MiM

This section describes the MiM relevant documents and how information should be entered into IUCLID when the composition of a MiM is not fully known.

When a mixture (in mixture) component is added to the main Mixture composition document and you click on Save, an additional set of information fields is generated in the navigation tree. Using the arrows to collapse and expand sections. To enter information for the sections, it is required to first create a New document.



Note that depending on the information you use to report your mixture in mixtures, not all the sections and fields need to be completed. Please check the Guidance on Annex VIII (outlined in Annex VIII to CLP Part B; 3.2.2) to determine which information is mandatory to be provided for your mixture in mixture.

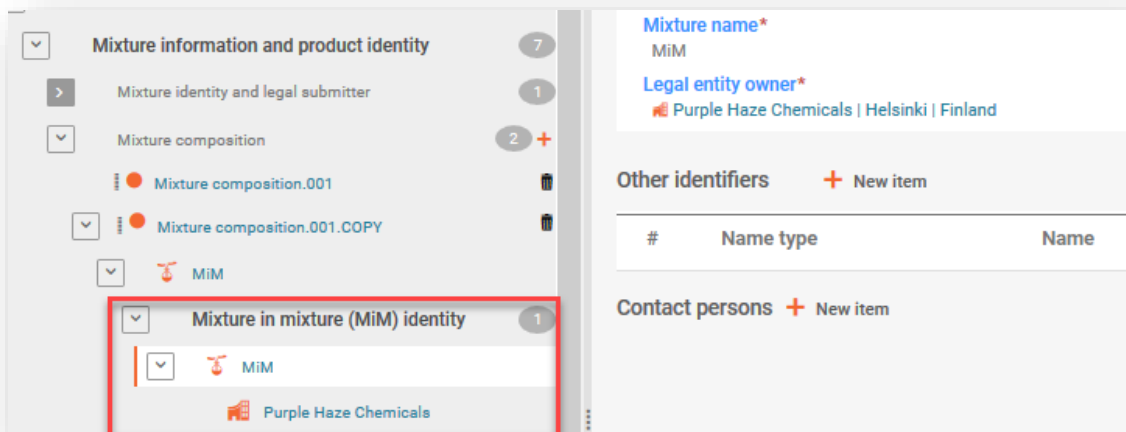
#### 3.2.2. Mixture in mixture

When a mixture is used in the composition of a second mixture placed on the market, the first mixture is referred to as a mixture in mixture ("MIM").

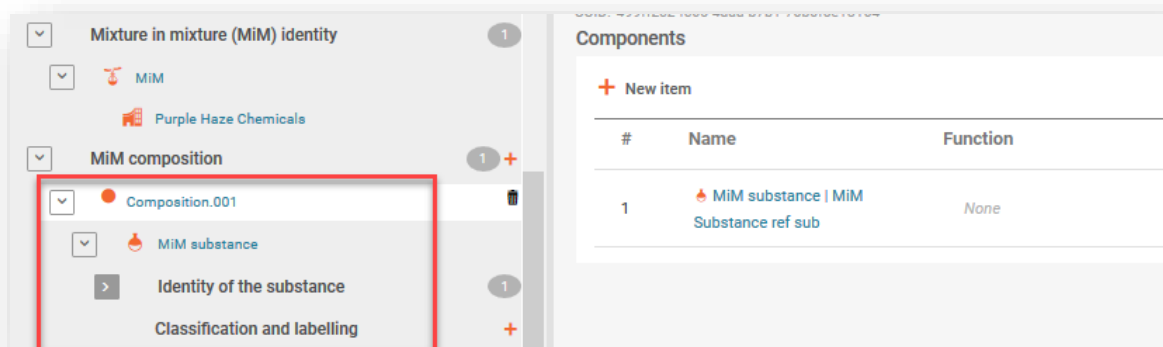
Information on the substances contained in a MIM shall be provided in accordance with the criteria of Section 3.2.1, unless the submitter does not have access to information on the full composition of the MIM. In the latter case,

- if a UFI has been created for the MIM and the appointed body has received the information on the MIM in a prior submission, the MIM shall be identified by means of its product identifier in accordance with Article 18(3)(a), together with its concentration and UFI;
- if a UFI has been created for the MIM, but the appointed body has not received the information on the MIM in a prior submission, the MIM shall be identified by means of its product identifier in accordance with Article 18(3)(a), together with its concentration and UFI and the compositional information contained in the Safety Data Sheet in accordance with Annex II to Regulation (EC) No 1907/2006 of the MIM and any other known components, as well as the name, email address and telephone number of the MIM supplier;
- in absence of a UFI, the MIM shall be identified by means of its product identifier in accordance with Article 18(3)(a), together with its concentration and the compositional information components contained in the Safety Data Sheet in accordance with Annex II to Regulation (EC) No 1907/2006 of the MIM and any other known components, as well as the name, email address and telephone number of the MIM supplier.

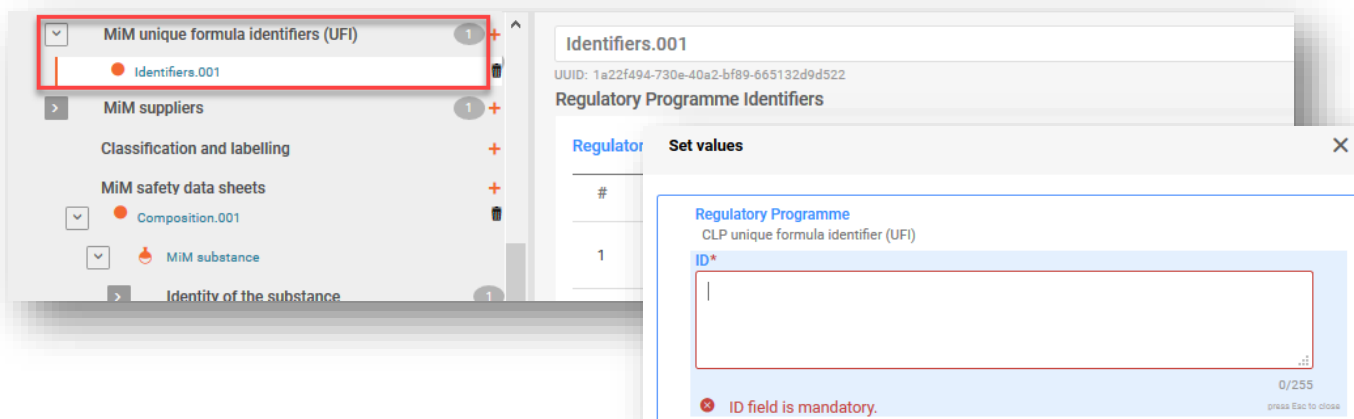
**MiM identity** was provided i.e. a name (and legal entity), during the creation process in the previous step. You can add information in the 'Other identifiers' field for the MiM e.g. if it conforms to a Standard Formula or a fuel as outlined in Annex VIII. It is not necessary to include contact persons for the MiM here as this can be done for in the MiM supplier section as described below.




**MiM composition:** Substance (only) components of the MiM are entered here. The substance component is further expanded to include information about the MiM substance's identity (reference substance) and classification (see section 4.3.5.3 and 4.3.5.4).

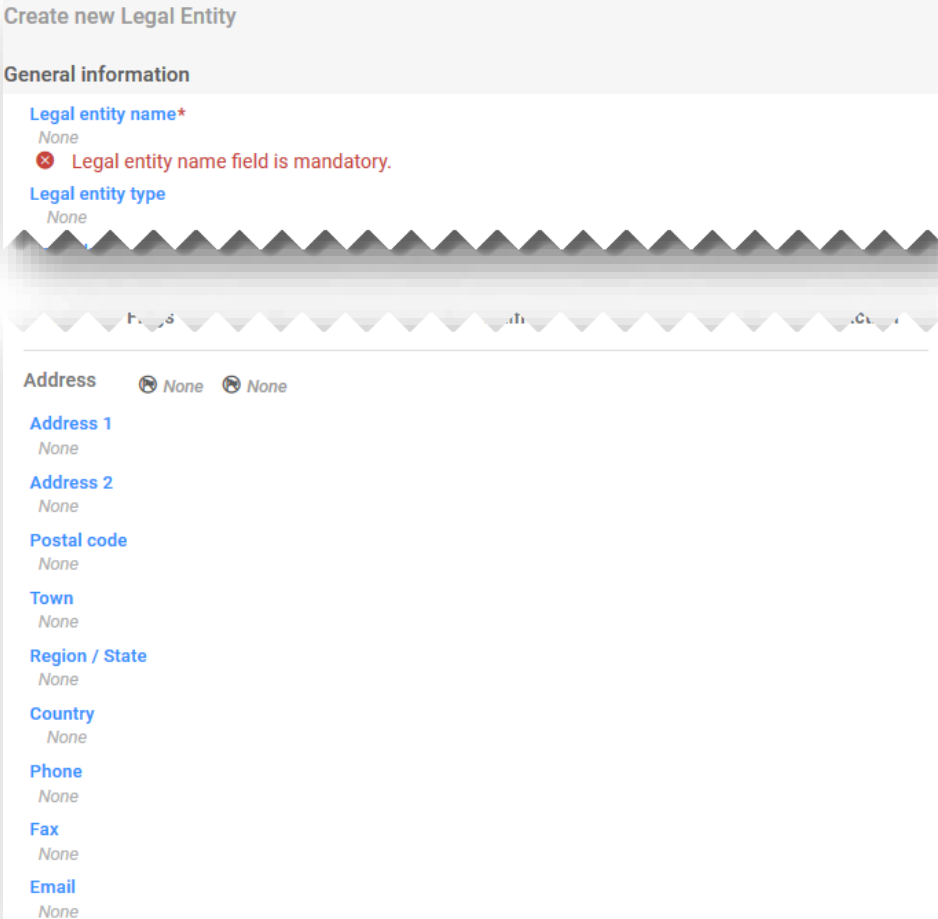


**MiM UFI:** The UFI of the MiM as provided by the supplier can be included in this field where available. The Regulatory programme (CLP unique formula identifier) must be selected and the UFI entered in the ID field.




**MiM supplier:** The supplier details can be included by making a selection from the list of available suppliers (meaning, legal entities), or, if the details are not listed, a +New document can be created and the relevant details for the MiM supplier provided (the name, email address and telephone number of the MiM supplier).

 When specifying the MiM supplier details, ensure to use **EU supplier** details. This is to assist Authorities in case of further follow up on composition.





Create new Legal Entity

General information

Legal entity name\*  
None  
 Legal entity name field is mandatory.

Legal entity type  
None

Address  None  None

Address 1  
None

Address 2  
None

Postal code  
None

Town  
None

Region / State  
None

Country  
None

Phone  
None

Fax  
None

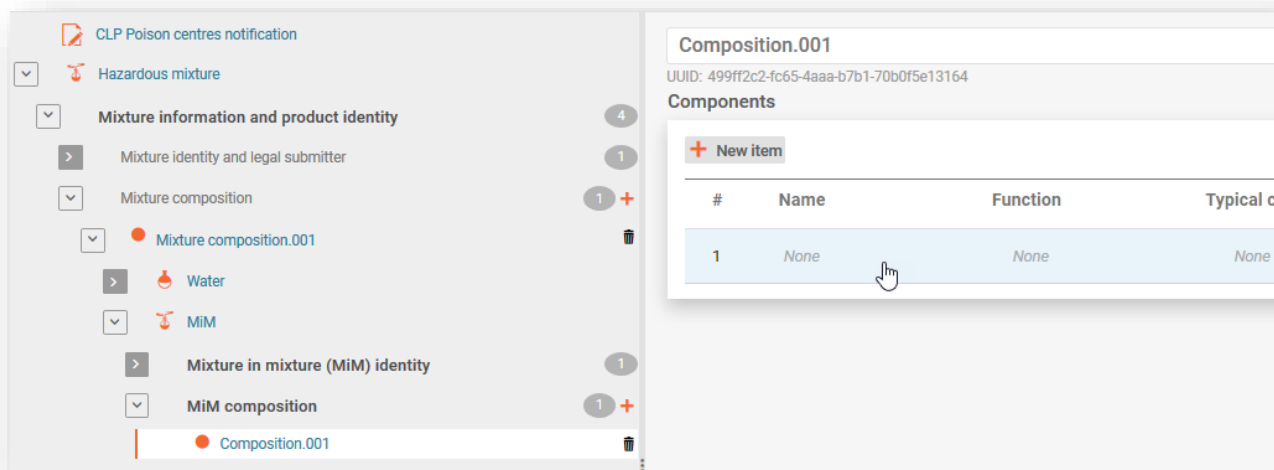
Email  
None

**Classification and labelling (MiM):** The classification of the MiM must be indicated here by including all the hazard categories and statements. The labelling elements of the MiM are not required but can be easily included using the Calculate function following verification of the results by the submitter.

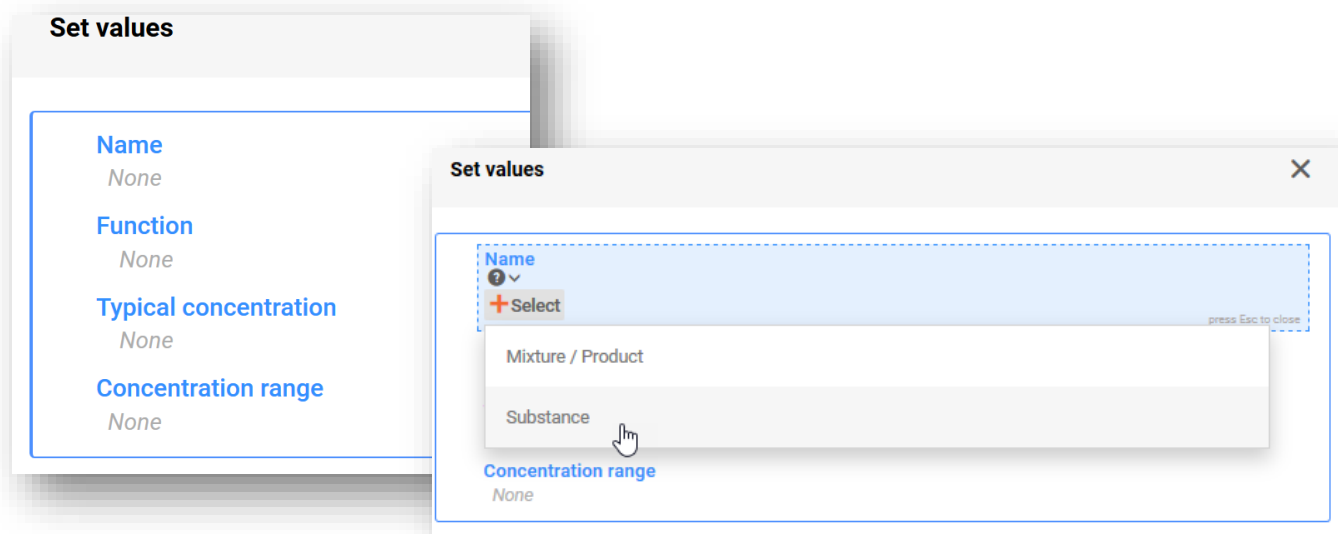
**MiM safety data sheet:** Not mandatory information in any case, but the field is available for optional upload in multiple languages.

### 5.4.3 Entering information for MiM composition

After having created the 'MiM composition' document, a 'Components' section appears. Here it is possible to add the known substances which are part of the composition of MiM. Each substance is added by clicking New item.



Clicking on the area of the created item (shaded blue) under 'Components' opens a specific Set values box for the MiM substances.



**Name** - Note that in the Name field, only Substance components are allowed to be added within the MiM composition.

**Function** is not mandatory to provide but can be provided voluntarily.

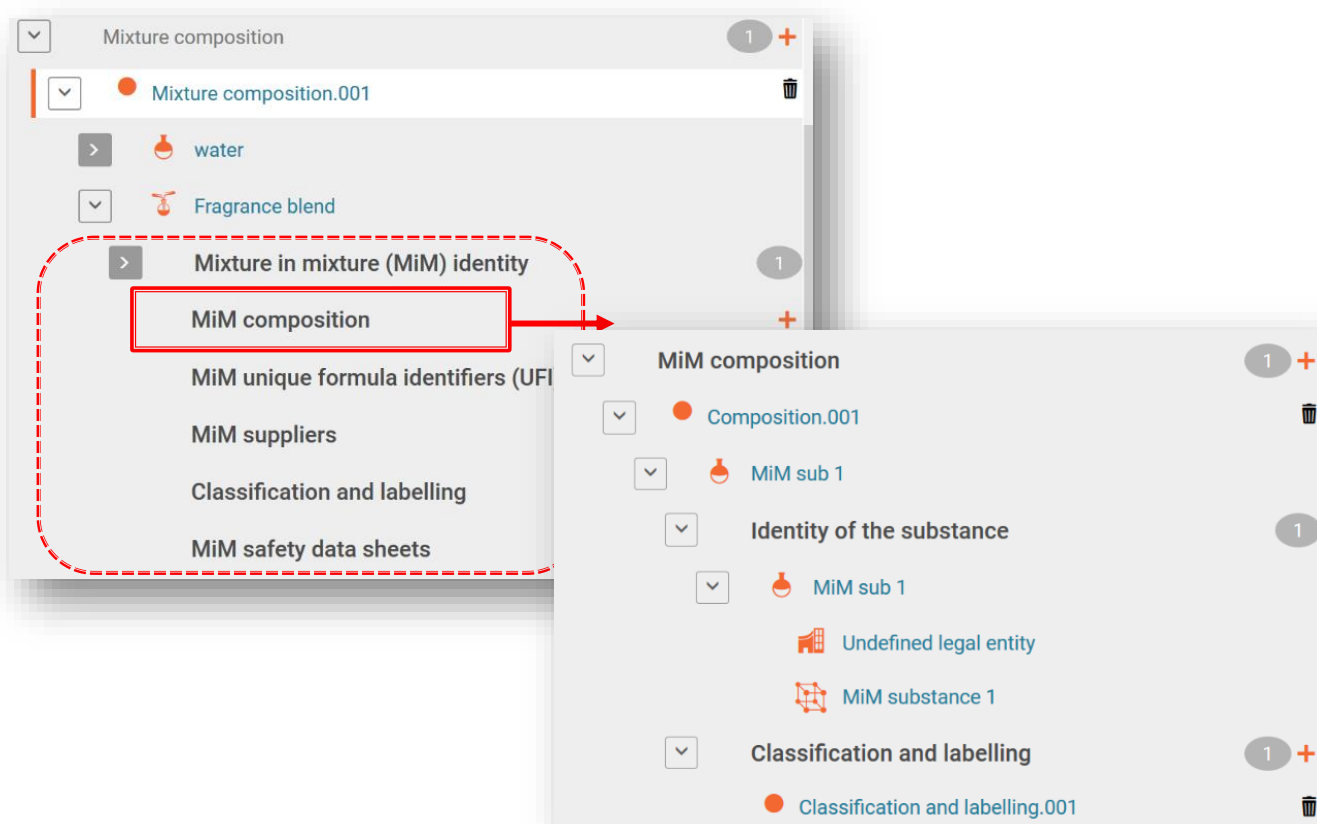
A '**typical concentration**' or a '**Concentration range**' has to be provided for the substance in the MiM. Normally this information is sourced from the SDS and it is not subject to any check.

