

Poison centre notifications

PCN: a practical guide

Version 6 - December 2023

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.

| Version | Changes | Date |
|---------|--|---------------|
| 1.0 | First edition | May 2020 |
| 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 |
| 5.0 | Updated version to support the changes included in IUCLID 6 (version 6.20); including the functionality for Disable submission in the ECHA Submission portal. Translated versions made available. | December 2021 |
| 5.1 | Inclusion of new information about new User Role in ECHA Accounts 'Submission Portal Manager restricted' in section 2.3 | June 2022 |
| 6.0 | Updated screen shots to reflect the latest version of IUCLID. Text on the foreign user/roles explained in more detail. Additional clarifications and improvements for readability made throughout the guide. | December 2023 |

PCN: a practical guide

Reference: ECHA-23-H-11-EN

ISBN: 978-92-9468-330-4

Cat. Number: ED-02-23-201-EN-N

DOI: 10.2823/777159

Publ.date: December 2023

Language: EN

© European Chemicals Agency, 2023
Cover page © European Chemicals Agency

If you have questions or comments in relation to this document please send them (quote the reference and issue date) using the information request form. The information request form can be accessed via the Contact ECHA page at:

<http://echa.europa.eu/contact>

European Chemicals Agency

P.O. Box 400, FI-00121 Helsinki, Finland

Table of Contents

| | |
|--|-----------|
| 1. INTRODUCTION | 7 |
| 1.1. Additional support material | 7 |
| 2. ACCESSING ECHA'S IT APPLICATIONS FOR POISON CENTRE NOTIFICATIONS (PCN) | 8 |
| Step 1 - Create an ECHA Account | 8 |
| Step 2 - Assign a Legal Entity to the ECHA Account | 9 |
| 2.1.1. Create a new Legal Entity | 10 |
| 2.1.2. Importing a pre-existing legal entity (LE) from IUCLID | 11 |
| Step 3 - Add users & define/manage user roles | 12 |
| Step 4 - Subscribing to the ECHA Cloud services | 14 |
| 3. PREPARE AND SUBMIT A POISON CENTRE NOTIFICATION (PCN) | 16 |
| 3.1. The Poison centre notification (PCN) format | 16 |
| 3.2. IUCLID for data preparation | 17 |
| 3.2.1. IUCLID Cloud Services | 17 |
| 3.2.2. IUCLID 6 via download from IUCLID website | 17 |
| 3.3. ECHA Submission portal for poison centre notifications | 18 |
| 3.4. System-to-system service | 20 |
| 4. CREATING AN EDITABLE DATASET IN IUCLID | 21 |
| 4.1. The IUCLID Dashboard | 21 |
| 4.2. Managing IUCLID entities outside the notification | 22 |
| 4.2.1. Managing Contact information | 22 |
| 4.2.2. Managing the Legal Entity | 23 |
| 4.3. Steps to prepare an initial Mixture/product dataset | 24 |
| 4.3.1. Create a New mixture/product dataset | 25 |
| 4.3.2. Set the working context | 25 |
| 4.3.3. Open and complete the Dossier Header | 27 |
| 4.3.3.1. Explaining Submission types | 28 |
| 4.3.3.2. Explaining Notification types | 29 |
| 4.3.4. General navigation and functionalities for data entry | 30 |
| 4.3.4.1. Creating a 'New document' | 31 |
| 4.3.4.2. 'Copying data from' existing documents | 32 |
| 4.3.4.3. Using the 'Cloning' functionality | 34 |
| 5. PREPARING A PCN - SECTION BY SECTION | 35 |
| 5.1. Mixture identity and legal submitter section | 35 |
| 5.1.1. Mixture name | 35 |
| 5.1.2. Legal submitter | 35 |
| 5.1.2.1. How to change the legal submitter UUID | 36 |
| 5.1.3. Other identifiers | 37 |
| 5.1.4. Contact person | 38 |

| | |
|---|-----------|
| 5.2. Mixture composition document | 39 |
| 5.3. Adding a substance component | 40 |
| 5.3.1. Downloading a Reference substance from the IUCLID website..... | 42 |
| 5.3.2. Creating and linking a Reference substance | 43 |
| On polymers | 43 |
| On micro-organisms..... | 45 |
| 5.3.3. Classification (and labelling) of the substance | 45 |
| 5.4. Adding a mixture-in-mixture (MiM) component..... | 46 |
| 5.4.1. Identify the MiM and specify concentration | 46 |
| 5.4.2. Completing information about the MiM | 49 |
| Entering substance identity and classification information for substances of the MiM component..... | 51 |
| 5.4.3. Preparing a notification for 100% MiM..... | 53 |
| 5.5. Product identity/information document..... | 57 |
| 5.5.1. Product identifiers | 57 |
| 5.5.2. Additional information..... | 59 |
| 5.5.2.1. 'Colour and physical state' | 59 |
| 5.5.2.2. 'Packaging' | 61 |
| 5.5.2.3. 'Product use category information' | 62 |
| 5.5.2.4. 'Country (Market placement)' | 64 |
| 5.6. Classification and labelling of the (final) mixture..... | 65 |
| 5.6.1. Classification information | 65 |
| 5.6.2. Labelling information | 66 |
| 5.7. Mixture safety data sheets and toxicological information..... | 68 |
| 5.8. Additional information | 69 |
| 6. MIXTURE COMPOSITION – SPECIFIC CASES | 70 |
| 6.1. Indicating a generic component identifier (GCI)..... | 70 |
| On GCI components..... | 70 |
| 6.2. Indicating Standard Formulas (SF) | 72 |
| 6.2.1. How to report a standard formula in the main mixture composition document..... | 73 |
| 6.2.2. How to report a standard formula in the MiM composition document..... | 75 |
| 6.2.3. Downloading ready-made Standard Formula datasets | 76 |
| 6.3. Indicating an interchangeable component group (ICG) | 77 |
| 6.3.1. Step 1- Indicating the group..... | 77 |
| 6.3.2. Step 2 – Indicating information for the components..... | 79 |
| 6.4. Notifying fuel mixtures | 80 |
| 6.4.1. Step 1 – Identify the fuel | 80 |
| 6.4.2. Step 2 – Add fuel components | 80 |
| 6.4.3. Step 3 – Identify components | 81 |
| 6.4.4. Step 4 – Complete compositional information | 81 |
| 7. OTHER CONSIDERATIONS FOR SPECIAL MIXTURES | 82 |
| 7.1. Indicating multi-component products | 82 |
| 7.2. Indicating combined mixture/article | 83 |

| | |
|--|------------|
| 8. GROUP SUBMISSIONS (FOR MIXTURES DIFFERING ONLY IN PERFUME COMPONENTS)..... | 83 |
| Step 1 – establish the correct submission type | 84 |
| Step 2 – enter individual mixture compositional information | 84 |
| Step 3 – enter and link product information for each mixture | 85 |
| Step 4 - include and link single or multiple information documents | 86 |
| 8.1.1. Reporting classification and labelling in the Group submission | 86 |
| 8.1.2. Reporting toxicological information in the Group submission | 87 |
| 8.1.3. Reporting pH in the Group submission | 87 |
| 9. VALIDATE AND CREATE A PCN DOSSIER..... | 88 |
| 9.1. Validation assistant report | 89 |
| 9.2. Submission checks..... | 89 |
| 9.3. Quality checks..... | 90 |
| 9.4. Creating a dossier..... | 91 |
| 10. DOSSIER REPORT AND EXPORT FUNCTIONS..... | 92 |
| 10.1. Exporting a dossier (or dataset) | 92 |
| 10.1.1. Bulk export functionality (datasets or dossiers) | 93 |
| 10.2. Generating a report for PCN | 94 |
| 11. MAKING UPDATES | 95 |
| 11.1. When the submission is an update | 95 |
| 11.1.1. Updates – ‘Justification’ field | 95 |
| 11.1.2. Updates – ‘Remarks’ field | 96 |
| 11.1.3. Updates – ‘Other update reasons’ | 96 |
| 11.1.4. Explaining the update types..... | 97 |
| 11.2. When the submission is a ‘New notification after a significant change of composition’ .. | 98 |
| 12. WORKING IN THE ECHA SUBMISSION PORTAL..... | 100 |
| 12.1. Upload dossier..... | 100 |
| 12.1.1. Proceed to submission from ECHA Cloud..... | 100 |
| 12.1.2. Upload in the ECHA Submission portal..... | 100 |
| 12.2. Submit | 101 |
| 12.3. Checking the Submission report | 102 |
| 12.3.1. Information contained in the Submission report | 103 |
| 12.3.2. Saving the Submission report | 104 |
| 12.4. Submission portal Validation report and resubmission after failure | 105 |
| 12.5. Searching poison centre notifications in the Submission portal | 106 |
| 12.5.1. Exporting search results from the portal to Excel | 107 |
| 12.6. Request to disable a submission in the ECHA Submission portal..... | 108 |
| APPENDIX 1. INSTRUCTIONS: ESTABLISHING A FOREIGN USER..... | 113 |
| APPENDIX 2. TROUBLESHOOTING BR570 AND LEGAL ENTITY CONSISTENCY | 117 |

| | |
|---|-----|
| A.2.1 How can legal entity inconsistencies occur in the dossier and portal?..... | 118 |
| A.2.1.1 When a third party is preparing/submitting in the portal on behalf of a duty holder. | 118 |
| A.2.1.2 When a second legal entity exists..... | 118 |
| A.2.1.3 Failure to add/update legal entity details in IUCLID offline | 119 |
| A.2.1.4 Mismanagement of S2S keys in the system-to-system service | 120 |

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 Regulation¹. In particular how information can be prepared and submitted to the Member States Appointed Bodies, for example, through the ECHA Submission portal.

The document explains how to access ECHAs 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 ECHAs IT tools.

1.1. Additional support material

Guidance on Annex VIII

Full information requirements according to the legal text are covered (translations are provided)
<https://echa.europa.eu/guidance-documents/guidance-on-clp>

The PCN validation rules list

Full list of validation rules, and the history of changes covered in English
https://poisoncentres.echa.europa.eu/documents/1789887/5577602/pcn_validation_rules_en.pdf/

The EuPCS practical guide

Full descriptions of the individual categories of the European product categorisation system (including translations) as other support on the topic

<https://poisoncentres.echa.europa.eu/eu-product-categorisation-system>

The ECHA Accounts manual

Explains how to create, export, import and manage your account in general:
https://www.echa.europa.eu/documents/10162/17247/howto_account_manual_industry_en.pdf/

IUCLID Functionalities Manual

Explanations of the complete functioning of IUCLID is comprehensively covered (translations are provided). The manual is also available in the IUCLID application itself.
<https://iuclid6.echa.europa.eu/documentation>

UFI user guide

Explains how the generator tool and algorithm work (translations available), plus additional support on this topic:
<https://poisoncentres.echa.europa.eu/ufi-generator>

¹ Annex VIII to CLP Regulation https://eur-lex.europa.eu/eli/reg_del/2020/1677/oj

2. Accessing ECHA's IT applications for poison centre notifications (PCN)

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 (PCNs).

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"

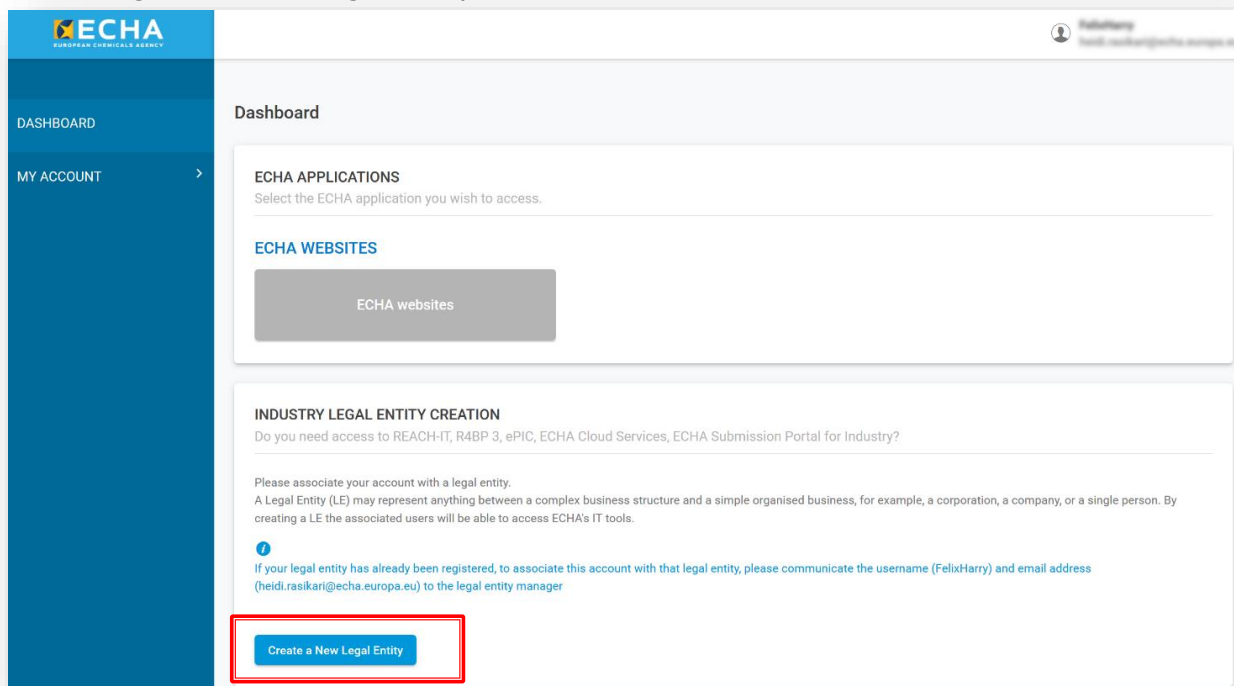
[What type of account do I need?](#)

[Need help?](#)

Step 2 - Assign a Legal Entity to the ECHA Account

Submissions made through the ECHA Submission portal are carried out by legal entities² 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 (LE) must be assigned to it. In order to use ECHA IT applications, a UUID number is generated and assigned to each Legal Entity in ECHA Accounts.



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

- i) **create a new Legal Entity** in ECHA Accounts and enter specific information about the company, or,
- ii) **import a pre-existing Legal Entity** e.g. from IUCLID desktop.



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.



Non-EU legal entities can work in ECHA Cloud Services e.g. to prepare information, but they cannot use the ECHA Submission portal to make submissions from their account.

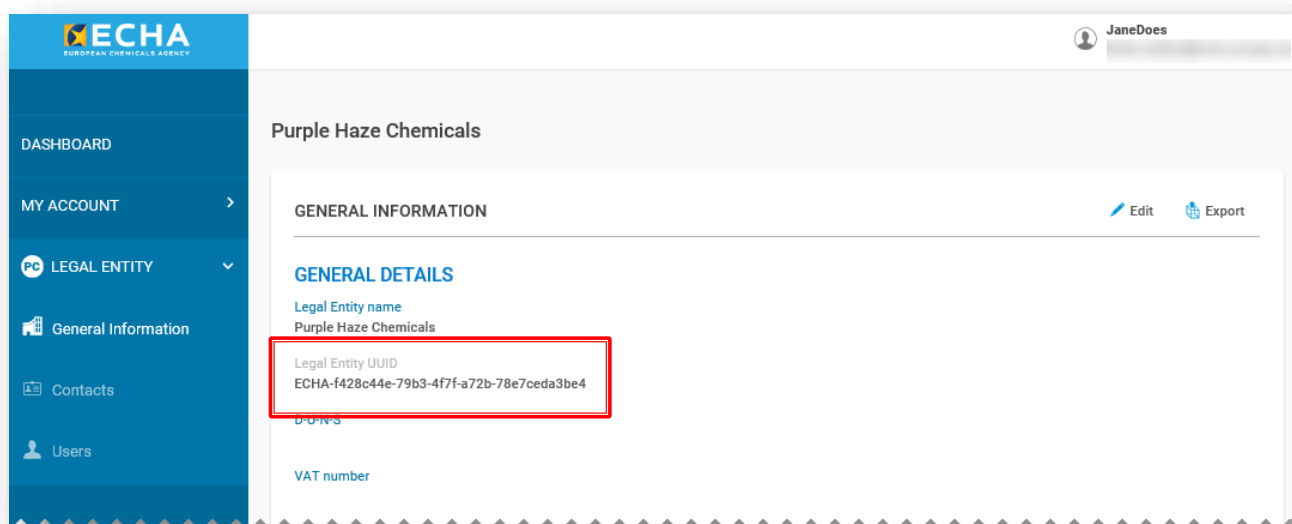
² A legal entity (LE) may represent anything between a complex business structure and a simple organised business, for example, to a corporation, a company, or a single person.

2.1.1. Create a new Legal Entity

Selecting 'Create a 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 automatically assigned a universal unique identifier (UUID) number so that the ECHA IT applications can explicitly identify the Legal Entity, its users and their actions.

The legal entity UUID acts as an unequivocal identifier and each legal entity must be represented by a single UUID number. The legal entity UUID numbers generated in ECHA Accounts contain the pre-fix 'ECHA-'.

! In some cases, a third party e.g. a consultant, may represent more than one company, and may prefer to create a different account for each company they represent. Note it is possible to use the same company information (e.g. name, VAT, address, etc.) for each account but a common convention is to use numerical identifiers attached to the representing company's name to facilitate the management of accounts linked to different companies.



The screenshot shows the ECHA Accounts interface for a user named 'JaneDoes'. The main content area displays the details for a legal entity named 'Purple Haze Chemicals'. Under the 'GENERAL INFORMATION' section, there is a 'GENERAL DETAILS' subsection. The 'Legal Entity name' is 'Purple Haze Chemicals'. The 'Legal Entity UUID' is 'ECHA-f428c44e-79b3-4f7f-a72b-78e7ceda3be4', which is highlighted with a red box. Other fields like 'VAT number' are visible but not filled in. The left sidebar contains navigation options: DASHBOARD, MY ACCOUNT, LEGAL ENTITY (with a sub-menu for General Information, Contacts, and Users), 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 (https://poisoncentres.echa.europa.eu/documents/1789887/5674408/msd_en.pdf/).

For information about the fees charged for those Member States, make contact or visit the Appointed Body websites <https://poisoncentres.echa.europa.eu/appointed-bodies>

2.1.2. Importing a pre-existing legal entity (LE) from IUCLID³

If you are a IUCLID desktop user, you will already have previously created a Legal Entity (the UUID number contains pre-fix 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 LE from ECHA Accounts to your working instance of IUCLID, or,
- ii) export your LE 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 Create Legal Entity form by activating the section 'Creation method', and selecting the file for upload. Refer to section 4.2.2 for details how to export your Legal Entity from IUCLID.

The screenshot shows the 'Create Legal Entity' form in ECHA Accounts. The 'CREATION METHOD' section is highlighted with a red box. It contains a radio button that is selected, with the text: '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 for this file, the 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.' Below this text is a file upload area with a document icon, the text 'Import IUCLID Format File *', and a 'Select file' button. Underneath the upload area, it says 'Please attach an IUCLID exchange format (LEOX file format)'. Other sections visible include 'ACCOUNT SECURITY' with a 'Security Question *' field containing 'What is your pet's name?' and 'ALERTS' with a toggle switch for 'Receive email alerts for unfamiliar signing-in activities to ECHA applications using your account'.



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.

³ 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

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

! It is possible for a Legal Entity (Company A) to appoint a third-party user from another Legal Entity (Company B) to work as if they were a user from the company who appointed them. For example, a company hiring a consultant to prepare and possibly submit information. This is achieved with the **foreign user** functionality as established in ECHA Accounts (**Appendix 1**). Confidentiality concerns must be fully explored before appointing a foreign user.

The screenshot displays the ECHA Accounts interface for 'Purple Haze Chemicals'. On the left is a navigation menu with options: DASHBOARD, MY ACCOUNT, LEGAL ENTITY (selected), General Information, Contacts, and Users. The main content area is titled 'LEGAL ENTITY USERS' and shows a table of users. A red box highlights the '+ Create new user' button in the top right corner. An overlay window titled 'Purple Haze Chemicals Create new User' is open, showing a progress bar with four steps: 1. Insert user details (checked), 2. Assign roles to user (current step), 3. Confirm addition of user, and 4. Inform the user. Under 'USER PROFILE', there is a list of roles to assign to the user account:

| Role |
|--------------------------------------|
| REACH Manager |
| REACH Reader |
| Submission Portal Manager |
| Submission Portal Manager Restricted |
| Submission Portal Reader |

The user roles define the user access level within the ECHA IT applications. The specific PCN related roles for users (including foreign users) include:

| User Role | Rights and Visibility |
|-------------------------------------|--|
| LE manager | The Legal Entity (LE) manager can view and edit the account and add, remove contacts or edit users' data. Only a user with the 'LE manager' role can edit the Legal Entity details – except for the specific LE UUID number and the country. |
| Submission portal manager | Users with this role can work in the ECHA Submission portal to: <ul style="list-style-type: none"> • make submissions from the legal entity account, • search and access submission information in the submission portal (such as submission and validation reports). |
| Submission portal restricted | A 'LE manager' can restrict users' visibility of information in the ECHA Submission portal. Users assigned with this role <ul style="list-style-type: none"> • can only see details on the submissions that they have submitted in the portal. • have restricted visibility of information in the Submission portal, and are limited only to the information they themselves have submitted. <p>NOTE that when this role is assigned in combination with other roles, then the stronger role defines the access rights, e.g. if someone is assigned the "Submission Portal Manager" role, those rights remain even if the "restricted" role is assigned – meaning that the user can still see all the submissions of the company.</p> |
| IUCLID full access | Users with this role: <ul style="list-style-type: none"> • can prepare submissions online in IUCLID Cloud • have complete access to dossier information in IUCLID and rights to edit existing datasets, prepare new notifications and create dossiers. <p>NOTE that when a user has been assigned the 'IUCLID full access' role they will also have access to all information available in IUCLID Cloud for that legal entity, regardless of any other roles assigned.</p> |
| IUCLID Read Only | Users assigned read only access can view dataset and dossier information but do not have the possibility to prepare or create dossiers. |
| IUCLID trial | Users (excluding foreign users) can work in the trial version of the IUCLID Cloud. |



Use caution when adding Foreign Users to your IUCLID Cloud instance or to the ECHA Submission portal to avoid exposing confidential business information.

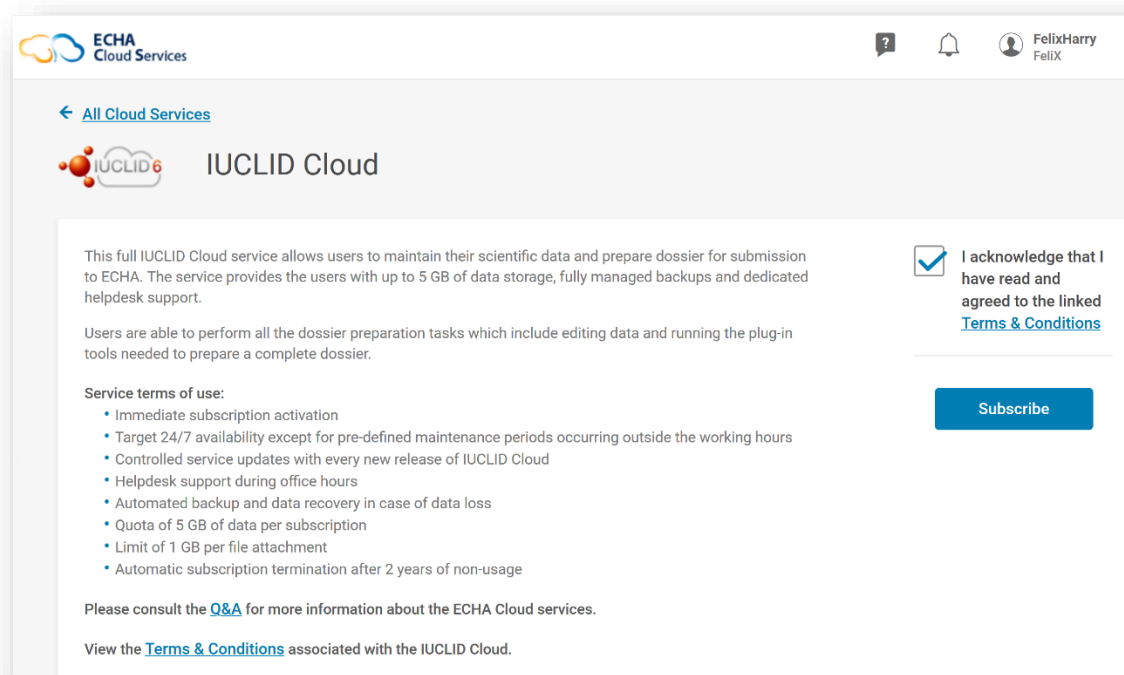
- Any third-party, EU or non-EU based, can be a foreign user, provided they have a valid ECHA Account detailing their legal entity information.
- A foreign user prepare and have access to information belonging to the appointing company in either IUCLID Cloud or the ECHA Submission portal, or both. This depends on the user roles assigned to them.
- It is possible to grant full access, partial access or no access to a foreign user.
- A foreign user will have full visibility in IUCLID Cloud if they assigned a IUCLID role. Therefore, to ensure complete confidentiality in IUCLID Cloud, do not assign any IUCLID user roles.
- To ensure complete confidentiality in the ECHA Submission portal, no portal roles should be assigned.
- ECHA strongly recommends entering into contractual agreements specifying what the foreign user is expected to do, or how to handle confidentiality issues. However, no guidelines for this have been established and therefore each contract needs to be determined by the parties involved on a case-by-case basis.

Step 4 - Subscribing to the ECHA 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 interface. 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', described as a full service for maintaining scientific data and preparing dossiers for submission to ECHA, with a 'Read more' link and a 'Subscribe' button. The second card is for 'IUCLID 6 Trial', described as a service for users to get familiarised with a trial version of IUCLID Cloud before starting to use the full service, also with a 'Read more' link and a 'Subscribe' button.

The Terms and Conditions to use the ECHA Cloud Services, in particular for IUCLID Cloud and ECHA Submission portal need to be accepted before use.



ECHA Cloud Services

[All Cloud Services](#)

IUCLID Cloud

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.

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

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.

Subscribe

! The **Terms and Conditions** are available in all EU languages here from the ECHA website: <https://echa.europa.eu/support/dossier-submission-tools/echa-cloud-services>

! Please pay attention to email notifications from ECHA Cloud Services if you are an infrequent user. If you do not access the service within a 24-month period you will be informed that **your account will expire and it will not be possible to access data** previously entered. Trial users are granted only a short time of inactivity (30 days) before the subscription expires.

Dear Consultant 1,

Your subscription for IUCLID Cloud Trial service will expire in 30 days as it has not been used since 10/08/2023 15:15.

Subscription information

- Legal Entity Name: Chemical Service
- Legal Entity UUID: ECHA-
- Subscription date: 10/08/2023 15:15
- Subscription UUID:
- IUCLID Cloud Trial URL: <https://25e7a0ad-4aaf-4f4a-96e9-dfd7b868218c.ecs-qa.echa.europa.local/iuclid6-web>

Please access your service to prevent the expiration of your subscription.

If you take no action, the subscription will be automatically expired. If you no longer want to use the service, please unsubscribe.

Kind regards,
ECHA Cloud Services

3. Prepare and submit a poison centre notification (PCN)

There are several options available 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
- IUCLID for data preparation
- ECHA Submission portal
- System-to-system (S2S) service

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 European Union/European Economic Area (EU/EEA).

The PCN format is .xml-based and is compatible with IUCLID and as such is incorporated into the 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 (S2S) service. Updates of the format occur annually.

Additional support on the PCN format

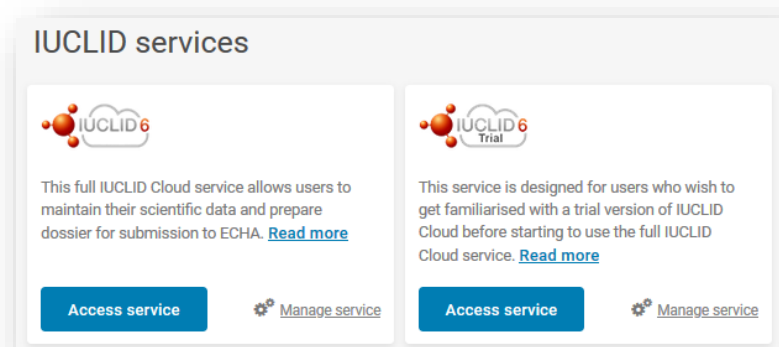
For system-to-system users, you can download the latest version of the PCN format and related documents from the poison centre website here:
<https://poisoncentres.echa.europa.eu/poison-centres-notification-format>

3.2. IUCLID for data preparation

This chapter looks at both the IUCLID Cloud (online) and IUCLID (offline) tools for manual preparation of poison centre notifications. Both tools offer the same interface. Explanations of the complete functioning of IUCLID is comprehensively covered in the **IUCLID Functionalities Manual**. The manual is also available in the IUCLID application itself - <https://iuclid6.echa.europa.eu/documentation>

3.2.1. IUCLID Cloud Services

Preparation in IUCLID Cloud is available through the ECHA Cloud Service (<https://idp-industry.echa.europa.eu/idp/>) which is maintained, backed-up, updated by ECHA and the data is securely stored in the Cloud. The **full IUCLID Cloud service** allows users to maintain their scientific data and prepare dossiers for submission. The **Trial version** can be used for getting familiar with the tool. It is not possible to make submissions via the Trial version.



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

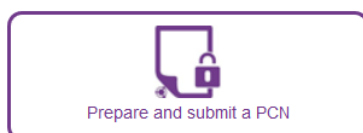


Ensure you have the latest version of IUCLID as only the most recent version can fully accommodate the poison centre requirements and avoid unnecessary failures.

3.3. ECHA Submission portal for poison centre notifications

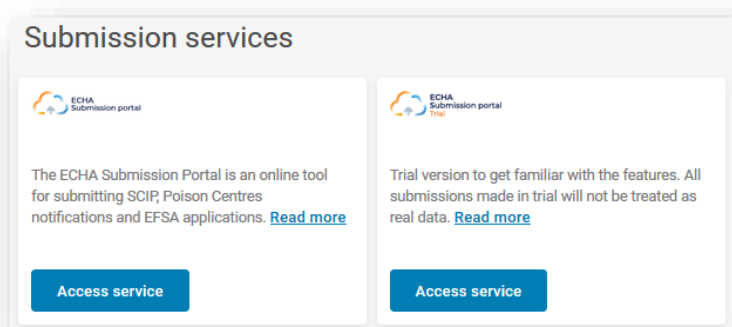
The ECHA Submission portal is an online tool for EU based companies for the submission of poison centre notifications to relevant Member State Appointed Bodies. To make submissions through the ECHA Submission portal a company must have an active ECHA Account, users must be assigned with the correct roles and be subscribed to the service.

Our support and Login page for PCN is here <https://poisoncentres.echa.europa.eu/prepare-and-submit-a-pcn>

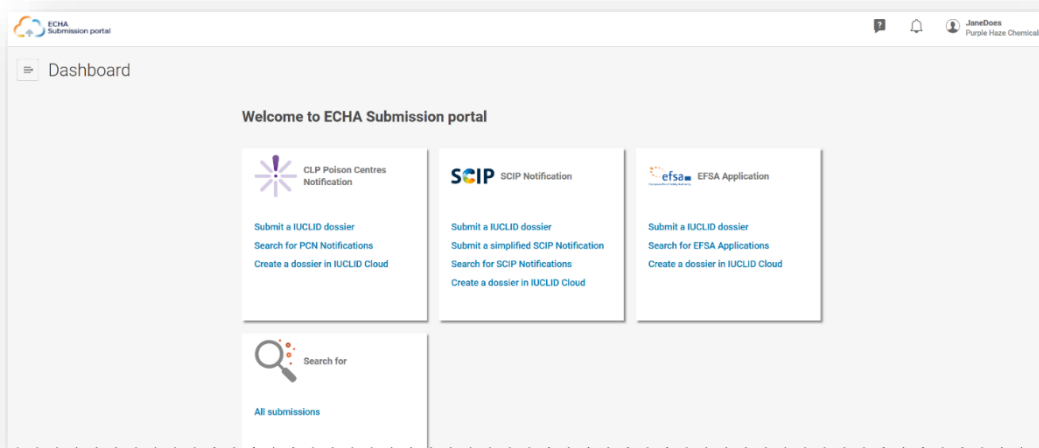


Submissions made through the portal can accommodate **multi-market notifications**, meaning that one submission can reach multiple Appointed Bodies.

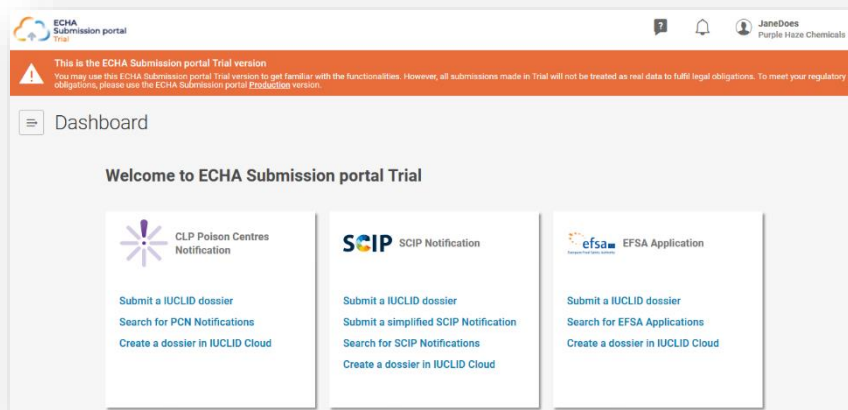
Data submission services available in the Cloud, include the **ECHA Submission portal** full service (production environment) and **ECHA Submission portal Trial version** (Testing environment). Each are explained further below.



The **ECHA Submission portal (full service)** 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.

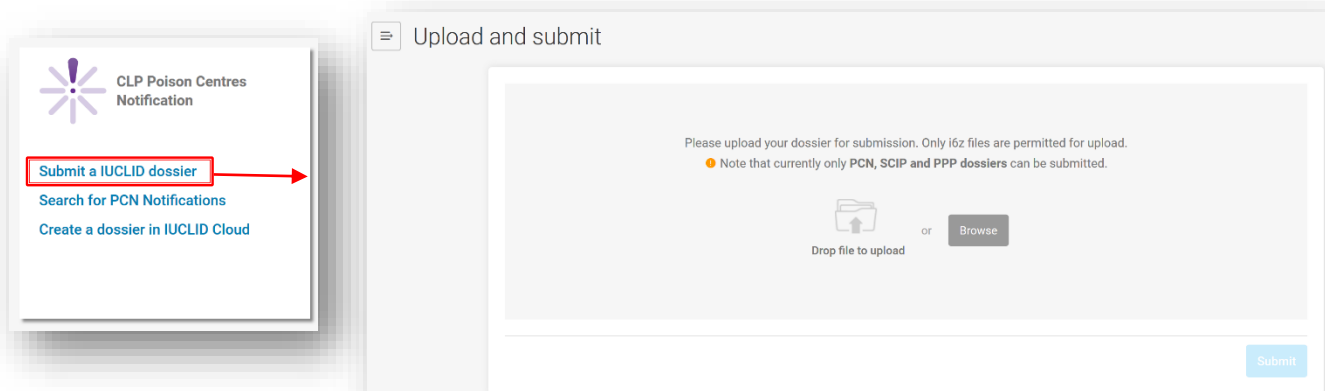


ECHA Submission portal trial version layout is designed to alert users they are in the Trial version. Any dossiers for testing purposes are not forwarded to recipients indicated in the notification.

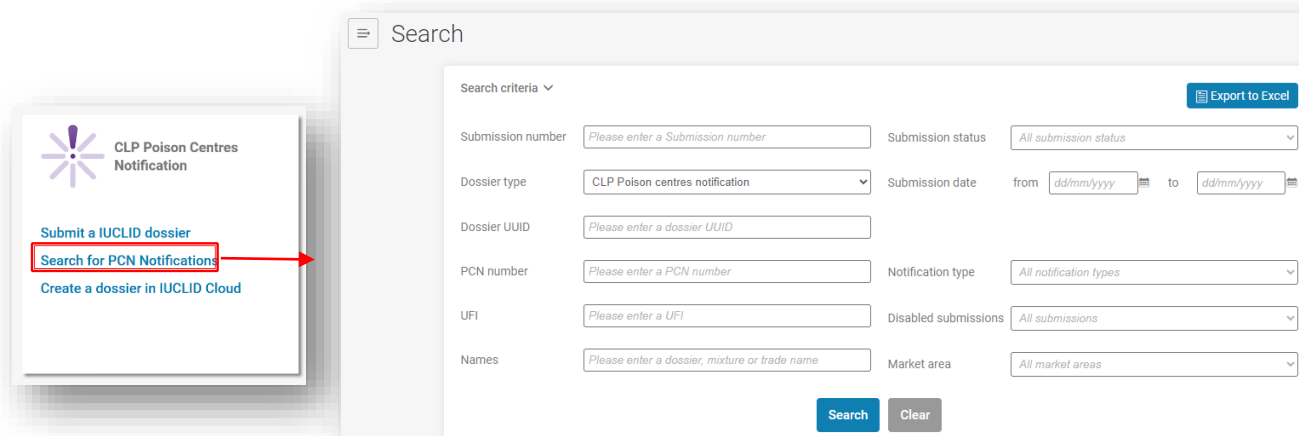


For poison centre notifications, the following functionalities in the ECHA Submission portal include:

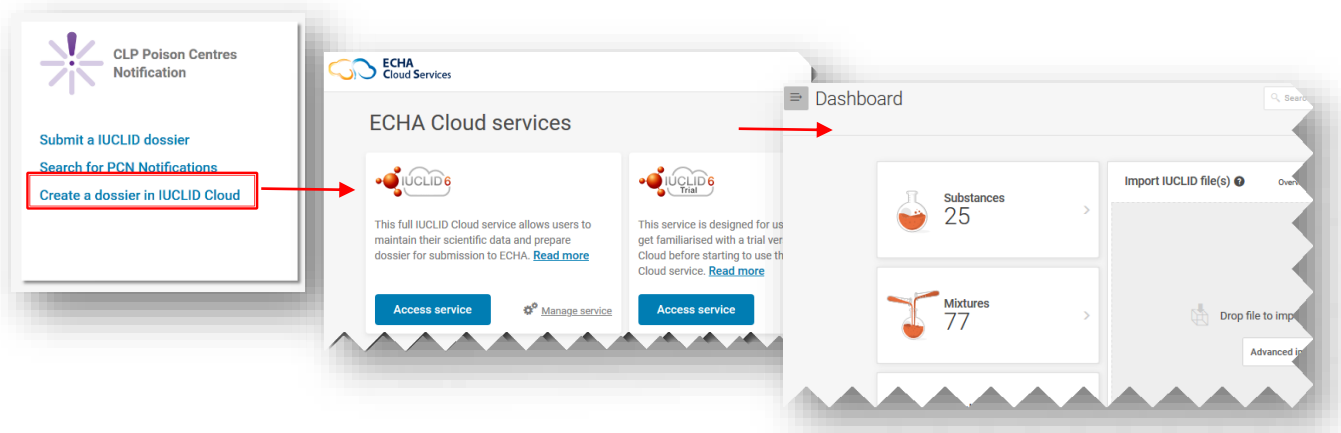
Submit a IUCLID dossier redirects you to the upload and submit page.



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.



Create a dossier in IUCLID Cloud redirects you to the ECHA Cloud services where you choose to access the service for IUCLID Full service or the IUCLID Trial version to begin the preparation of a dossier.



3.4. 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

Additional support on the system-to-system service

Guide to the PCN format - The guide for developers assists system-to-system users for poison centre notifications

<https://poisoncentres.echa.europa.eu/documents/1789887/5577602/Guide+to+PCN+format.pdf/>

The **Developers Guide to the IUCLID format** - This guide contains the full IUCLID format

https://iuclid6.echa.europa.eu/documents/1387205/1806384/iuclid_i6z_format_developer_guide_en.pdf/

System-to-system integration for industry - Visit the ECHA website for more information on gaining access to the service, technical/practical documentation and related files.

<https://echa.europa.eu/system-to-system-submission-service>

4. Creating an editable dataset in IUCLID

This chapter details the process of preparing a CLP poison centre notification 'Dataset' in IUCLID (.i6z file containing information about a substance or a mixture). Further, the relevant 'Documents' which contain the data entry fields according to the information requirements laid out in Annex VIII to the CLP Regulation are explained.

4.1. The IUCLID Dashboard

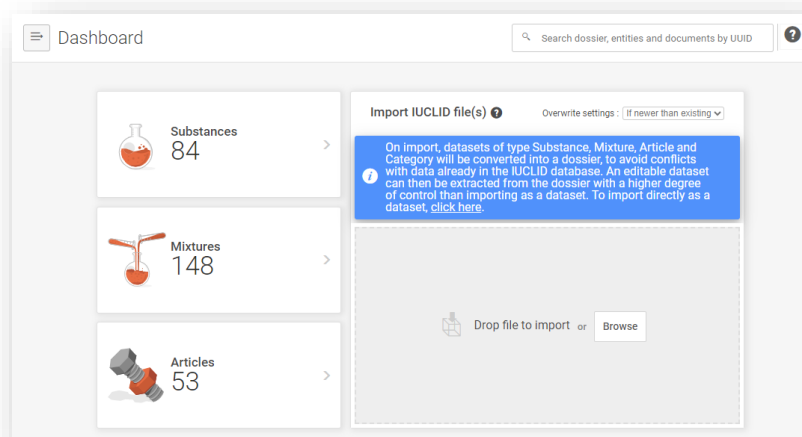
The IUCLID Dashboard is home to the following widgets:

Substances 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. Note if you have prepared substance dossiers for other notification types, they will also be included here.

Mixtures stores information about the Mixture datasets available as well as any dossiers prepared.

Articles is only used for making notifications to the SCIP database, which was established under the Waste Framework Directive (WFD)⁴.

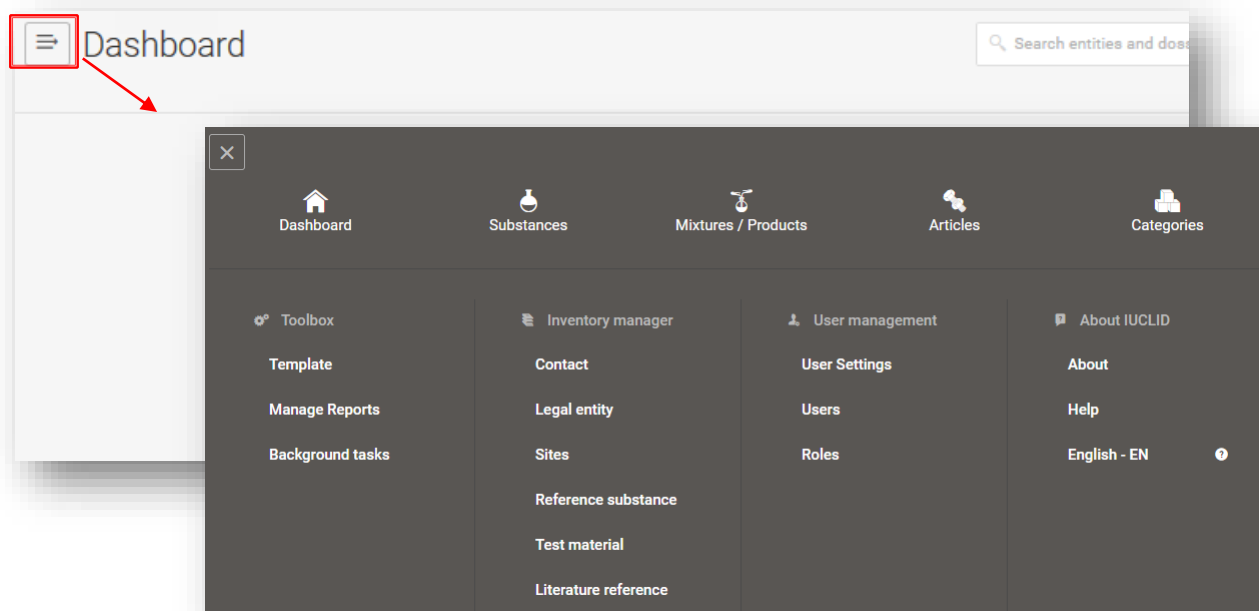
The **Import IUCLID files** area allows you import .i6z files to your working instance of IUCLID. This could include Legal Entities, Reference substances, or Substance/Mixture datasets and Dossiers.



⁴ 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>).

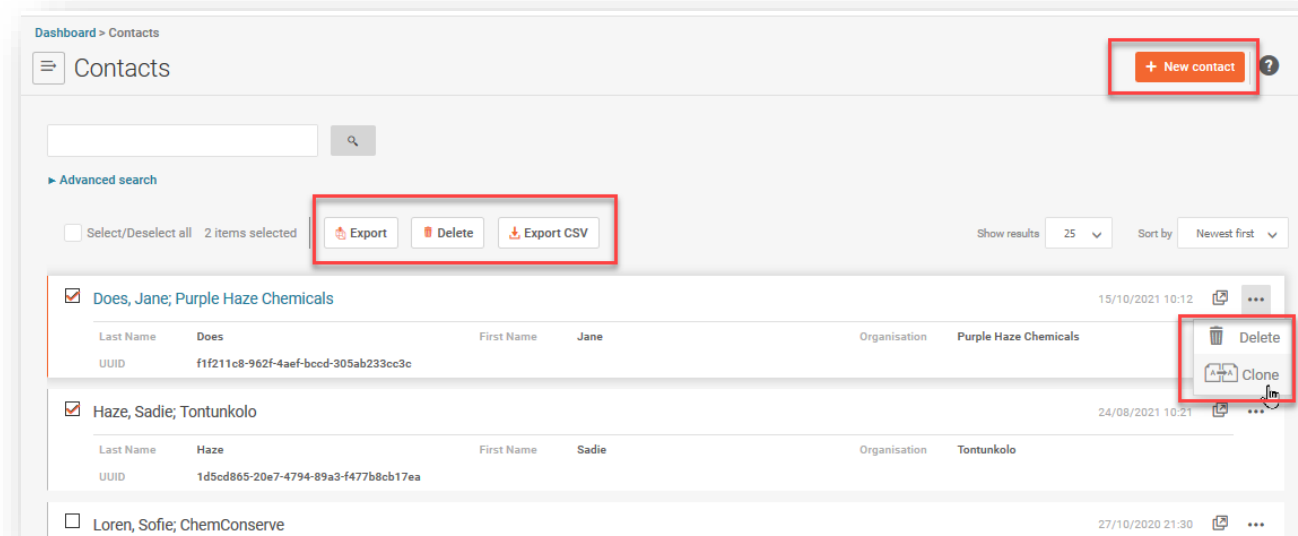
4.2. Managing IUCLID entities outside the notification

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 entity specific 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

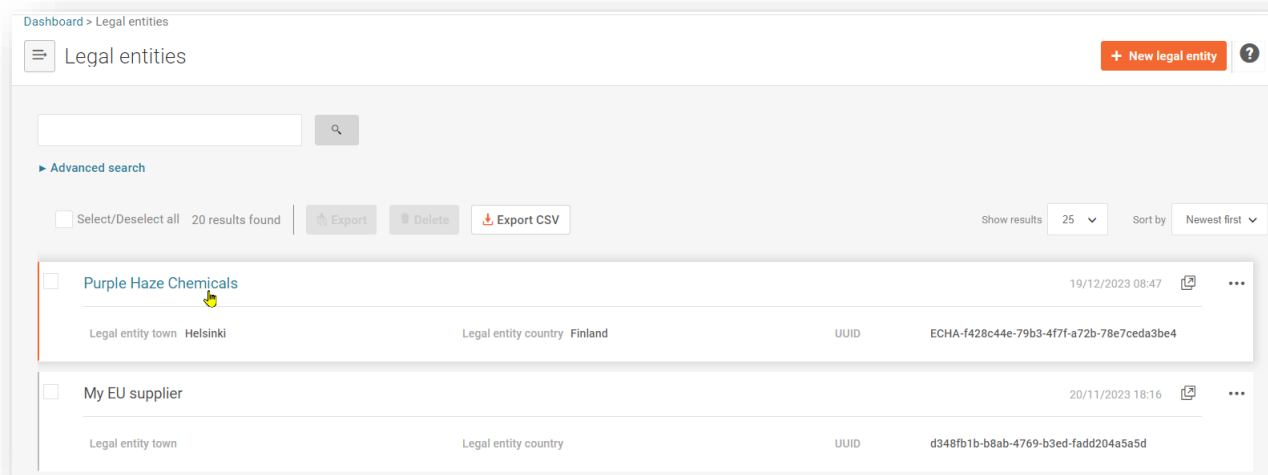
When managing Contacts outside the notification (it is possible to manage them also from within a notification), it is possible to create new or edit existing contacts, export selected contacts and clone them as well.



4.2.2. Managing the Legal Entity

In some cases, the Legal Entity details may need to be exported from IUCLID, for example, by a IUCLID Desktop user (described in section 2.1.2).

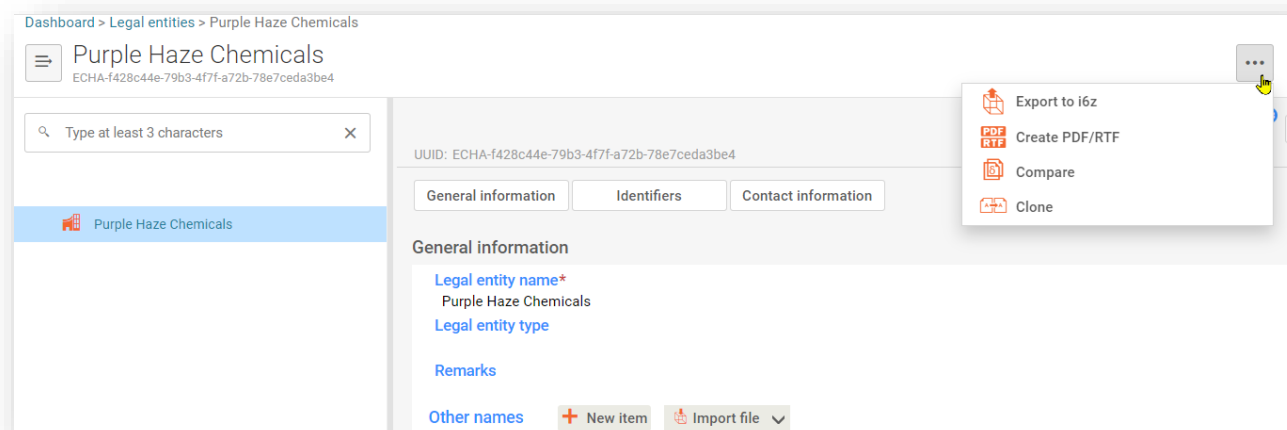
Selecting 'Legal Entity' from the Dashboard takes you to the complete list of legal entities in your IUCLID instance.



The screenshot shows the 'Legal entities' dashboard in IUCLID. At the top, there is a breadcrumb 'Dashboard > Legal entities' and a '+ New legal entity' button. Below is a search bar and an 'Advanced search' link. A summary bar indicates '20 results found' and includes 'Export', 'Delete', and 'Export CSV' buttons. The main area displays a table of legal entities:

| Entity Name | Legal entity town | Legal entity country | UUID | Created/Updated |
|-----------------------|-------------------|----------------------|---|------------------|
| Purple Haze Chemicals | Helsinki | Finland | ECHA-f428c44e-79b3-4f7f-a72b-78e7ceda3be4 | 19/12/2023 08:47 |
| My EU supplier | | | d348fb1b-b8ab-4769-b3ed-fadd204a5a5d | 20/11/2023 18:16 |

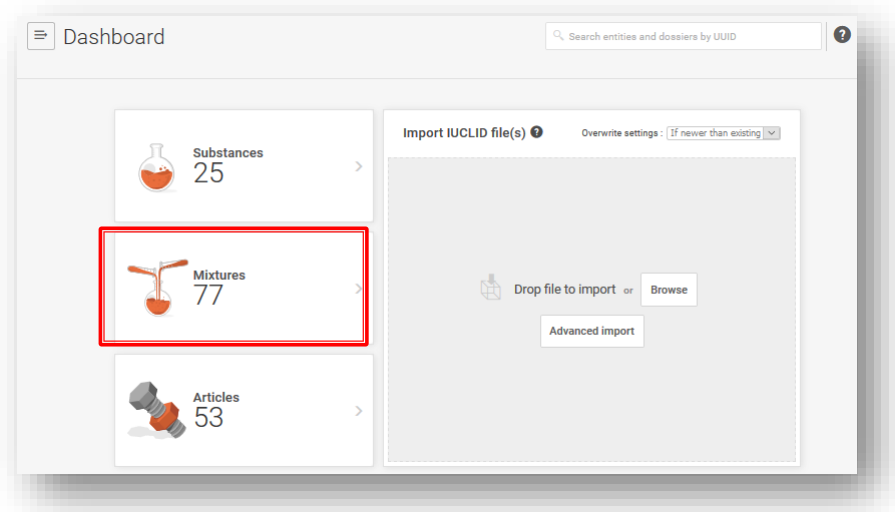
Once a legal entity is selected, the information about that legal entity is displayed and can be exported following the prompts, and saved e.g. to your desktop, before importing where relevant.



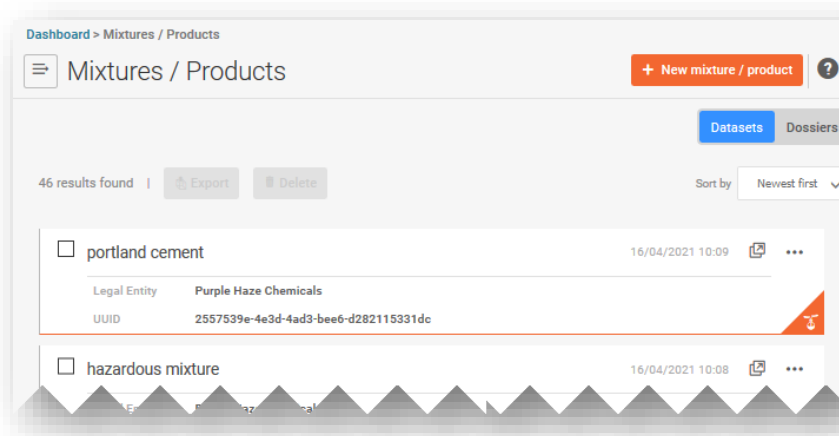
The screenshot shows the details page for 'Purple Haze Chemicals' in IUCLID. The breadcrumb is 'Dashboard > Legal entities > Purple Haze Chemicals'. The page title is 'Purple Haze Chemicals' with the UUID 'ECHA-f428c44e-79b3-4f7f-a72b-78e7ceda3be4'. There is a search bar and a sidebar with a navigation menu. The main content area has tabs for 'General information', 'Identifiers', and 'Contact information'. The 'General information' tab is active, showing fields for 'Legal entity name*' (Purple Haze Chemicals) and 'Legal entity type'. A 'Remarks' section is also visible. At the bottom, there are 'Other names' and buttons for '+ New item' and 'Import file'. An export menu is open on the right, showing options: 'Export to i6z', 'Create PDF/RTF', 'Compare', and 'Clone'.

4.3. Steps to prepare an initial Mixture/product dataset

This section will explore the general principles for creating a dataset customised for poison centre notifications, field by field. Begin by clicking on 'Mixtures':

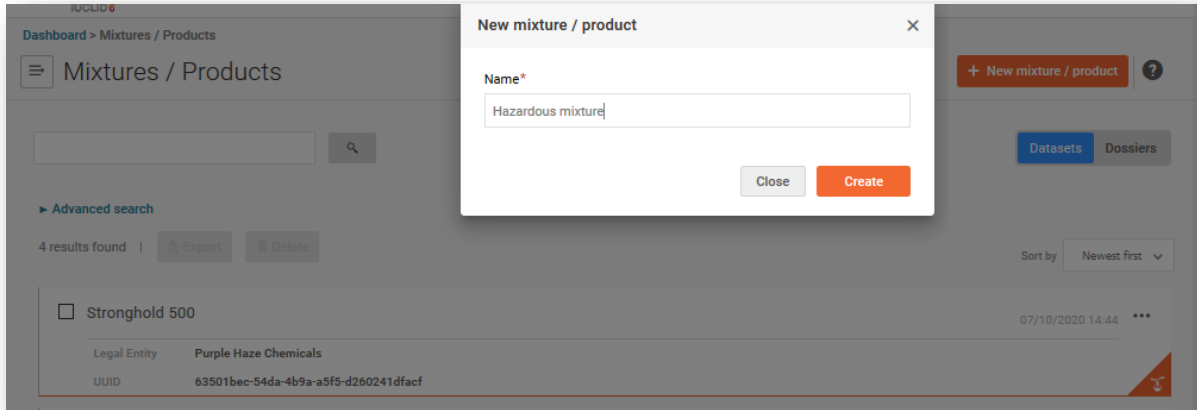


You are then re-directed to the Mixtures/Products page which lists all 'datasets' under preparation (orange mixture symbol) or you can switch to view all 'dossiers' that have been previously created (purple lock symbol).



4.3.1. Create a New mixture/product dataset

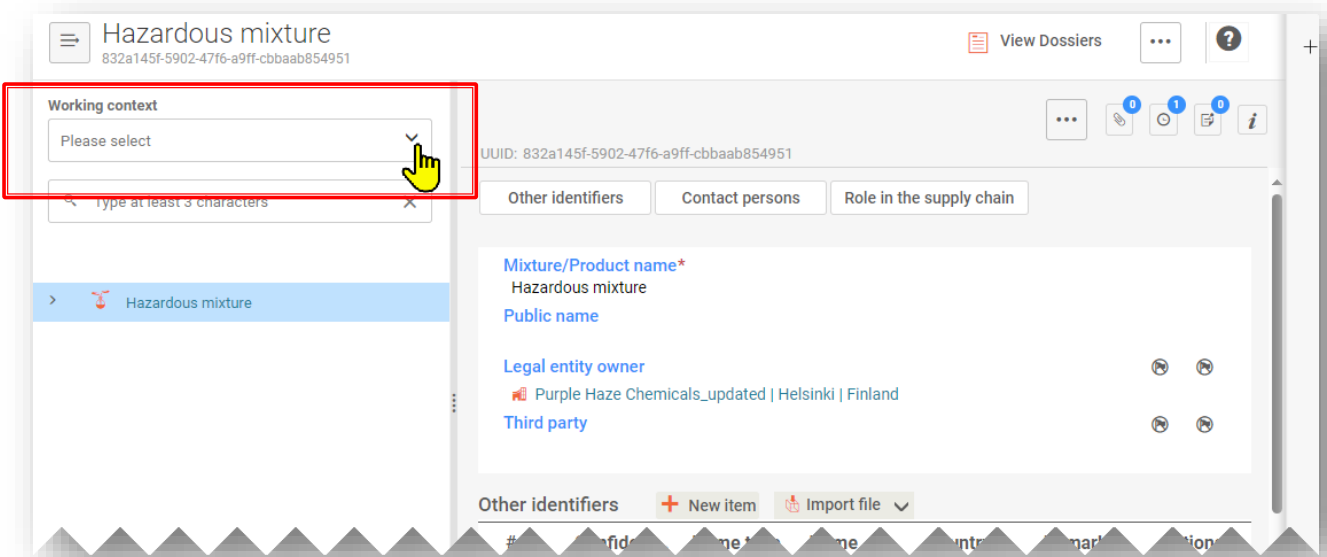
The '+New mixture/product' button starts the creation process of a new mixture/product dataset. To complete the process, you need to enter a name for the mixture and press 'Create'.