### 5.4.4 Entering information about a MiM's substance identity and classification

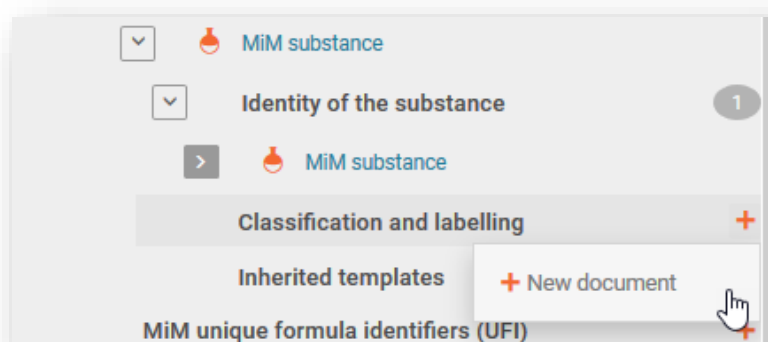
From the Set values box, selecting Name begins the process of identifying the substance components of a MiM. Identifying the substance can be achieved in one of two ways:

- By selecting an existing dataset, or
- By creating a new dataset

In any case, each substance component included in the MiM composition has to be linked to a reference substance in the 'Identity of the substance' document, and the classification provided. Use the '>' arrows in the navigation tree to further open the MiM substance section to reveal the Identity of the substance and the Classification and labelling documents.

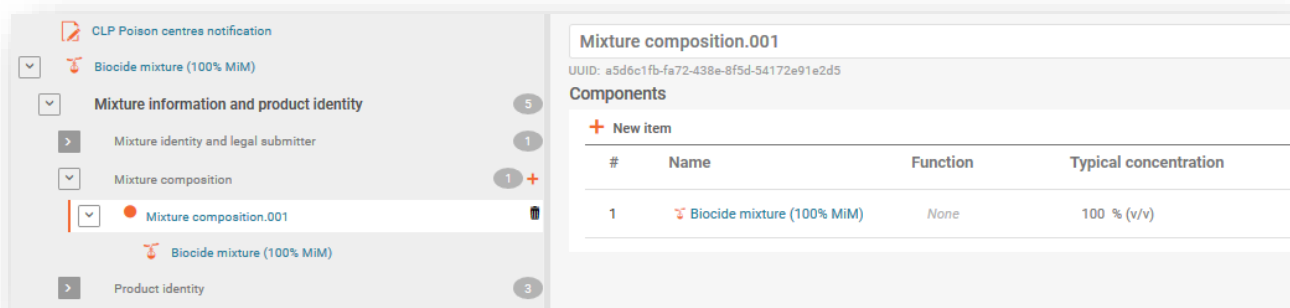


A New '**Classification and labelling**' document will first need to be created then filled in with, as a minimum, the classification of the substance for physical and human health hazards or the indication 'Not classified', as applicable. The labelling information is not mandatory but can be provided on voluntary basis.



### 5.4.5 Preparing a notification for 100% MiM

In specific situations, when the submitter is not in possession of sufficient compositional information as required by Annex VIII (and it is not able to obtain it from the supplier), it can be acceptable to make a notification where one mixture in mixture constitutes 100% of the final mixture composition.

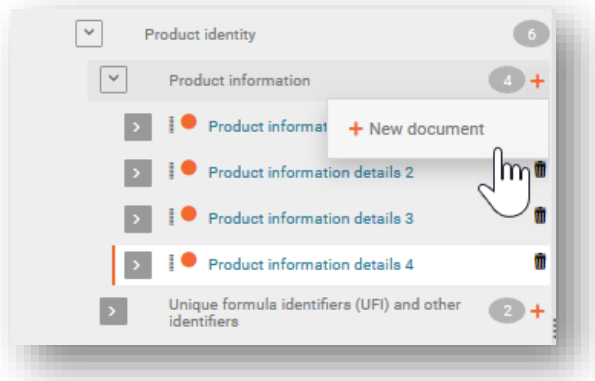


This still requires a full notification, meaning that you:

1. Create a new mixture dataset for the working context of **CLP poison centre notification**
2. Enter all the required information in the notification for the final mixture
  - a. Dossier header section (e.g. markets, languages, notification type)
  - b. Product information section (e.g. packaging, use type, main intended use, trade names, colour, physical state)
  - c. UFI and other identifiers section (generate and add your own UFI)
  - d. Mixture information (e.g. classification & labelling, toxicological information, pH)
3. Create a mixture composition document and enter all the required information for the mixture in mixture
  - a. Add a Mixture component
  - b. Provide the name of the mixture and specify a legal entity (this could be an undefined legal entity or even your own)
  - c. A 'Set values' box will be created to enter the typical concentration. Here is where you would specify 100%.
  - d. Once you save this information, open the MiM component in the left-hand side of the page – you will see a number of additional sections to complete
4. The MiM component sections include:
  - a. MiM identity (automatically filled in from step 3.b)
  - b. MiM composition (this is where you would add the individual substance components of the MiM. Each substance requires a name and a concentration.
  - c. In the next level down of each substance, you need to:
    - i. create New document for the Identity of the substance and provide a link to a reference substance  
*Plus*
    - ii. create New document for the Classification and Labelling and indicate the classification of the MiM
  - d. MiM UFI section – here is where you add the UFI of the supplied mixture
  - e. MiM supplier – here you add the supplier details
  - f. Classification & labelling – add the classification of the MiM
  - g. MiM safety datasheets – here it is possible to attach safety datasheets

## 5.5 Product identity (information) document

The product identity document contains the information required for the identification of the product or products containing the mixture as placed on the market. To create a product identity document, select New document (from the navigation tree).



Creating multiple product information documents is possible for a mixture where it may be desirable to separate the information for specific products containing the mixture e.g. there may be different trade names or UFI's or perhaps different market areas. It may also be useful to have a separate product information record if e.g. a duty holder is including additional information for a distributor customer.

The product identity document contains the sections Group submission (relevant only for that specific submission type and covered in section chapter 8), Product identifiers (section 5.5.1) and Additional information (section 5.5.2).

Product information.001  
 UUID: a565021a-048e-4bbb-9e6f-285af827ad0b

**Group submission**  
 For a group submission, specify to which mixture it applies:  
 None

**Product identifiers**

Trade names + New item

#	Trade name

Other names + New item

#	Other name

Unique Formula Identifier (UFI) and other identifiers  
 None

**Additional information**

Colour and physical state  
[Link to the information about colour and physical state](#)  
 None

Packaging  
 Product not packaged  
[Link to the packaging information](#)  
 None

Product use category  
 Use type  
 None  
 Main intended use  
 None  
 Secondary uses  
 None

Market placement  
 Active market (country)  
 None  
 Ceased market (country)  
 None

### 5.5.1 Product identifiers

Product identifiers include trade and other names and the UFI. Individual items are added by clicking on the +New item.

The screenshot shows a web interface titled "Product identifiers". It contains two main sections: "Trade names" and "Other names". Each section has a "+ New item" button. The "Trade names" section contains a table with two rows, both listing "Zuper final mixture". The "Other names" section is currently empty. Below these sections, there is a field for "Unique Formula Identifiers (UFI)" with the value "0200-U0CW-500C-Q2U3".

#	Trade name	Action
1	Zuper final mixture	
2	Super final mixture	

#	Other name	Action

Unique Formula Identifiers (UFI)  
0200-U0CW-500C-Q2U3

**Trade names:** The trade name of the product, as indicated on the label, is to be entered here. It is possible to include multiple trade names in the one IUCLID document (for instance when the same mixture is placed on the market with different trade names, but the same product information applies). Alternatively, they can be each added individually in separate Product documents. In any event, multiple trade names should not be included in a single "Trade name" field, but rather included as different new items.

If you have **multiple trade names**, they need to be included as individual items. **Do not** include all trade names in a single field of entry.

The screenshot shows the "Trade names" section of the form. A single row is present with the trade name "Shiny, Kiiltävä, Brillante, Glänzende". A large red "X" is overlaid on the right side of the row, indicating that this entry is incorrect because it contains multiple trade names in a single field.

#	Trade name	Action
1	Shiny, Kiiltävä, Brillante, Glänzende	

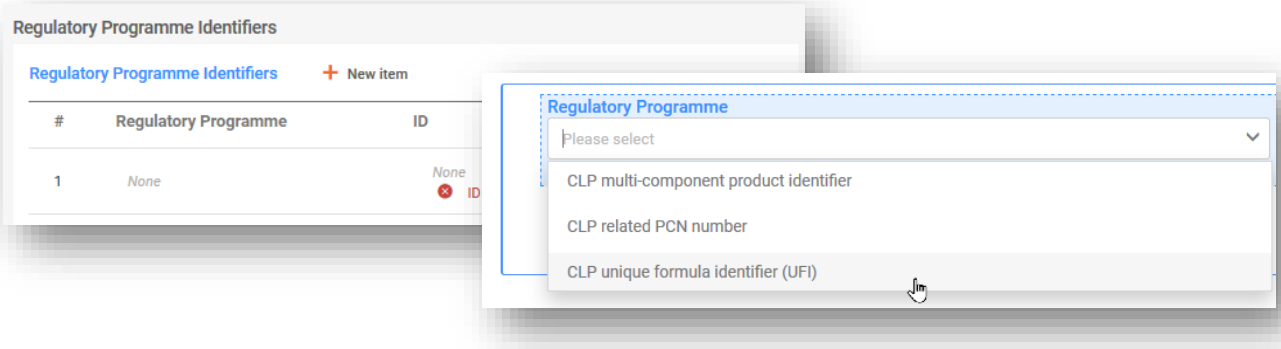
**Other names:** Any other names which may appear on the label and can be useful to facilitate the identification of the mixture, can be included in this section.

#### UFI and other identifiers:

A single or multiple Unique Formula Identifier (UFI) are added in this section of Regulatory Programme Identifiers. There are three CLP PCN relevant identifiers:

- i. **UFI** – a 16-character alphanumeric code with a defined format, is included in this section. The UFI generator tool is available from ECHA's Poison Centre Website <https://poisoncentres.echa.europa.eu/ufi-generator>
- ii. **Related PCN number** - If you are submitting a 'New notification after a significant change of composition' then you need to indicate the CLP related PCN number (See chapter 11 for details on updates).

- iii. **Multi-component product identifier** – allows to indicate that certain mixtures (notified separately) belong to the same multi-component product (see section 7.2 for full details).



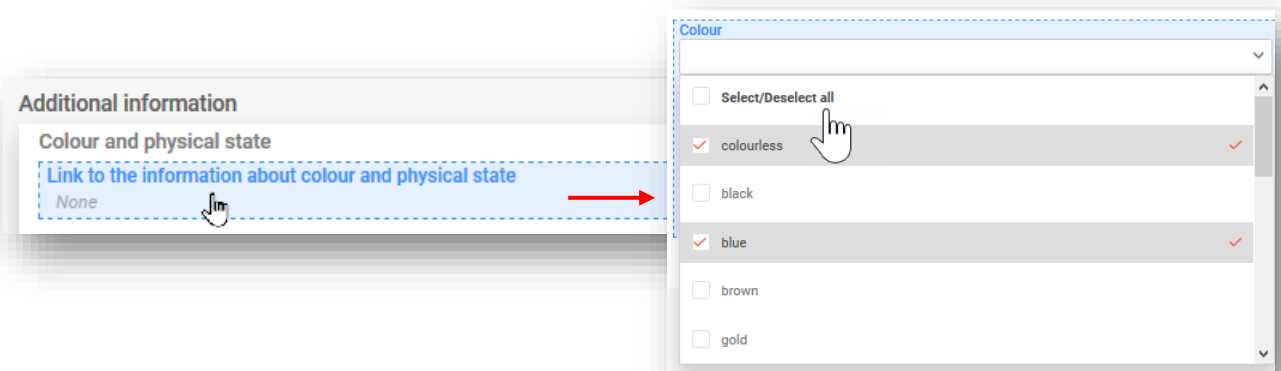
<p><b>UFI Generator tool</b>  <a href="https://ufi.echa.europa.eu/#/create">https://ufi.echa.europa.eu/#/create</a></p>	
<p><b>UFI user guide</b> (translations available) and other support  <a href="https://poisoncentres.echa.europa.eu/ufi-generator">https://poisoncentres.echa.europa.eu/ufi-generator</a></p>	

## 5.5.2 Additional information

Additional information on the product includes the following fields:

### 5.5.2.1 Colour

Single or multiple colour selections are available. Selecting multiple colours, e.g. colourless and blue, means that the product is placed on the market in these variations (for instance when a mixture composition differs for colourants which are identified with the same Generic Component Identifier, see section 6.1).



### 5.5.2.2 Physical state

A selection must be made for the physical state at 20°C 101 hPa of the product (i.e. gas/liquid/solid). Optional information for the form and intensity can be included from the available picklist (e.g. solid: flakes; transparent).

Physical state at 20°C and 1013 hPa  
liquid

Form

Please select

- aerosol dispenser: not specified
- aerosol dispenser: foam aerosol
- aerosol dispenser: spray aerosol
- gas
- gel
- liquid
- liquid: viscous
- liquid: volatile



Note that making a selection for a physical state enables/disables certain 'Forms'.

### 5.5.2.3 Packaging

If a mixture is supplied in different types and sizes of packaging, information on all the relevant types and sizes (no ranges permitted) placed on the market have to be included. Additionally you can indicate if the product is not packaged.

Additional information

Colour and physical state

[Link to the information about colour and physical state](#)

None

Packaging

Product not packaged

[Link to the packaging information](#)

None

Multiple packaging sizes can be indicated in one packaging item.

Create new FLEXIBLE\_RECORD.Packaging

Packaging

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

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

- Size of packaging in contact with the product (container size)  
1 L
- Size of packaging in contact with the product (container size)  
500 mL
- Size of packaging in contact with the product (container size)  
100 mL
- Size of packaging in contact with the product (container size)  
50 mL

Packaging related attachments + New item

#	Type of attachment	Attached document	Action
---	--------------------	-------------------	--------

However, different packaging items are required if more than one packaging type is used

Packaging

Product not packaged

[Link to the packaging information](#)

barrel / drum | 25 L ×

bottle | 1 L | 500 mL | 100 mL | 50 mL ×

[+ Select](#)

**!** Note that mixtures for use at industrial sites only that can benefit from a limited submission, are not mandatorily required to have packaging indicated.

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

Packaging

Type of packaging in contact with the product (container type)  
None

Size of packaging in contact with the product (container size) [+ New item](#)

Packaging related attachments [+ New item](#)

#	Type of attachment	Attached document	Action
1	None	None	

#### 5.5.2.4 Product use category information

Product use category

**Use type**

Consumer

**Main intended use**

PC-AIR-4 Air care products for vehicles

**Secondary uses**

None

- i. **Use type:** The selection of the use type(s) 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 supplied for use at industrial sites will also need to reflect other use types if it is used as a mixture for further formulation in professional or consumer use products.

Product use category

**Use type**

Select/Deselect all


consumer ✓

professional

industrial

None

- ii. **Main intended use:** A single main intended use category per Product details record is required. The categories listed are those available from the European Product Categorisation System (EuPCS). Scroll through the list or use the search functionality

-  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 as Main intended use.

**Main intended use**

PP-BIO-1 Biocidal products for human hygiene (P Products > PP Biocides and plant protection products > PP-BIO Biocidal products > PP-BIO-1 Biocidal products for human hygiene)

**Secondary uses**

- PC-CLN-3 Bleaching products for cleaning or laundry use (excludes biocidal products) (P Products > PC Chemical products (excludes biocidal products) > PC-CLN Cleaning, care and maintenance products (excludes biocidal products) > PC-CLN-3 Bleaching products for cleaning or laundry use (excludes biocidal products))

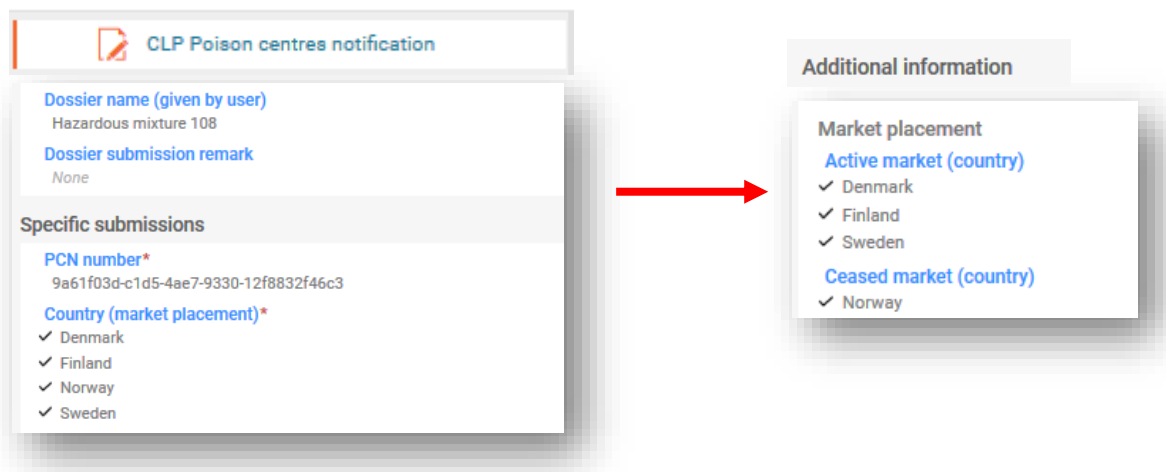
- iii. **Secondary uses:** This is optional information that can be provided for those products that fit several main intended use categories.

**EuPCS practical guide** and supporting material available:  
<https://poisoncentres.echa.europa.eu/eu-product-categorisation-system>



### 5.5.2.5 Market placement


The complete lists of market areas included in the product record must match the full list indicated in the dossier header. In case of multiple Product records, each Country indicated in the dossier header must be selected at least once, either in the “Active market” or in the “Ceased market” lists.



- i. **Active market:** Earlier in the preparation phase, all the relevant market areas were indicated in the dossier header for the whole notification. These market areas need to be indicated accordingly per product record. If the same product is placed on different market areas, all the relevant countries can be selected in the same product record. Alternatively, several product information documents can be created and the countries assigned as relevant.
- ii. **Ceased market:** The submitter can indicate in an update whether the placing on a specific market area of a product has ceased. The relevant Country or Countries can be selected in this list. At the same time the same countries have to be deselected by the “Active market” list of the same Product record.

## 5.6 Classification and labelling of the (final) mixture

This section must contain all the correct and relevant hazard statements from a predefined list of existing values (according to the CLP regulation criteria).

 Only a single classification and labelling (C&L) record can exist for a mixture for a standard submission. Entering multiple C&L records for this submission type will result in a validation rule failure. See Chapter 7 for more on classification and labelling for group submissions.

### 5.6.1 Classification information

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

#### Classification

Not classified  
Hazard categories & statements  
None

**Physical and health hazards:** Select all the hazard category and statement for each of the hazard classes your mixture falls under, by selecting from the pick list. Pre-emptive text is available for searching.

#### Classification

Not classified  
Hazard categories & statements  
skin  
 (Acute toxicity - dermal) Acute Tox. 1-H310: Fatal in contact with skin.  
 (Acute toxicity - dermal) Acute Tox. 2-H310: Fatal in contact with skin.  
 (Acute toxicity - dermal) Acute Tox. 3-H311: Toxic in contact with skin.  
 (Acute toxicity - dermal) Acute Tox. 4-H312: Harmful in contact with skin.  
 Skin Corr. 1-H314: Causes severe skin burns and eye damage.  
 Skin Corr. 1A-H314: Causes severe skin burns and eye damage.  
None

**Environmental hazards:** If your mixture is classified for physical or human health hazards, then it is not mandatory to indicate any environmental hazards though they can be included for completeness. If your mixture is only classified for environmental hazards and you are making a voluntary notification, then you will need to indicate the classification accordingly.

**Additional hazard classes:** Free text fields are available to include additional hazard classes and statements in all relevant languages.

## 5.6.2 Labelling information

Like with the substance and mixture in mixture datasets, the labelling elements (mandatory for the final mixture) can be automatically filled using the calculate button. The submitter should verify and possibly correct or complete the information generated. The fields included in the labelling document include the following:

**Signal word:** Danger, warning or no signal word are available in the drop-down list.

The screenshot shows a 'Labelling' section with a 'Calculate' button. Below it is a 'Signal word' dropdown menu. The menu is open, showing three options: 'Danger', 'Warning', and 'No signal word'. A mouse cursor is pointing at the 'No signal word' option.

**Hazard pictogram:** Multiple selections of hazard pictograms are available according to the CLP Regulation.

The screenshot shows a 'Hazard pictogram' section with a 'Code' label. Below it is a row of nine hazard pictograms with their corresponding GHS codes and checkboxes. The checkboxes for GHS02, GHS03, GHS04, GHS05, GHS06, GHS07, GHS08, and GHS09 are checked.

GHS Code	Description	Checked
GHS01	exploding bomb	<input type="checkbox"/>
GHS02	flame	<input checked="" type="checkbox"/>
GHS03	flame over circle	<input checked="" type="checkbox"/>
GHS04	gas cylinder	<input checked="" type="checkbox"/>
GHS05	corrosion	<input checked="" type="checkbox"/>
GHS06	skull and crossbones	<input checked="" type="checkbox"/>
GHS07	exclamation mark	<input checked="" type="checkbox"/>
GHS08	health hazard	<input checked="" type="checkbox"/>
GHS09	environment	<input checked="" type="checkbox"/>

**Hazard and Precautionary statements:** This section must contain all the correct and relevant (labelling) hazard and precautionary statements from a predefined list of existing values (according to the CLP Regulation criteria).

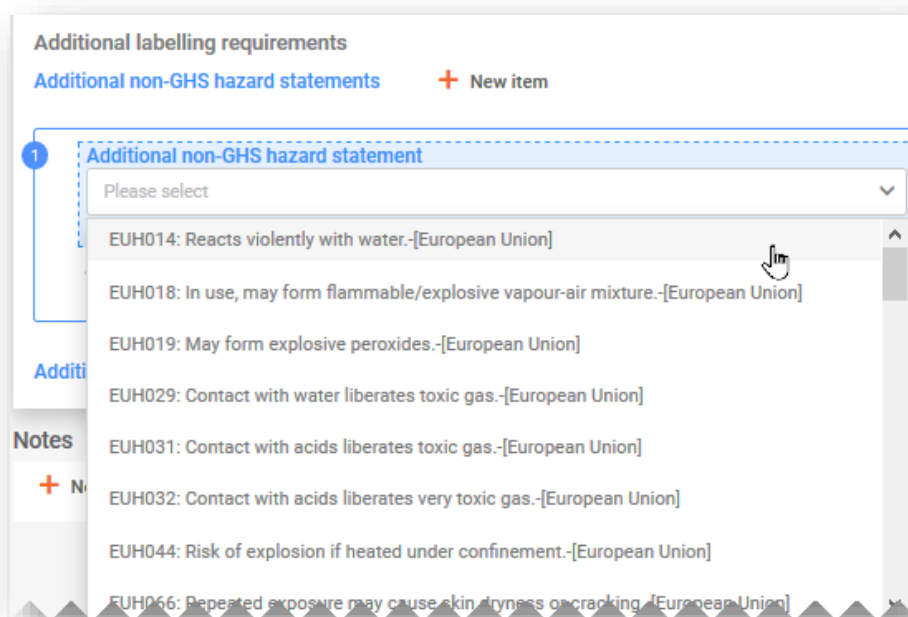


Some statements contain free text fields to include additional text information. This information should be **provided in all the relevant languages** where the mixture will be placed on the market.

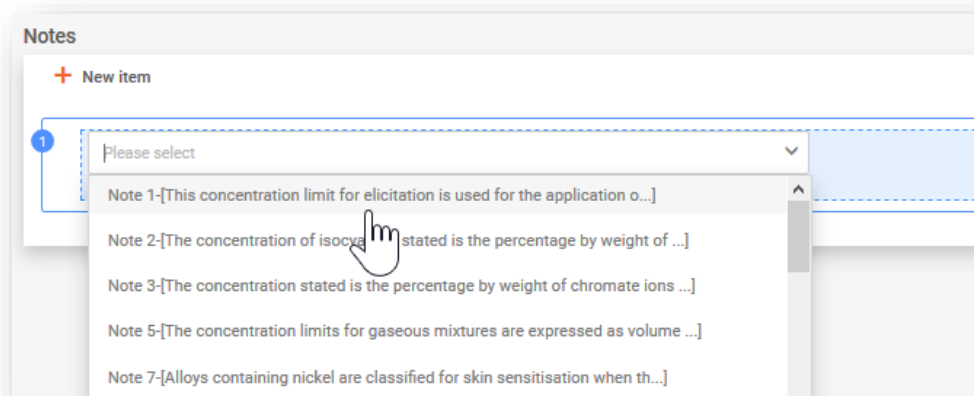
The screenshot shows a 'Hazard statements' section with a '+ New item' button. Below it is a list of hazard statements. The first statement is H351: Suspected of causing cancer. The second statement is H200: Unstable explosives. A dropdown menu is open over the H200 statement, showing three options: 'H200: Unstable explosives.', 'H201: Explosive; mass explosion hazard.', and 'H202: Explosive, severe projection hazard.'

**Additional labelling requirements:** This section refers to the supplemental hazard information, namely EUH-Statements.

Some mixtures are classified only for **EUH208**, which applies to mixtures that are not classified as sensitisers but however contain at least one sensitising substance. The Guidance on Annex VIII considers these mixtures are only subject to voluntary notification.



**Notes:** This section includes a picklist from which you can select additional sub-categories for GHS classification.



## 5.7 Mixture SDS and toxicological information

Create a new record for the toxicological information or copy from an existing one where available and relevant. 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.

**Toxicological information:** Only one toxicological information document is allowed per notification of standard submissions. However, if the submission is for multiple markets/languages, then this information must be given for each language selected in the dossier header. Toxicological information for group submissions is covered in Chapter 7.



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.

**Safety data sheet:** Attaching the safety data sheet (SDS) of the mixture is not mandatory and does not release the duty holder from the provision of information in the required format. Multiple SDS attachments are possible, and Country and Language information can be included.

**Mixture safety data sheets and toxicological information.001**

UUID: b11658f9-abe7-4d6c-a9c7-6a846e6f18d1

**Information on mixtures**

Safety data sheets of mixture / product ⓘ

+ New item

#	Safety data sheet	Country	Language
1	None	None	None
2	<a href="#">1_windowx SDS.pdf</a>	None	None

**Toxicological information (section 11 of SDS)**

fi

Tiedot myrkyllisistä vaikutuksista:  
Seoksen myrkyllisyysominaisuuksista ei ole kokeelliseen näyttöön perustuvia tietoja

Vaaralliset terveysvaikutukset:  
Jos altistus on toistuvaa, pitkäaikaista tai työperäisen altistumisen raja-arvot ylittävää, tuotteella voi olla haitallisia terveysvaikutuksia altistustavasta riippuen:

A- Nieleminen (välitön vaikutus):  
- Välitön myrkyllisyys: Saatavilla olevien tietojen perusteella luokituskriteerit eivät täyty, eikä tuote sisällä nieltynä

## 5.8 Additional information

The Additional information section contains the information for pH. To provide this information, you can create a new pH document or use the 'Copy data from...' functionality. For information on how to provide pH for a group submission, refer to Chapter 8.

There are two options to provide information on the pH, either:

- i) **pH not available:** 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. In this case the justification for not providing a value must be given.

The screenshot shows a dropdown menu titled 'Justification' with the following options:

- pH is above 15
- pH is below -3
- substance/mixture is a gas
- substance/mixture is non-polar/aprotic
- substance/mixture is non-soluble (in water)
- substance/mixture not stable
- substance/mixture reacts with water

- ii) **pH available:** To provide a pH value you can provide an exact value or a range:

- To indicate the exact pH value, only a single numerical entry is required
- To provide a range you must use the relevant operators e.g. <, >. The **operator 'ca' is not accepted** for reporting the pH in poison centre notifications.

! When the pH = <3 or >=10, the preferred maximum range width is 1 unit.

When the pH 3 < or <10, the preferred maximum range width is 3 units.

Going beyond these limits will trigger a quality rule contained in a validation report and sent with the notification to the Member State (i.e. this will trigger a warning, see section 5.1.1).

**Solution concentration:** This is a mandatory field when the pH value is provided.

The screenshot shows a form titled 'Key value for chemical safety assessment' with the following fields:

- pH is not relevant
- pH value**: > 6.5 < 6.8
- Solution concentration (%)**: 100

press Esc to close

## 6. Mixture composition – specific cases


This section covers the mixture composition document in specific circumstances

- Indicating a generic component identifier (GCI)
- Indicating a standard formula (SF)
- Indicating an interchangeable component identifier (ICG)

### 6.1 Indicating a generic component identifier (GCI)

A generic component identifier can be used to identify those components used exclusively to add perfume or colour, and only if they are **not classified for any health hazard**. These are referred to in this document as “GCI components”.

The same type of GCI, i.e. “perfumes” or “colouring agents”, can be used to identify one or more components. However, the concentration of a given GCI cannot exceed in total 5% for the sum of perfumes, and 25% for the sum of colouring agents.

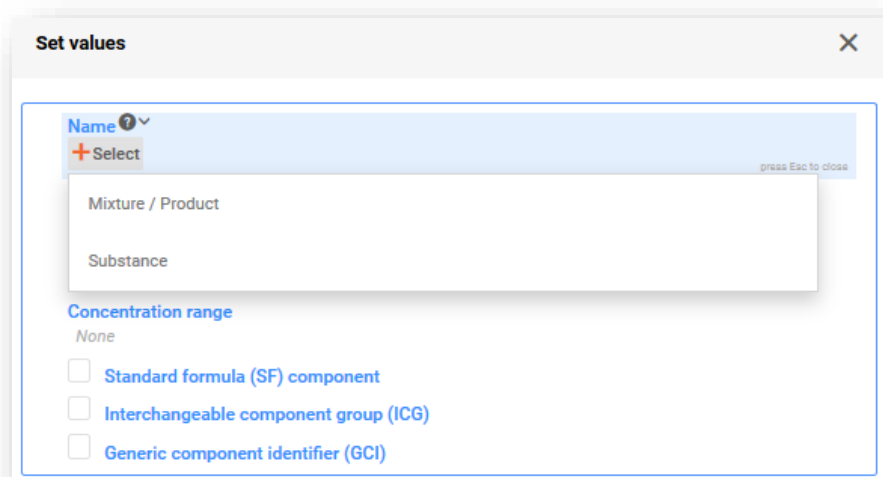
 Note that a classification record is mandatory for GCI components.

If there are multiple components to be identified with the same GCI and have the same classification for physical and/or environmental hazards, these can be covered by one single GCI component.

Alternatively, the same GCI can be used more than once in the same composition, as long as the maximum concentration threshold of 5% or 25% is not exceeded.

GCI components can be either substances or mixture in mixtures. In either case, a GCI component must have a name, and a function specified (i.e. either ‘perfume’ or ‘colourant’), a concentration indicated, and the GCI check box must be flagged.

To add a GCI component from the mixture composition document, select New item, and a Set values box will appear.



**Set values** X

Name ⓘ  
+ Select press Esc to close

Mixture / Product

Substance

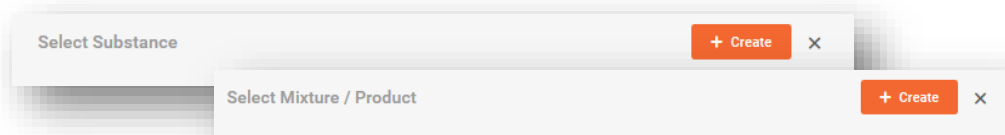
**Concentration range**  
None

Standard formula (SF) component

Interchangeable component group (ICG)

Generic component identifier (GCI)

In the Name field, select 'Substance' or 'Mixture' to open the respective listing page. You can select an available dataset from the list if it has already been prepared earlier, or, you can +Create a new one.

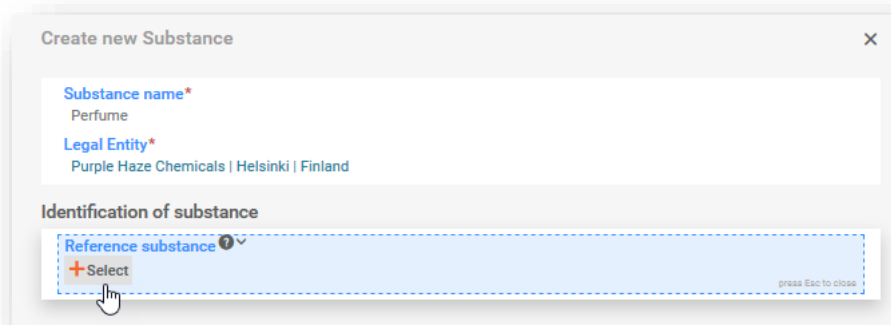


To create a new one, provide the name of the component (e.g. "Perfume" or "Colouring agent") and specify a legal entity.

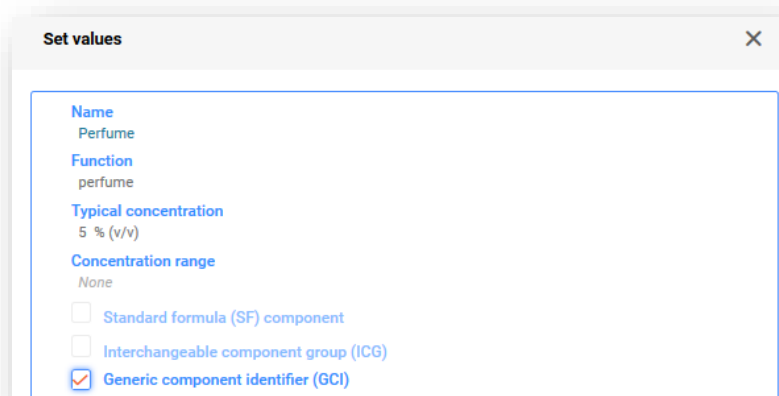


Note that the **legal entity** is mandatory to create the IUCLID dataset, however, this is not mandatory for PCN purposes and no checks concerning this information are carried out. Currently a Legal Entity selection must be made e.g. it could be your own legal entity.

The reference substance information is not required for GCI substance components



Complete the Set values box with the function, concentration and mark the GCI checkbox. If the GCI component covers multiple perfumes or colouring agents, their total concentration has to be provided.



If the GCI component is added as a mixture, the standard identification requirements for mixture in mixtures do not apply (i.e. no need to provide UFI, composition and supplier's details).

## 6.2 Indicating Standard Formula (SF)

**Standard Formulas** have been developed specifically for cement, gypsum, ready-mixed concrete and are listed in Part D, Annex VIII. For mixtures that conform to a Standard Formula specific, less strict requirements apply and the submission can deviate from the standard requirements.

You can prepare specific Standard Formula datasets (compositional information) by **downloading ready-made datasets** from the Poison Centre website or prepare your own.

A mixture may include a Standard Formula as either:

- i. one that constitutes 100% of the final mixture (in this case the mixture as a whole conforms with the standard formula), or,
- ii. one which conforms only in part with a standard formula as it contains other components in addition to it.

Standard formula components can be reported:

- i. in the main mixture composition, each individual component flagged as Standard Formula

The screenshot shows the 'Mixture composition.001' document. The left sidebar lists 'Mixture composition' with a sub-item 'Mixture composition.001' highlighted. The main table lists components with a 'Standard formula (SF) compo...' column containing checkboxes.

#	Name	Function	Typical concentration	Concentration range	Standard formula (SF) compo...
1	Portland cement clinker   Portland cement clinker	None	None	86.5 100 % (w/w)	<input checked="" type="checkbox"/>
2	Calcium sulfate   Calcium sulfate	None	None	0 8 % (w/w)	<input checked="" type="checkbox"/>
3	Flue dust/inorganic natural mineral materials	None	None	0 5 % (w/w)	<input checked="" type="checkbox"/>
4	Iron(II) sulfate   Iron(II) sulfate   Iron(II) sulfate	None	None	0 1 % (w/w)	<input checked="" type="checkbox"/>
5	Tin(II) sulfate   Tin(II) sulfate   Tin(II) sulfate	None	None	0 0.1 % (w/w)	<input checked="" type="checkbox"/>

- ii. in a MiM composition document (flagged as a Standard Formula) and consisting of components in a Standard formula composition document

The screenshot shows the 'Standard formula (SF) identity' document. The left sidebar lists 'Standard formula (SF) identity' with a sub-item 'SF composition' highlighted. The main table lists components with a 'Concentration range' column.

#	Name	Function	Typical concentration	Concentration range
1	Tin (II) sulfate	None	None	0 0.1 % (w/w)
2	Iron(II) sulfate   Iron(II) sulfate   Iron(II) sulfate	None	None	0 1 % (w/w)
3	Flue dust/inorganic natural mineral materials	None	None	0 5 % (w/w)
4	Calcium sulfate   Calcium sulfate   Calcium sulfate	None	None	0 8 % (w/w)
5	Portland cement clinker   Portland cement clinker   Portland cement clinker	None	None	86.5 100 % (w/w)

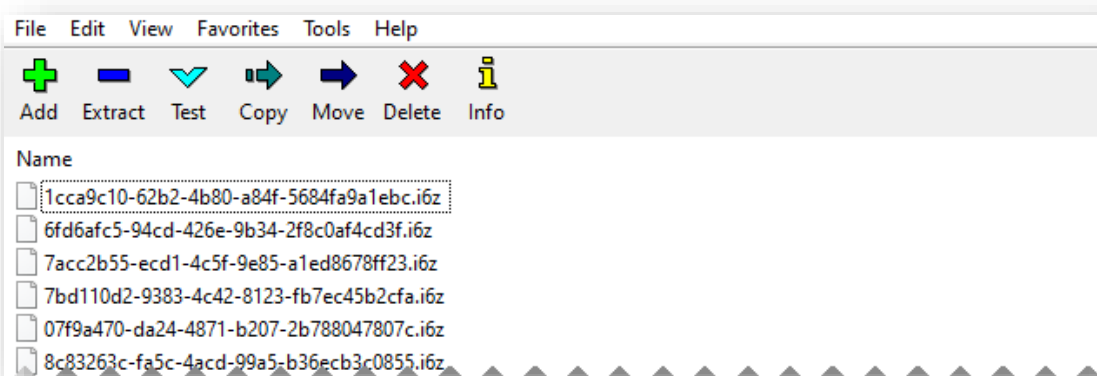
### 6.2.1 Downloading ready-made Standard Formula datasets

For each Standard Formula, the list in Part D of Annex VIII specifies the composition (components' identity and concentration). For example:

Cement Standard Formula – 1		
Product description	Portland cement <i>with one main constituent: clinker</i>	
Component name	EC No	Concentration (w/w%)
Portland cement clinker	266-043-4	86,5 – 100
Calcium sulfate	231-900-3	0 – 8
Flue dust <sup>(1)</sup>	270-659-9	0 – 5
Inorganic natural mineral materials	310-127-6	
Iron(II) sulfate	231-753-5	0 – 1
Tin(II) sulfate	231-302-2	0 – 0,1

For ease, Standard Formula datasets have been pre-prepared and are available for download and use in your IUCLID instance. Note that only the compositional information (name and numerical identifiers, and concentration as defined in the legal text have been included in the dataset. Therefore, you will need to complement these datasets with other information e.g. the classification. Of course, preparing your own Standard Formula datasets is also possible if preferred.