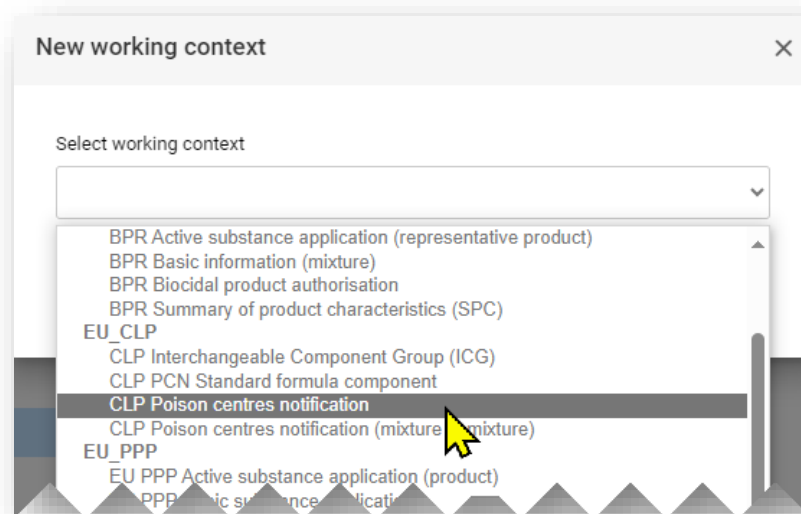
! The Mixture dataset is identified by its name given upon creation. Any name can be used however suggested to select a name which is commonly used for that mixture within the company. This can be for instance an internal name or a formulation identifier. If necessary, this name can be changed.

4.3.2. Set the working context

Once the Mixture dataset has been created, it can be opened, and the 'Working context' selected. The working context customises the IUCLID fields relevant to the selected legislation and process.

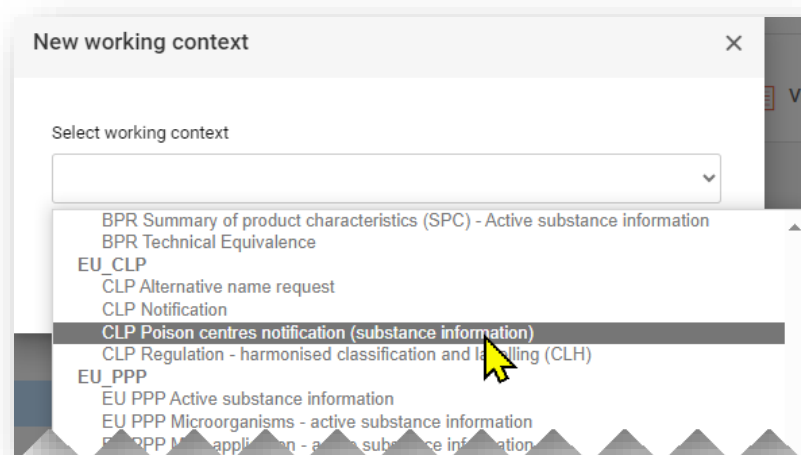


For example, the working context selection 'CLP Poison centre notification' is used to prepare a poison centre notification.




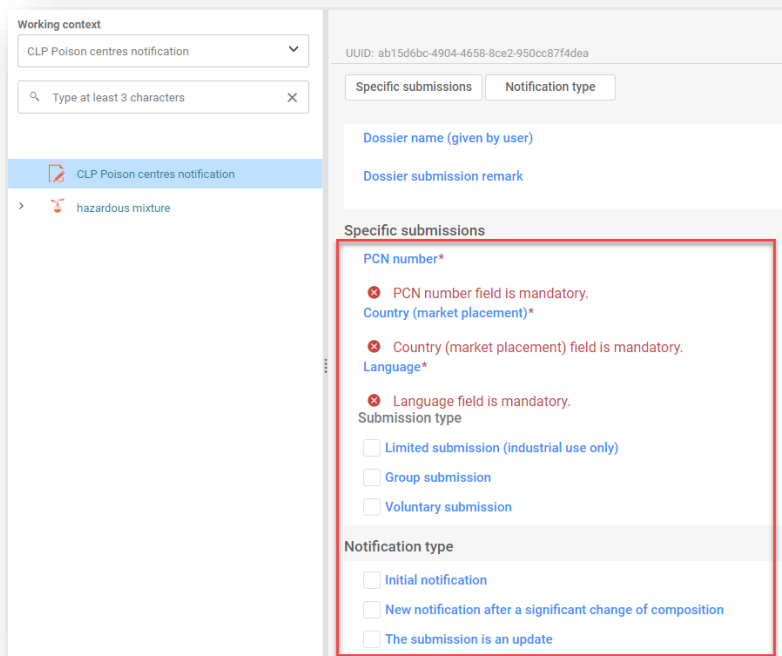
Other selections relevant to poison centre notifications (various components) are available but not generally required to be selected if creating component datasets directly in the 'Composition document' of the final mixture. More information on how to create these datasets in a notification are discussed in later sections of this guide, including mixture-in-mixtures, interchangeable component groups, and standard formula components.

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' – see the section in this guide on how to add substance components.



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 to the notification 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 is 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>

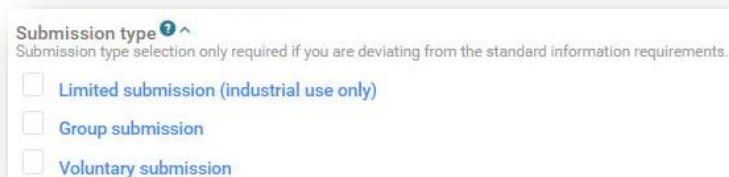


Indicating the **languages** prior to data preparation is necessary as it creates the multilingual fields required for free text fields which must be provided in all relevant languages e.g. for the toxicological information.

Following successful submission, **market areas** cannot be deleted in an update. Note, this applies even in case of ceasing the market in a specific country.

4.3.3.1. Explaining Submission types

Submission type is set to 'Standard' submission type requirements by default. Therefore, it is not required to make a selection for the Submission type unless you are deviating from the standard information requirements through either a limited, group or voluntary submission (or combination of these).




Submission type ⓘ ^
Submission type selection only required if you are deviating from the standard information requirements.

Limited submission (industrial use only)

Group submission

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 downstream to further re-formulate a mixture intended for consumer or professional use, this option cannot be selected.

The limited submission option can also be applied to industrial mixtures included in a final mixture intended for professional or consumer uses that are outside the scope of Article 45 and Annex VIII (i.e. **mixtures with an end use not subject to notification**).

A '**Group submission**' (described further in this guide) is available for the creation of a dossier containing information for several mixtures provided:

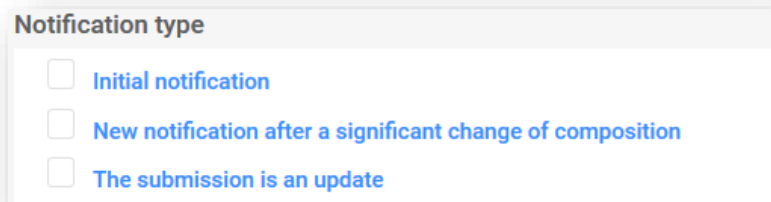
- all mixtures contain the same composition except for certain perfumes under specific conditions;
- reported concentrations/ranges for each of the components is the same (except certain perfumes);
- all mixtures in the group have the same classification for health and physical hazards

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

 The EU-based company submitting the voluntary notification is still responsible for the accuracy of the notification and keeping up to date according to the Terms & Conditions of the [Terms & Conditions of the ECHA submission Portal](#)

4.3.3.2. Explaining 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.

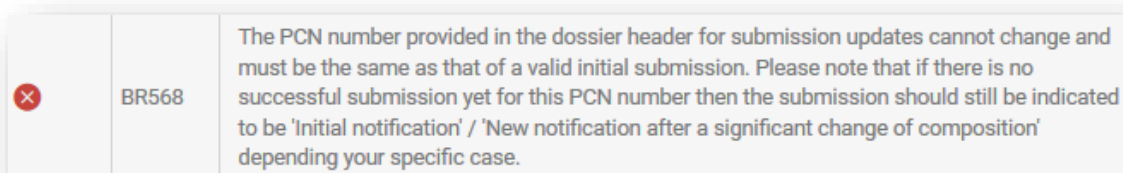



Notification type

- 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.

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



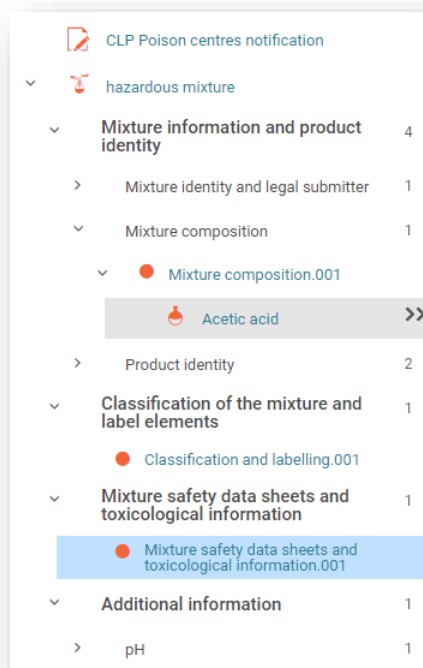
| | | |
|---|-------|--|
|  | BR568 | The PCN number provided in the dossier header for submission updates cannot change and must be the same as that of a valid initial submission. Please note that if there is no successful submission yet for this PCN number then the submission should still be indicated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

'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 and a new UFI is needed – see later in this guide.

'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 later in this guide.

4.3.4. General navigation and functionalities for data entry

The navigation tree, or table of contents (TOC), featured on the left-hand side of the page, allows easy movement between the dossier header and the customised sections and sub-section created for the poison centre notification mixture-dataset. Documents need to be created for each of the sections. The navigation tree allows you to navigate in the dataset using the collapsible/expandable arrows.

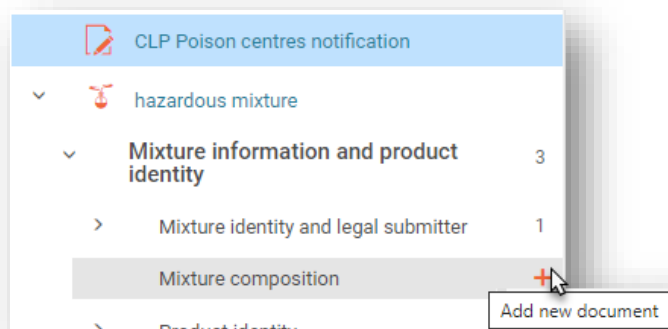


Each of the created sections and documents can be managed by additional features.

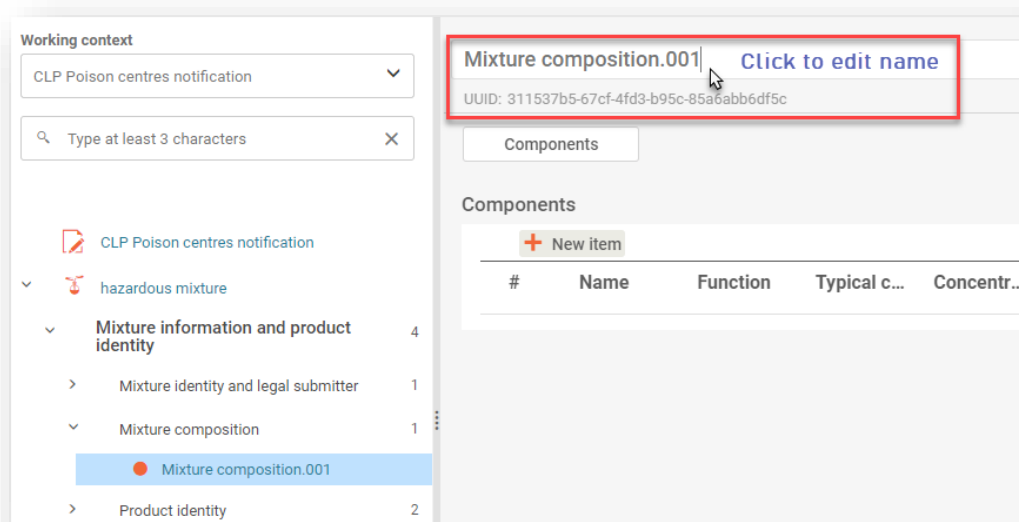
| Function | Symbol |
|--------------------------------------|--------|
| Collapses a section | ∨ |
| Expands a section | > |
| Go to sub-tree | >> |
| Adds a New document | + |
| IUCLID document | ● |
| Trash-can deletes unwanted documents | 🗑️ |
| Substance | 🧪 |
| Mixture/product | 🧴 |

4.3.4.1. Creating a 'New document'

Before information can be entered into the dataset, a document containing relevant entry fields, must be created by clicking on the orange + and selecting 'Add new document'.



When a new document has been created it is represented in the table of contents by a filled orange circle and given a default name and number (e.g. [Mixture composition.001]) and a specific document UUID⁵ number. The name of the document can be edited to suit.



⁵ In order to ensure the correct relationship between the various documents contained in a IUCLID dossier, a UUID is associated to each document (e.g. Legal entity, Substance, Reference substance etc.). Additionally, the dossier is identified with a UUID. Note that IUCLID, by default, keeps the UUID the same if, for example, the Substance, Reference Substance document is "the same" in different dossiers.

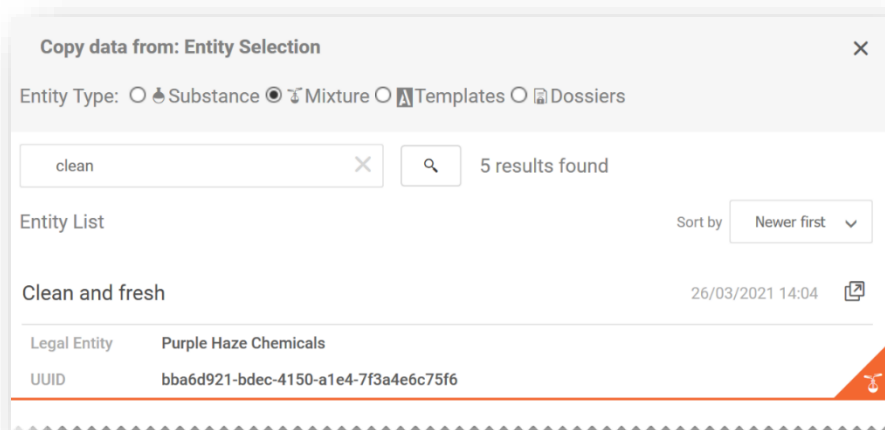
4.3.4.2. 'Copying data from' existing documents

If you have previously created information documents for other mixture-datasets, they will be available for re-use in other datasets.

To include previously prepared information, click on the three dots '...' in the top right-hand corner of the dataset you are working in. A number of functionalities including 'Copy data from ...' will become available.

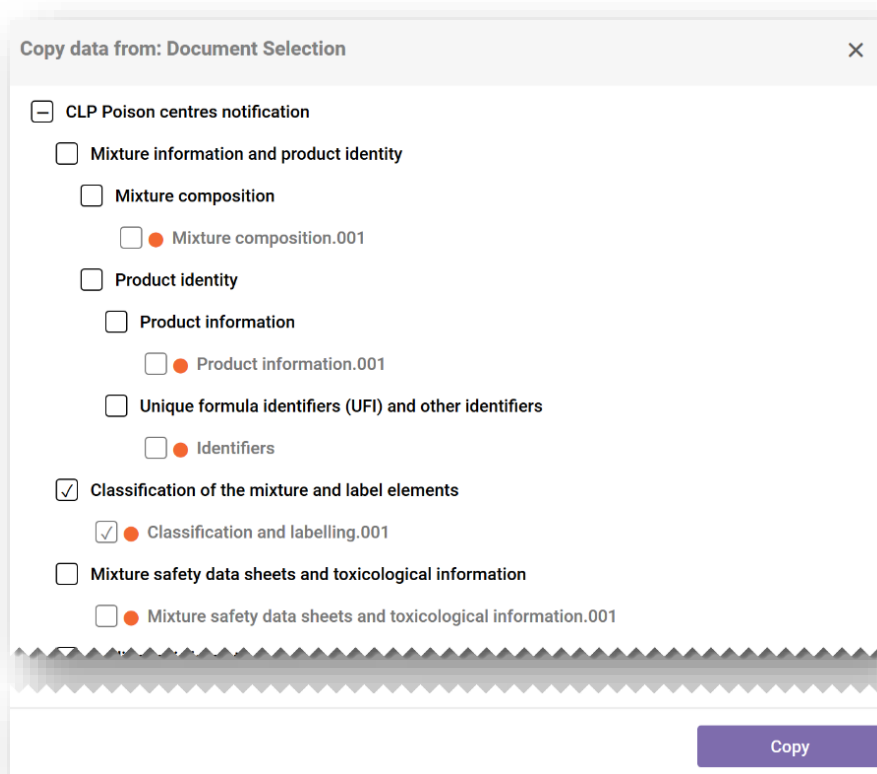


A list of available datasets to select information is presented. The entity type is set by default to 'Mixtures' (i.e. mixture-datasets), but it is possible to select 'Dossiers'. You may wish to use the search function to assist locating your source information and making your selection faster.

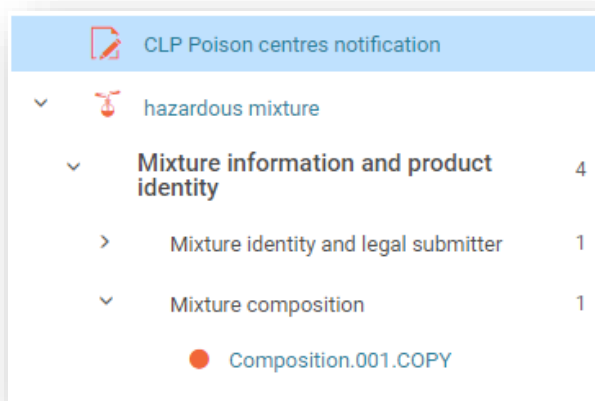


You **can bulk copy data from a dossier** to a newly created dataset by selecting the Entity type Dossier and selecting the information you would like copied.

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 re-named.

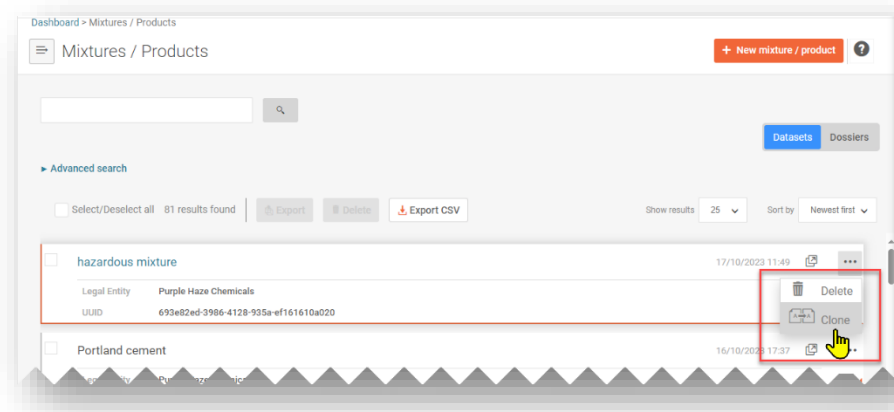


4.3.4.3. Using the 'Cloning' functionality

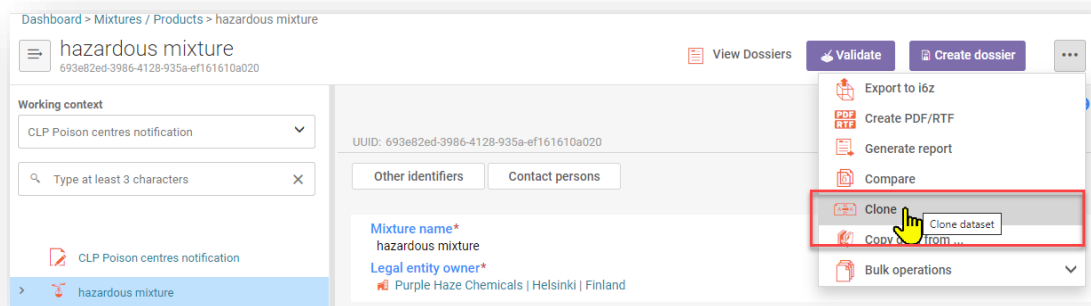
The 'Clone' functionality is available to facilitate e.g. the preparation of update dossiers by replicating a mixture-dataset in order to edit and create a new dossier from that. In this way, you do not need to re-enter all the information related to the mixture, such as composition, toxicological information 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.

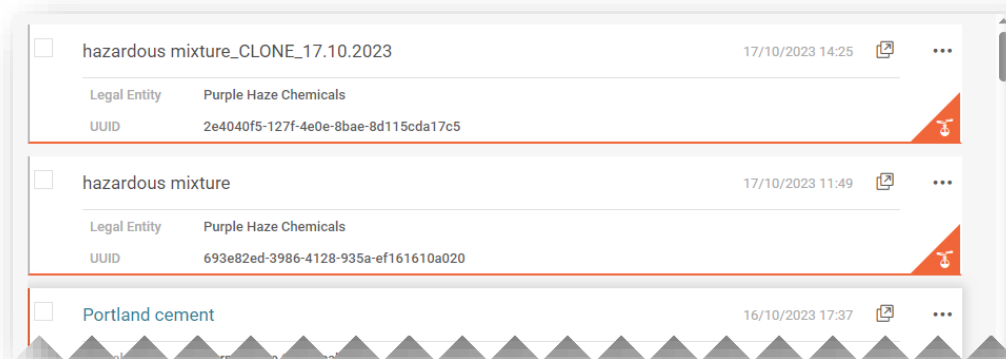
This functionality is available in the list of datasets by clicking on the three dots '...' of the dataset you wish to replicate and select 'Clone'.



Alternatively, you can open the mixture-dataset itself and create a cloned copy by clicking on the three dots '...' 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 'original mixture name _CLONE_[date]' which you can edit accordingly before creating a new dossier.



5. Preparing a PCN - section by section

5.1. Mixture identity and legal submitter section

5.1.1. Mixture name

This is the name of the mixture entered when the new Mixture/product-dataset was created. It can be the trade name of your product, though it does not necessarily need to be. This field is editable.

The screenshot shows the 'Working context' sidebar on the left with 'hazardous mixture' selected. The main panel displays the 'Mixture identity and legal submitter' section. The 'Mixture name' field contains 'hazardous mixture' and is highlighted with a blue dashed border. Below it, the 'Legal entity owner' is 'Purple Haze Chemicals | Helsinki | Finland'. There are also sections for 'Other identifiers' and 'Contact persons'.

5.1.2. Legal submitter

The legal submitter 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.

The screenshot shows the 'Working context' sidebar on the left with 'Purple Haze Chemicals' selected. The main panel displays the 'Legal submitter' section. The 'Legal entity name' is 'Purple Haze Chemicals' and the 'Legal entity type' is 'Purple Haze Chemicals'. The 'Legal entity UUID' is 'ECHA-f428c44e-79b3-4f7f-a72b-78e7ceda3be4', which is highlighted with a red box. There are also sections for 'General information', 'Identifiers', and 'Contact information'.



The Legal Entity UUID specified at the mixture level must be consistent with the Legal Entity in the ECHA Submission portal upon submission. Note that changing the Legal Entity Name does not change the UUID of the submitting legal entity. All changes associated with the legal entity need to be managed in ECHA Accounts.

5.1.2.1. How to change the legal submitter UUID

The Legal Entity Owner details can be changed to a different legal entity if needed from the Mixture Identity section. To remove a legal entity, first click on the hyperlinked name of the Legal Entity Owner to activate the process. Then click on the 'X' to remove the legal entity assigned.

The screenshot shows a sidebar on the left with a tree view containing 'CLP Poison centres notification', 'hazardous mixture', 'Mixture information and product identity', and 'Mixture identity and legal submitter'. The main area displays 'Mixture name*' as 'hazardous mixture' and 'Legal entity owner*' as 'Purple Haze Chemicals | Helsinki | Finland'. Below this are sections for 'Other identifiers' and 'Contact persons', each with a '+ New item' button. A yellow hand cursor points to the 'Legal entity owner' field.

The field will prompt you to 'Select' a new legal entity.

The screenshot shows the 'Legal entity owner' field with a '+ Select' button and 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 a 'Select Legal entity' dialog box with a search bar containing 'Type at least 3 characters' and '6 results found'. Below the search bar is a table with the following data:

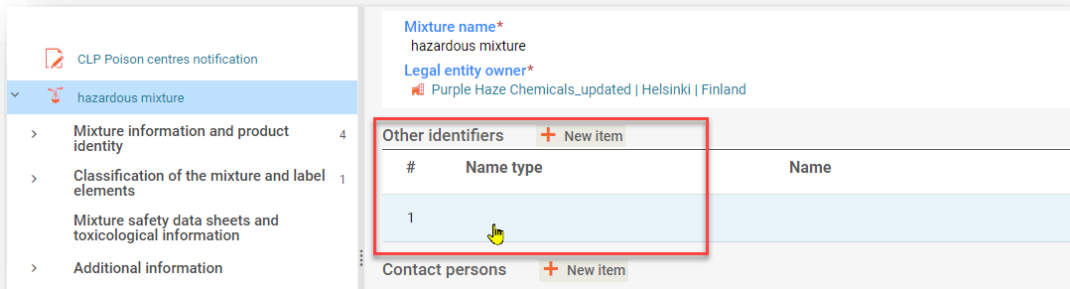
| Chem supplies | | | | 28/04/2021 16:57 | |
|-------------------|------------|----------------------|---------|------------------|--------------------------------------|
| Legal entity town | Small Town | Legal entity country | Ireland | UUID | 8b67b1fa-f2fe-459f-bafb-71c00e89a5e0 |



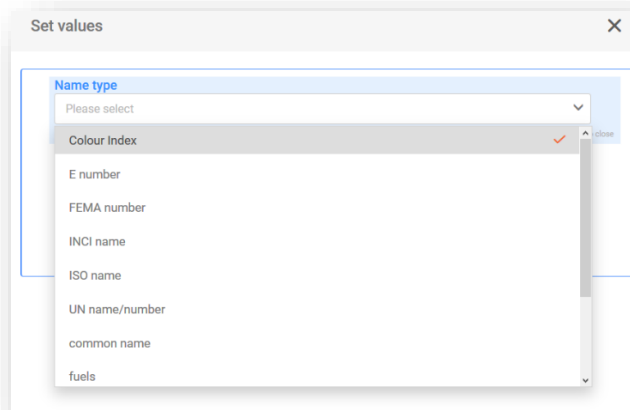
Do not edit the name or other details e.g. contact details, of the legal entity in the dataset. Doing so does not change the legal entity UUID of the legal submitter. If you need to update this information then you are required to do this in the ECHA Accounts.

5.1.3. Other identifiers

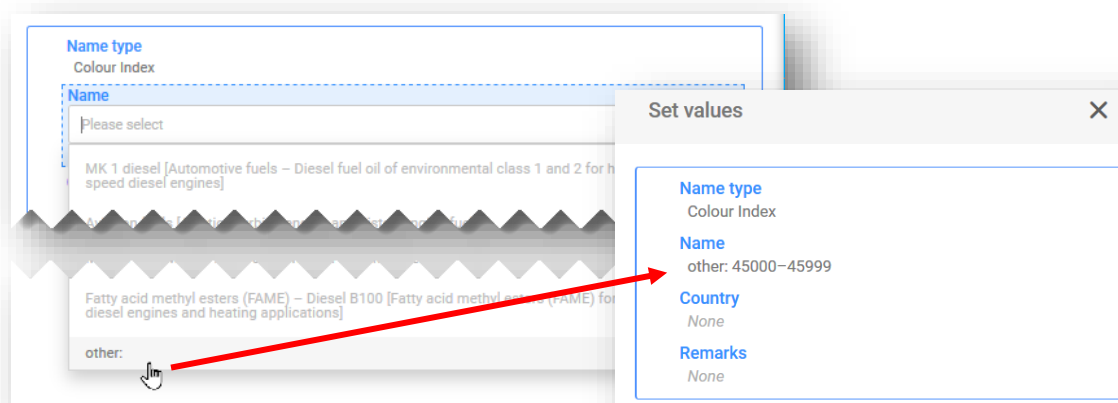
Can be used to add additional information about the mixture.



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'.



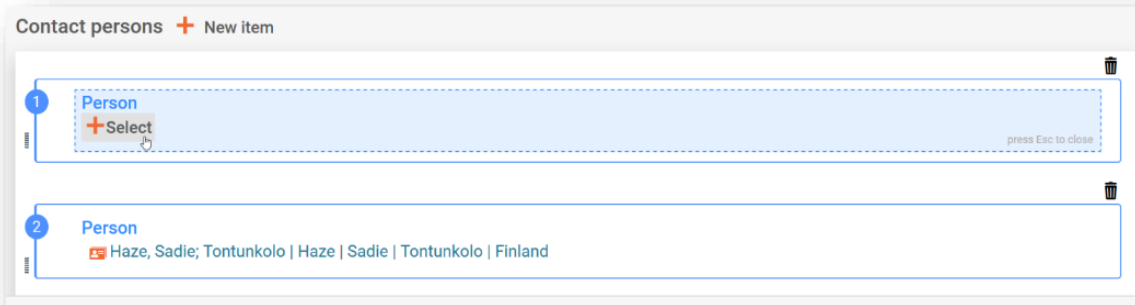
If 'Other' is selected from the Name field, further information can be provided in the free text field.



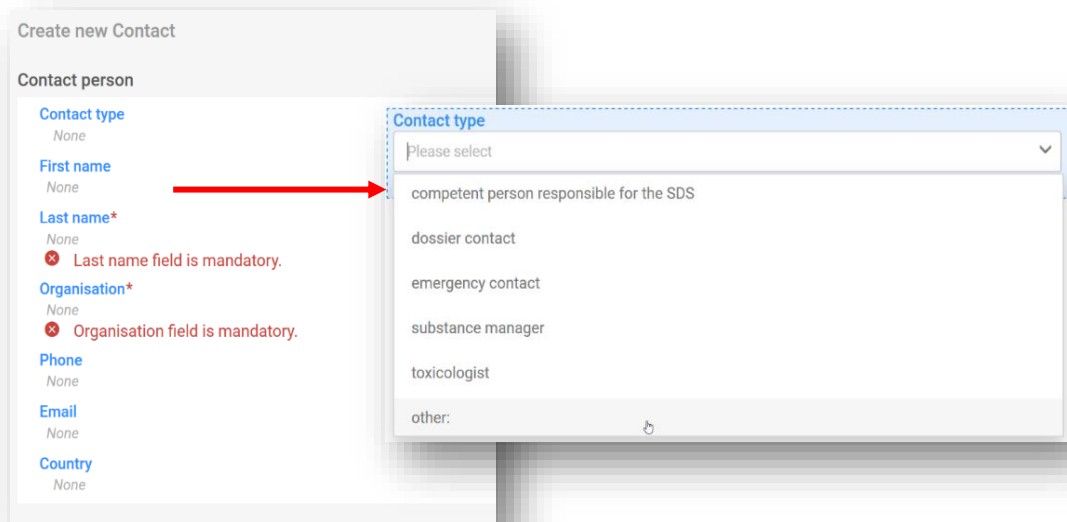
5.1.4. Contact person

A 'Contact person(s)' is used to record the persons role and contact, for example, a contact for rapid access for a limited submission (please select 'Emergency contact' in this case), 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.



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.

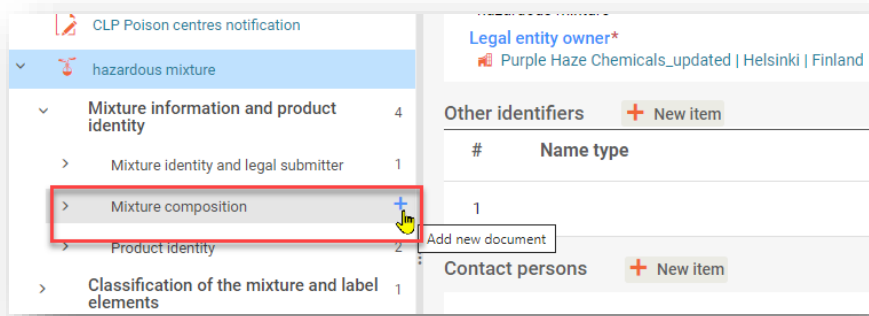


In case of **limited submissions**, the contact type '**Emergency contact**' has to be selected for identifying rapid access for limited submissions.

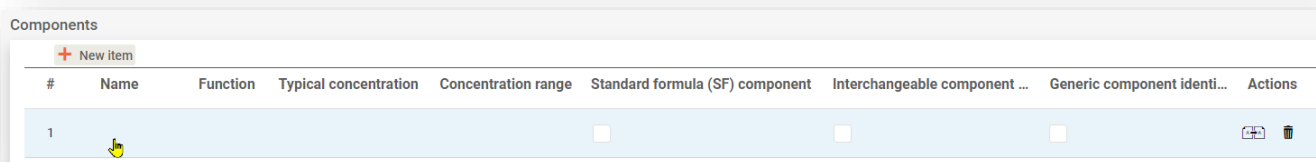
Further, if the mixture is placed on the market in a **single market area**, then you must provide only one emergency contact record containing this information. If the submission is for **multiple market areas**, then you need to provide multiple Contact person(s) records. Each record will contain the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

5.2. Mixture composition document

The 'Mixture composition document' contains the details of all the components of the mixture as placed on the market. To enter compositional information, a 'New document' must be created first.



After you create the Mixture composition document, a Components section is created where the individual substances and mixture components of the final mixture are added, by selecting '+ New item'. An item is created and can be opened and completed by clicking on the blue-shaded area.



A Set values box opens and specific values for each component must be entered: Name, Function, Typical concentration/Concentration range:

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

'Function': The function is only mandatory to indicate if you are indicating a GCI (generic component identifier) component (i.e. perfumes or colourants) and if you are preparing a Group Submission (only certain perfume components can vary across the compositions). In any other case, the information can be voluntarily provided.

'Typical concentration/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). Units must be reported in the same way for all components. Operators (>, <, ≤, ≥) must be included for reporting ranges.

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



Only where components fit specific conditions outlined in Annex VIII to the CLP Regulation should these component types be flagged: **Standard formula (SF) component, Interchangeable component group (ICG), Generic component identifier (GCI)**

5.3. Adding a substance component

Each 'Substance component' of the final mixture is identified by information contained in a 'Substance dataset'. Substance datasets are also required for all the substances contained in reported 'mixture-in-mixtures' (MiM).

From the (main) Mixture composition document, you need to first create a '+ New item'. The generated field for the component is numbered. A drag and drop feature allows you to re-order the components from highest to lowest concentration. Clicking on the field (shaded blue) opens the Set values box where you select 'Substance' in the Name field. Add as many items as is required.

Mixture composition.001
 UUID: 9a9c97d1-89d9-4fd9-a0a6-663ce009d216

Components

Components

+ New item

| # | Name | Function |
|---|-------------|----------|
| 1 | | |
| 2 | Substance X | |
| 3 | substance Y | |

Set values

Name

+ Select

Mixture / Product

Substance

Concentration range

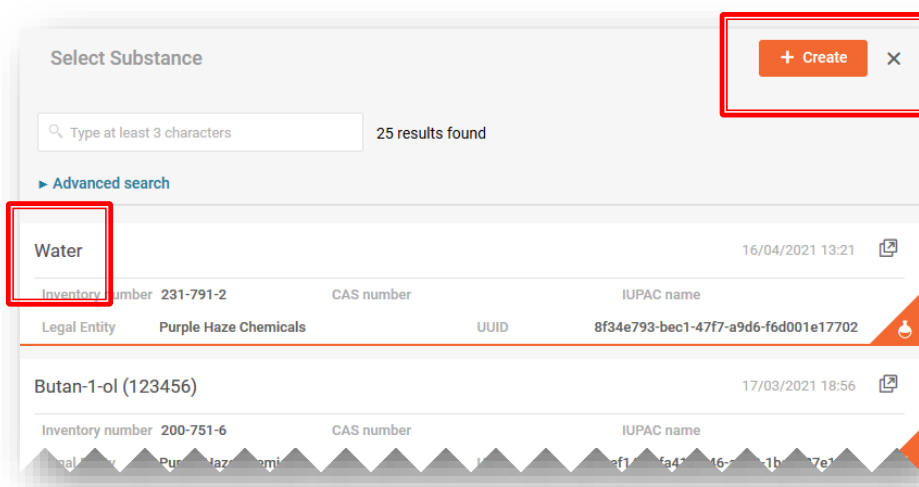
None

Standard formula (SF) component

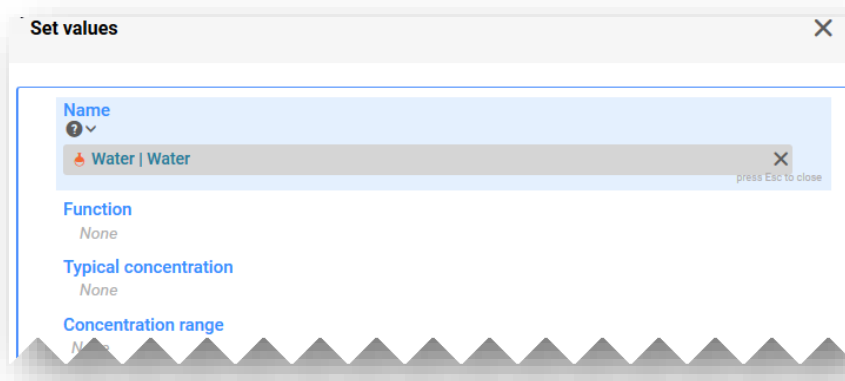
Interchangeable component group (ICG)

Generic component identifier (GCI)

The substance can be included in one of two ways, either by selecting a previously prepared Substance dataset from the list, or, by Creating a new Substance dataset. Both are explained below.



- 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, such as the reference substance and any classification and labelling.



- 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 available list (if available) or if not available, you can either download and import them directly into your working environment or create your own Reference substance document.

'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 all be included in this field. It is recommended to include additional names in the Reference substance document in the field 'Synonyms' – see below.

Create new Substance

Reference substance
None

Legal Entity*
Undefined Company Name | Helsinki | Finland

Substance name*
None
Substance name field is mandatory.

Other substance identifiers + New item

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

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 to download and import them as a ready-made set from the IUCLID website (<https://iuclid6.echa.europa.eu/get-reference-substances>).

! Note that the set of Reference substances was created in 2007 and is available for download is but it is not maintained, therefore errors and inconsistencies can exist. It is the responsibility of the notifier to verify the information used in the notification.

From the 'Search and download Reference substance' page of the IUCLID website, begin by searching for the substance using an EC or other product identifier. From the results list, you can download and save the file locally (.i6z format) to a more meaningful name.

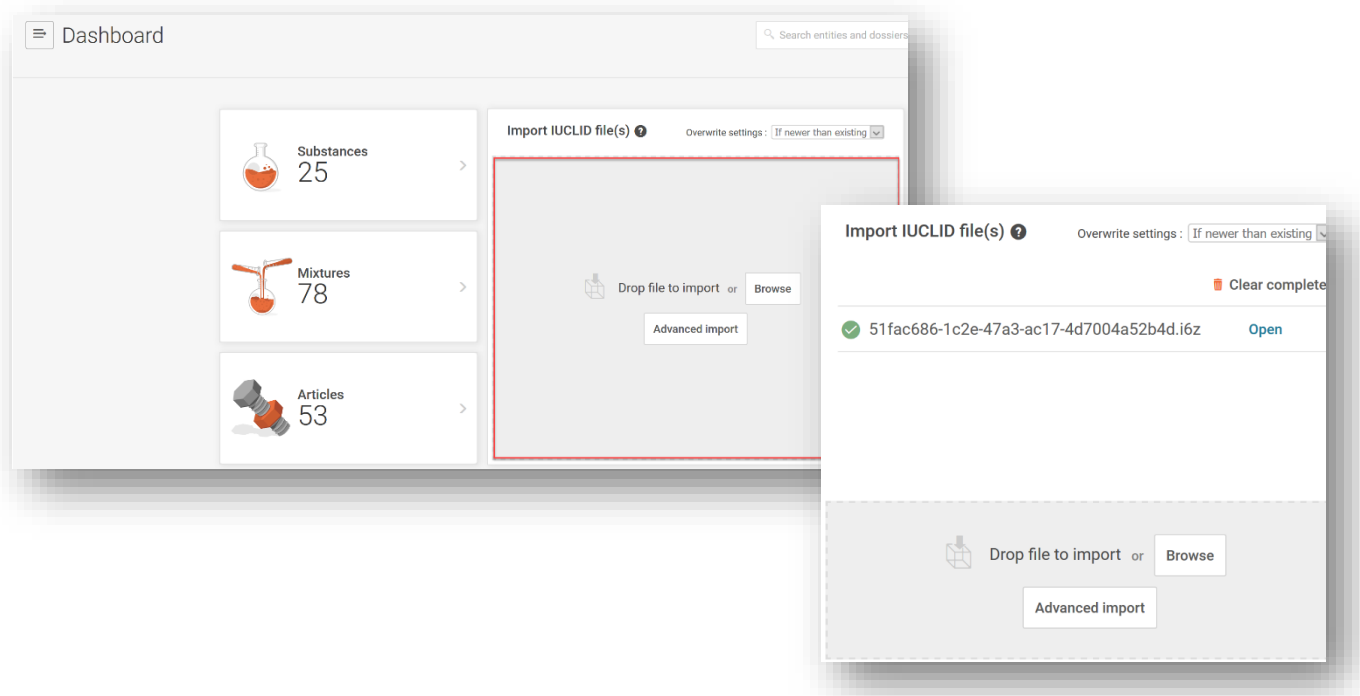
Search for and download Reference substances

EC Num: 200-659-6
CAS Num:
EC Name:
IUPAC Name:
Molecular Formula:

Search Reset

| EC Num | CAS Num | EC Name | IUPAC Name | Molecular Formula | Link to i6z file |
|-----------|---------|----------|------------|-------------------|------------------|
| 200-659-6 | 67-56-1 | methanol | methanol | CH4O | Download |

To import the Reference substance into your working instance of IUCLID, select 'Browse', and locate the file that you have previously saved e.g. on your desktop. Once the Reference substance file has been successfully imported, it will be available in the Reference substance list.



5.3.2. Creating and linking a Reference substance

Linking a Substance dataset to a Reference substance can be done either a) making a selection from the list of Reference substances or b) create a new Reference substance. To create a new one, a minimum of information must be provided:

- i) A Reference substance name
- ii) 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.

! On polymers

Polymers are considered to be substances therefore Article 45 notification obligations do not apply to the polymer itself, however, if the polymer is placed on the market as part of a mixture, it needs to be identified in the same way as any other component. To identify the polymer 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. If an identifier is ambiguous additional information is to be provided to support its identification. Note, you do not need to specify the monomers in the notification.

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



The 'Inventory number' picklist does not contain an exhaustive list of substances. If the substance is not found in the EC inventory, you can manually enter the EC number details, but note that there are specific rules checking it's format.

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

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

| # | Identifier | Identitiv | Remarks | Action |
|---|------------|-----------|---------|--------|
| | | | | |

Molecular and structural information

Molecular formula

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 | Identitiv | Remarks | Action |
|---|----------------|-----------|---------|--------|
| 1 | other: Finnish | Vettä | None | |
| 2 | other: Swedish | Vatten | None | |



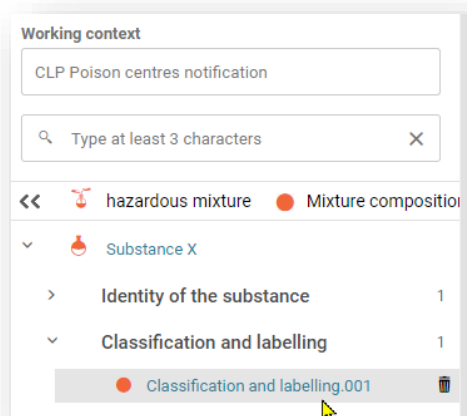
On micro-organisms

Micro-organisms in general are living organisms and according to the biocides guidance on micro-organisms, CLP provisions are not applicable to micro-organisms. However, Annex VIII to CLP requires the identification of all components as a name and product identifier. If you need to identify a micro-organism in the notification, please provide any known information that can help their identification e.g. strain or species,

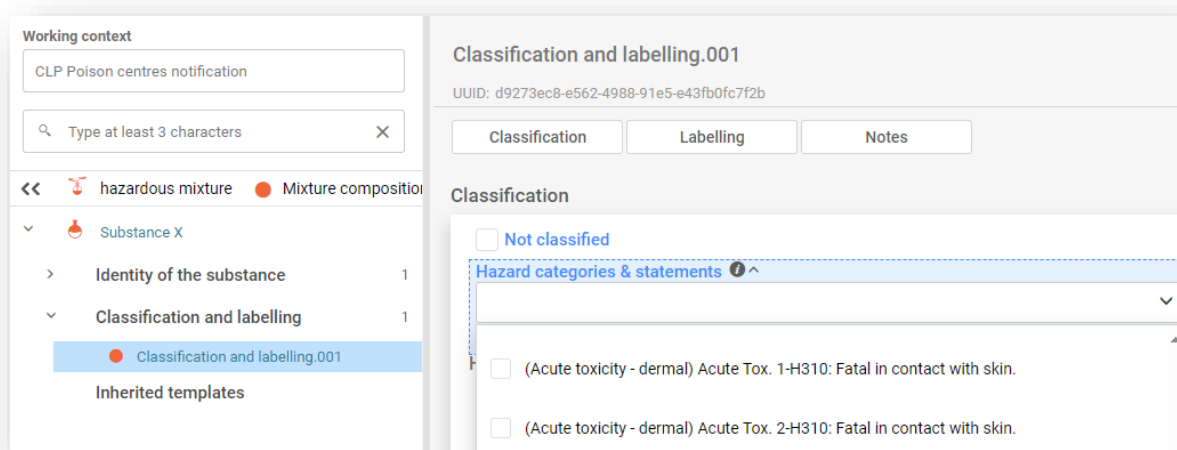
Quite often biocidal products containing micro-organisms are classified as H317 or trigger the warning phrase "*Micro-organisms may have the potential to provoke sensitising reactions*". If the mixture is classified as **H317** based on test data, bridging principles or due to sensitising ingredient substances of the mixture, and thus is a classified mixture under the scope of CLP Annex VIII, then a poison centre notification is required. If the classification is derived on the basis that the mixture contains a living micro-organism, and is based on Directive 2000/54/EC (on the protection of workers from risks related to exposure to biological agents at work), then a notification is not required.

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.

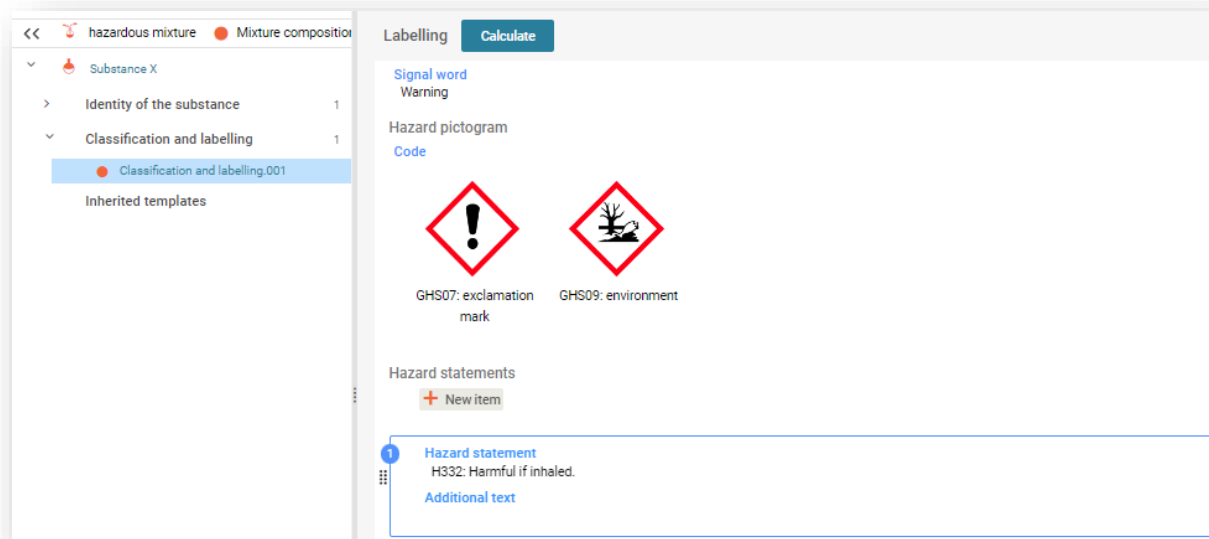


The new document must have the **classification of the substance** indicated by making a selection from the 'Hazard categories and statements' picklist. Specific concentration limits and M-factors, if applicable, can also be indicated in the specific fields. If it is not classified for any physical,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



The '**Labelling**' information related to substance components is not necessary but may be included on a voluntary basis. Note that the 'Calculate' functionality uses the classification information entered in the previous step to derive labelling information.

! 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.



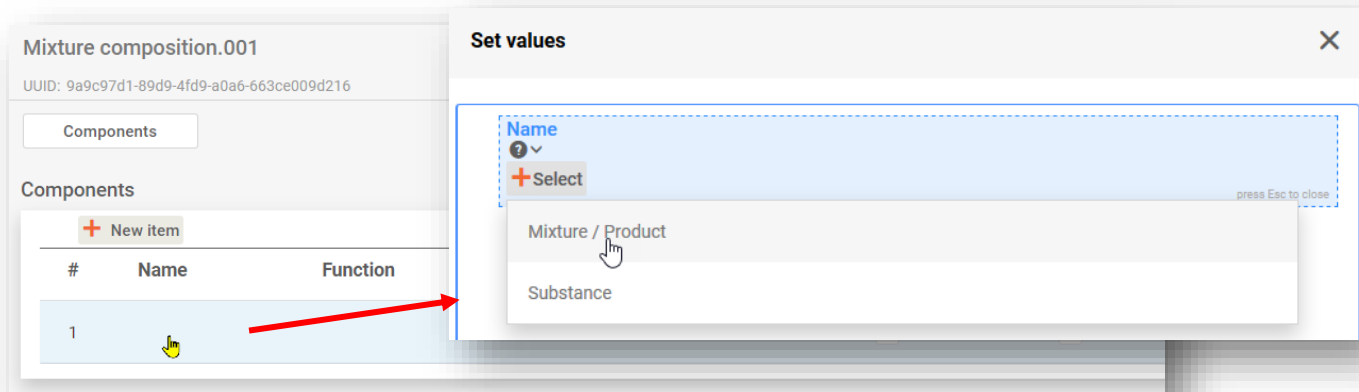
5.4. Adding a mixture-in-mixture (MiM) component

5.4.1. Identify the MiM and specify concentration

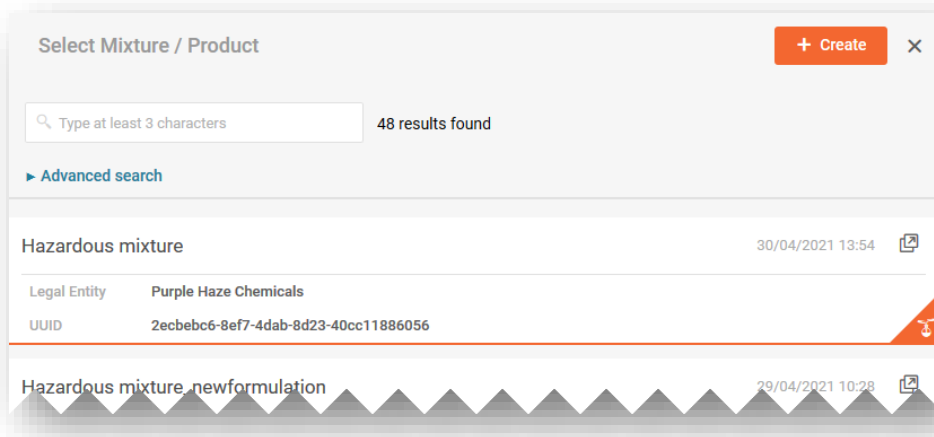
Creating a Mixture dataset is required for each MiM component that is included in the final mixture that will be placed on the market. If reporting the known substances of the MiM, individual substance datasets are required, each to be identified with their respective identifier and linked to a Reference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

! If all the substances in the mixture-in-mixture component 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, check if you have two of the same substances reported – these will have to be merged and reported only once.

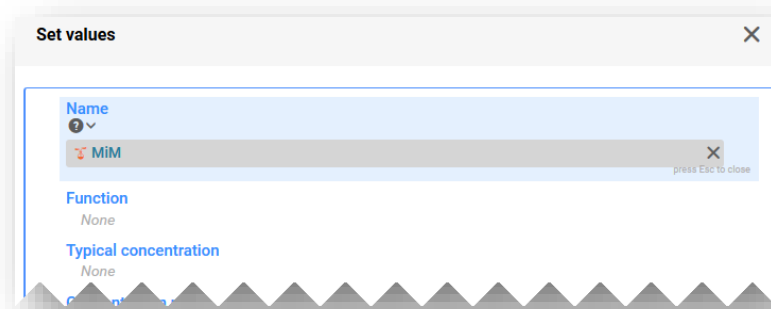
From the (main) mixture composition document, you need to first create a '+ New item'. Clicking on the field (shaded blue) opens the Set values box where you select 'Mixture' in the Name field.



The MiM can be added in one of two ways, either by selecting a previously prepared Mixture dataset from the list if available, or, Creating a new Mixture dataset and enter the relevant information



Selecting a Mixture dataset from the list automatically populates the Set values box with the name of the MiM component linked to its associated information.



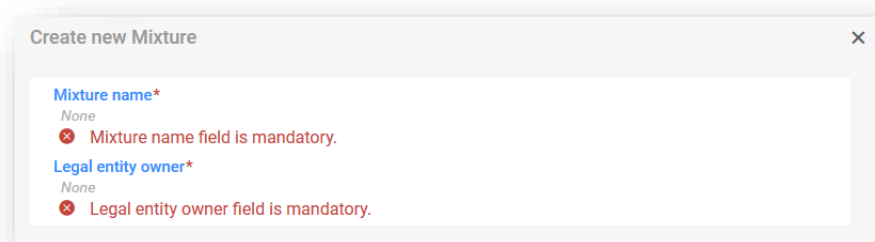
When **creating a Mixture dataset**, you need to enter information manually for the mixture component, including:

'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. These can be included in the section 'Other identifiers'

'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.

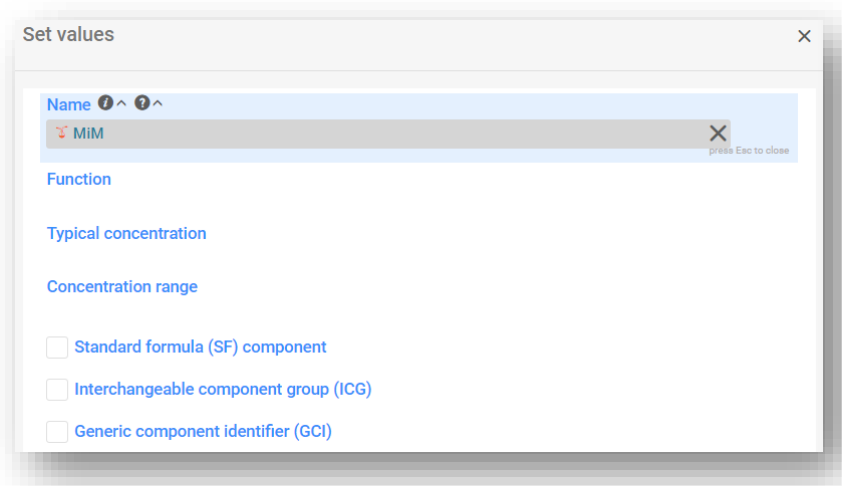


Once the mixture name has been provided and saved, the Set values box needs to be completed for the following fields:

'Function': The function is only mandatory to include if you are indicating a GCI (generic component identifier) component or if you are preparing a Group Submission. In the first case, a selection must be made between perfumes or colourants. In the second case, for the components which perfumes should be selected. In any other case, the information can be voluntarily provided.

'Typical concentration/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). Note that units should be reported in the same way for all components. 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.