! Instructions on how to import and change the legal entity for the dataset are provided <https://poisoncentres.echa.europa.eu/poison-centres-notification-format>



## 6.2.2 Entering information when the final mixture conforms to 100% Standard Formula

When the mixture as a whole conforms to a standard formula, the Standard Formula name and description should be included as the name of the mixture and should be provided in the 'Other identifiers' section of the 'Mixture identity and legal submitter'.

The Name type Standard formula (SF) should be selected, which activates a drop-down list in the Name field. This includes all the Standard Formulas names from Part D of Annex VIII.

The screenshot shows the 'Set values' dialog for a mixture named 'portland cement'. The 'Name type' is set to 'standard formula (SF)'. A dropdown list of standard formula names is displayed, including:

- Cement Standard Formula - 1 [Portland cement with one main constituent: clinker]
- Cement Standard Formula - 2 [Portland-slag cement and Blast furnace cement with two main constituents: clinker and slag]
- Cement Standard Formula - 3 [Portland-silica fume cement Portland cements with two main constituents: clinker and silica fume]
- Cement Standard Formula - 4 [Portland-pozzolana cement, Pozzolanic cement Portland cements with two main constituents: clinker and pozzolan (natural or natural calcined pozzolan)]
- Cement Standard Formula - 5 [Portland-fly ash cement, Pozzolanic cement Portland cements with two main constituents: clinker and fly ash (siliceous and calcareous fly ash)]
- Cement Standard Formula - 6 [Portland-burnt shale cement Portland cements with two main constituents: clinker and burnt shale]

To report a Standard Formula substance component in the main mixture composition document, add a +New item to include a substance component.

The screenshot shows the 'Composition.001' document. The 'Components' table lists five substances, with the 'Standard formula (SF) component' checkbox checked for items 1, 2, 3, and 4.

#	Name	Function	Typical concentration	Concentration range	Standard formula (SF) compo...	Interchangeable component g...
1 1	None	None	None	None	<input type="checkbox"/>	<input type="checkbox"/>
1 2	Tin(II) sulfate (iron(II) sulfate) (iron(II) sulfate)	None	None	0.1 % (w/w)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1 3	Flue dust/inorganic natural mineral materials	None	None	0.5 % (w/w)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1 4	Calcium sulfate (Calcium sulfate) (Calcium sulfate)	None	None	0.8 % (w/w)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1 5	Portland cement clinker (Portland cement clinker) (Portland cement clinker)	None	None	86.5 100 % (w/w)	<input checked="" type="checkbox"/>	<input type="checkbox"/>

Each substance component is to be reported (the name and concentration) in accordance with Part D of Annex VIII and linked to a reference substance. Finally, each component is flagged as 'Standard formula (SF) component'.

The screenshot shows the 'Set values' dialog for a substance component. The 'Name' field is filled with 'Tin(II) sulfate', the 'Function' field is set to 'None', and the 'Standard formula (SF) component' checkbox is checked.

Note that the Standard Formulas in Part D contain group of components sharing the same concentration range.

Cement Standard Formula – 1		
Product description	Portland cement <i>with one main constituent: clinker</i>	
Component name	EC No	Concentration (w/w%)
Portland cement clinker	266-043-4	86,5 – 100
Calcium sulfate	231-900-3	0 – 8
Flue dust <sup>(1)</sup>	270-659-9	0 – 5
Inorganic natural mineral materials	310-127-6	
Iron(II) sulfate	231-753-5	0 – 1
Tin(II) sulfate	231-302-2	0 – 0,1

In these cases, a 'Mixture' component is created and included in the final mixture composition. Name the 'Mixture' by including the names of the grouped components (e.g. 'Flue dust/ Inorganic natural mineral material'). The individual components of the 'Mixture' (e.g. Flue dust and Inorganic natural mineral materials) also need to be identified but only the 'Mixture' has to be flagged as a Standard Formula component.

The screenshot shows a software interface for configuring a 'Mixture in mixture (MIM) identity'. The sidebar on the left contains a tree view with the following items: 'Mixture information and product identity', 'Mixture identity and legal submitter', 'Mixture composition', 'Composition.001', 'Iron(II) sulfate', 'Flue dust/Inorganic natural mineral materials' (highlighted with a red box), 'Mixture in mixture (MIM) identity', 'MIM composition', 'Composition (mixture).001', 'Flue dust', 'Inorganic natural mineral materials', 'MIM unique formula identifiers (UFI)', 'MIM suppliers', 'Classification and labelling', 'MIM safety data sheets', 'Inherited templates', 'Calcium sulfate', and 'Portland cement clinker'. The main window displays a 'Components' table with the following data:

#	Name	Function	Typical concentration	Concentration range	Standard formula (SF) component
1	Portland cement clinker   Portland cement clinker   Portland cement clinker	None	None	86.5-100 % (w/w)	<input checked="" type="checkbox"/>
2	Calcium sulfate   Calcium sulfate   Calcium sulfate	None	None	0-8 % (w/w)	<input checked="" type="checkbox"/>
3	Flue dust/Inorganic natural mineral materials	None	None	0-5 % (w/w)	<input checked="" type="checkbox"/>
4	Iron(II) sulfate   Iron(II) sulfate   Iron(II) sulfate	None	None	0-1 % (w/w)	<input checked="" type="checkbox"/>
5	Tin (II) sulfate	None	None	0-0.1 % (w/w)	<input checked="" type="checkbox"/>

### 6.2.3 Entering information when part of the mixture conforms to a Standard Formula

When the final mixture composition contains additional components besides those from the Standard Formula from Part D, they will have to be included following the standard rules for reporting components. The additional components that do not belong to the Standard Formula **must not** be flagged as a 'Standard Formula (SF) component'.

In this case the name of the Standard Formula needs to be indicated for each component (substance or MiM) which confirms with the Standard Formula and not for the main mixture (which does not conform with any Standard Formula).

It is also possible to include a Standard Formula in its entirety, as a mixture component i.e. a MiM. To do this from the main Mixture composition, select +New item and click on the corresponding field (shaded blue) to open the Set Values box and select Mixture/Product.

The screenshot shows two overlapping windows. The background window is titled 'Mixture composition.001' and contains a 'Components' table with one row: # 1, Name None, Function None, Typical co... None. A '+ New item' button is visible above the table. The foreground window is titled 'Set values' and contains a 'Name' dropdown menu with a 'Select' button. The dropdown menu is open, showing 'Mixture / Product' (highlighted) and 'Substance'. Below the dropdown, there is a 'Concentration range' section with 'None' selected, and three checkboxes: 'Standard formula (SF) component', 'Interchangeable component group (ICG)', and 'Generic component identifier (GCI)', all of which are currently unchecked.

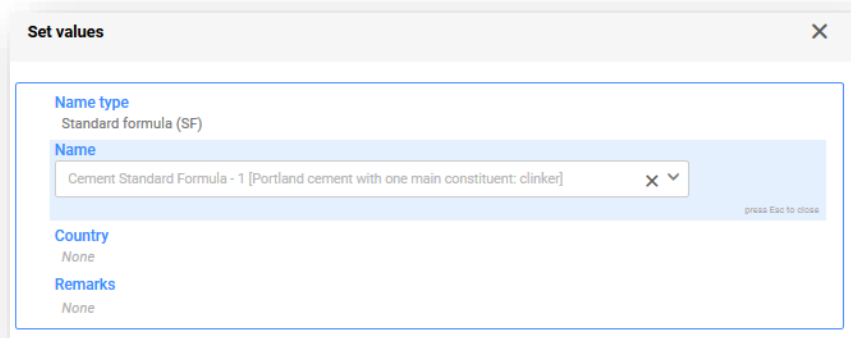
Once the MiM component is added and a Legal Entity is selected, select +New item in the 'Other identifiers' field.

The screenshot shows the 'Create new Mixture' dialog box. It has two main input fields: 'Mixture name\*' with the value 'Cement Standard Formula 1 [Portland cement with one main clinker]' and 'Legal entity owner\*' with the value 'Undefined Company Name | Helsinki | Finland'. Below these is an 'Other identifiers' section with a '+ New item' button. Underneath is a table with the following columns: #, Name type, Name, Country, Remarks, and Action. The table contains one row: # 1, Name type None, Name None, Country None, Remarks None, and Action (trash icon).

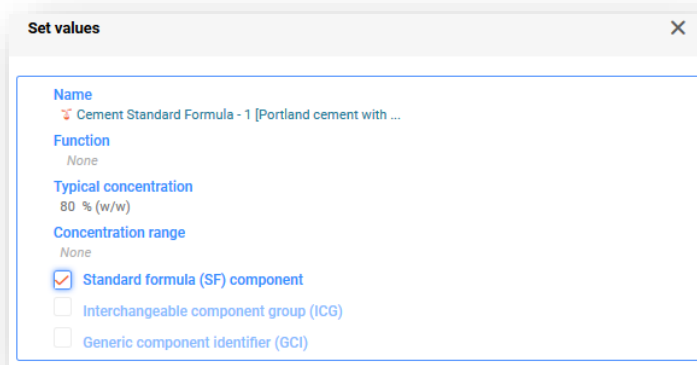


Note that the **legal entity** is mandatory to create the IUCLID dataset, however, this is not mandatory for PCN purposes and no checks concerning this information are carried out. Currently a Legal Entity selection must be made e.g. it could be your own legal entity.

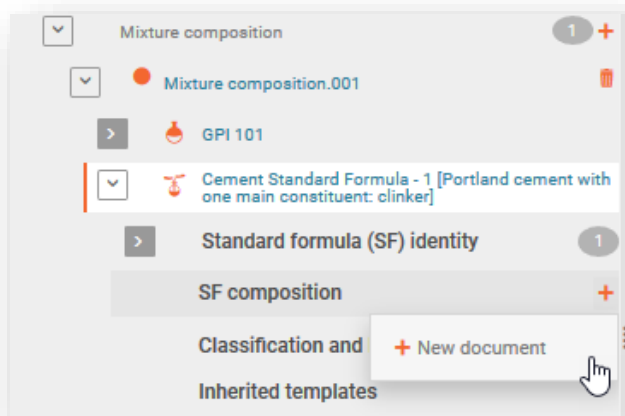
A Set values box opens and a selection regarding the Standard Formula information in the 'Name type' and 'Name' field needs to be made.




Add the concentration of the MiM in the final mixture and make the selection 'Standard Formula (SF) component'.



Now that the MiM Standard Formula component has been added, the individual components of the MiM must be reported in the Standard Formula composition section (create New document first) accessible via the navigation tree on the left-hand side of the page.



 The identity and concentration of each component must be reported according to the values detailed in Part D of Annex VIII to CLP.

The Standard Formula MiM composition document is where each individual component is identified. Clicking +New item assists with the creation of a component record (via the Set values box).

The screenshot shows a software interface with a hierarchical tree on the left and a 'Components' table on the right. The tree structure is as follows:

- Mixture composition (1 +)
  - Mixture composition.001
    - GPI 101
    - Cement Standard Formula - 1 [Portland cement with one main constituent: clinker]
      - Standard formula (SF) identity (1)
      - SF composition (1 +)
        - Composition.001
- Classification and labelling (+)

The 'Components' table on the right has the following structure:

#	Name	Function
+ New item		

**!** Note that it is the duty of the submitter to provide as much detailed information as possible. Therefore, if it is possible to provide more precise concentration ranges than those indicated in the Standard Formula in Part D of Annex VIII (e.g. if available on the SDS), this should be done. The components can still be flagged as 'SF components' so that the rules checking the normal concentration ranges are waived.

## 6.3 Indicating an interchangeable component group (ICG)

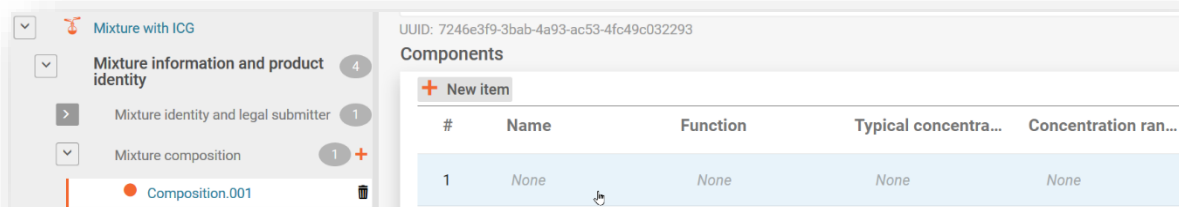
An interchangeable component group (ICG) consists of multiple similar components (fitting certain criteria), where each can be used interchangeably in a mixture without altering that mixture's overall classification, hazard or emergency health response.

Using the ICG is envisaged when it is not possible to know the exact concentration at each point in time of certain components if they are used interchangeably. For more details about the criteria that components have to meet in order to be notified as part of an ICG, refer to the Guidance on Annex VIII.

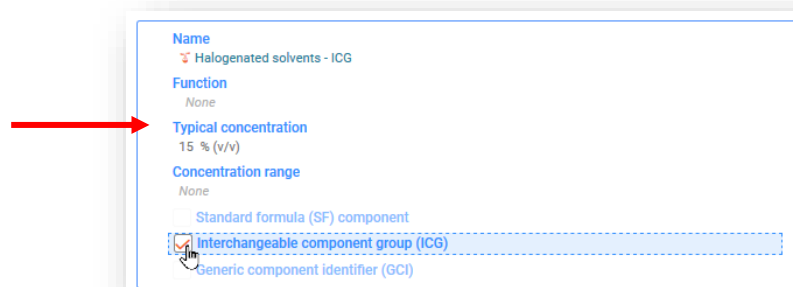
The components within an Interchangeable Component Group are called interchangeable components. When preparing a poison centre notification, the 'group' is first created as for a Mixture/product (i.e. MiM) and then the interchangeable components (substances or MiMs) within it are further identified.

### 6.3.1 Step 1- Indicating the group

The mixture composition document is where all components, i.e. substances or MiMs, and the ICGs are added by selecting +New item



A **mixture component** is created for the ICG (i.e. a MiM) and a **name** is entered for the group in the 'Name' field that corresponds to the technical function(s) of the grouped components. A selection for the **legal entity** (it can be undefined) is required. The **concentration** of the ICG component (and not the single components grouped) in the final mixture is provided and the **ICG check box** is marked.



The **name** of the grouped components should be meaningful and indicative of the components contained to allow the emergency operator to easily identify which kind of components can be present in the final mixture.



The **legal entity** is mandatory to create the IUCLID dataset, however, this is not mandatory for PCN purposes and no checks concerning this information are carried out. Currently a Legal Entity selection must be made e.g. it could be your own legal entity.

### 6.3.2 Step 2 – Indicating information for the components

Once the the ICG is created in the Mixture composition document, an ICG relevant documents will be visible in the navigation tree. The interchangeable components can then be added in the "ICG composition" document. Interchangeable components have to be identified following the standard rules for substances or MiMs.

Each MiM component included in an ICG will have to be identified by:

- i. its name and the full composition (if available); or
- ii. its name and UFI (if available), or
- iii. its name, the composition from the SDS and the supplier's details.

Each substance component included in an ICG has to be identified as per any other substance and requires a link to a reference substance.

#	Name	Function	Typical concentration	Concentration range
1	Interchangeable component 1   Interchangeable component 1	None	None	None
2	Interchangeable component 2   Interchangeable component 2	None	None	None
3	Interchangeable component 3   Interchangeable component 3	None	None	None



The components included in an ICG do not require concentration information.

The information on **classification** can be provided for the ICG as a whole, in particular when all the components have exactly the same composition. When small differences exist (possible at subcategory level), the classification should be provided for each component individually. In this case the classification for the ICG should not be provided.

Information about **pH** and **toxicological properties** for the ICG as a whole (i.e. relevant to all the components included in the ICG) can be provided but it is not legally required.



A MiM flagged as an ICG cannot include a component additionally flagged as:

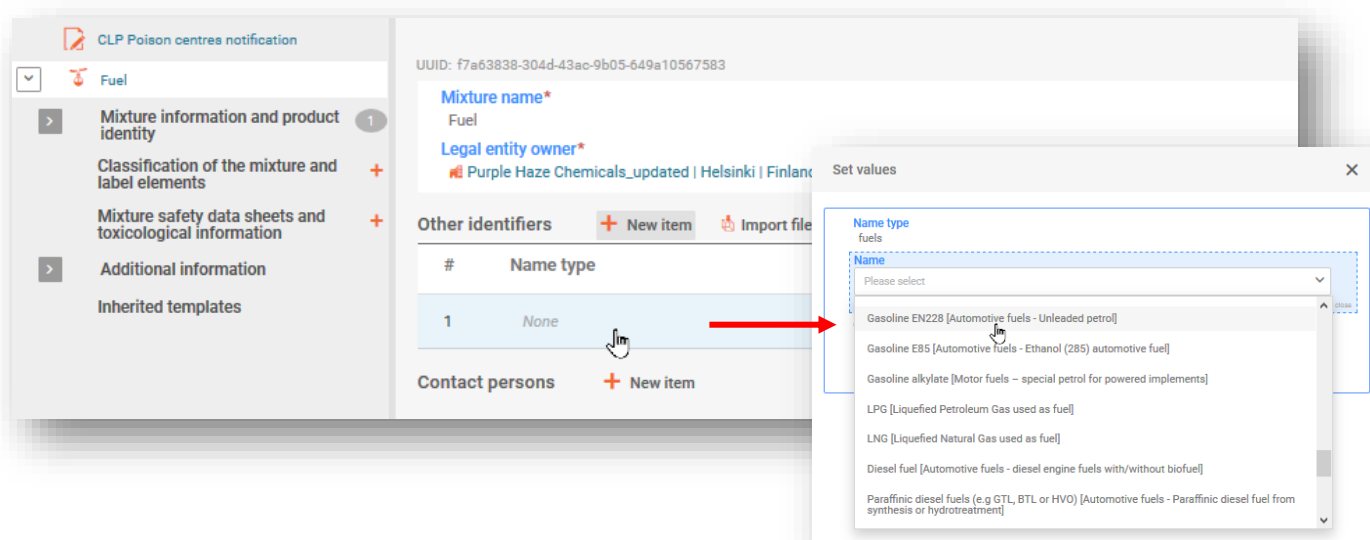
- Standard Formula
- Generic Component Identifier
- another Interchangeable Component Group

## 6.4 Notifying fuel mixtures

Like mixtures conforming to Standard Formulas, certain **fuels** (i.e. those listed in Table 3, Annex VIII) can also deviate from standard requirements. For allowed fuels, the composition can be reported according to the Safety Data Sheet (and, in addition, any the other available compositional information available).