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

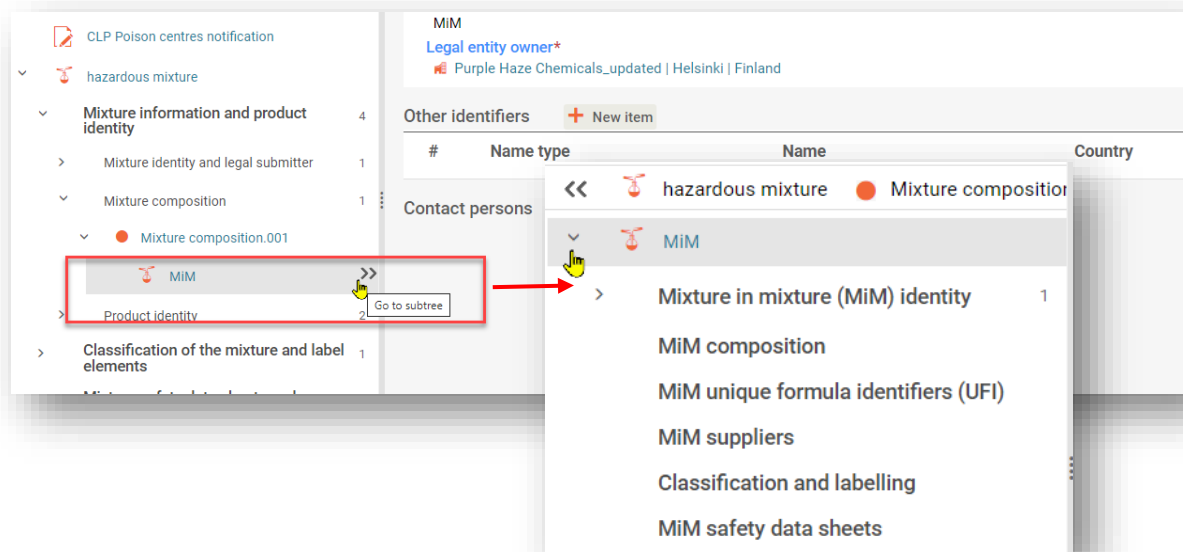


Only where components fit specific conditions outlined in Annex VIII to the CLP Regulation should these component types be indicated: **Standard formula (SF) component, Interchangeable component group (ICG), Generic component identifier (GCI)**

5.4.2. Completing information about the MiM

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

When a MiM component is added to the main mixture composition document and the 'Save' button is clicked, an additional sub-set of information fields are generated in the navigation tree. The following sections become visible when using the arrows to expand the document: MiM identity, MiM composition, MiM UFI, MiM supplier, (MiM) classification and labelling, and MiM safety data sheets. New documents will first need to be created for the relevant sections before information can be entered.



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 (<https://echa.europa.eu/guidance-documents/guidance-on-clp>) to determine which information is mandatory to be provided for your mixture-in-mixture as outlined in Annex VIII to CLP Part B; 3.2.2.

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 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': Note that the name of the MiM (and legal entity) was provided during the creation process in the previous step. You can add information in the Other Identifiers section 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 – refer to the 'MiM supplier' section described below.

Working context: CLP Poison centres notification

UUID: 34131dbe-0243-4e50-a874-34c2dc8adddd

Other identifiers | Contact persons

Mixture name*
MIM

Legal entity owner*
Purple Haze Chemicals_updated | Helsinki | Finland

Other identifiers + New item

| # | Name type | Name | Country |
|----------------------------|-----------|------|---------|
| Contact persons + New item | | | |

'MiM composition': Substance (only) components of the MiM are entered here. Clicking on the area of the created item (shaded blue) in the Components section opens a specific Set values box for: **'Name'** of the substance, **'Function'** is not mandatory to provide but can be provided voluntarily, and **'Typical concentration'** or a **'Concentration range'** has to be provided.

Components

+ New item

| # | Name | Function | Typical concentration |
|---|-------------|----------|-----------------------|
| 1 | | | |
| 2 | Substance X | | 45 % (w/w) |

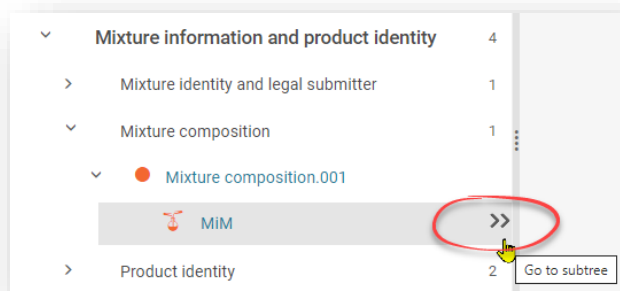
Note that the substance identity and classification information must be provided for each substance of the MiM through, see the steps involved below.



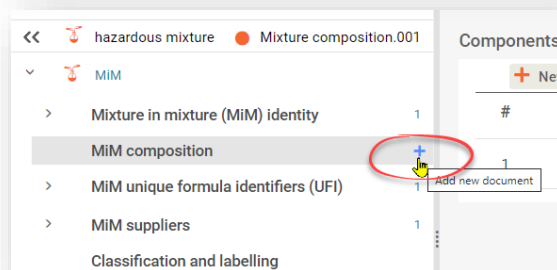
Entering substance identity and classification information for substances of the MiM component

The principles are the same as for identifying substances in the Main mixture composition (Section 5.3)

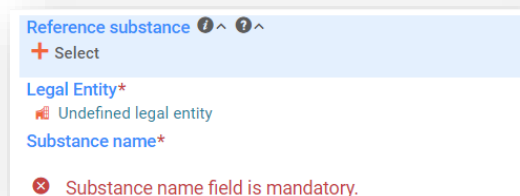
1. Go to the sub-tree menu of the MiM component



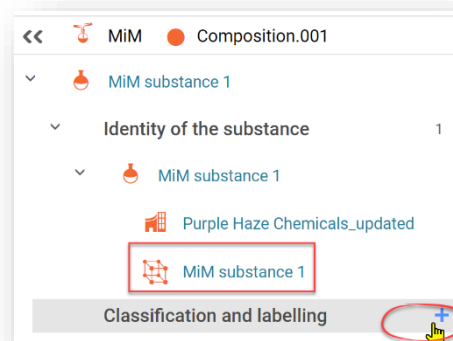
2. Add a new MiM composition document, followed by adding the substances of the MiM (if known) as a new substance item into components table, then link the substance to a reference substance



3. From the Set values box, selecting 'Name' initiates the process of identifying the substance as earlier described. Substances have to be linked to a Reference substance.



4. Create a new Classification and labelling document for the MiM substance and enter its classification details (labelling is not required)



'MiM UFI': The UFI of the MiM as provided by the supplier can be included in this field if available. The 'Regulatory programme' needs to contain 'CLP unique formula identifier)' and the UFI entered in the ID field.

'MiM supplier': The supplier details can be included by making a selection from the list of Legal entities. If the details are not listed, a '+New document' can be created and the relevant details for the MiM supplier provided (at least, the name, email address and telephone number of the MiM supplier). Note that the legal entity UUID of the MiM supplier is not required.


⚠ 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. If you do not provide EU supplier details, a quality rule (QLT847) will be triggered.


'Classification (and labelling)' (of the MiM): Similarly to the main mixture, the classification of the MiM must be indicated by making a selection from the 'Hazard categories and statements' picklist. The **labelling** elements of the MiM are not required but can be included voluntarily. The Calculate functionality can be used to assist this process 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. Preparing a notification for 100% MiM

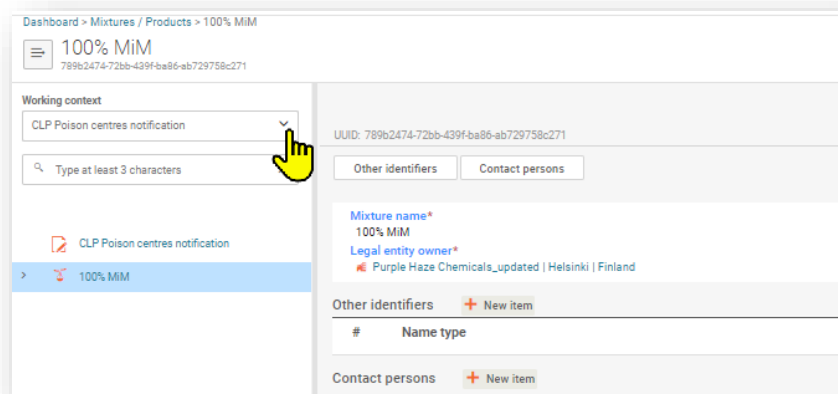
In specific situations, when the submitter is not in possession of sufficient compositional information as required by Annex VIII (and it is not able to obtain it from the supplier), it can be acceptable to make a notification where one mixture-in-mixture constitutes 100% of the final mixture composition.

 Please note, that completing the MiM section will depend on what information you have available.

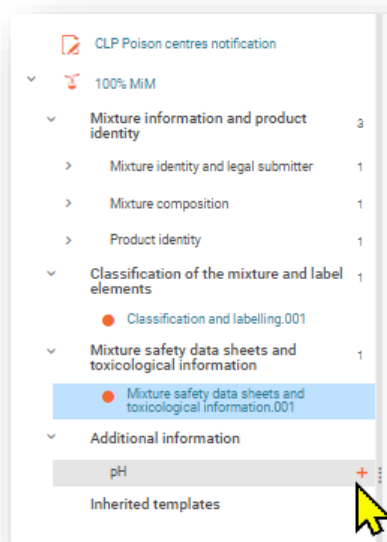
 If you are duty holder making a notification for a hazardous mixture through the 100% MiM route, you are remain responsible for the data in the notification if it is not representative of the product itself.

A 100% MiM notification still requires a full notification, meaning that you:

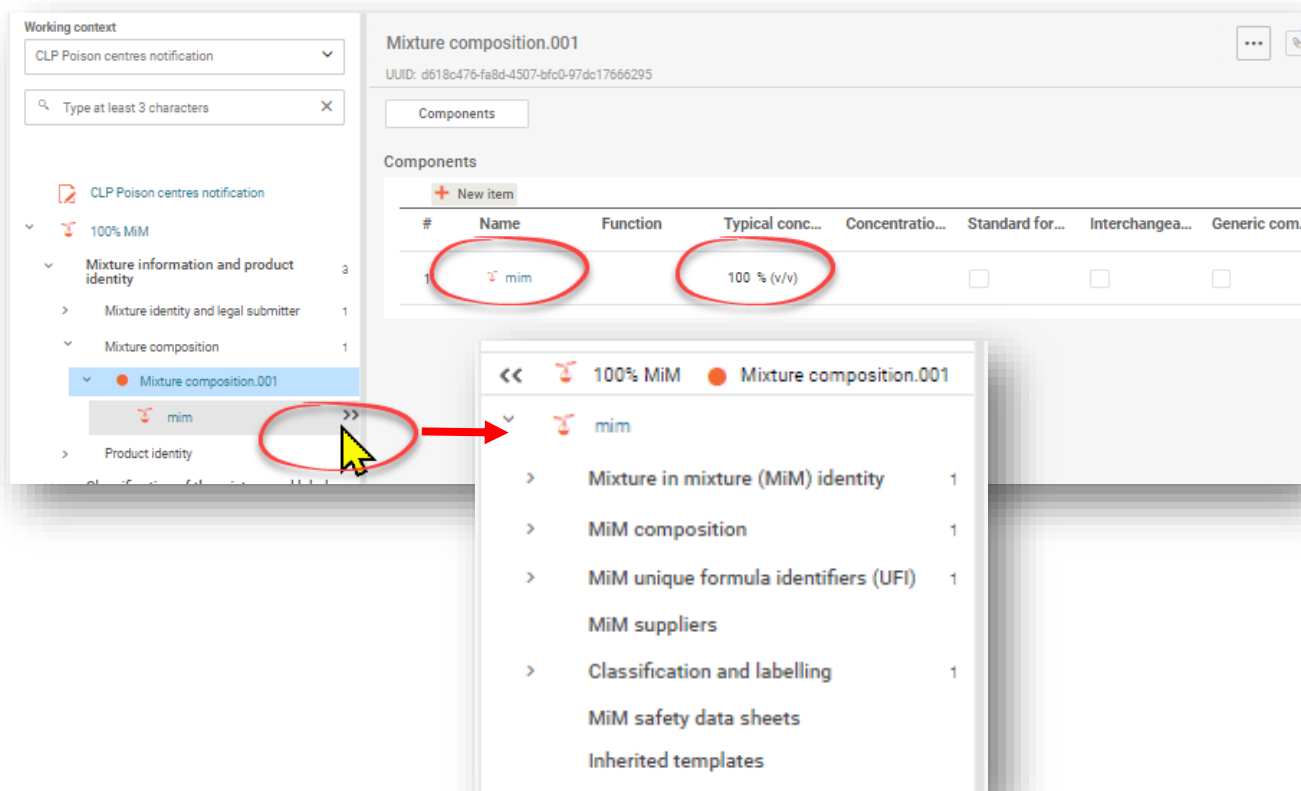
1. Create a new Mixture dataset and specify the working context as **CLP poison centre notification**



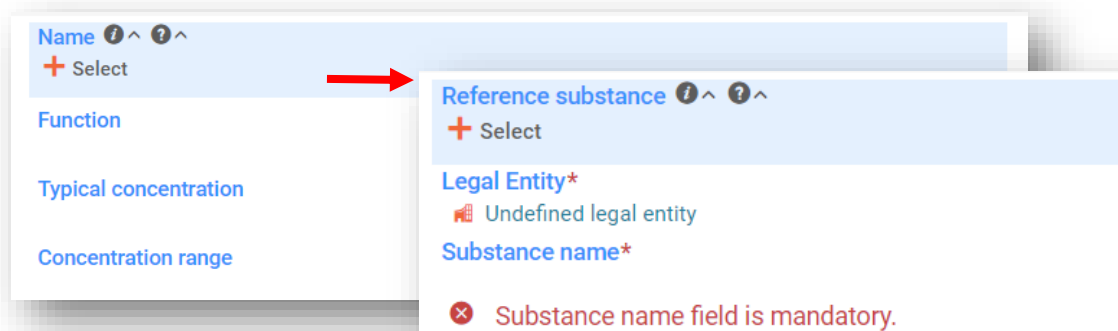
2. Enter all the required information in the notification for the final mixture
 - a. Dossier header section (e.g. markets, languages, notification type)
 - b. Product information section (e.g. packaging, use type, main intended use, trade names, colour, physical state)
 - c. UFI and other identifiers section (generate and add your own UFI)
 - d. Mixture information (e.g. classification & labelling, toxicological information, pH)



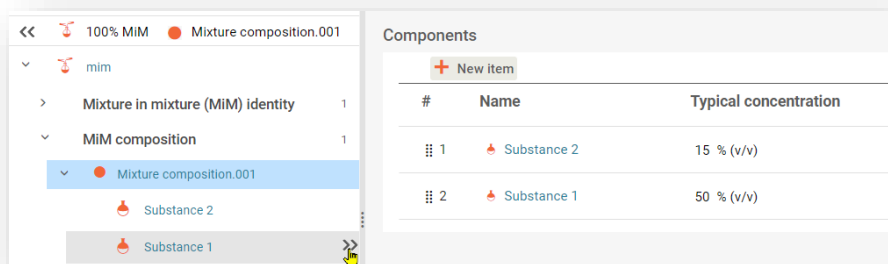
3. Create a mixture composition document and enter all the required information for the mixture-in-mixture
 - a. Add a mixture component from the +New item
 - b. Provide the name of the mixture and specify a legal entity (this could be an undefined legal entity or even your own)
 - c. A Set values box 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 sub-tree – you will see a number of additional sections to complete.



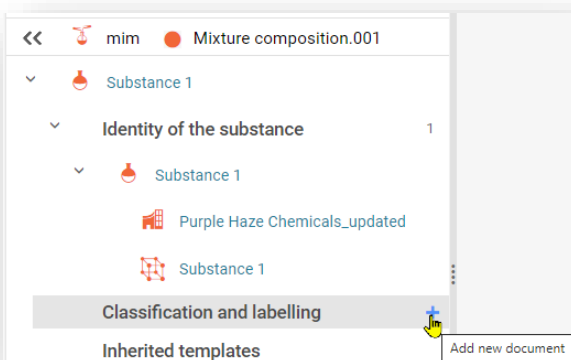
4. The MiM components sections include:
 - a. MiM identity (automatically filled in from step 3.b)
 - b. MiM composition (this is where you would add the individual substance components of the MiM if available e.g. from the SDS). Note that each substance requires a reference substance name, a substance name, and a concentration.



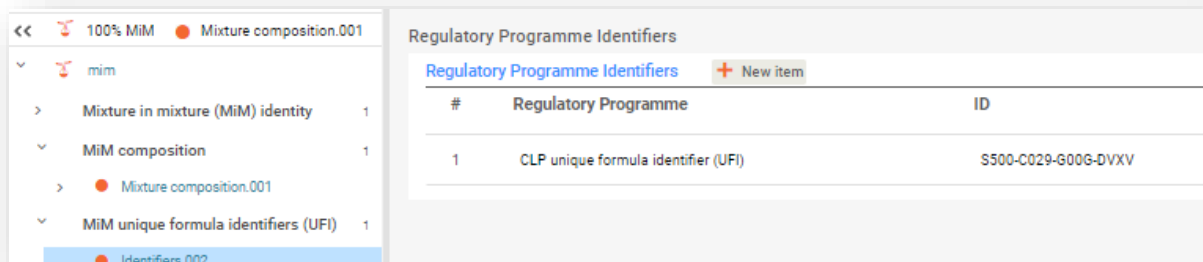
- c. Once all the components of the MiM have been added to the MiM composition, and a reference substance linked, you need to go to the sub-tree of the individual substances to provide additional information on it's classification



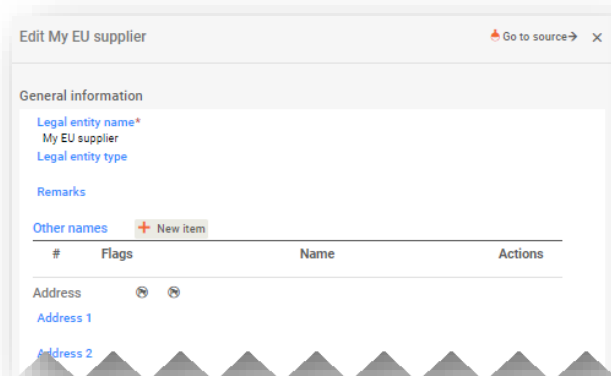
- d. In the sub-tree of each substance, you can check it is linked to a reference substance, and create a Classification and Labelling document.



- 5. Back in the MiM UFI section is where you add the UFI of the supplied mixture



- 6. MiM supplier – here you add the EU supplier details (unless you are the importer of the MiM)



7. Classification & labelling – add the classification of the MiM

Working context: CLP Poison centres notification

Classification and labelling.001
 UUID: 7f855198-63ef-4de6-a441-36e2f2448ae7

Classification

Not classified

Hazard categories & statements

Skin Sens. 1-H317: May cause an allergic skin reaction.

Health hazards

Reproductive toxicity

Specific effect

8. MiM safety datasheets – here it is possible to attach safety datasheets

Working context: CLP Poison centres notification

Safety data sheet for the mixture.001
 UUID: 009dcadd-6be8-4781-9b93-7f89217cb2f0

Information on mixtures

Information on mixtures

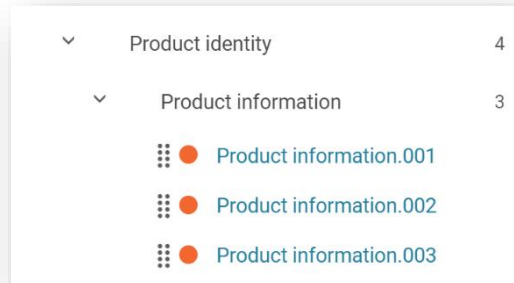
Safety data sheets of mixture / product

+ New item

| # | Safety data sheet | Country | Language |
|---|--|---------|----------|
| 1 | ✘ Safety data sheet field is mandatory. | | |

5.5. Product identity/information document

The 'Product information document' (Product identity section) contains the information required for the identification of the product or products containing the mixture as placed on the market. To create a Product information 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 separate product information documents if e.g. a duty holder is including additional information for a distributor customer.

The Product information document contains the sections 'Group submission' (relevant only for that specific submission type and covered in section chapter 8), '**Product identifiers**' and '**Additional information**' (covered below).

5.5.1. Product identifiers

Product identifiers include trade and other names and the unique formula identifier (UFI). Individual items are added by clicking on '+New item'.

Product identifiers

[Trade names](#) + New item

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

[Other names](#) + New item

| # | 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 information documents.



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.

| # | 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.

'Unique formula identifiers (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' that need to be included here where relevant:

- i. **UFI** – a 16-character alphanumeric code with a defined format, is included in this section. The UFI generator tool (and relevant support) is available from ECHAs 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).

Regulatory Programme Identifiers

Regulatory Programme Identifiers + New item

| # | Regulatory Programme | ID | Action |
|---|----------------------|----|--------|
| 1 | None | | |

Regulatory Programme

Please select

CLP multi-component product identifier

CLP related PCN number

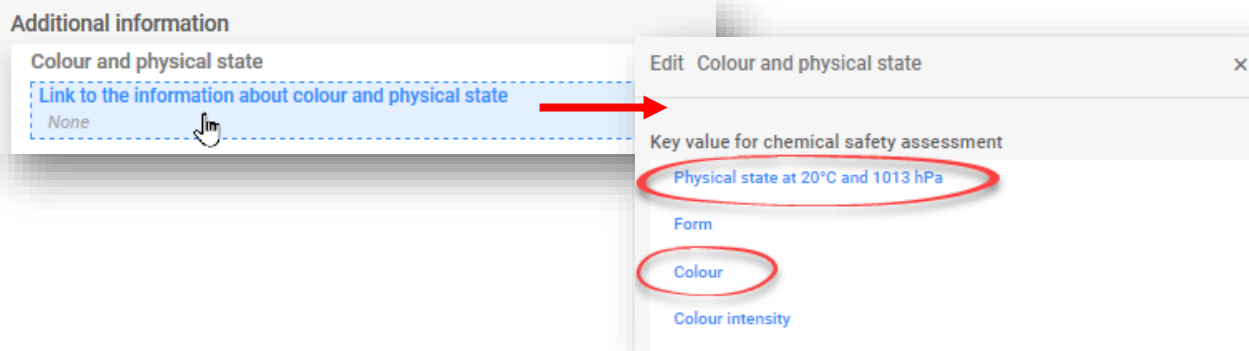
CLP unique formula identifier (UFI)

5.5.2. Additional information

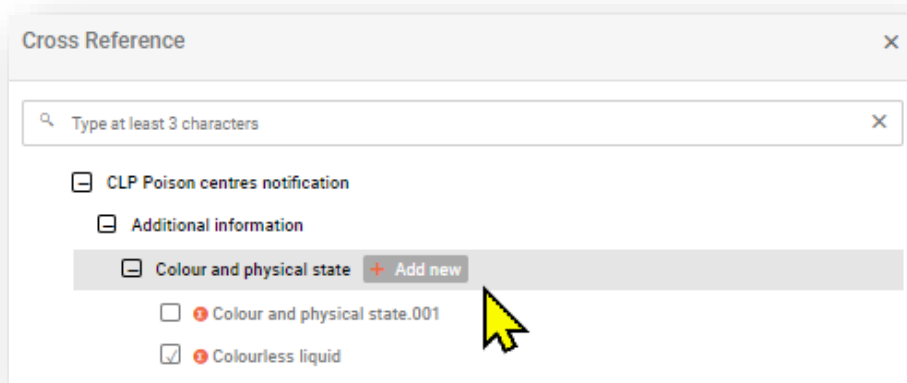
'Additional information' on the product includes the following fields:

5.5.2.1. 'Colour and physical state'

A link to this information is required by either i) selecting from any existing information records, or 2) creating a new document and entering information

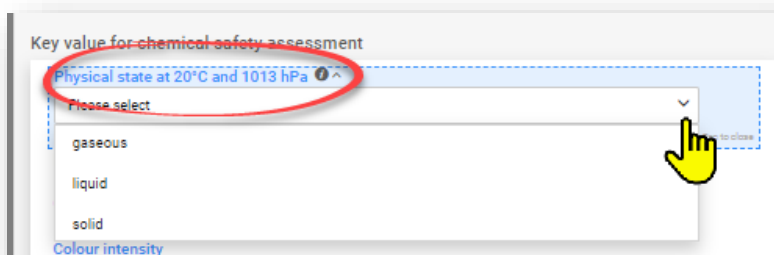


The example below shows that it is possible to make a selection for colour and physical state can be made from two existing information records or, add a new one. This will vary from notification to notification depending on what has been entered earlier.



In any case, information must be provided for:

- i) the physical state at 20°C 101 hPa of the product (i.e. gas/liquid/solid).



- ii) and the colour. Note that 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 (GCI)).

The screenshot shows a form titled "Key value for chemical safety assessment". Under the heading "Physical state at 20°C and 1013 hPa", the value "liquid" is selected. Below this, the "Form" dropdown is open, showing a list of options: "colourless" (checked), "black", "blue", "brown", and "gold". A yellow hand cursor is pointing at the "blue" option. The "Colour" label is circled in red.

Optional information for the form and intensity can be included from the available picklist

The first screenshot shows the "Form" dropdown menu open, displaying options: "Please select", "gas under pressure: dissolved gas", "gas under pressure: liquefied gas", "gas under pressure: refrigerated liquefied gas", "cream / paste", "foam", "gel", and "liquid". A yellow hand cursor is pointing at the "liquid" option. The "Form" label is circled in red.

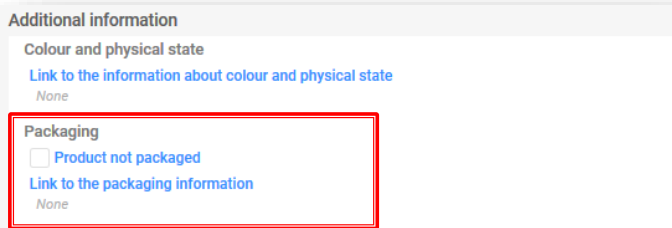
The second screenshot shows the "Colour intensity" dropdown menu open, displaying options: "Please select", "transparent", "light", "dark", and "fluorescent". A yellow hand cursor is pointing at the "light" option. The "Colour intensity" label is circled in red.



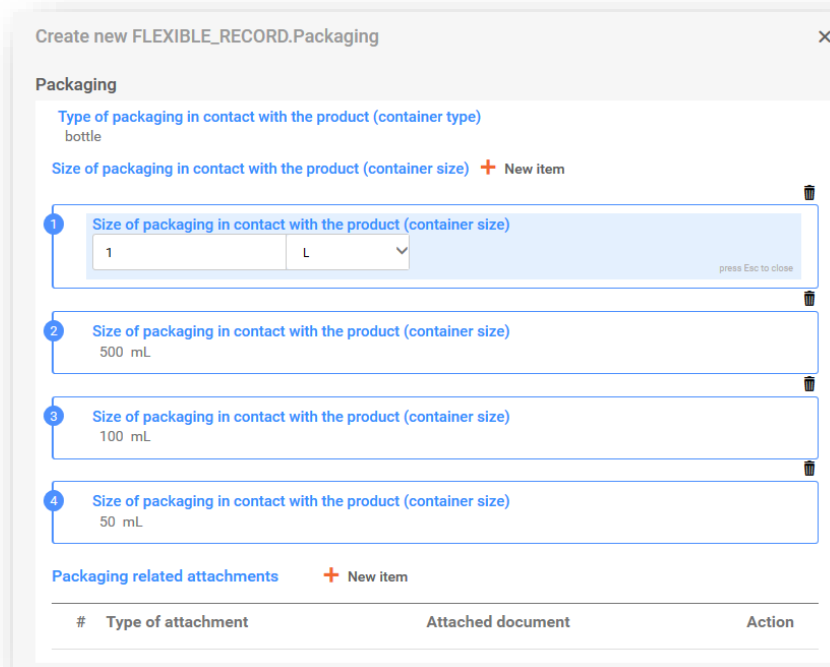
Note that making a selection for a physical state enables/disables certain 'Forms'.

5.5.2.2. '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 in the check box.



Multiple packaging sizes can be indicated in one packaging item.



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



! Note that mixtures for use at industrial sites 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 | |

5.5.2.3. '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 information document 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

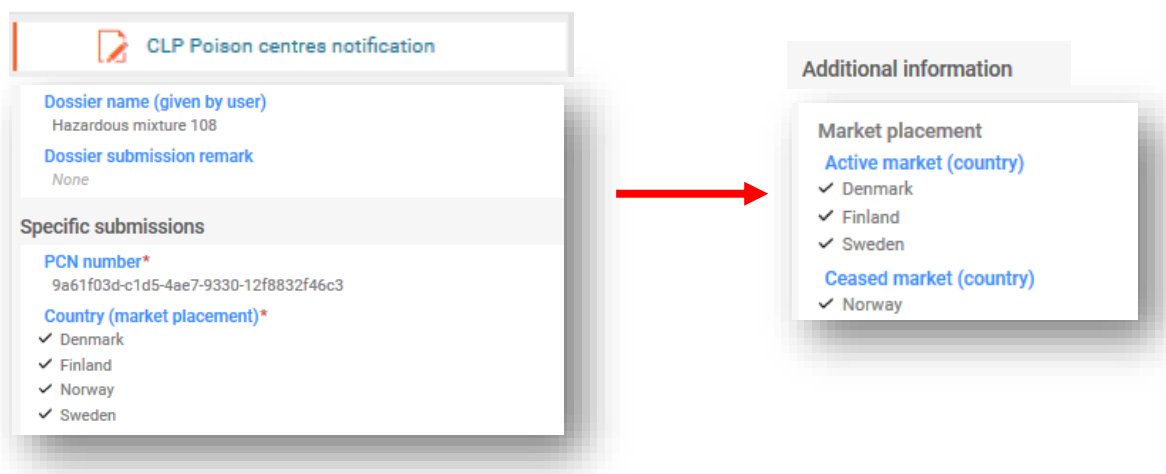
- PC-CLN-3 Bleaching products for cleaning or laundry use (excludes biocidal products) (P Products > PC Chemical products (excludes biocidal products) > PC-CLN Cleaning, care and maintenance products (excludes biocidal products) > PC-CLN-3 Bleaching products for cleaning or laundry use (excludes biocidal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

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

 The **EuPCS practical guide** should be consulted in case of doubt as it contains full descriptions of each category with examples. You can find it and other supporting material available from our website in all EU languages:
<https://poisoncentres.echa.europa.eu/eu-product-categorisation-system>

5.5.2.4. 'Country (Market placement)'

The complete lists of market areas included in the Product information-document(s) must match the full list indicated in the dossier header. In case of multiple product information documents, 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 (country)'**: 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 information document. 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 (country)'**: 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 information document.



Ceasing a product from the market is a functionality in the IT tools and included in the PCN format. The information about a product ceased from the market can be included in an updated dossier and **not to be confused** with the solution for disabling a submitted dossier!

5.6. Classification and labelling of the (final) mixture

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



Only a single classification and labelling (C&L) document can exist for a mixture for a standard submission. Entering multiple C&L documents for this submission type will result in a validation rule failure.

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 statements 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' window with a 'Calculate' button. Below it is a 'Signal word' dropdown menu. The menu is open, showing the following options: 'Please select', 'Danger', 'Warning', and 'No signal word'. A mouse cursor is hovering over 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' selection interface. It displays nine hazard pictograms in a row, each with a checkbox below it. The checkboxes are: GHS01: exploding bomb (unchecked), GHS02: flame (checked), GHS03: flame over circle (checked), GHS04: gas cylinder (checked), GHS05: corrosion (checked), GHS06: skull and crossbones (checked), GHS07: exclamation mark (checked), GHS08: health hazard (checked), and GHS09: environment (checked).

'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).



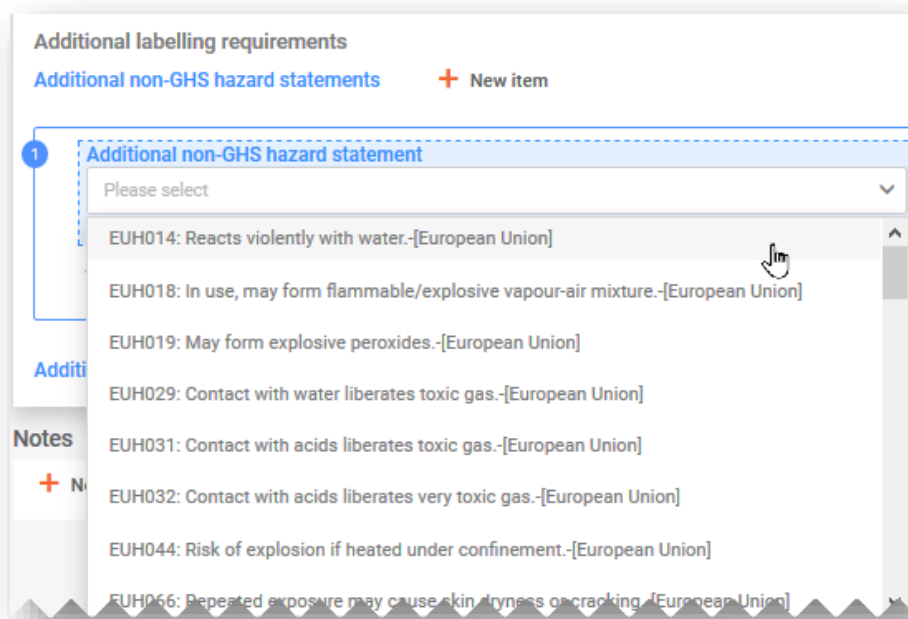
Some statements contain free text fields to include additional text information. It is possible to include this information **in all relevant languages** where the mixture will be placed on the market.

The screenshot shows the 'Hazard statements' interface. It has a '+ New item' button. There are two items listed:

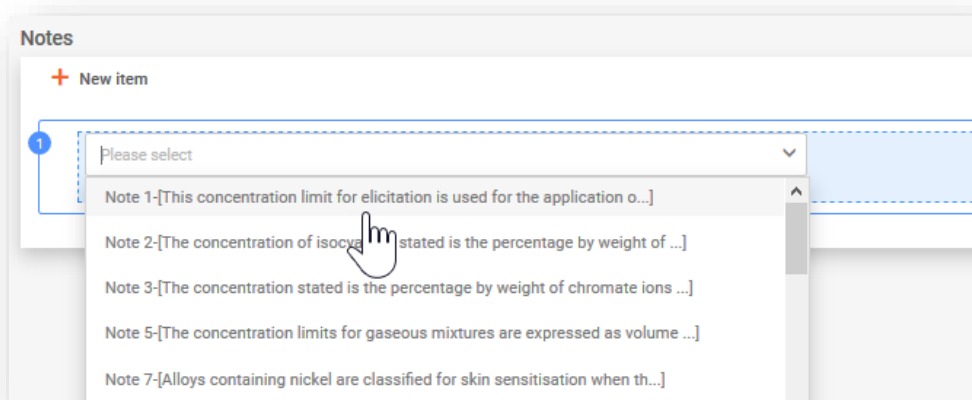
- Hazard statement**
H351: Suspected of causing cancer <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.
Additional text
nl
Free text field for additional information
- Hazard statement**
Please select
H200: Unstable explosives.
H201: Explosive; mass explosion hazard.
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 safety data sheets and toxicological information

Create a New document 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 (section 11 of SDS)': Only one Toxicological information document is allowed per notification of standard submission. However, if the submission is for multiple markets/languages, then this information must be given for each language selected in the dossier header.




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 sheets of mixture/product': 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 | 1_windox SDS.pdf | 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 pH data. To provide this information, you can create a New pH document or use the 'Copy data from...' functionality if relevant.

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.

A screenshot of a software interface showing a dropdown menu for justifying why pH is not available. The menu is titled 'Justification' and has a checked box for 'pH is not available'. The dropdown list contains 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) **Provide 'pH value'**: 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.

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

A screenshot of a software interface for 'Key value for chemical safety assessment'. It shows a checked box for 'pH is not relevant' and a section for 'pH value' with a range input field containing '> 6.5' and '< 6.8'. Below this is a 'Solution concentration (%)' field with the value '100'. A small 'press Esc to close' text is visible in the bottom right corner of the input area.

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 total concentration of components identified with a given GCI cannot exceed in total 5% for the sum of perfumes, and 25% for the sum of colouring agents.



On GCI components

Note that a classification & labelling document is mandatory for GCI components.

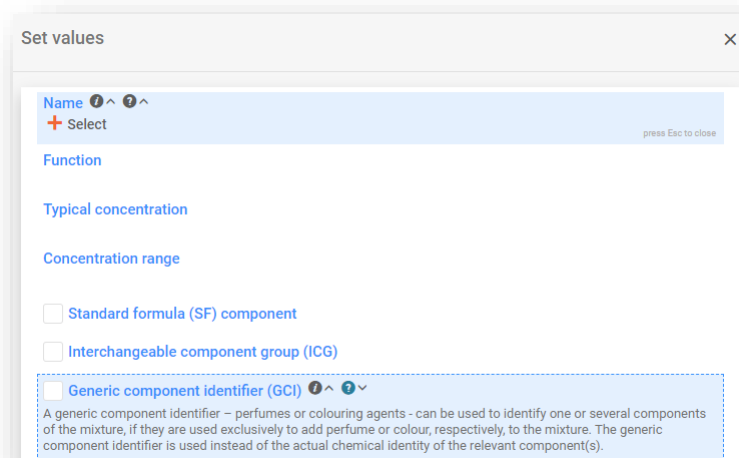
The same GCI can be used more than once in the same composition, as long as the maximum concentration threshold of 5% or 25% is not exceeded.

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

Where multiple components can be identified with the same GCI but do not have the same **classification** for physical hazards, it is recommended to include different GCI components each with the relevant classification record.

GCI components can be either substances or mixture-in-mixtures. In either case, a GCI component must have a 'name' (e.g. 'Perfumes' or 'Colouring agents'), 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

Name

+ Select press Esc to close

Function

Typical concentration

Concentration range

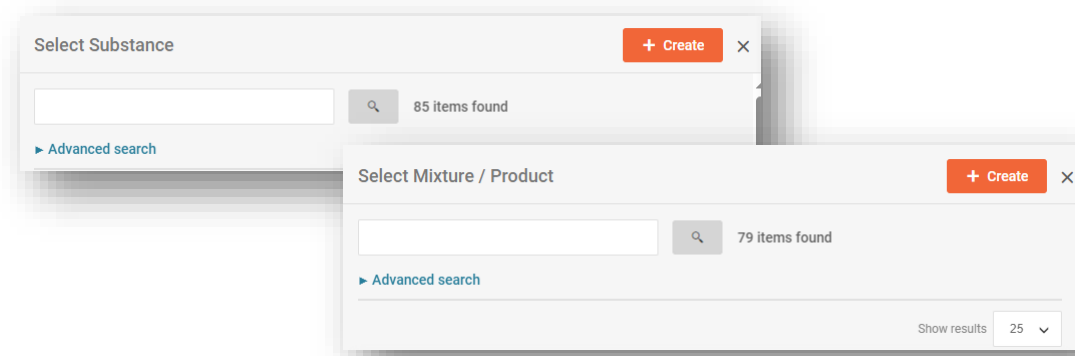
Standard formula (SF) component

Interchangeable component group (ICG)

Generic component identifier (GCI)

A generic component identifier – perfumes or colouring agents - can be used to identify one or several components of the mixture, if they are used exclusively to add perfume or colour, respectively, to the mixture. The generic component identifier is used instead of the actual chemical identity of the relevant component(s).

In the Name field, select 'Substance' or 'Mixture/Product' 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 substance item, select +create and provide the Substance Name of the GCI component (e.g. 'Perfumes' or 'Colouring agents'). Enter 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.

The image shows a 'Set values' form for a GCI component. The form has a title bar with 'Set values' and a close 'X' button. The form contains the following fields and options:

- Name**: Perfume
- Function**: perfume
- Typical concentration**: 5 % (v/v)
- Concentration range**: None
- Standard formula (SF) component
- Interchangeable component group (ICG)
- Generic component identifier (GCI)

To create a new mixture item, select +create and provide the Mixture Name and specify a Legal Entity. Enter the Function, Concentration, and mark the 'GCI' checkbox



Note that the Legal Entity (LE) 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 LE selection must be made e.g. it could be your own LE.

The Reference substance information is not required for GCI substance components.

If the GCI component covers multiple perfumes or colouring agents, their total concentration has to be provided (or a range according to table 2, Annex VIII).

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 Formulas (SF)

Standard formulas have been developed specifically for cement, gypsum, ready-mixed concrete and are listed in Part D, Annex VIII.



The identity and concentration of each component must be reported according to the values detailed in Part D of Annex VIII to CLP. 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 ⁽¹⁾ | 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 |

Currently, the regulation contains 23 Standard Formulas, each indicating the components contained with their concentration ranges. For mixtures that conform to a specific Standard Formula, less strict requirements in terms of composition apply and the submission can partially deviate from the standard requirements.

You can prepare your own Standard Formula datasets in IUCLID (Section 6.2.1 – 6.2.2) or download ready-made datasets from the Poison Centre website (See section 6.2.3).

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 and this can be used as such in the submission; no additional components are present in the mixture), or,
- ii. one which constitutes only part of the final mixture as it contains other components in addition to those specified in the Standard Formula.

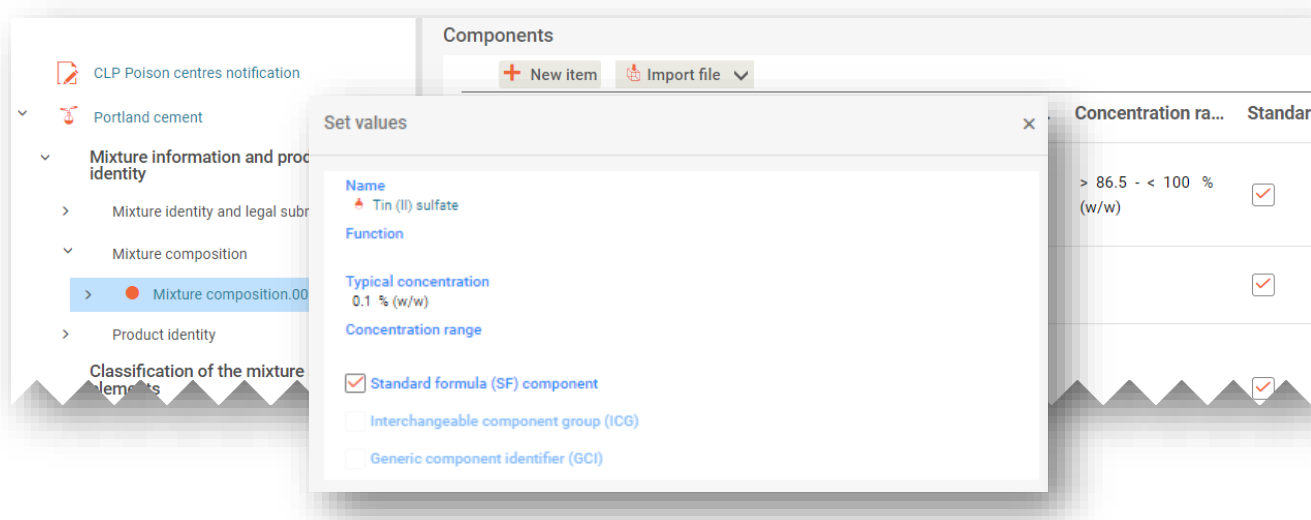
In either case, the Standard Formula can be reported in the composition document of the main mixture or as a MiM.

6.2.1. How to report a standard formula in the main mixture composition document

When the mixture conforms to 100% of a standard formula, or constitutes only part of it, the standard formula components can be reported in the (main) mixture composition document. Here, each component is individually added and flagged as 'Standard formula (SF) component'.

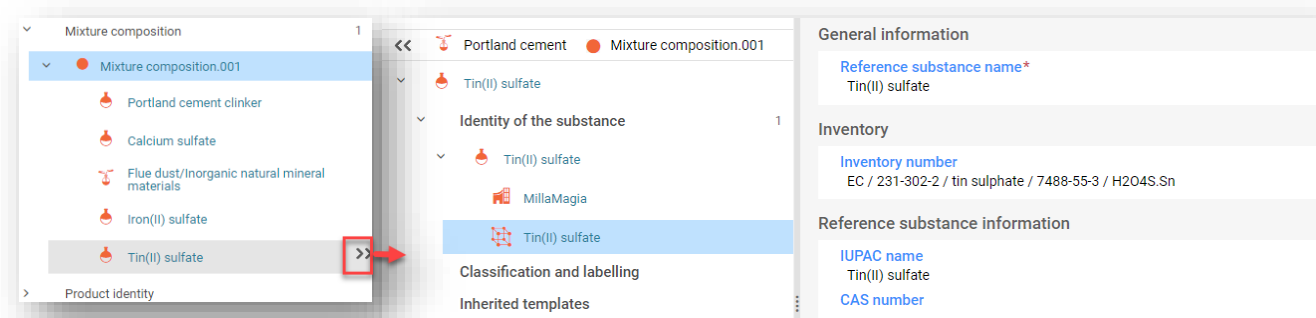
Step 1. From the mixture composition document, first click on +New item and then click on the empty row of the composition table generated.

A 'Set values' box is opened and you can enter information for each individual component's name (remember that all substances need to be linked to a reference substance as well) in accordance with its concentration (in line with Part D of Annex VIII); then you need to flag it as 'Standard formula'.



If you add additional components that do not belong to the Standard Formula, they **must not** be flagged as a Standard Formula component.

Step 2. After the addition of every relevant SF component to the mixture composition document where each component has been linked to a Reference substance, the classification information must also be entered:



Step 3. If the mixture conforms to 100% Standard formula, then its specific name should be indicated (in addition to the given mixture name) in the 'Other identifiers' field of the 'Mixture identity and legal submitter' section. To do this, go to the Mixture Identity document, click on +New item in the Other Identifiers field. Click on the empty row that appears in the table below. 'Standard formula (SF)' should be selected from the Name Type field, which then activates a drop-down list in the 'Name' field where you can make your relevant selection.

The screenshot shows the 'Other Identifiers' section of the PCN system. The 'Mixture name' is 'Portland cement' and the 'Legal entity owner' is 'Purple Haze Chemicals | Helsinki | Finland'. The 'Other Identifiers' table has one row with '# 1'. A dropdown menu is open for the 'Name' field, showing 'Name type' as 'standard formula (SF)' and a list of six 'Cement Standard Formula' options. A hand cursor is pointing to the first row in the table.



Note that the **Legal Entity** (LE) 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 LE selection must be made e.g. it could be your own LE.



In some of the Standard Formulas, some of the components may share the same concentration range, e.g. flue dust and inorganic natural mineral materials. In this case, a mixture component (i.e. a MiM) is to be created. Enter the 'Name' of the mixture component e.g. 'Flue dust/inorganic natural mineral material', then the individual substances of the mixture component (e.g. i) Flue dust and ii) Inorganic natural mineral materials). Flag the substances and the MiM component a 'Standard formula (SF) component'.

| 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 ⁽¹⁾ | 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 |

6.2.2. How to report a standard formula in the MiM composition document

It is possible to report a standard formula in the MiM composition document instead of the main mixture composition, for either a 100% SF or a partial SF component.

Step 1. From the mixture composition document, first click on +New item and then click on the empty row of the composition table generated.

A 'Set values' box is opened and you can select that the component is a Mixture (i.e. a MiM), and then provide details for the Mixture component's name e.g. Portland cement in the example below, and legal entity (this is not checked). In addition, report the concentration as either 100% MiM or other percentage accordingly, and mark the check box 'Standard formula component'.

Step 2. Go to the sub-tree of the MiM component and create a new document for the MiM composition. Complete the MiM composition document by entering more information on the individual components as in the relevant SF from Part D of Annex VIII (including reference substance and classification details) – as well as other information required for the MiM where available and appropriate e.g. UFI or suppliers.

! 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 in 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.

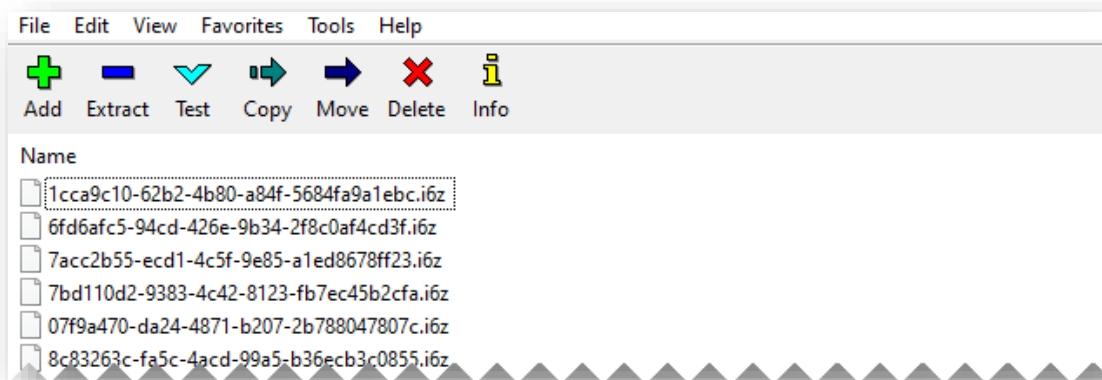
6.2.3. Downloading ready-made Standard Formula datasets

For each Standard formula (SF), the composition (components identity and concentration) is specified in Part D of Annex VIII. 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 ⁽¹⁾ | 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, SF 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 SF datasets is also possible if preferred.

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



6.3. Indicating an interchangeable component group (ICG)

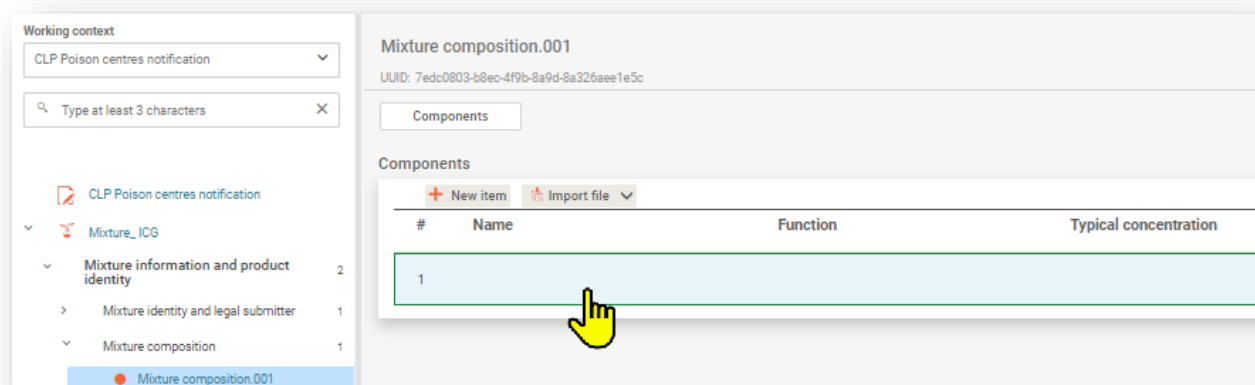
An 'Interchangeable component group (ICG)' consists of multiple components that are similar to each other according to certain criteria, where each component can be used interchangeably in a mixture without altering that mixtures overall classification, hazard or emergency health response.

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 and/or purchased from different suppliers. 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 (<https://echa.europa.eu/guidance-documents/guidance-on-clp>).

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

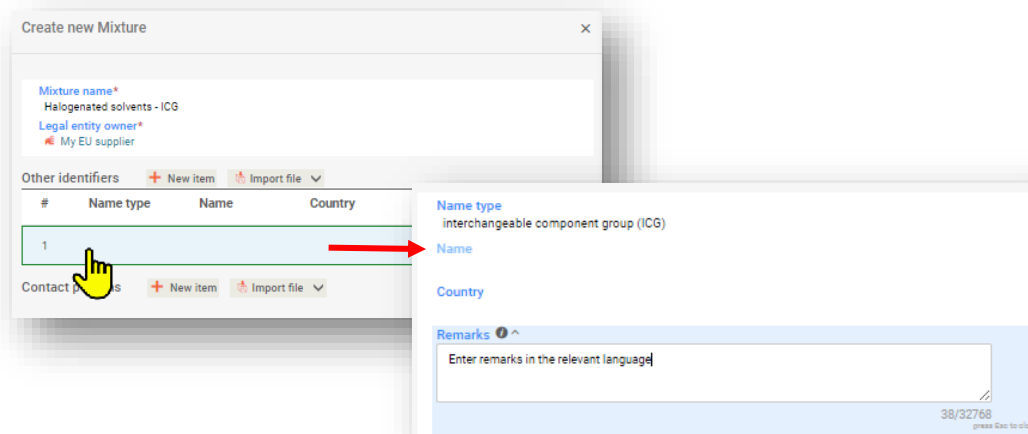


A **mixture component** is created for the ICG (i.e. a MiM) and a **name** is entered for the group in the Name field that corresponds to the technical function(s) of the grouped components.



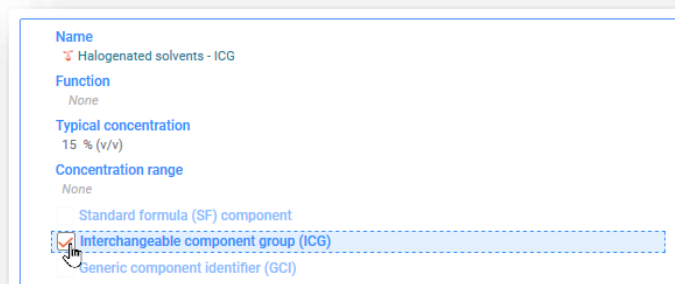
The **name** of the grouped components should be meaningful and indicative of the components contained to allow the emergency operator to easily identify which kind of components can be present in the final mixture.

A selection for the **legal entity** is required. A more detailed description of the ICG can be provided in all the relevant languages by adding a '+New item' in the Other identifiers section and selecting the Name type 'Interchangeable Component Group (ICG)'. The information is to be included in the multi-language Remarks field.



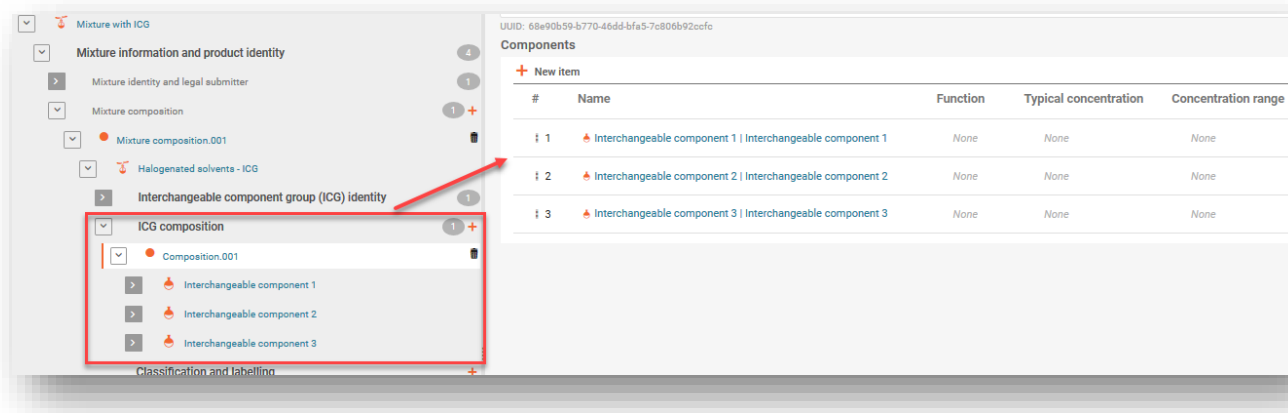
The **Legal Entity** (LE) is mandatory to create the IUCLID dataset, however, this is not mandatory for PCN purposes and no checks concerning this information are carried out. Currently a LE selection must be made e.g. it could be your own LE.

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.




6.3.2. Step 2 – Indicating information for the components

Once the ICG is created/flagged in the Mixture composition document, the individual interchangeable components can then be added in the specific 'ICG composition' document.



Interchangeable components have to be identified following the standard rules for substances or MiMs, i.e.:


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

 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.

Information about **concentration** has to be provided for the ICG as a whole, and not for the single components grouped in the ICG. If the concentration of the individual interchangeable components is known, these should not be notified as part of an ICG.

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

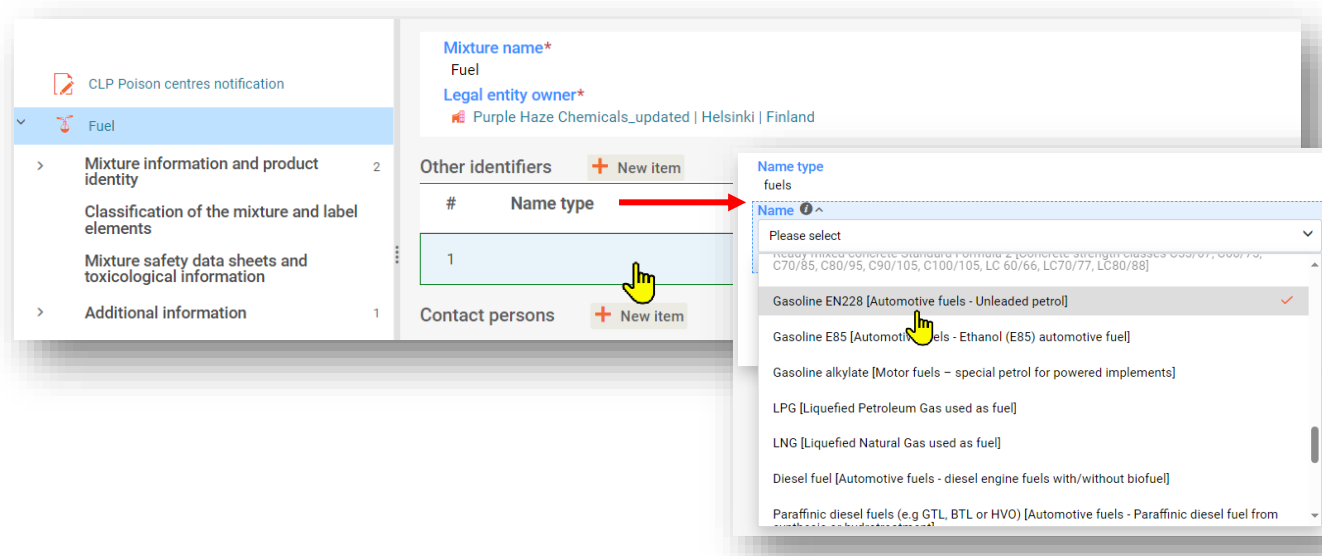
- Standard Formula
- Generic Component Identifier
- another Interchangeable Component Group

6.4. Notifying fuel mixtures

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

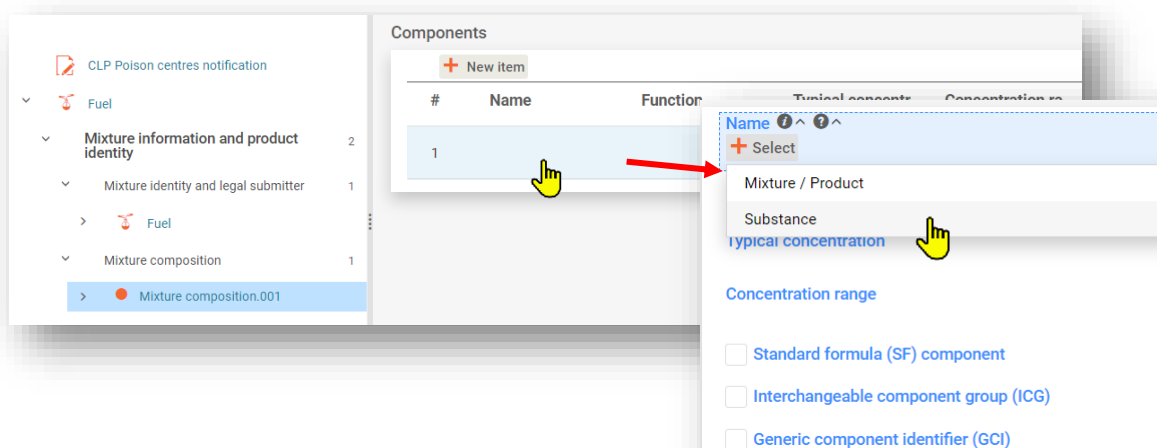
6.4.1. Step 1 – Identify the fuel

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 fuels name from the picklist.