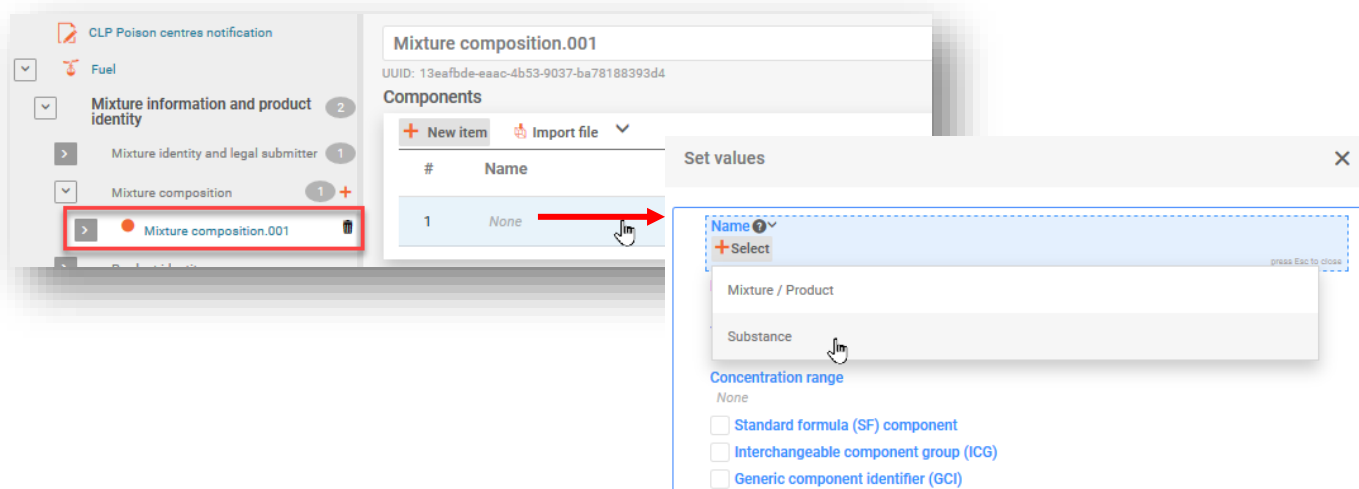
### 6.4.1 Step 1 – identify the fuel

Identify the fuel at the main mixture level in the Other identifiers section by selecting 'Fuels' in the Name type field and making a selection of the relevant fuel's name from the picklist.



### 6.4.2 Step 2 – add fuel components

In the mixture composition document add each component by creating a New item and providing the information for the component by selecting the component (Substance or Mixture) in the Name field.



### 6.4.3 Step 3 – Identify components

All reported substances must be named and linked to a Reference substance document and classification information provided.

Create new Substance

Reference substance Ethanol press Esc to close

Legal Entity\*  
Purple Haze Chemicals\_updated | Helsinki | Finland

Substance name\*  
Ethanol

Other substance identifiers New item Import file

#	Identifier	Identity	Country	Remarks	Action
---	------------	----------	---------	---------	--------

### 6.4.4 Step 4 – Complete compositional information

Complete the Set values box by providing the compositional details for each component and select the Standard Formula component check box. The remaining sections of the notification must be completed.

Name  
 Ethanol | Ethanol

Function  
None

Typical concentration  
None

Concentration range  
> 0 <= 10 % (v/v)

Standard formula (SF) component

Interchangeable component group (ICG)

Generic component identifier (GCI)

The components need to be flagged as 'Standard Formula components' so that the rules checking the normal concentration ranges are waived.

## 7. Other considerations for special mixtures

This section covers:

- Multi-component products
- Combination of mixture/article

### 7.1 Indicating multi-component products

Multi-component products are products containing a set of distinct mixtures (e.g. reagents, testing kits, dish washing tablets, etc.) where each mixture has to be notified individually with its own unique formula identifier (UFI).

The UFI and other identifiers section allows to indicate that certain mixtures (notified separately) belong to the same (multi-component) product by indicating a PCN multi-component product identifier.

The PCN multi-component identifier

- can be used in all notifications related to the same multi-component product
- is not checked by the validation rules
- can be used as relevant by the notifier e.g. an existing identifier (e.g. UFI of the other mixture, trade name of the multi-component product); or a new identifier (e.g. a universal unique identifier (UUID))

! If your mixture/product is related to a **multi-component** product, then all relevant information (e.g. on the mixture created upon use) should in addition, be included in the toxicological information field. In this case, it must be clear which information refers to the mixture and which to the multi-component product.


## 7.2 Indicating combined mixture/article

Some mixtures are placed on the market in combination with articles and may be required to be notified. For example, a cleaning wipe is an example of a combination of a mixture and an article (functioning as a carrier).



Assess your 'object' by applying the criteria detailed in Chapter 2 of the *Guidance on requirements for substances in articles*. More information can also be found on the topic in the *Guidance on Annex VIII*.

Indicating **mixture/article combinations** is not supported by the PCN format. Though it is possible that this information could be included in the Packaging related documents, e.g. by attaching a picture.

Packaging related attachments		+ New item	
#.	Type of attachment	Attached document	Action
1	other: combination mixture/article	x36 cleaning wipes.png	

### Guidance on requirements for substances in articles

<https://echa.europa.eu/guidance-documents/guidance-on-reach>.



## 8. Group submissions

A group submission can be prepared for several mixtures provided:

- i) all mixtures contain the same composition except for certain perfumes under specific conditions
- ii) reported concentrations/ranges for each of the components is the same
- iii) all mixtures in the group have the same classification for health and physical hazards

### 8.1 Step 1 – establish the correct submission type

Specify the Submission type as Group submission in the dossier header.

The screenshot shows the 'Working context' dropdown set to 'CLP Poison centres notification'. The left sidebar lists navigation options: 'Group submission - candles', 'Mixture information and product identity' (with a '1' badge), 'Classification of the mixture and label elements', 'Mixture safety data sheets and toxicological information', 'Additional information', and 'Inherited templates'. The main content area displays the following fields:

- UUID: 5c30be51-77c8-49d3-8b79-c39339e3e784
- Dossier name (given by user): None
- Dossier submission remark: None
- Specific submissions:
  - PCN number\*: 00353c61-c924-406b-b406-27b017a67d38
  - Country (market placement)\*:  Austria
  - Language\*:  German
- Submission type (highlighted with a red box):
  - Limited submission (industrial use only)
  - Group submission
  - Voluntary submission

### 8.2 Step 2 – enter individual mixture compositional information

Multiple Mixture composition documents are required for a group submission. A Mixture composition document must be created to reflect the composition of each mixture contained in the notification

The screenshot shows a list of 'Mixture composition' documents. At the top, there is a dropdown arrow, the title 'Mixture composition', a count '3', and a plus sign. Below the title, there is a '+New document' button with a hand cursor. The list contains three items:

- Mixture composition.002 (with a trash icon)
- Mixture composition.003 (with a trash icon)

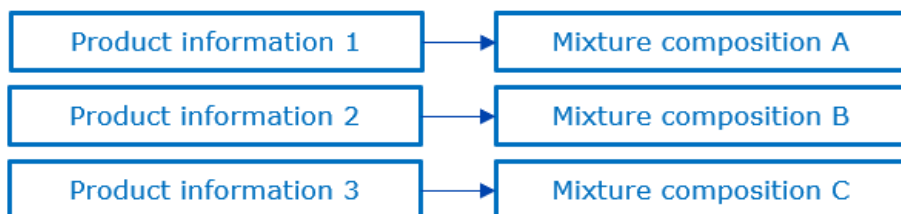
All components (substances or MiMs) are added to each Mixture composition document – note that you can use the 'Copy data from ...' functionality to avoid repetitive data entry of shared components.

! All substance components and MiM substances are required to be linked to a reference substance and the classification information provided.

The Function of the perfume component must be specified as 'Perfume' and the concentrations are indicated either as an exact concentration (i.e. Typical), or as a range.

### 8.3 Step 3 – enter and link product information for each mixture

In a group submission, one Product information document must be created and linked to each mixture composition that it represents:



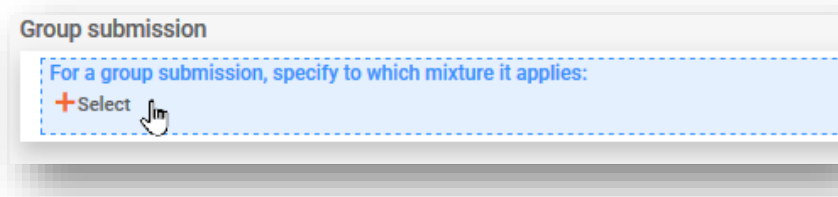
Selecting and linking the Mixture composition to a Product information document is achieved in the field 'For a group submission, specify to which mixture it applies'.

## 8.4 Step 4 - include and link single or multiple information documents

Additionally, multiple documents can be created for:

- i) Classification & Labelling
- ii) Toxicological information
- iii) pH

It is always necessary to indicate to which mixture composition the specific record refers to, by using the specific field. Note a single document can link to one or multiple mixtures.



### 8.4.1 Reporting classification and labelling in the group submission

For group submissions, multiple classification and labelling document may be reported (for instance if the classification for environmental hazards is different across the mixtures of the group and the submitter decides to provide this information).

The screenshot shows the 'Classification and labelling.001' form. The form is titled 'Classification and labelling.001' and has a UUID: 8fbb18e0-570f-412c-8dc0-ee2cb4118d96. It is a 'Group submission'. The 'Classification' section is expanded, showing 'Not classified' (unchecked), 'Hazard categories & statements' (checked), 'Skin Sens. 1-H317: May cause an allergic skin reaction.', 'Health hazards', 'Reproductive toxicity', 'Specific effect' (None), and 'Route of exposure' (None). A search overlay is open on the right, titled 'Select existing document', with a search bar and '3 results found'. A red arrow points from the dropdown menu in the 'Group submission' section to the search overlay. The search results are:

Mixture / Product	Group submission - candles	UUID	245337cf-9e9c-4ead-85cf-2a26d0774e44	12/10/2021 14:50
MixtureComposition (Flexible Record) / Citrus				
Mixture / Product	Group submission - candles	UUID	d4dd21da-5982-4f4a-a0ab-1c3a1ab73ec1	12/10/2021 14:50
MixtureComposition (Flexible Record) / Eucalyptus				
Mixture / Product	Group submission - candles	UUID	d90f4f05-02c8-4bfd-b85b-ecb93e75bb1c	12/10/2021 15:09
MixtureComposition (Flexible Record) / Lavender				



The same C&L record can be linked to multiple compositions of the same group submission.

### 8.4.2 Reporting toxicological information in the group submission

In the case of group submissions, multiple toxicological information documents may be reported, if relevant. Each document has to be linked to the relevant mixture composition. Alternatively, one single document can be linked to multiple compositions by selecting them from the specific field.

**Mixture safety data sheets and toxicological information.001**

UUID: 269db2ec-6f29-459a-ba85-28c11160a8e8

**Group submission**

For a group submission, specify to which mixture it applies:  
None

**Information on mixtures**

Safety data sheets of mixture / product

+ New item

#	Safety data sheet	Country
Toxicological information (section 11 of SDS)		
None		

⊗ This field is mandatory.

### 8.4.3 Reporting pH in the group submission

Single or multiple pH information documents may be reported. Each document has to be linked to the relevant mixture composition. Alternatively, one single document can be linked to multiple composition by selecting them from the specific field.

**pH.001**

UUID: 16ee2ff7-c12e-41fe-9f63-0b3dc84f4551

**Group submission**

For a group submission, specify to which mixture it applies:

- MixtureComposition (Flexible Record) | Lavender
- MixtureComposition (Flexible Record) | Eucalyptus
- MixtureComposition (Flexible Record) | Citrus

**Key value for chemical safety assessment**

pH is not available

**Justification**

substance/mixture is non-soluble (in water)
X
v

**pH value**

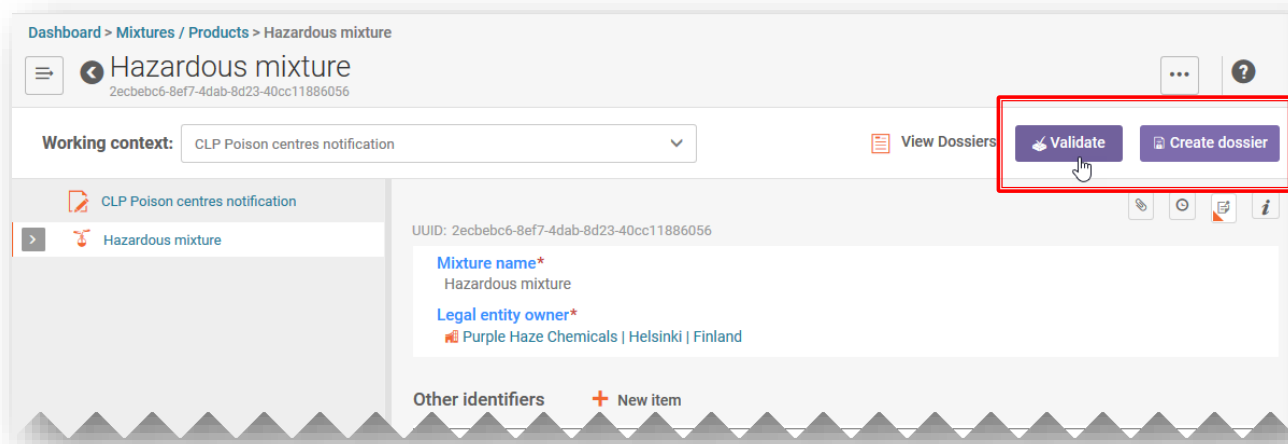
None

**Solution concentration (%)**

None

## 9. Validate and create a PCN dossier

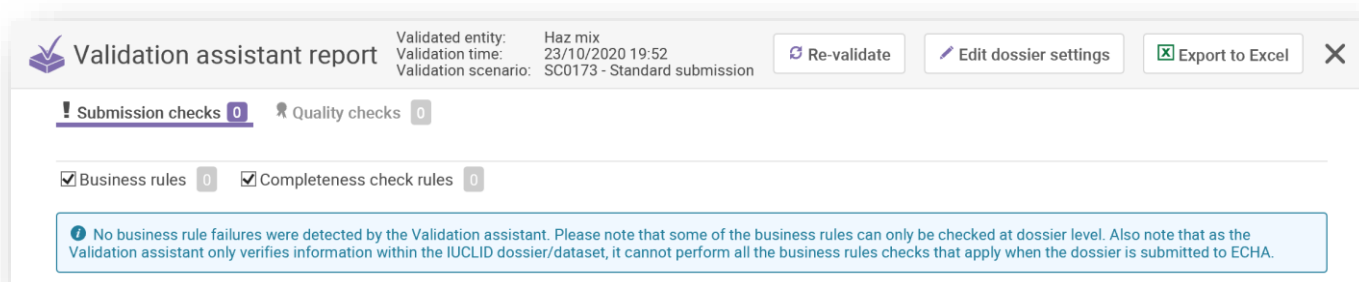
Before creating a dossier, it is recommended to first check the dataset for any errors or missing information using the 'Validate' functionality. This functionality carries out a number of checks according to a set of pre-defined rules to verify that you have provided the information as expected.



The Validation Assistant will display the outcome of the check in a Validation Assistant Report as either:

- i) **Succeed** without triggering any rules
- ii) **Succeed with warnings** i.e. quality rule triggered, denoted by the orange '!'
- iii) **Fail** i.e. a business rule triggered, denoted by the red 'X'

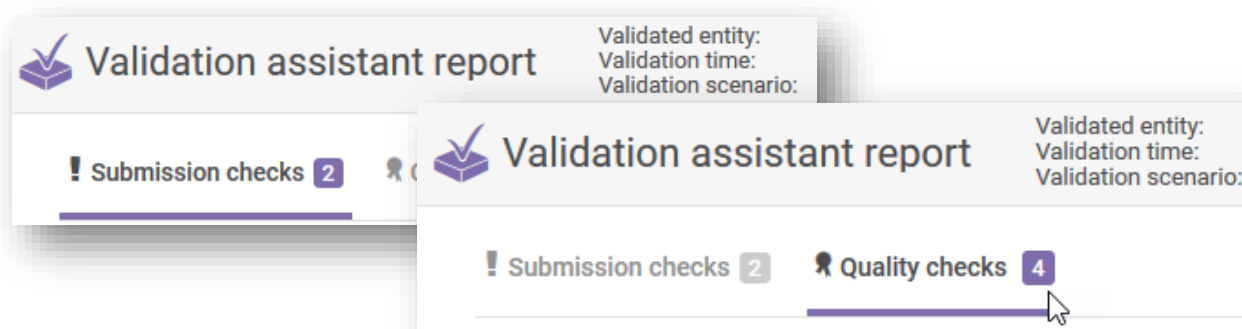
When no rules are triggered, the validation assistant will display a message to highlight that additional checks are performed in the system upon submission.



Because of the additional checks run in the ECHA Submission portal, note that it is possible to trigger a rule after you have submitted the information even if the Validation Assistant Report passes prior to submission. These Portal rules check the consistency between the information the user is submitting and the information already available in the database (for example, from previous submissions made by the same user or by other users).

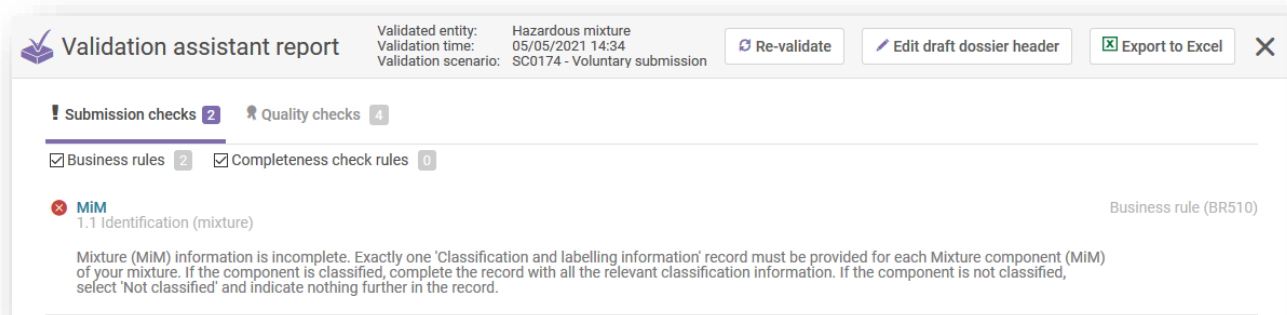
## 9.1 Validation Assistant Report

When the Validation Assistant Report is generated there are two tabs – one for failures (marked Submission Checks) and the other for warnings (marked Quality checks). Each tab indicates the number of rules that have been triggered and you can switch between both lists to view the results.



## 9.2 Submission checks

A submission check indicates a failure and the dossier would not be accepted by the system. In turn the dossier will not be forwarded to the authorities. It is recommended to check the sections of the dossier which require actions by clicking in the hyperlinked failure in the Validation Assistant Report and making changes where relevant.



If you are submitting an initial submission which has failed, then once the corrections have been made, and a new dossier created, it still remains an initial submission and not an update.

## 9.3 Quality checks

A quality check serves as a warning or reminder that there may be shortcomings or inconsistencies. Note though, that these rules do not prevent a successful submission. In other words, notifications that are 'Successful *with warnings*' will be dispatched to the relevant Appointed Bodies along with the validation report detailing the warnings listed.

However, the need for reviewing and possibly correcting the information should be considered.



A validation report containing warnings may lead to further clarification requests by Member States at a later stage. Nevertheless, you may have valid reasons for ignoring the warning.

Validation assistant report

Validated entity: Hazardous mixture  
Validation time: 05/05/2021 14:34  
Validation scenario: SC0174 - Voluntary submission

Re-validate Edit draft dossier header Export to Excel

Submission checks 2 Quality checks 4

Quality concerns have been detected for this substance dataset / dossier. You are advised to revise the sections corresponding to the warning messages as they may trigger follow-up actions from ECHA. While the quality warnings have been designed to assist the user in detecting inconsistencies in the information provided, there may be special circumstances in which some of the warnings can be ignored. The use of this tool is without prejudice to the expert assessment carried out by ECHA to establish the adequacy of the information required under Article 10, 17 and 18 of the REACH Regulation.

Mixture composition.001  
Mixture composition Components, (1) Quality check (QLT502)

'Mixture composition' information should be improved. When the reported concentration value is >1%, then concentration should be rounded up to one decimal for each Substance component and Mixture component of your Mixture composition.

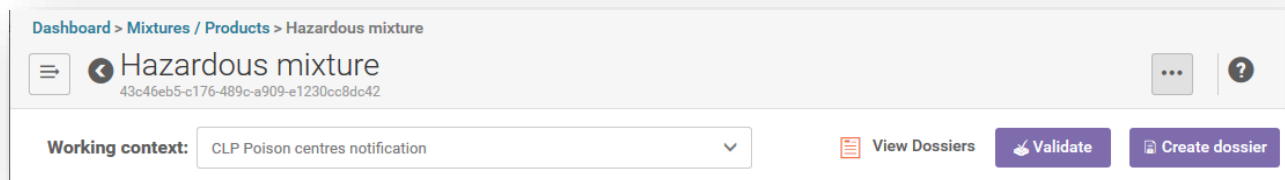
For a complete list of all the rules, i.e. those checked in the IUCLID and the Portal, you may refer to latest version of the **Validation rules for poison centre notifications**

<https://poisoncentres.echa.europa.eu/poison-centres-notification-format>

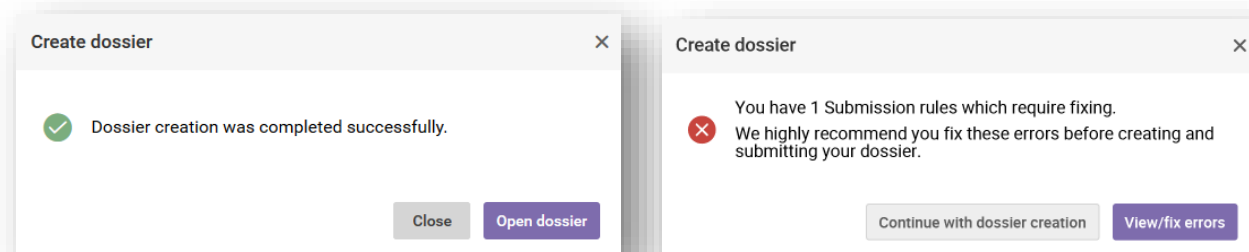


## 9.4 Creating a dossier

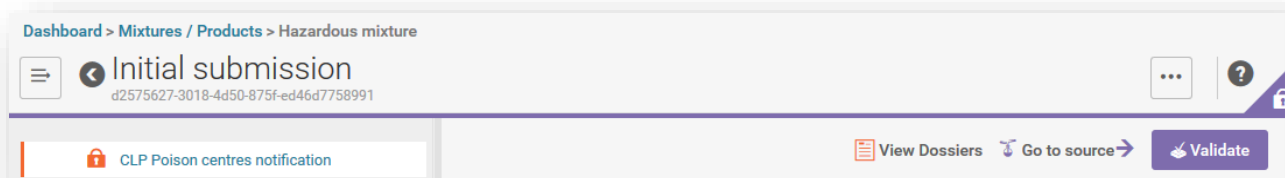
The 'Create dossier' functionality is available from the mixture page. Once clicked, you are directed to the Dossier Header of which the details can be checked.



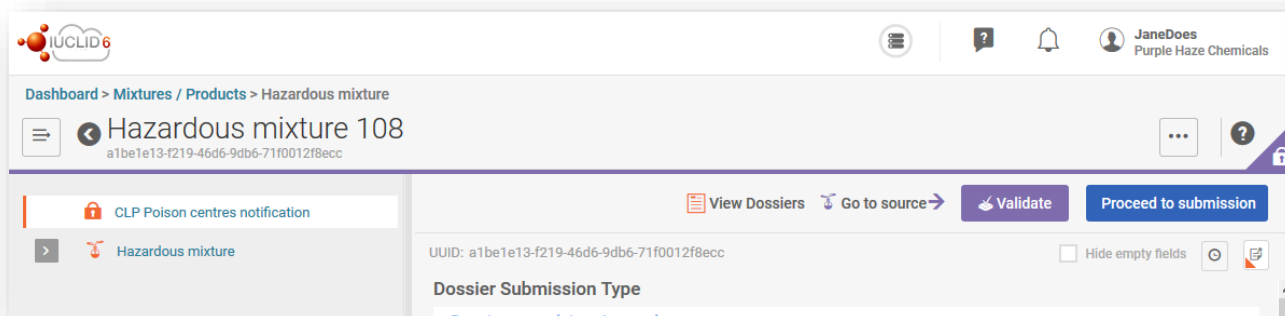
Clicking again on 'Create dossier' at the bottom of the dossier header will either successfully create the dossier or display a message that there are a number of rules that require fixing.



Once the dossier has been created it will appear with the purple lock symbol.

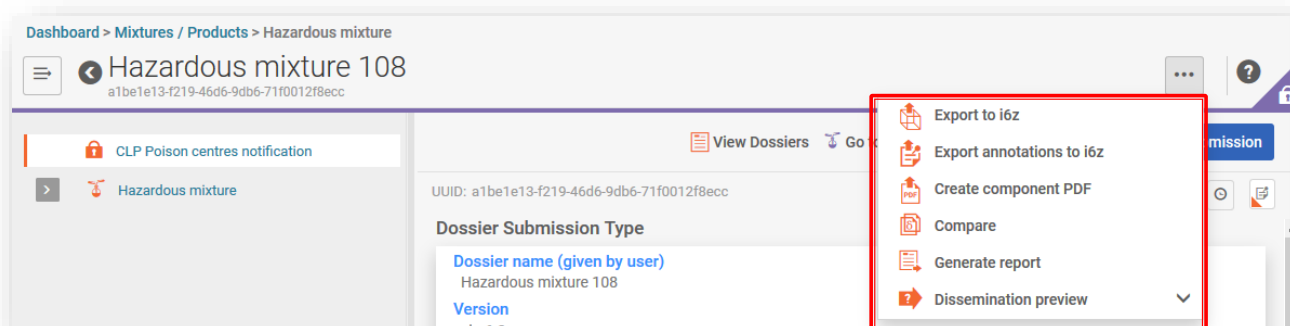


If you are working in IUCLID Cloud, there will also be the option to 'Proceed to submission'



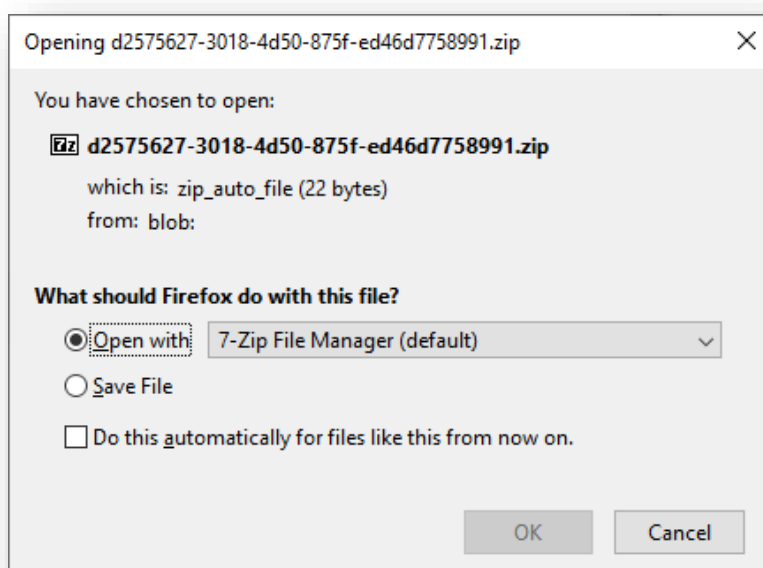
## 10. Dossier report and export functions

From the dossier, clicking on the ellipsis '...', opens a window where various functionalities can be utilised. Of most importance for PCN are the 'Export to i6z' and the 'Generate report' from the respective listing page.



### 10.1 Exporting a dossier (or dataset)

You can export a single dossier or dataset locally by clicking '...' in the top left corner and selecting Export to i6z. You may want to give the dossier a meaningful name to help you with dossier management



### 10.1.1 Bulk export functionality (datasets or dossiers)

Substance and mixture datasets as well as dossiers can also be exported either singly or in bulk by marking the tick box. Note that each item needs to be selected, there is no 'Select/deselect all' feature.

Once you select 'Export', the export settings box will open (you have the possibility to change the exported information) and you can export the selected items to a zip file.

The screenshot shows the 'Mixtures / Products' dashboard with an 'Export Settings' dialog box open. The dialog box contains the following sections:

- Export Settings**
  - Export to previous major version:  Export to previous major version
- Detail level of document fields**
  - Detailed fields (e.g. needed for robust endpoint summaries)
  - Fields marked "confidential"
- Flags for confidentiality**
  - Select information to be included
    - Data for which a confidentiality flag may be set, but it is not.
    - CBI
    - IP
    - no PA
- Flags for regulatory programme**
  - Select information to be included
    - No regulatory purposes
    - AU: AICIS
    - CA: CEPA
    - CA: PCPA
    - EU: BPR
    - EU: CLP
    - EU: PPP
    - EU: REACH
    - JP: CSCL
    - NZ: HSNO
    - OECD: CoCAP
    - US: EPA HPV
    - US: FIFRA
    - US: TSCA
    - other:
- Included Annotations**

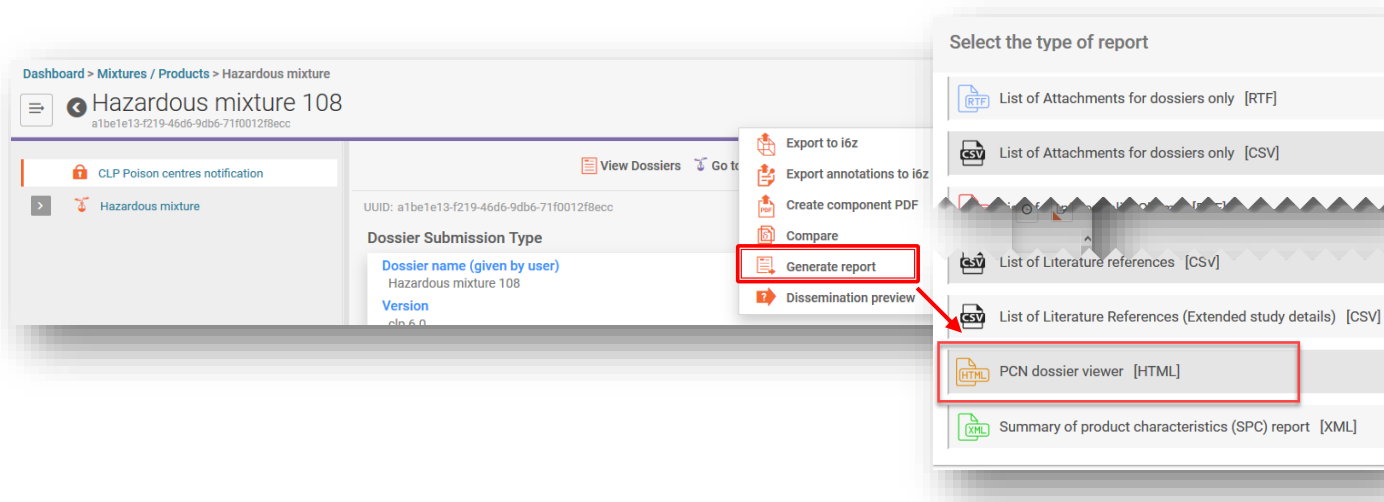
At the bottom right of the dialog box is an 'Export to zip' button.

The background interface shows a list of products with the following data:

Item	Legal Entity	UUID
<input checked="" type="checkbox"/> Clean and fresh	Purple Haze C	bba6d921-bde
<input checked="" type="checkbox"/> Zap	Purple Haze C	b0997c56-2ab
<input type="checkbox"/> Zing	Purple Haze C	1960f3c8-9f38
<input checked="" type="checkbox"/> Super strong cement	Purple Haze C	a9c36483-52f

## 10.2 Generating a report for PCN

Clicking on 'Generate report' from the dossier opens a list of the available report types in IUCLID.



Selecting **PCN Dossier Viewer** generates a web-based report with tabs for different sections of the dossier.




Note that HTML report can be printed as a pdf using the browser settings available.

The screenshot shows the PCN Dossier Viewer web-based report for 'Cleanbright'. The report is organized into several sections:

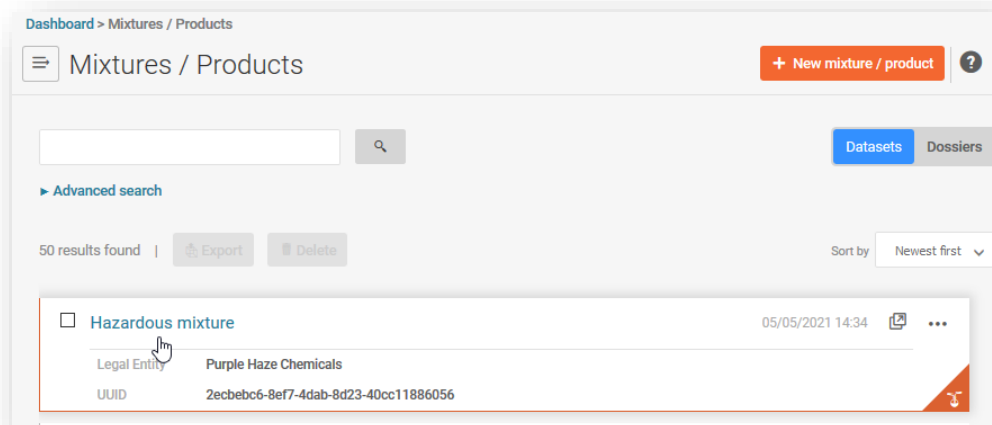
- Product details:** Name(s) Cleanbright, UFI(s) 0200-U0CW-500H-QNQU, Packaging bottle (1 L), State liquid, Form, Colour black, Colour intensity, Attachments.
- Submission details:** Submitted by Purple Haze Chemicals, Notification type Initial notification.
- Uses:** Types of uses Consumer, Main intended use PC-DET-1.1 Laundry detergent for hand washing.
- Classification and labelling:** Classification, Skin sensitisation: Skin Sens. 1-H317: May cause an allergic skin reaction. Labelling: Signal word Danger, Pictograms (Explosive), Hazard statements: H201: Explosive; mass explosion hazard.
- pH:** Not relevant: substance/mixture is non-polar/aprotic.
- Emergency contact:** NA.

## 11. Making updates

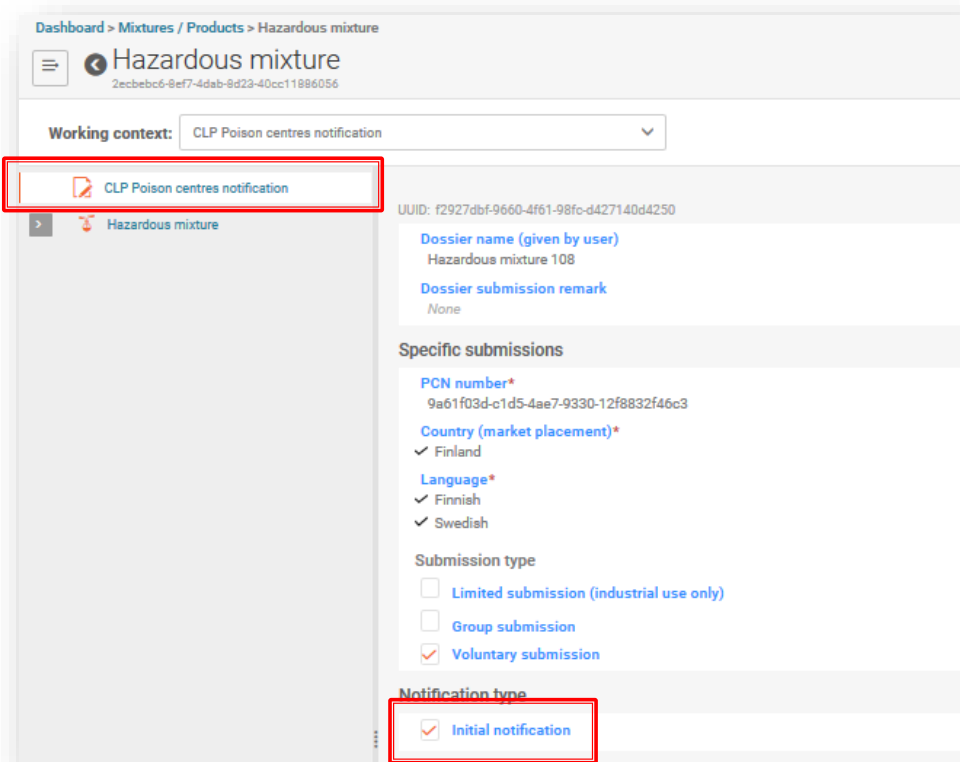
Once a dossier has been created, and a successful submission made, it is possible to update the mixture dataset and create an updated dossier.

 The duty holder must ensure that the relevant appointed bodies have a valid and up to date notification at all times, reflecting the mixture as placed on the market.

From the mixture/product listing page, select the dataset to be updated.



Once the dataset is open, open the 'Dossier header' and change any relevant information then in the Notification type section, de-select 'Initial submission' - then select 'The submission is an update' (section 11.1) or 'New notification after a significant change of composition' (section 11.2).



## 11.1 When the 'submission is an update'

From the relevant mixture dataset, open the draft dossier header and unselect 'initial notification' in order to activate the 'The submission is an update' selection. If an update is required for a notification that does not trigger the need for a new UFI, then the submission is considered 'an update'.

Notification type

- Initial notification
- New notification after a significant change of composition
- The submission is an update

An updated submission always requires a justification. The available picklist contains a limited set of reasons for updating.

Notification type

- The submission is an update

Reason for updating

Justification + New item

1 Justification  
expansion of market area

Remarks  
None

- cease product from market
- change in mixture composition without requiring a new UFI
- change in the mixture classification
- change in the product identifier
- correction of error
- correction/deletion of trade name
- expansion of market area
- new toxicological information available
- re-place product on market

### 11.1.2 Updates – Remarks field

It may be that you need to enter more information about the update in the Remarks field. Note the free text field is available for all relevant languages.

Reason for updating

Justification + New item

1 Justification  
correction of error

Remarks  
fi

[Here you can add more details in free text regarding the the error that was corrected in the update]

101/255

### 11.1.3 Updates – Other update reasons

It may also be that an update reason is not listed in the picklist, for example, a change in the emergency contact, or a new packaging type. For this purpose, enter the reason in the free text field for every relevant language (i.e. as indicated in the dossier header).

### 11.1.4 Explaining the update types

Some updates are listed in Annex VIII Part B section 4.1, require you to update the notification before you place the mixture, as changed, on the market. These are explained in **Guidance on Annex VIII** <https://echa.europa.eu/guidance-documents/guidance-on-clp>

These update reasons are also reflected in the picklist include:

- **Change in the mixture classification**
- **Change in the product identifier**
- **New toxicological information available**

In addition to this, the picklist also allows:

- **Cease product from the market** – see section 5.5.2.5 on how to indicate ceased markets in the product information section. Additionally, the Remarks field for update justifications can be used to specify which market areas are concerned by the update.
- **Re-place product on the market**
- **Change in the mixture composition without requiring a new UFI**
- **Correction of error** – This is when you entered invalid information in an existing notification e.g. wrong phone number. Use the Remarks field for update justifications and specify what the error was.
- **Correction/deletion of trade name** - When there is a misspelling of the trade name or when the incorrect trade name has been entered.
- **Expansion of market area** – allows you indicate new market areas, but it is not possible to remove them from a notification. Note a quality rule will be triggered in this case.



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

## 11.2 When the submission is a 'New notification after a significant change of 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.



You must also indicate the PCN number from the previous related submission this becomes the related PCN number.