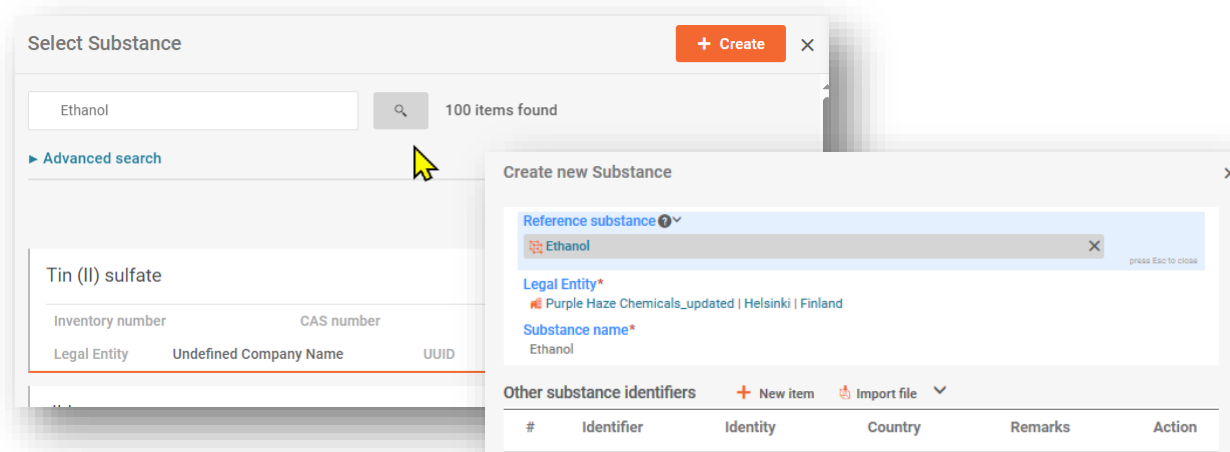
6.4.2. Step 2 – Add fuel components

In the (main) mixture composition document, add each component by creating a New item and providing the information for the component by selecting the component type (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.



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 (SF) component' check box. The remaining sections of the notification must be completed.

The image shows a 'Set values box' for a substance component. It contains the following information:

- 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 (SF) component' 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

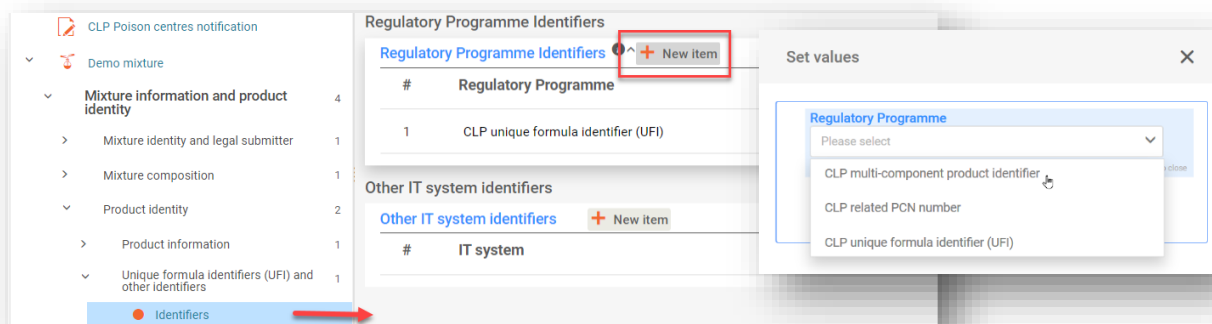
7.1. Indicating multi-component products

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:

- should be used in all notifications related to the same multi-component product
- format is not checked by the validation rules but a rule is in place to ensure that if 'CLP multi-component product identifier' was included, then there should be another notifications submitted with the same 'CLP multi-component product identifier' identifier.
- Existing identifiers can be used as relevant by the notifier e.g. the trade name of the multi-component product); or a new identifier or 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** (<https://echa.europa.eu/guidance-documents/guidance-on-reach>).

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 | |

8. Group submissions (for mixtures differing only in perfume components)

A group submission (GS) can be optionally prepared for several mixtures provided:

- i) all mixtures contain the same composition except for certain perfumes under specific conditions (and where the total concentration of the differing perfumes contained in each mixture, does not exceed 5%).
- ii) reported concentrations/ranges for each of the components is the same (except for certain perfumes)
- iii) all mixtures in the group have the same classification for health and physical hazards

The sections below provide only specific information relevant for a Group submission. The dossier must contain all the information required by Annex VIII as applicable and explained in the previous sections.

Step 1 – establish the correct submission type

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

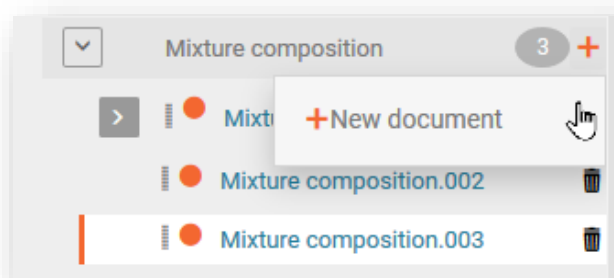
The screenshot shows a form titled 'Specific submissions' with the following fields:

- PCN number***: 00353c61-c924-406b-b406-27b017a67d38
- Country (market placement)***: Austria (checked)
- Language***: German (checked)
- Submission type** (highlighted with a red box):
 - Limited submission (industrial use only)
 - Group submission
 - Voluntary submission

! A single mixture that is marketed under different mixture/product information e.g. trade names, UFI, is notified with a **standard submission**. Please note that standard notifications can include multiple product information documents as described in section 5.5

Step 2 – enter individual mixture compositional information

Multiple mixture composition documents are required for a Group submission. An individual mixture composition document must be created to reflect the composition of each mixture contained in the notification.



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. Therefore, it is possible to first create a document containing only the common composition and duplicate it as many times as the number of the mixtures to be included in the group (see section 4.3.4.3). The specific, not-common components can then be added to each relevant composition document.

! All substance components and MiM-substance components 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'. Concentrations are to be indicated either as an exact concentration (i.e. 'Typical concentration'), or as a 'Concentration range'.

Name
 Lavender oil | Lavender oil

Function
 perfume

Typical concentration
 None

Concentration range
 >= 2.9 <= 3.1 % (w/w)

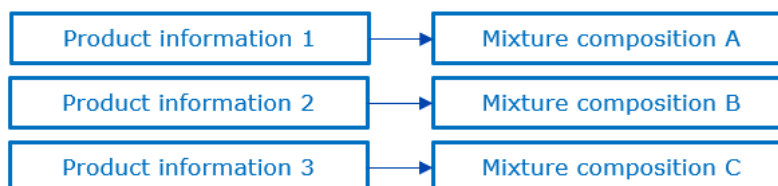
Standard formula (SF) component

Interchangeable component group (ICG)

Generic component identifier (GCI)

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'.

Product information.001
 UUID: a2eceb02-c82c-4fd3-bf6d-efd906b1fad2

Group submission

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

Select existing document **+ Create** **X**

Type at least 3 characters **3 results found**

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

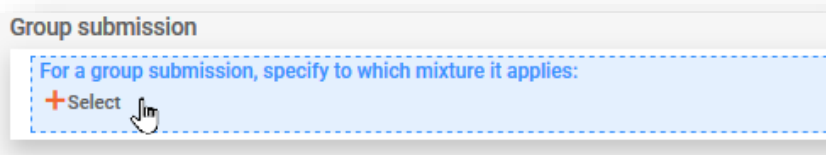
Currently, each Product information document can be linked to one mixture composition only. Therefore, even if the same product information applies to several mixture compositions, then several documents will have to be created.

Step 4 - include and link single or multiple information documents

Additionally, multiple documents can be created for:

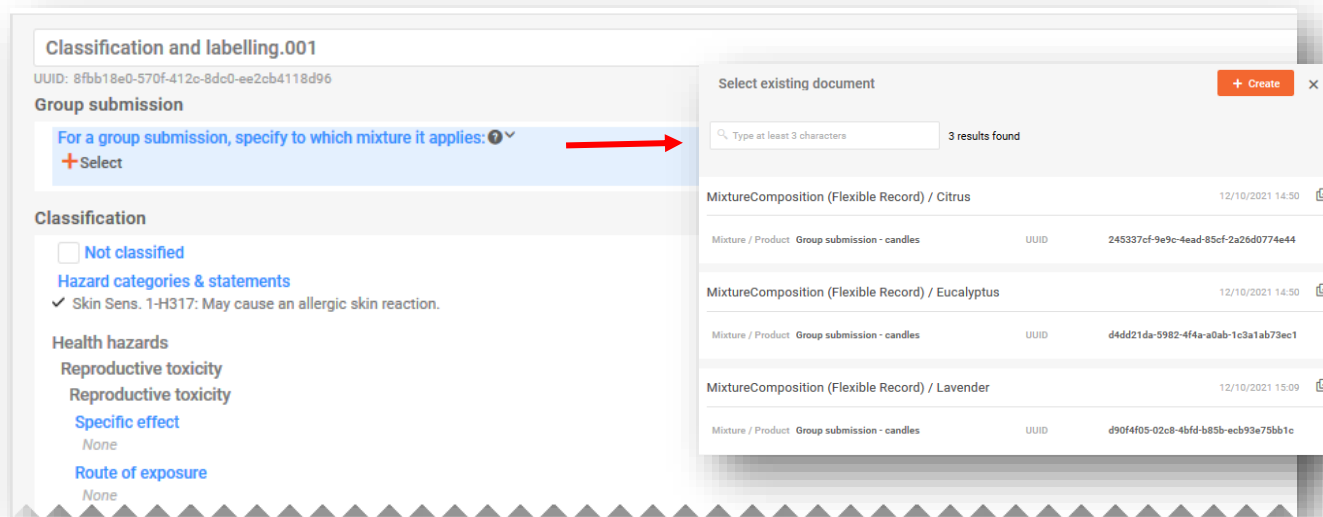
- i) Classification & Labelling
- ii) Toxicological information
- iii) pH

It is always necessary to indicate to which mixture composition the specific record refers to, by using the specific field. Note in these cases a single document can link to one or multiple mixtures. Therefore, if the same information applies to several mixture compositions, these can all be selected in the same field.



8.1.1. Reporting classification and labelling in the Group submission

For Group submissions, multiple Classification and labelling (C&L) documents 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 same C&L document can be linked to multiple compositions of the same Group submission.

8.1.2. 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.

The screenshot shows a form titled "Mixture safety data sheets and toxicological information.001" with a UUID of 269db2ec-6f29-459a-ba85-28c11160a8e8. It is a "Group submission" and currently has "None" selected for the mixture it applies to. Under "Information on mixtures", there is a section for "Safety data sheets of mixture / product" with a "+ New item" button. Below this is a table with columns for "#", "Safety data sheet", and "Country". A dashed red box highlights the "Toxicological information (section 11 of SDS)" field, which is currently set to "None" and has a red error message: "This field is mandatory."

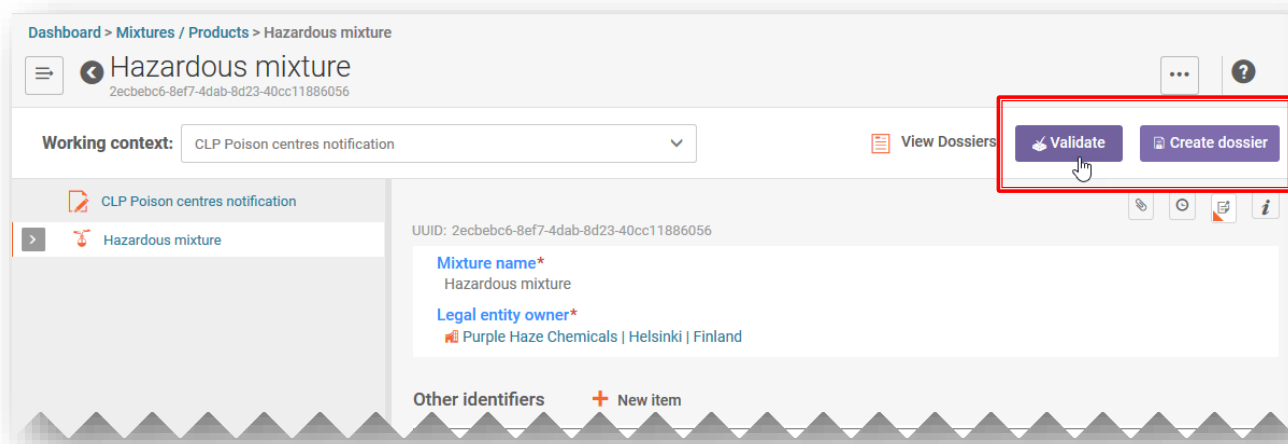
8.1.3. Reporting pH in the Group submission

Single or multiple pH documents may be reported. 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.

The screenshot shows a form titled "pH.001" with a UUID of 16ee2ff7-c12e-41fe-9f63-0b3dc84f4551. It is a "Group submission" and is linked to three mixture compositions: "Lavender", "Eucalyptus", and "Citrus". Under "Key value for chemical safety assessment", the option "pH is not available" is checked. A "Justification" field contains the text "substance/mixture is non-soluble (in water)". Below this, the "pH value" and "Solution concentration (%)" fields are both set to "None".

9. Validate and create a PCN dossier

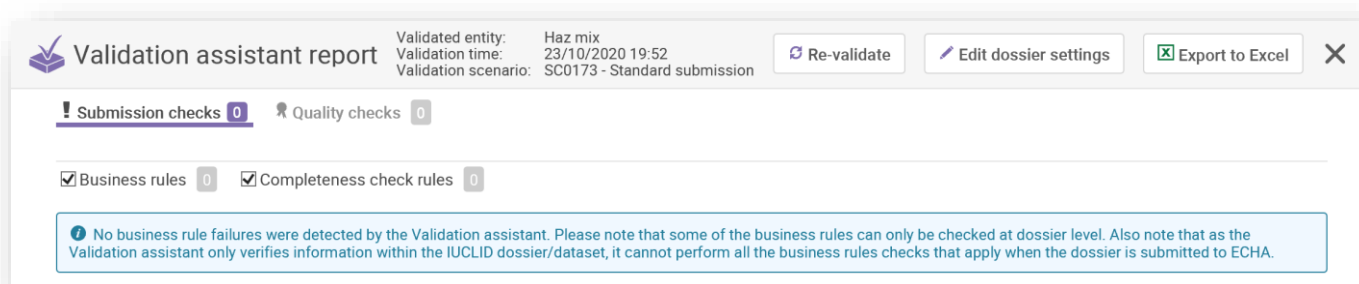
Before creating a dossier, it is recommended to first check the dataset for any errors or missing information using the 'Validate' functionality. This functionality carries out a number of checks according to a set of pre-defined rules to verify that you have provided the information as expected.



The Validate function 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

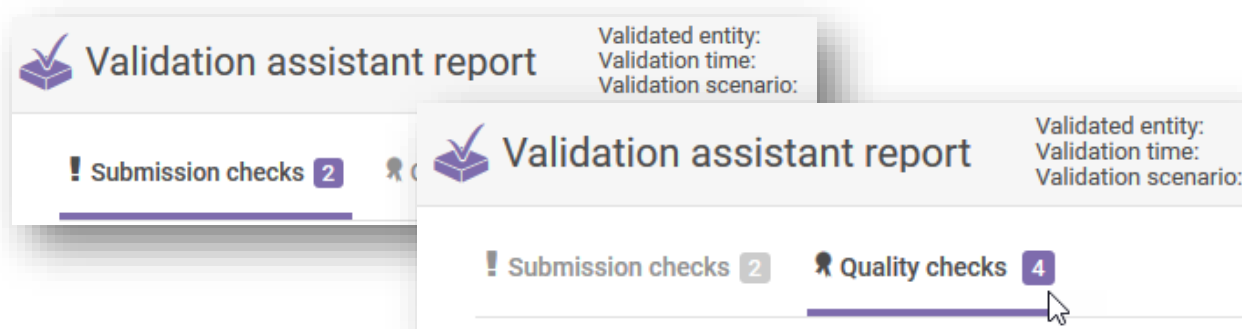
When no rules are triggered, the 'Validation assistant report' will display a message to highlight that additional checks are performed in the system upon submission.



! 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).

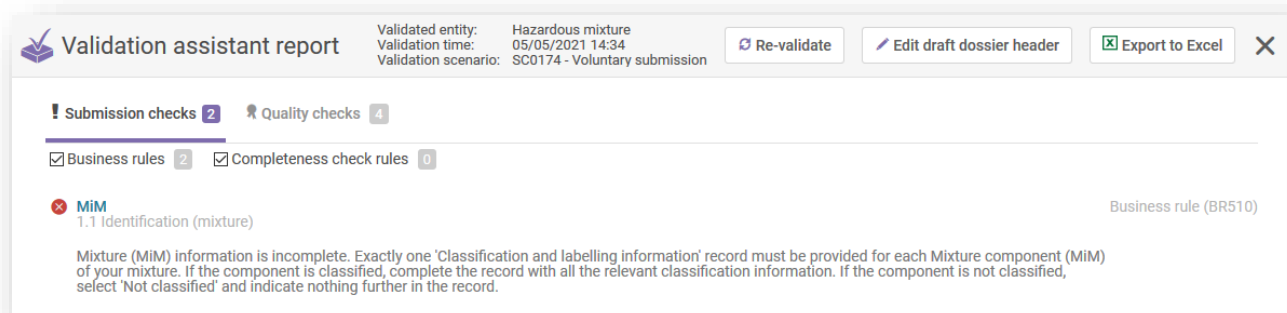
9.1. Validation assistant report

When the 'Validation assistant report' is generated there are two tabs – one for failures (marked as Submission Checks) and the other for warnings (marked as 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 which means that the dossier would not be accepted by the system, nor forwarded to the authorities. It is recommended to check the sections of the dossier which require action 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. Nevertheless, this cannot be assessed by the system and it depends on the specific case. 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 assistant report' detailing the warnings listed.

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



A 'Validation assistant 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.

Note that warnings do not necessarily require corrections. It is the submitters responsibility to assess whether corections are needed.

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.

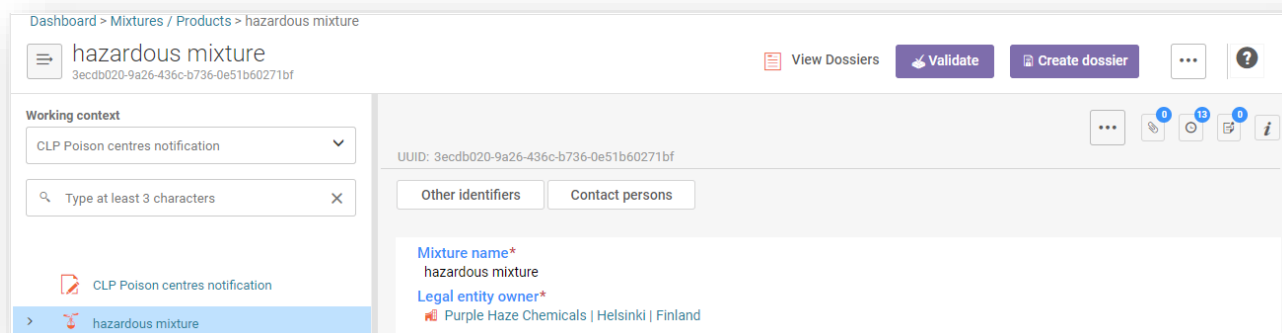
Mixture composition.001
Mixture composition Components, (1) Quality check (QLT502)

'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.

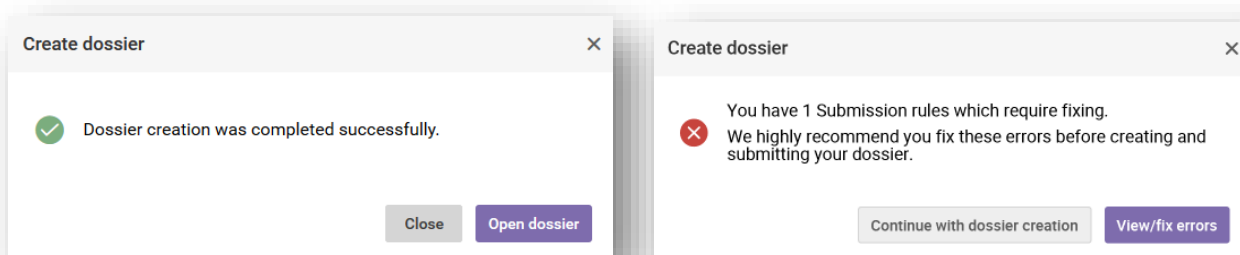
For a complete list of all the rules, i.e. those checked in the IUCLID and the Portal, you may refer to latest version of the **Validation rules for poison centre notifications**
<https://poisoncentres.echa.europa.eu/poison-centres-notification-format>

9.4. Creating a dossier

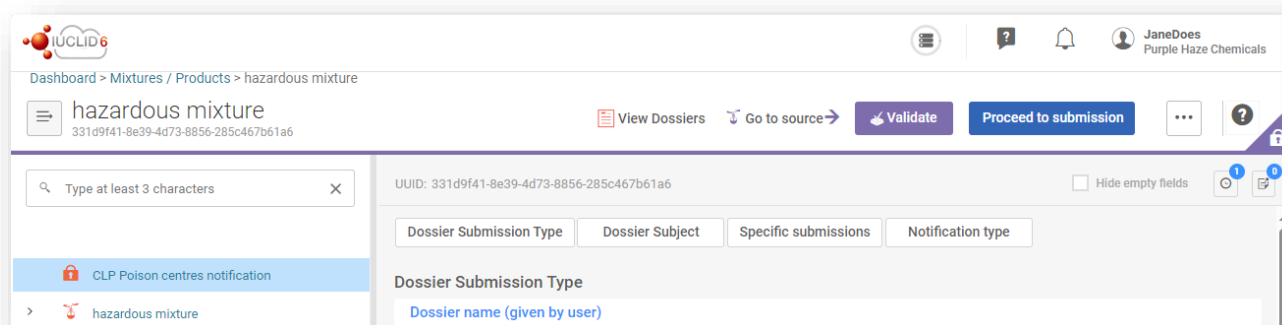
The 'Create dossier' functionality is available from the mixture page. Once clicked, you are directed to the dossier header of which the details can be checked.



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

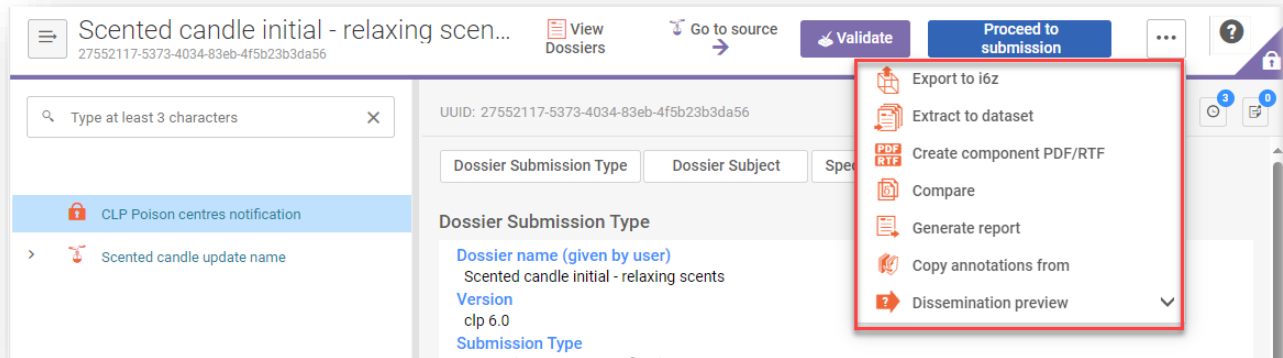


Once the dossier has been created it will appear with the purple lock symbol. If you are working in IUCLID Cloud, there will also be the option to 'Proceed to submission'.



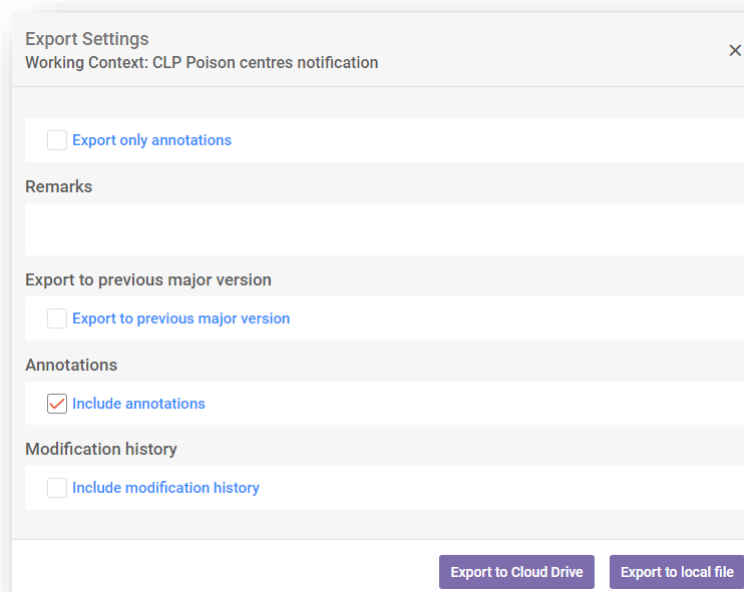
10. Dossier report and export functions

From in the dossier, clicking on the three dots '...' opens a window where various functionalities are available. Of most importance for PCN are the 'Export to i6z' and the 'Generate report'.



10.1. Exporting a dossier (or dataset)

You can export a single dossier or dataset locally by clicking on the three dots '...' 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 next to each item. Note that each item needs to be selected individually, there is no 'Select/deselect all' feature.

Once you select 'Export', the Export settings box will open for datasets (and there you have the possibility to change the exported information) before exporting the selected items to a zip file.

The screenshot displays the 'Mixtures / Products' dashboard. At the top, there is a search bar and a '+ New mixture / product' button. Below the search bar, there are tabs for 'Datasets' and 'Dossiers'. A table lists three items: 'Wax blend', 'mimosa', and 'Rapeseed and coconut wax blend'. Each item has a checkbox, a date, and a menu icon. The 'Wax blend' item is selected. Below the table, there are buttons for 'Export', 'Delete', and 'Export CSV'. An 'Export Settings' dialog box is open, showing options for 'Remarks', 'Export to previous major version', 'Detail level of document fields', 'Flags for confidentiality', and 'Flags for regulatory programme'. The 'Export to zip' button is visible at the bottom right of the dialog box.