Only one related PCN number is allowed in a notification, therefore in the event that a mixture undergoes multiple significant changes in composition, only the last previous PCN number should be indicated as the related PCN number.

#	Regulatory Programme	ID	Action
1	CLP related PCN number	bdf7444-435c-4419-992f-8bba78010345	
2	CLP unique formula identifier (UFI)	G200-U0CW-500E-QR1T	

## 12. Working in the ECHA Submission portal

The ECHA Submission portal provides companies with an online platform to upload/submit and review/manage poison centre notifications submitted to Appointed Bodies and their poison centres.

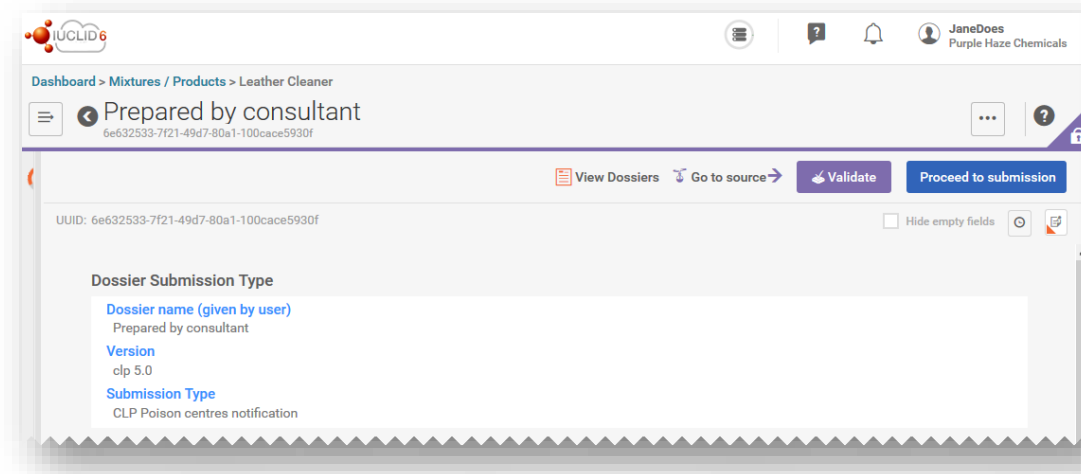
### 12.1 Upload dossier

Uploading a dossier (.i6z file) can be done either:

- I. Directly from IUCLID Cloud i.e. via 'Proceed to submission', or.
- II. Manually in the ECHA Submission portal via the 'Browse' feature.

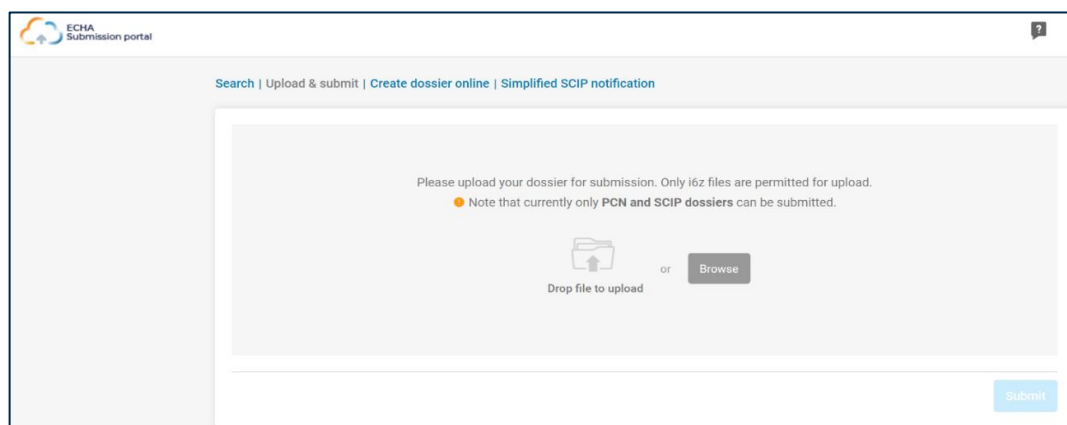
#### 12.1.1 Proceed to submission from ECHA Cloud

Clicking 'Proceed to submission' automatically uploads the dossier to the ECHA Submission portal.



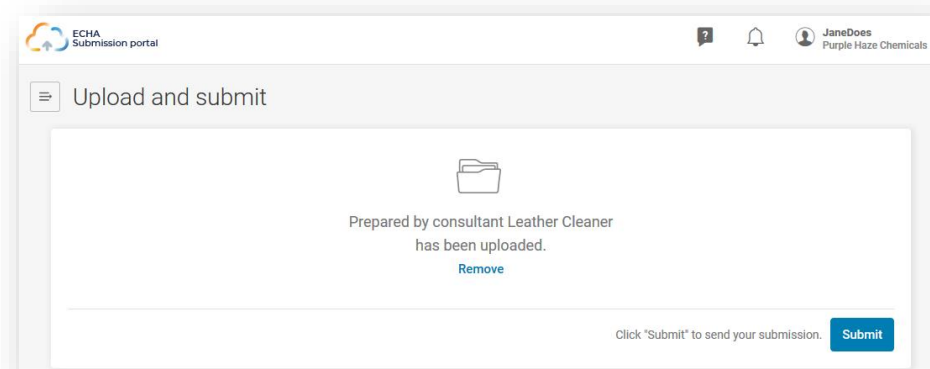
#### 12.1.2 Upload in the ECHA Submission portal

Select 'Submit a IUCLID dossier' from the CLP Poison Centres Notification area, to go to the upload and submit page from the Portal dashboard.

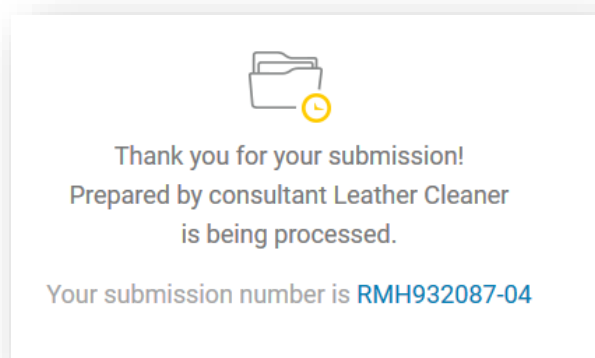


## 12.2 Submit

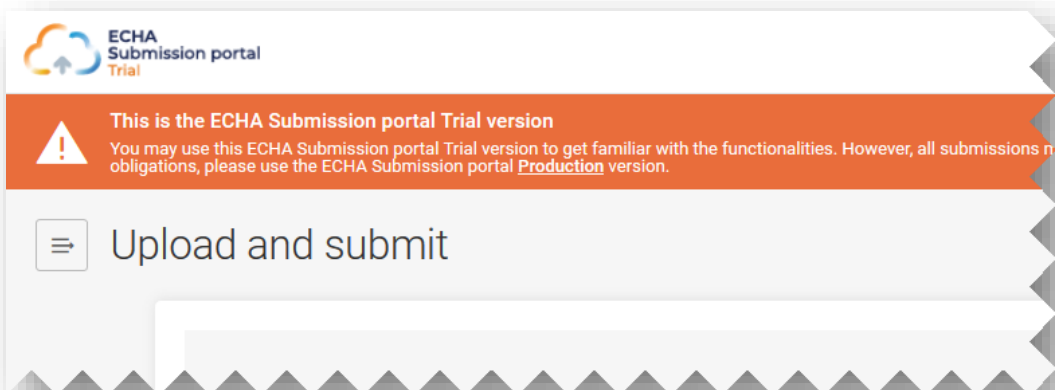
Once uploaded, the dossier will need to be submitted. If needed, the dossier can be removed from the upload section.



Following a successful submission, a submission number is automatically assigned by the submission system. This number can be used to track or monitor a submission if any issues arise during the submission process.




A Trial environment is available for testing purposes. Please ensure you are using the correct environment before submitting your test dossiers!




## 12.3 The Submission report

A submission report is generated for every submission and summarises the status and context of the submission.

 The ECHA Submission portal does not send any communication about the notification after a submission has been made. Please check the Submission report for the status and the Submission events

[Go to search](#)

**Submission status: Succeeded** 

Dossier type: CLP Poison centres notification	Submitted by: Jane Does
Submission number: RMH113838-21	Purple Haze Chemicals
Submitted IUCLID version: 6_5	ECHA-f428c44e-79b3-4f7f-a72b-78e7ceda3be4

---

### Submission information

PCN number	32469096-c55b-40a3-adce-bc3c4b412069
Mixture name	Hazardous mixture_newformulation
Dossier name	Dossier 108
Dossier UUID	4b237e77-c280-47ec-9369-7f1389c23788
File name	4b237e77-c280-47ec-9369-7f1389c23788.i6z
Reason for submission	New notification after a significant change of co...
Type of submission	

### Product information

Use type	Consumer
Name(s)	Cleanbright
Identifier(s)	2800-UORP-S00H-1AWX

### Recipients (Member States - market placement)

Finland

### Submission events

29/04/2021 10:28	Dossier submitted
29/04/2021 10:28	Dossier passed validation checks
29/04/2021 10:29	Dossier received by FI

---

### Submission history

PCN number  
f1aaf8e1-96b6-4d5f-9e38-325c2c23be1c

---

29/04/2021 10:06 [RMH179461-08](#) ▲

29/04/2021 10:15 [RMH822990-03](#) ✕

↓

PCN number  
32469096-c55b-40a3-adce-bc3c4b412069

---





29/04/2021 10:21 [RMH097512-20](#) ✕

29/04/2021 10:28 [RMH113838-21](#) ✓

### 12.3.1 Information contained in the submission report

The Submission report header details the status of the submission, the submission number, the IUCLID version of the submitted dossier, and the details (name and legal entity UUID number) of the submitter. The Submission report contains the additional following information.

#### Submission status:

Status	Description
Succeeded 	Succeeded status means that all automated validation rules have passed and the dossier has been forwarded to the Appointed Body. No validation report is generated.
Succeeded (with warnings) 	Succeeded (with warning) means that some quality rules have been detected and are visible in the validation report.
Failed 	Failed means that you need to address the error in your notification as indicated in the Validation report, and resubmit according to the notification type (see section 4.2.3).
Pending 	Pending means that the submission has not been processed yet. Try to refresh the submission report page if it is displayed for a longer period, <b>do not resubmit</b> .

**Submission information** includes the data and meta data for the submission either entered by you (e.g. Mixture or dossier name) or generated by the system (e.g. dossier UUID).

**Product information** is a summary of the use types, the tradenames and UFI codes.

**Recipients** includes all the Member States that were indicated in the notifications (dossier header section)

**Submission events** The submission events details the time stamp of the main events such as when the dossier was submitted, when the submission passed/failed the validation checks and when it has been received by the selected recipients.

**Submission history** can be used to track all submissions related to a particular PCN number. This is especially useful where updates have occurred, and even in cases of where a new notification has been made following a significant change in composition.

### 12.3.2 Saving the Submission report

Using your browser default functionality, the Submission report can be saved and printed in PDF if, for example, you need **proof of notification**.

Proof of notification.pdf - Adobe Acrobat Reader DC

File Edit View Sign Window Help

Home Tools Proof of notificatio... x

1 / 1 100%

ECHA Submission Portal Page 1 of 1

ECHA Submission portal JaneDoes Purple Haze Chemicals

Submission report

Go to search

Submission status: Succeeded ✓

Dossier type:	CLP Poison centres notification	Submitted by:	Jane Does
Submission number:	RMH113838-21		Purple Haze Chemicals
Submitted IUCLID version:	6_5		ECHA-f428c44e-79b3-4f7f-a72b-78e7ceda3be4

**Submission information**

PCN number	32469096-c55b-40a3-adce-bc3c4b412069
Mixture name	Hazardous mixture_newformulation
Dossier name	Dossier 108
Dossier UUID	4b237e77-c280-47ec-9369-7f1389c23788
File name	4b237e77-c280-47ec-9369-7f1389c23788.i6z
Reason for submission	New notification after a significant change of composition

Type of submission

**Product information**

Use type	Consumer
Name(s)	Cleanbright
Identifier(s)	2800-U0RP-S00H-1AWX

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

Finland

**Submission events**

29/04/2021 10:28	Dossier submitted
29/04/2021 10:28	Dossier passed validation checks
29/04/2021 10:29	Dossier received by FI

**Submission history**

## 12.4 Submission portal validation report and resubmission after failure

Given that additional checks are performed by the system upon submission, it is possible to trigger a validation or quality rule.

The ECHA Submission portal creates a Validation Report – the link to this report is available from the Submission Report. Only in case the Submission status is set to 'Succeeded with warnings' is when the Validation Report is also forwarded to the Appointed Body.

The image shows two screenshots of the ECHA Submission portal interface. The top screenshot displays the 'Submission report' page. At the top right, the user 'JaneDoes' (Purple Haze Chemicals) is logged in. The page shows the submission status as 'Failed'. A red box highlights the 'View Validation report' link, with a red arrow pointing to the bottom screenshot.

**Submission report details:**

- Submission status: Failed
- Dossier type: CLP Poison centres notification
- Submitted by: Jane Does
- Submission number: RMH531982-10
- Submitted IUCLID version: 6\_5
- Purple Haze Chemicals
- ECHA-f428c44e-79b3-4f7f-a72b-78e7ceda3be4

The bottom screenshot displays the 'Validation report' page. It shows the same submission details as above. A table lists the validation rules that failed:

Level	Rule	Document name Section number and name	Message
✖	BR510	MiM, 1.1, Identification (mixture)	Mixture (MiM) information is incomplete. Exactly one 'Classification and labelling information' record must be provided for each Mixture component (MiM) of your mixture. If the component is classified, complete the record with all the relevant classification information. If the component is not classified, select 'Not classified' and indicate nothing further in the record.
✖	BR527	MiM, 1.1, Identification (mixture)	Mixture in mixture (MiM) identification is incomplete. When you cannot provide the full composition of the MiM, you have to provide either UFI number in 'Regulatory programme identifiers' or available composition of the mixture (from SDS, unless the MiM is not hazardous) and information about the 'Supplier'.
⚠	QLT502	Mixture composition.001, Mixture composition, Components, (1)	'Mixture composition' information should be improved. When the reported concentration value is >1%, then concentration should be rounded up to one decimal for each Substance component of mixture component in your Mixture composition.

## 12.5 Searching poison centre notifications in the Submission portal

All the submissions made by the active legal entity will be listed in the search page, each submission is assigned a Submission number.

- Search criteria can be entered accordingly e.g. by submission number, PCN number, UFI, submission status, etc.
- A 'Sort by' functionality (either 'Newer first' or 'Older first') is available
- Scroll through functionality can be used to scroll through each page if there are multiple pages of search results.

**ECHA Submission portal**

**Search**

Search criteria ▼ Export to Excel

Submission number:  Submission status:

Dossier type:  Submission date: from  to

Dossier UUID:

PCN number:  Submission reason:

UFI:

Names:

Search Clear




Page 1 of 37 results

Sort by:

<b>RMH091863-18</b>			07/10/2021 15:19
PCN number	b8f2c447-8955-4169-a20f-743af3a0c3dc	UFI(s)	8200-U0CW-500K-QF8E, 4500-0029-6003-D0UR
Names	GS first test, Group submission - detergents, Clean a...	Dossier LUID	115b6fb8-5e03-4360-8092-db53a488e730
			<span>PCN</span>
<b>RMH60191-10</b>			07/10/2021 15:17
<b>RMH60191-10</b>			07/10/2021 15:17
PCN number	9a61f03d-c1d5-4ae7-9330-12f8832f46c3	UFI(s)	0200-U0CW-500H-QNQU
Names	Hazardous mixture 108, Hazardous mixture, Cleanbr...	Dossier LUID	899765d7-9759-4226-82ef-3da729227d52
			<span>PCN</span>
<b>RMH531982-10</b>			05/05/2021 14:29
PCN number	9a61f03d-c1d5-4ae7-9330-12f8832f46c3	UFI(s)	0200-U0CW-500H-QNQU
Names	Hazardous mixture 108, Hazardous mixture, Cleanbr...	Dossier LUID	899765d7-9759-4226-82ef-3da729227d52
			<span>PCN</span>

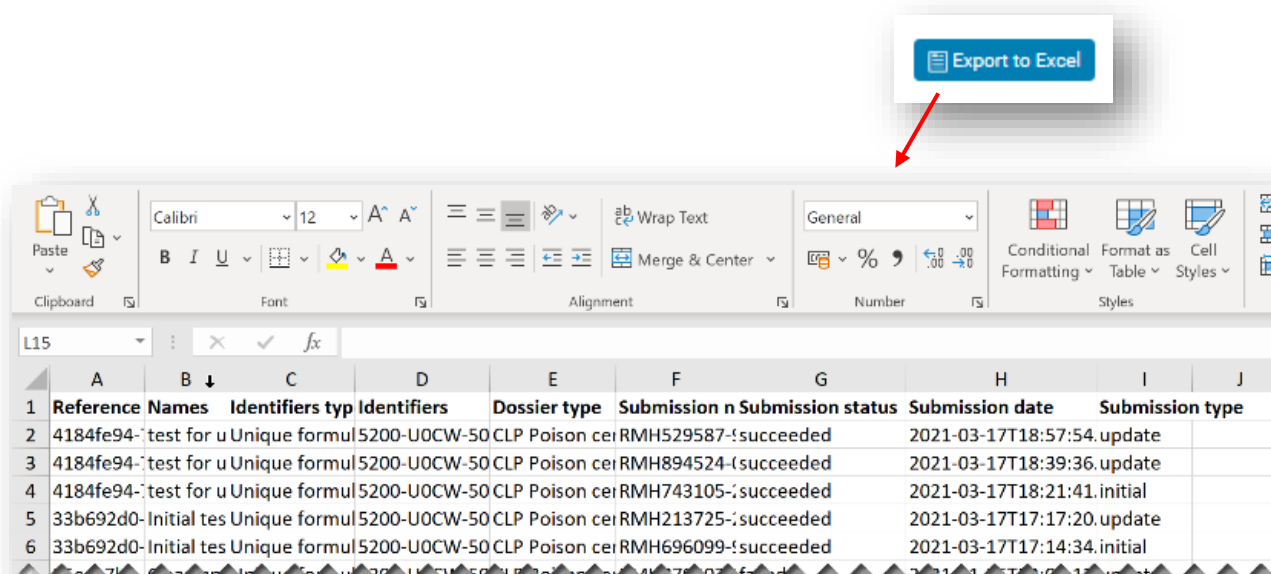
Items/page:

The submission number is a link to the submission report for a particular submission. There are various symbols to indicate if the submission is an initial or update, or if it has a successful (☑) or failed status (☒). Hovering over the symbol in the application will display what the symbol represents.

Notification type	Description
Initial Submission 	A successful initial submission must always exist for a notification
Update Submission 	An updated submission is where certain changes have been made that do not affect the mixture composition
New notification after a change in composition 	A new notification after a change of composition still keeps the link between the previous mixture composition (through the previous PCN number)

### 12.5.1 Exporting search results from the portal to Excel

An 'Export to Excel' functionality is available in the top right-hand corner of the search page, which exports specific information about the dossier.



The screenshot shows an Excel spreadsheet with the following data:

Reference Names	Identifiers typ	Identifiers	Dossier type	Submission n	Submission status	Submission date	Submission type
4184fe94- test for u	Unique formul	5200-U0CW-50 CLP	Poison ce	RMH529587-!	succeeded	2021-03-17T18:57:54.	update
4184fe94- test for u	Unique formul	5200-U0CW-50 CLP	Poison ce	RMH894524-!	succeeded	2021-03-17T18:39:36.	update
4184fe94- test for u	Unique formul	5200-U0CW-50 CLP	Poison ce	RMH743105-!	succeeded	2021-03-17T18:21:41.	initial
33b692d0- Initial tes	Unique formul	5200-U0CW-50 CLP	Poison ce	RMH213725-!	succeeded	2021-03-17T17:17:20.	update
33b692d0- Initial tes	Unique formul	5200-U0CW-50 CLP	Poison ce	RMH696099-!	succeeded	2021-03-17T17:14:34.	initial

## Appendix 1. Instructions: establishing a foreign user

The following is an example of how to set up a foreign user (i.e. 'third party') in ECHA Accounts. A foreign user is essentially an external user that has been appointed by the legal entity manager of a company to work on their behalf e.g. in IUCLID Cloud and the ECHA Submission portal.

In the context of this manual, a foreign user can perform actions on behalf of the company such as the preparation and submission of poison centre notifications.



Granting access to a foreign user may expose confidential data. It is important that companies agree on the scope of access and how the confidential information is handled.

The steps below outline an example of how to establish a foreign user in ECHA Accounts.

**Step 1.** A consultancy company sends their ECHA Account username (SafeConsults) and legal entity UUID number to the duty holder i.e. the legal submitter, 'Purple Haze Chemicals'. This process occurs outside of the ECHA Accounts functionality.

**Step 2.** The duty holder 'Purple Haze Chemicals' clicks Add foreign user to launch the 3-step wizard in order to add 'SafeConsults' as a foreign user to her legal entity profile.

**Purple Haze Chemicals**

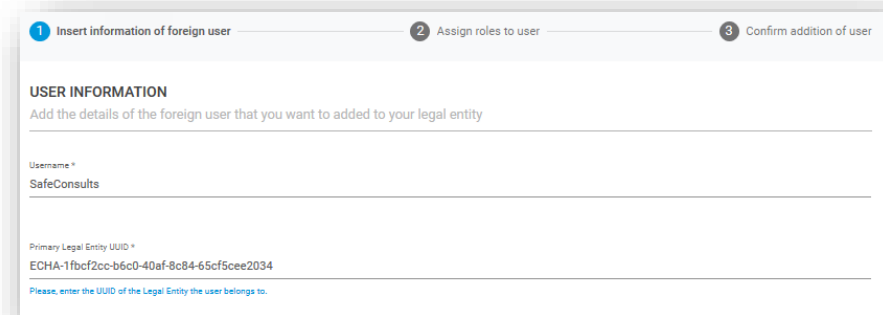
**LEGAL ENTITY USERS** + Create new user Add foreign user

View the list of users associated with the Legal Entity

Sort by Username

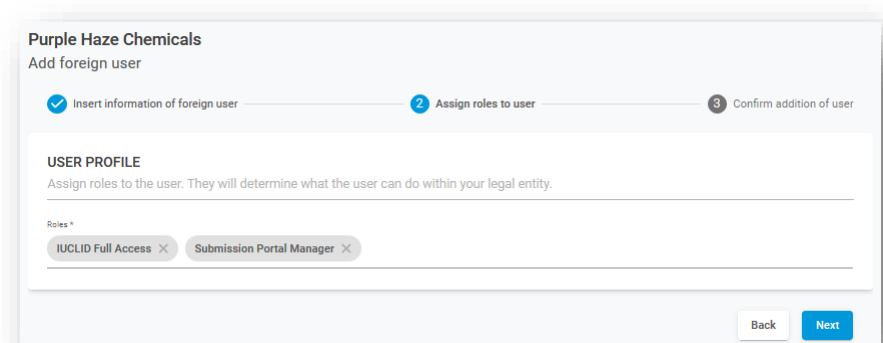
Username	Name	Email	User roles	Status	Actions
JaneDoes	Jane Does		LE Manager IUCLID Beta Full Access IUCLID Full Access REACH Manager Submission Portal Manager	Active	

In the first wizard step, Purple Haze Chemicals enters the user name and UUID provided by the consultant that was sent to her.



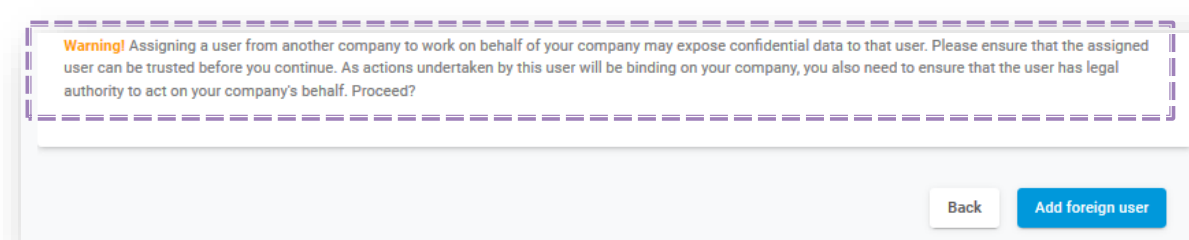
The screenshot shows the first step of a three-step wizard. The progress bar at the top indicates '1 Insert information of foreign user' is active, '2 Assign roles to user' is next, and '3 Confirm addition of user' is last. The main content area is titled 'USER INFORMATION' and contains the instruction 'Add the details of the foreign user that you want to added to your legal entity'. There are two input fields: 'Username \*' with the value 'SafeConsults' and 'Primary Legal Entity UUID \*' with the value 'ECHA-1fbcf2cc-b6cd-40af-8c84-65cf5cee2034'. A small blue link below the second field reads 'Please, enter the UUID of the Legal Entity the user belongs to.'

The second wizard step requires defining the user profile and is completed by adding the User roles according to preferences of Purple Haze Chemicals, e.g. which service to use (Cloud or Portal) and which rights (full access or read only)



The screenshot shows the second step of the wizard. The progress bar indicates '1 Insert information of foreign user' is completed, '2 Assign roles to user' is active, and '3 Confirm addition of user' is next. The main content area is titled 'USER PROFILE' and contains the instruction 'Assign roles to the user. They will determine what the user can do within your legal entity.' There is a 'Roles \*' section with two selected roles: 'IUCLID Full Access' and 'Submission Portal Manager'. At the bottom right, there are 'Back' and 'Next' buttons.

In the third and final step of the wizard, a warning message appears before the completion process is finalised



The screenshot shows the final step of the wizard. A warning message is displayed in a dashed purple box: 'Warning! Assigning a user from another company to work on behalf of your company may expose confidential data to that user. Please ensure that the assigned user can be trusted before you continue. As actions undertaken by this user will be binding on your company, you also need to ensure that the user has legal authority to act on your company's behalf. Proceed?'. Below the warning, there are 'Back' and 'Add foreign user' buttons.

Where **local installations of IUCLID** are in use, note that after JaneDoes adds the details of her foreign user consultant in ECHA Accounts, she would then need to export and send her own legal entity information in IUCLID format to them.

The consultant imports the legal entity file into their own IUCLID system who initiates a notification and assigns it to the Duty holder's legal entity. The consultant switches to the legal entity of the Duty holder in the ECHA Submission portal when the dossier is ready to be submitted.

**Step 3.** Purple Haze Chemicals can now see the details of the foreign user consultant in the list of legal entity users. Note that the consultant company will also be able to see in ECHA Accounts the list of legal entities for which they work for as well.

The screenshot displays two panels from the ECHA Accounts system. The left panel, titled 'Purple Haze Chemicals', shows a 'LEGAL ENTITY USERS' list. It includes a search bar and a table with columns for Username, Name, Email, User roles, Status, and Action. Two users are listed: Jane Does and John Smith. A purple arrow points from the 'John Smith' row in the table to the right panel.

The right panel, titled 'Purple Haze Chemicals View account details', shows the user information for John Smith. It includes sections for 'USER INFORMATION', 'GENERAL DETAILS', 'LEGAL ENTITY', and 'USER PROFILE'. The 'LEGAL ENTITY' section shows the Primary Legal Entity Name as 'SaferConsults' and the Primary Legal Entity UUID as 'ECHA-1fbcf2cc-b6c0-40af-8c84-65cf5cee2034'. The 'USER PROFILE' section shows the user's roles: 'IUCLID Full Access', 'IUCLID Trial Full Access', and 'Submission Portal Manager'.

**Step 4.** The ECHA Cloud services and ECHA Submission portal share the same options in the top bar. From here, the consultant can select the legal entity on whose behalf to work on by selecting 'Switch legal entity'. Note that the foreign user will only see the data relevant to the selected legal entity

The screenshot shows the top bar of the ECHA Accounts interface. The user is logged in as 'SaferConsults SaferConsults'. The top bar contains several navigation options: 'ECHA Cloud', 'ECHA Submission portal', 'Manage account', 'Switch legal entity', and 'Logout'. The 'Switch legal entity' option is highlighted with a purple box, and a hand cursor is pointing at it. Below this option, a dropdown menu is visible, showing two legal entities: 'SaferConsults' and 'Purple Haze Chemicals'.

Switching the legal entity is one of those features that allow users being members of more than one legal entity to change the acting legal entity. The selection of the acting legal entity in one application (e.g. ECHA Cloud services) is carried to the other one (e.g. ECHA Submission portal), so users need to perform the action just once.

If a consultant is working for many customers, they can use this functionality to move from one customer's data to the other without having to log out and log in again.

**Step 5.** The consultant can now prepare/submit a dossier on behalf of the legal entity Purple Haze Chemicals.

The screenshot shows the IUCLID 6 interface for a 'Haz mix' dossier. The 'Working context' is set to 'CLP Poison centres notification'. The 'Legal entity owner' field is highlighted with a red box, displaying 'Purple Haze Chemicals | Helsinki | Finland'. The 'Mixture name' field is also visible, containing 'Haz mix'. The interface includes a sidebar with navigation options and a main content area with a table for 'Other identifiers'.

Where local installations of IUCLID are in use, the consultant initiates a notification and assigns it to the Duty holder's legal entity. The consultant switches to the legal entity of the Duty holder in the ECHA Submission portal when the dossier is ready to be submitted.

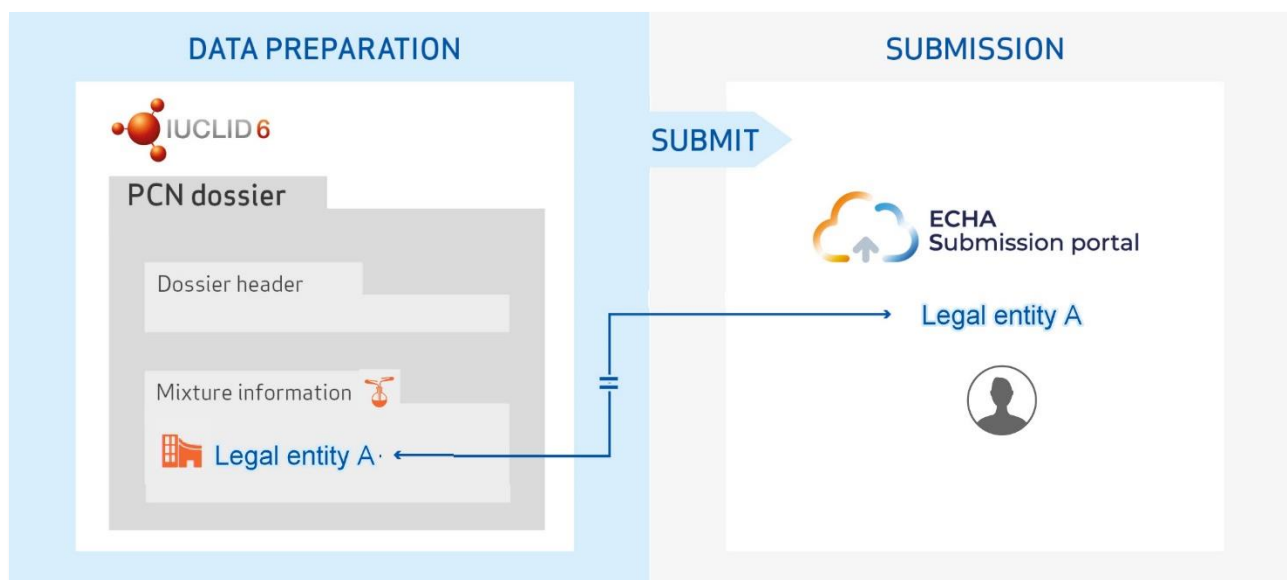
⚠ When the legal entity of the submitter does not match the legal entity of the dossier, the error BR570 will present itself in the validation report, failing the submission.

The screenshot shows the ECHA Submission portal 'Validation report' page. The submission status is 'Failed'. The error message BR570 is highlighted, stating: 'The Legal Entity information provided in the dossier is either empty or not the same as the Legal Entity information of your ECHA account. If you intend to submit the dossier on behalf of the dossier's Legal Entity, please check whether you need to switch Legal Entity.' The report also includes details about the dossier type, submission number, and validated IUCLID version.

Level	Rule	Document name Section number and name	Message
✖	BR570		The Legal Entity information provided in the dossier is either empty or not the same as the Legal Entity information of your ECHA account. If you intend to submit the dossier on behalf of the dossier's Legal Entity, please check whether you need to switch Legal Entity.

## Appendix 2. Troubleshooting BR570 and legal entity consistency

The legal entity UUID in the PCN dossier (mixture level) must match the UUID of the logged in user in the ECHA Submission portal.



When a company is preparing and submitting their own notifications, the legal entities available in the dossier should, in theory, already be synchronised with the legal entity in the ECHA Submission portal. This would be the case, for example:

- of a duty holder (formulator, toll formulator, EU importer) notifying their own mixture without the assistance of a third party.
- an EU company who shares the same legal entity as their EU subsidiaries, prepares and submits on their behalf.

There are other scenarios, however, where different legal entities may be involved in a notification, it is essential they establish sound legal entity management.



The legal entity UUID of the logged in user's company in the ECHA Submission portal 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.


## A.2.1 How can legal entity inconsistencies occur in the dossier and portal?

### A.2.1.1 When a third party is preparing/submitting in the portal on behalf of a duty holder.

There are instances where a legal entity preparing a dossier may be different to the legal entity legally required to make the submission and would likely result in a legal entity inconsistency. This would, in practice, be expected in the following examples:

- An EU company 'Mother company' submitting on behalf of EU Subsidiary duty holder (different legal entities)
- A non-EU company preparing a notification on behalf of their EU Subsidiary duty holder
- A consultant submitting on behalf of a Duty Holder


Ensuring consistency in the legal entities in the ECHA Submission portal and the dossier in such cases can be achieved by establishing a 'foreign user' and ensuring correct legal entity management in ECHA Accounts, covered in [Appendix 11](#).

 A foreign user can perform actions on behalf of the company that grants them permission to use an account from their own ECHA account.

### A.2.1.2 When a duplicate legal entity exists

In some cases, a legal entity may have unknowingly created two different versions of the 'same' legal entity i.e. the name is the same but the associated UUID number is different. When the system compares if the legal entities are matching, it compares the UUID's associated to the legal entities.

This may be expected if a company has previously created a legal entity object in IUCLID, and did not import the file to ECHA Accounts when it was created, rather, creating a new legal entity object.

 Having two duplicate legal entities may result in business rule failures due to inconsistencies in the UUIDs.

It is possible to change the legal entity details in the ECHA Submission portal or in the IUCLID notification.

### A.2.1.3 Failure to add/update legal entity details in IUCLID offline

In cases where a company has installed IUCLID Desktop Client to work offline in their local systems, any legal entity changes made in ECHA Accounts will have to be manually replicated in the dossier preparation tool.

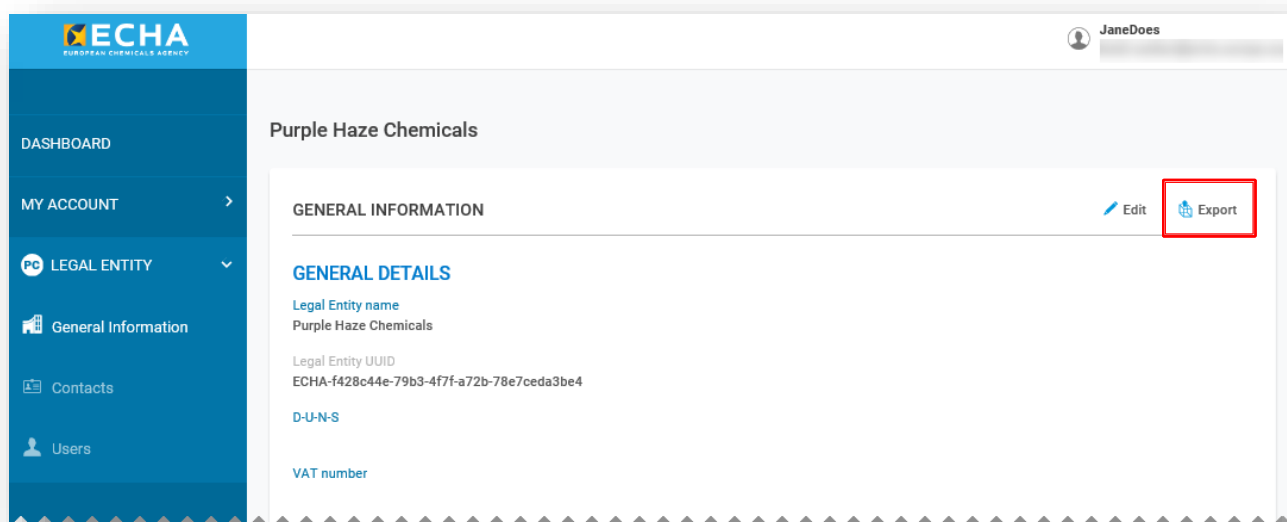
To add/update legal entity details into the IUCLID instance, the following steps are required:

In the ECHA Submission portal

1. Connect to the ECHA Submission portal of the legal entity of which the change is required for
2. From the top-right corner menu of the user tab, select 'Manage account'

In ECHA Accounts

3. Go to 'My account', select 'Legal entity' and from the legal entity page, select 'Export'
4. Save the legal entity .i6z file locally.



In IUCLID Desktop dashboard

5. Open the IUCLID6 Desktop Client. From the Dashboard page select 'Import' or 'Browse' and add the .i6z legal entity file that you saved in the previous step.
6. After successfully importing the legal entity, it can be opened and you will be able to check it's UUID number

#### A.2.1.4 Mismanagement of S2S keys in the system-to-system service

In cases where a third party user i.e. having a different legal entity, is preparing and submitting through system to system to the ECHA Submission portal on behalf of the legal submitter, they will need to do so using the legal submitter's S2S keys.

In practice, different legal entities would be expected in the following examples:

- Consultant or other 3<sup>rd</sup> party company on behalf of the Customer
- EU or non-EU Mother company on behalf of a Subsidiary (different legal entities). In case the Mother company submits on behalf of more than one Subsidiary, the Mother company should create/obtain the S2S keys for all the companies.



Defining multiple S2S accounts for the same company is not currently allowed. As a result, if both the third party and duty holder would like to submit through S2S, they have to share the same S2S key.

An inconsistency between legal entities can be avoided by establishing a 'foreign user' in ECHA Accounts and ensuring correct usage of the S2S key. This is explained in the 'How to join the system to system services' but in general, this is achieved by the following:

1. In ECHA Accounts the legal submitter adds a third party as a foreign user (see **Appendix 1**) and then, either assigns the third party the S2S Keys Manager role, so that they can generate the S2S key (or generate the S2S key themselves and send it directly to the third party).
2. In the third party's system, a dossier is created which includes the legal submitter's legal entity (at the mixture level).
3. The third party submits the dossier in the ECHA Submission portal using the legal submitter's S2S key.



Avoid a business rule failure and ensure the consistency of legal entities in the dossier and in the S2S key.