Dashboard > Mixtures / Products

Mixtures / Products

+ New mixture / product

Datasets Dossiers

Advanced search

Select/Deselect all 5 items selected Export Delete Export CSV Show results 25 Sort by Newest first

| | | | |
|-------------------------------------|--------------------------------|--------------------------------|-----|
| <input checked="" type="checkbox"/> | Wax blend | 12/07/2021 12:39 | ... |
| | Legal Entity | Purple Haze Chemicals | |
| | UUID | 045f4648-8a34-4c2b-af1c-e47... | |
| <input checked="" type="checkbox"/> | mimosa | | |
| | Legal Entity | Eco-chemicals | |
| | UUID | 64c8d474-1c45-4da9-8118-94... | |
| <input checked="" type="checkbox"/> | Rapeseed and coconut wax blend | | |
| | Legal Entity | Undefined Company Name | |
| | UUID | a09bce43-b7e2-4586-9659-a5f... | |

Export Settings

Remarks

Export to previous major version

Export to previous major version

Detail level of document fields

Detailed fields (e.g. needed for robust study 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

Flags for regulatory programme

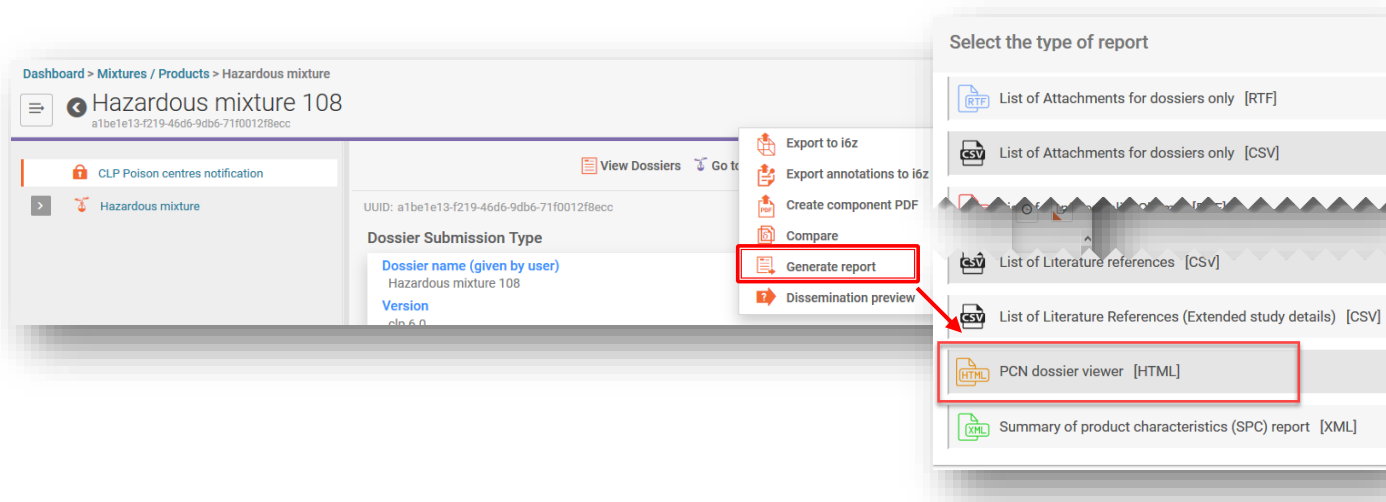
Select information to be included

- ✓ No regulatory purposes
- ✓ AU: AICIS
- ✓ CA: CEPA
- ✓ CA: PCPA
- ✓ EU: BPR
- ✓ EU: CLP

Export to zip

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 the HTML report (in full or selected section) 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 with expandable tabs:

- 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 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/product dataset and create an updated dossier.

To update a mixture/product dataset it is possible to

- i) Overwrite the previously existing dataset
- ii) Create a 'Clone' of the previously prepared dataset and edit accordingly
- iii) Create a new mixture/product dataset and enter new/copy previously prepared information as relevant



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.

11.1. When the submission is an update

From the relevant Mixture dataset, open the dossier header and select 'Update'. If 'Initial notification' is selected, then unselect this field in order to activate the full list of Notification types and select 'The submission is an update'. 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

11.1.1. Updates – 'Justification' field

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

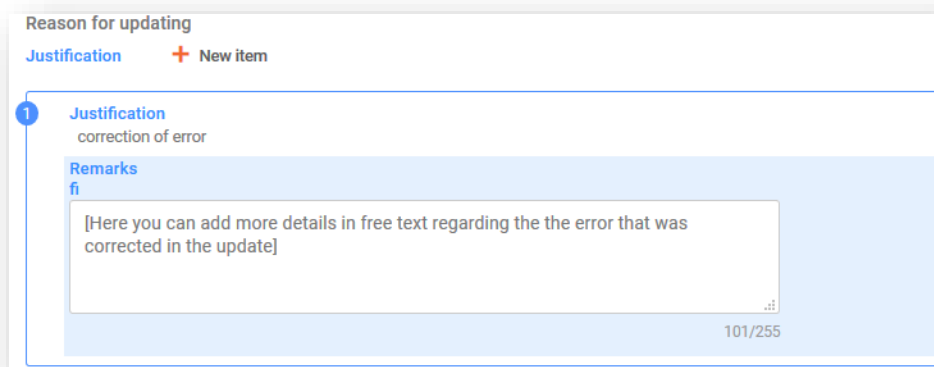
1 Justification
expansion of market area

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.



The screenshot shows a web form titled "Reason for updating". At the top, there are two options: "Justification" (selected) and "+ New item". Below this, a blue-bordered box contains the following information:

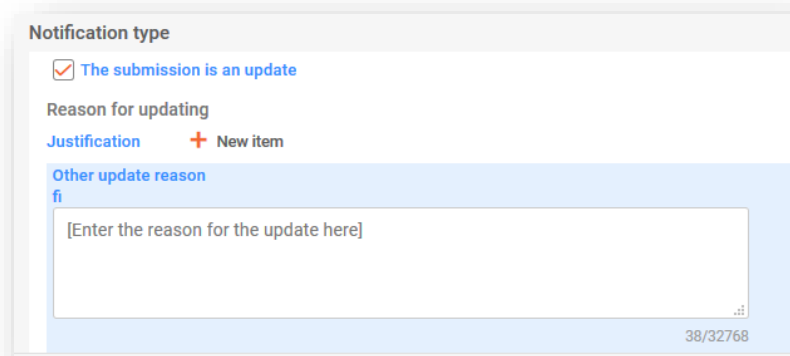
- Justification**: correction of error
- Remarks**: A text area with the placeholder text "[Here you can add more details in free text regarding the the error that was corrected in the update]". The text area has a character count of 101/255.

The following are examples when the Remarks field can be used to provide additional useful information:

- When the generic justification '**Correction of error**' is selected. The additional information will allow the reader to easily identify the new or corrected information.
- When a '**Change in mixture composition without requiring a new UFI**' is selected. The additional information clarifies that a change in perfume components occurred in mixtures within a Group submission.

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, multiple free text fields are available for every relevant language.



The screenshot shows a web form titled "Notification type". At the top, there is a checked checkbox labeled "The submission is an update". Below this, there is a section titled "Reason for updating" with two options: "Justification" (selected) and "+ New item". Below this, a blue-bordered box contains the following information:

- Other update reason**: A text area with the placeholder text "[Enter the reason for the update here]". The text area has a character count of 38/32768.

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 cited in Annex VIII part B section 4.1 are also reflected in the available picklist and include:

- **'Change in the mixture classification'** – any change in mixture classification must be reported in an update, including a change from a hazardous mixture to a non-hazardous mixture.
- **'Change in the product identifier'** – new trade names, additional UFI's or any other names.
- **'New toxicological information available'**

In addition to this, the picklist also facilitates other reasons:

- **'Cease product from the market'** – see section 5.5.2.4 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'** – for example, when re-placing a previously ceased product back on the market.
- **'Change in the mixture composition without requiring a new UFI'** - for example in an update a standard submission to a group (and vice-versa).
- **'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'** – For example, if 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 after the submission process has been initiated, 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 mixtures on the market. In this case, you must make a notification for the new composition. This new notification must be linked to the previous notification:

- i) Generate a new PCN number in the dossier header (first you need copy the original PCN number as you will need that in step iii) below)

The screenshot shows a form with the following fields:

- Dossier name (given by user)
- Dossier submission remark
- Specific submissions
 - PCN number* (with a help icon and a dropdown arrow) containing the value: f7dfd9c1-f48b-444e-a5ac-4a013f31d8e9. A yellow hand cursor is pointing at the 'Generate a new PCN number' button next to it.
 - Country (market placement)*

- ii) Deselect 'Initial' notification type and select 'New notification following a significant change in composition' in the dossier header

The screenshot shows the 'Notification type' section with three radio button options:

- Initial notification
- New notification after a significant change of composition (with a help icon and a dropdown arrow). A yellow hand cursor is pointing at this option.
- The submission is an update

- iii) Generate and assign **a new UFI** and enter the previous PCN number (this becomes the **related PCN number**) in the Regulatory Programme Identifiers

The screenshot shows a table titled 'Regulatory Programme Identifiers' with a '+ New item' button. The table has three columns: '#', 'Regulatory Programme', and 'ID'.

| # | Regulatory Programme | ID |
|---|-------------------------------------|--------------------------------------|
| 1 | CLP related PCN number | f7dfd9c1-f48b-444e-a5ac-4a013f31d8e9 |
| 2 | CLP unique formula identifier (UFI) | UFI 2 |



If your new mixture composition changes the classification from hazardous to non-hazardous a new UFI is not needed (the original UFI cannot be used in the new notification) and you can select the 'Voluntary submission' in the dossier header – note that the quality rule QLT508 will be triggered.

- iv) Make the necessary changes throughout the dataset where relevant e.g. related to the composition, toxicological information, trade name etc.



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

Identifiers

UUID: 4ceb404b-25d8-4090-be4a-4a4876a27379

Regulatory Programme Identifiers

Regulatory Programme Identifiers + New item

| # | Regulatory Programme | ID | Action |
|---|-------------------------------------|--------------------------------------|--------|
| 1 | CLP related PCN number | bdfc7444-435c-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.

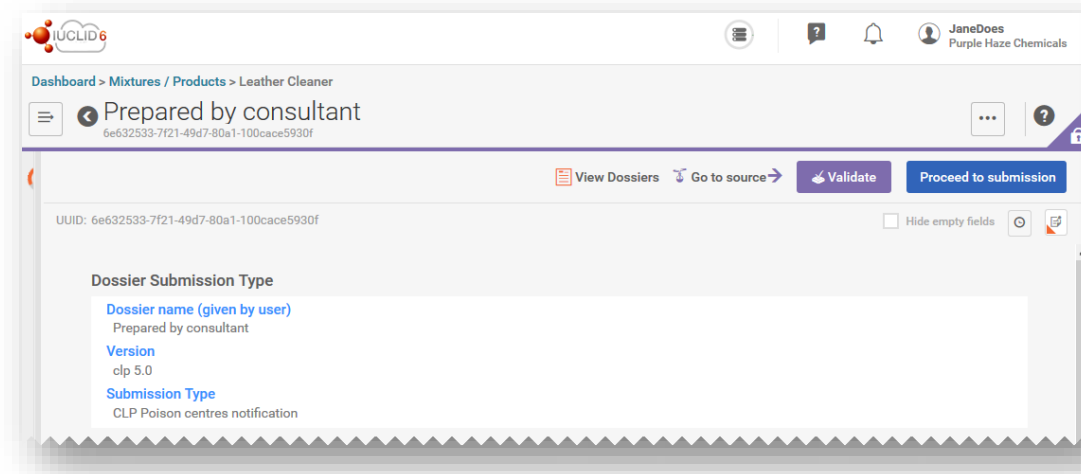
12.1. Upload dossier

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

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

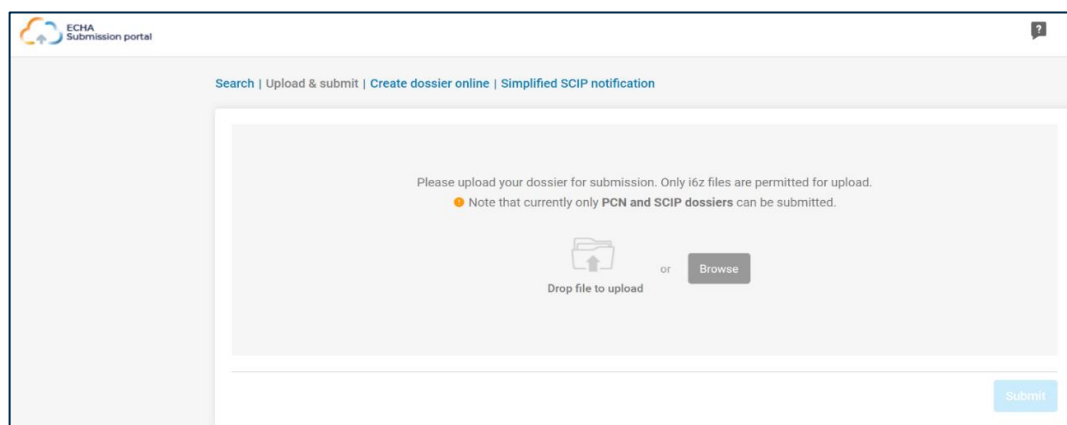
12.1.1. Proceed to submission from ECHA Cloud

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



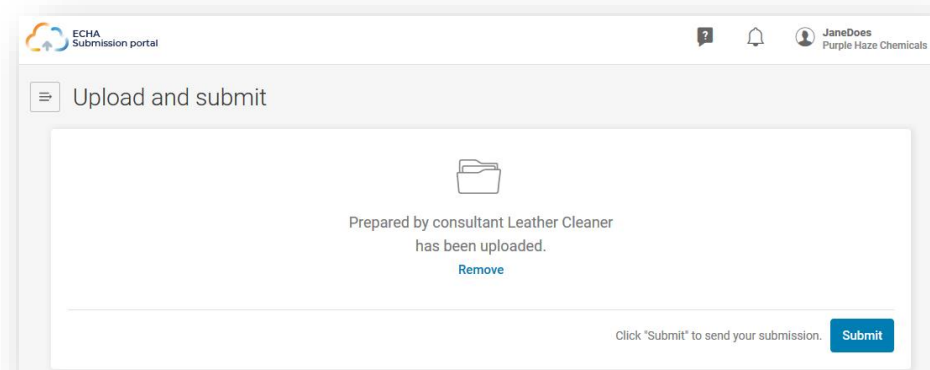
12.1.2. Upload in the ECHA Submission portal

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

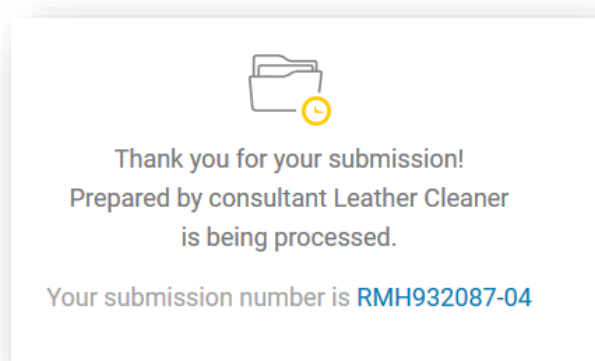



12.2. Submit

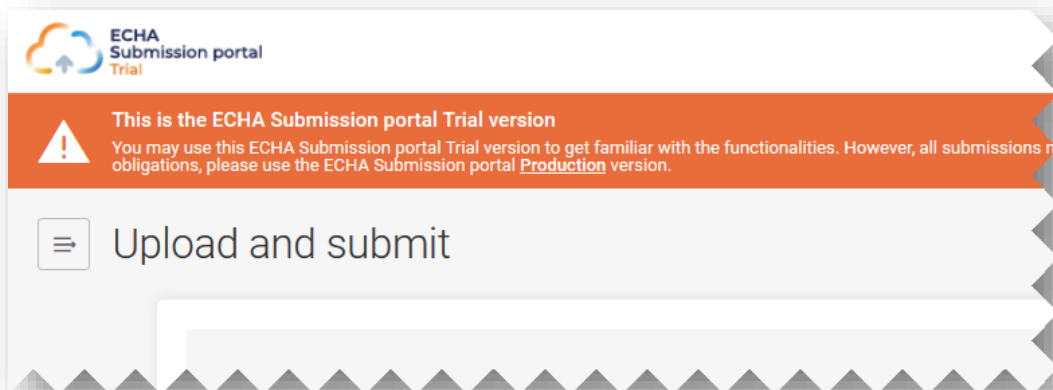
Once uploaded (either automatically from the IUCLID Cloud, or manually by the logged in user), the dossier will need to be submitted by clicking on the 'Submit' button. If needed, the dossier can be removed from the upload section.



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. Checking 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 Submission 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' 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 submitting legal entity. 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, do not resubmit. |
| Disabled  | Disabled means the submission has been disabled but it still remains visible to the legal submitter and the relevant Appointed Bodies. |

Submission information includes the data and meta-data for the submission either entered by the submitter (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 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**.

The screenshot shows the Adobe Acrobat Reader DC interface displaying a PDF document titled "Proof of notification.pdf". The document content is the ECHA Submission Portal page for a submission report. The page header includes the ECHA logo and the user name "JaneDoes Purple Haze Chemicals". The main heading is "Submission report". The submission status is "Succeeded".

Submission details:

- Dossier type: CLP Poison centres notification
- Submitted by: Jane Does, Purple Haze Chemicals
- Submission number: RMH113838-21
- Submitted IUCLID version: 6_5
- ECHA ID: 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: (blank)

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:

(This section is currently empty in the screenshot.)

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 rule ('BRXXX') or quality rule ('QLTXXX'). For a complete list of all the rules you may refer to latest version of the **Validation rules for poison centre notifications** <https://poisoncentres.echa.europa.eu/poison-centres-notification-format>

The ECHA Submission portal creates a 'Validation report' – the link to this report is available from the Submission Report. When the Submission Status is set to 'Succeeded with warnings' the Validation report is also forwarded to the Appointed Body.

! If you have failed a Validation or Quality check and need additional support from the Helpdesk, make sure you include the specific rule number. It is also helpful to send screenshots of the area that is triggering the rule.

The image shows two screenshots of the ECHA Submission portal. The top screenshot shows the 'Submission report' page for a submission that has failed. A red box highlights the 'View Validation report' link, with a red arrow pointing to the bottom screenshot. The bottom screenshot shows the 'Validation report' page, which lists the specific validation rules that failed.

Submission report details:

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

Validation report details:

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

| 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 in mixture. Component name: Mixture compo |

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
- It is also possible to scroll through the pages if there are multiple pages of search results.

The screenshot displays the ECHA Submission portal search interface. The search criteria section is highlighted with a red box. The results table shows PCN numbers, names, and dates. The 'Sort by' dropdown is also highlighted with a red box. The pagination controls at the bottom are also highlighted with a red box.

Search criteria:

- Search criteria:
- Submission number:
- Dossier type:
- Dossier UUID:
- PCN number:
- UFI:
- Names:
- Submission status:
- Submission date: from to
- Submission reason:

Results:




Page 1 of 37 results

Sort by:

| PCN number | UFI(s) | Submission date |
|---|--|------------------|
| RMH091863-18 | 8200-U0CW-500K-QF8E, 4500-0029-6003-D0UR | 07/10/2021 15:19 |
| PCN number: b8f2c447-8955-4169-a20f-743af3a0c3dc | UFI(s): 115b6fb8-5e03-4360-8092-db53a488e730 | |
| Names: GS first test, Group submission - detergents, Clean a... | Dossier UUID: 115b6fb8-5e03-4360-8092-db53a488e730 | |
| RMH601991-10 | 0200-U0CW-500H-QNQU | 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 UUID: 899765d7-9759-4226-82ef-3da729227d52 | |
| RMH531982-10 | 0200-U0CW-500H-QNQU | 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 UUID: 899765d7-9759-4226-82ef-3da729227d52 | |

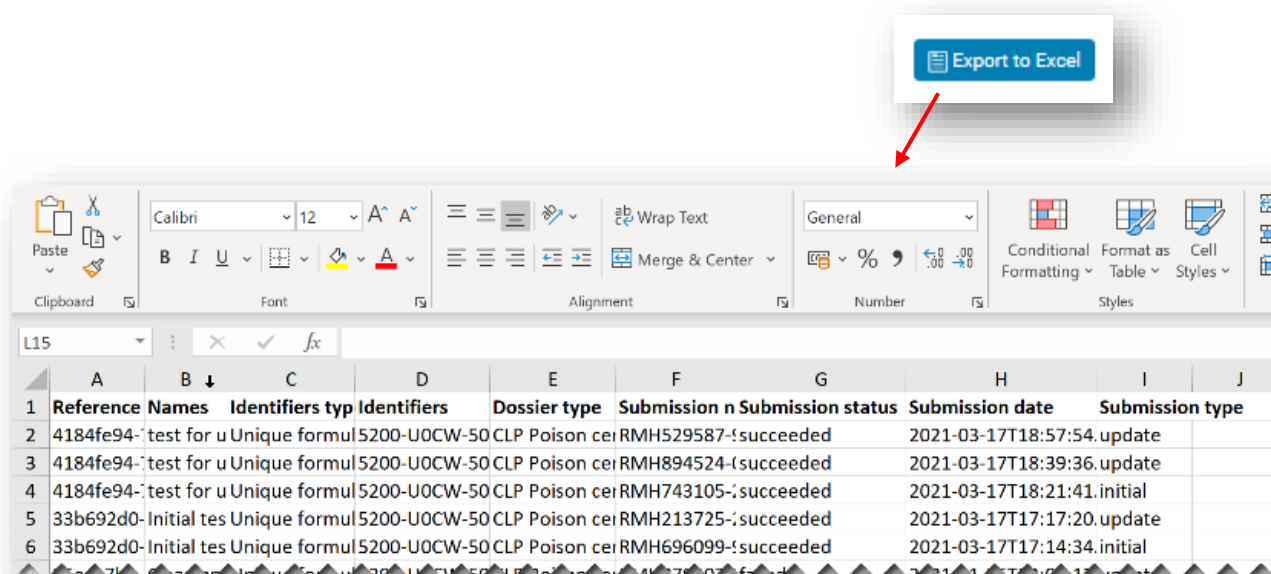
Items/page:

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 maintains 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 |

12.6. Request to disable a submission in the ECHA Submission portal

It is possible to disable a successfully submitted dossier in the ECHA Submission portal. Disabling a submitted dossier may be needed because a company:

- notified wrong information that cannot be deleted or fully replaced due to existing validation rules for updates
- has submitted the wrong submission type e.g. a new notification for significant change of composition instead of an update of an existing notification having the same composition
- mistakenly submitted a test dossier in the production environment
- made a submission from the wrong legal entity account e.g. as a consultant



The disabling feature is only to be used in specific circumstances, namely when incorrect data has been submitted that **cannot be corrected in an update**.

Disabled submissions are **not to be confused** with ceasing a product from the market'.

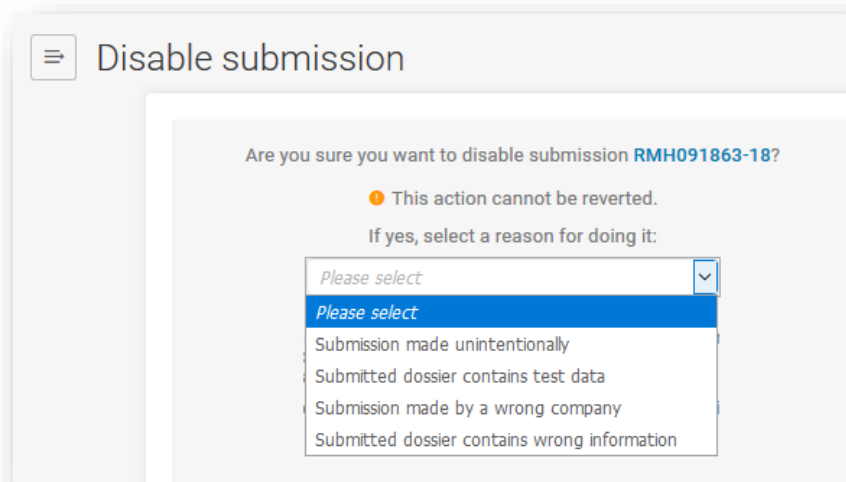
The 'Disable submission' functionality can be accessed via the three dots '...' from the Submission report. Only the latest valid submission e.g. if the notification has been updated, will offer this feature.

The screenshot shows a 'Submission report' page. At the top, there is a 'Go to search' link and a 'View Validation report' link. The main content area displays submission details: 'Submission status: Succeeded' with a warning icon, 'Dossier type: CLP Poison centres notification', 'Submitted by: Jane Does', 'Submission number: RMH091863-18', and 'Submitted IUCLID version: 6_6'. A red box highlights the 'Disable submission' button, which is located next to a three-dot menu icon. Below the main details, there are two sections: 'Submission information' and 'Recipients (Member States - market placement)'. The 'Submission information' section shows 'PCN number: b8f2c447-8955-4169-a20f-743af3a0c3dc' and 'Mixture name: Purple Haze Chemicals'. The 'Recipients' section shows 'Finland' and 'Perman'.



In case of updated submissions, it is only possible to disable the latest submission – therefore you also need to consider if you need to also disable the initial submission after you have disabled the updated submission.

Once you have clicked on 'Disable submission', a reason must be selected according to the list provided.



☰ Disable submission

Are you sure you want to disable submission **RMH091863-18**?

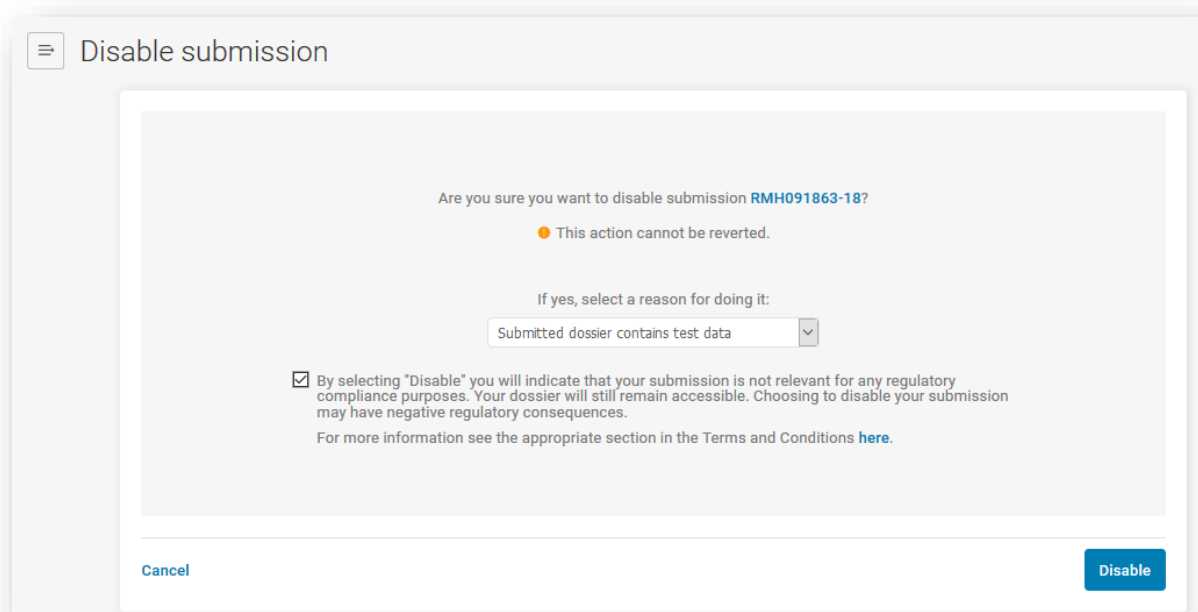
⚠ This action cannot be reverted.

If yes, select a reason for doing it:

Please select

- Please select
- Submission made unintentionally
- Submitted dossier contains test data
- Submission made by a wrong company
- Submitted dossier contains wrong information

You must also declare that you have read and understand the possible regulatory consequences before the 'Disable' feature is activated. The Terms and Conditions for the service and use of the ECHA Submission portal is available in all EU languages <https://echa.europa.eu/support/dossier-submission-tools/echa-cloud-services>



☰ Disable submission

Are you sure you want to disable submission **RMH091863-18**?

⚠ This action cannot be reverted.

If yes, select a reason for doing it:

Submitted dossier contains test data

By selecting "Disable" you will indicate that your submission is not relevant for any regulatory compliance purposes. Your dossier will still remain accessible. Choosing to disable your submission may have negative regulatory consequences.

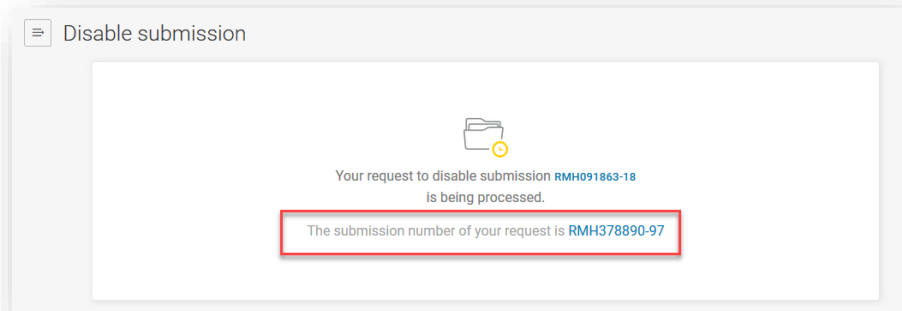
For more information see the appropriate section in the Terms and Conditions [here](#).

Cancel Disable

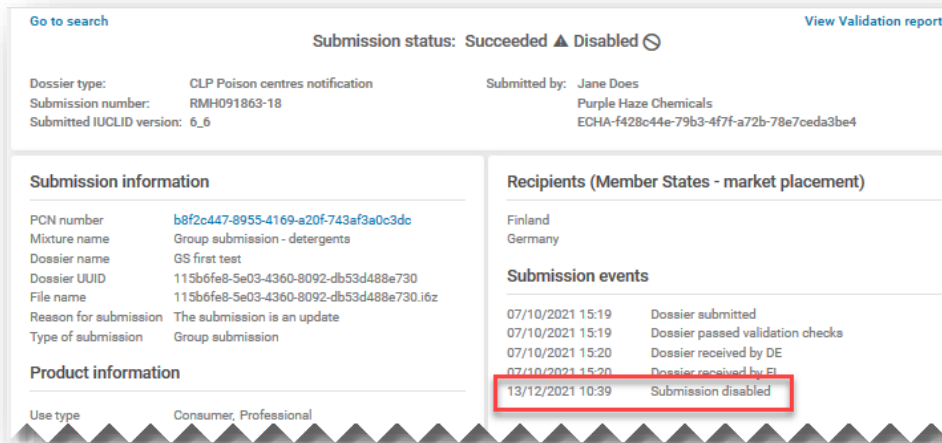


When disabling a submission, it is responsibility of the company to inform downstream customers who may be affected by the disabling process as there is no communication to inform those companies who make reference to such submissions.

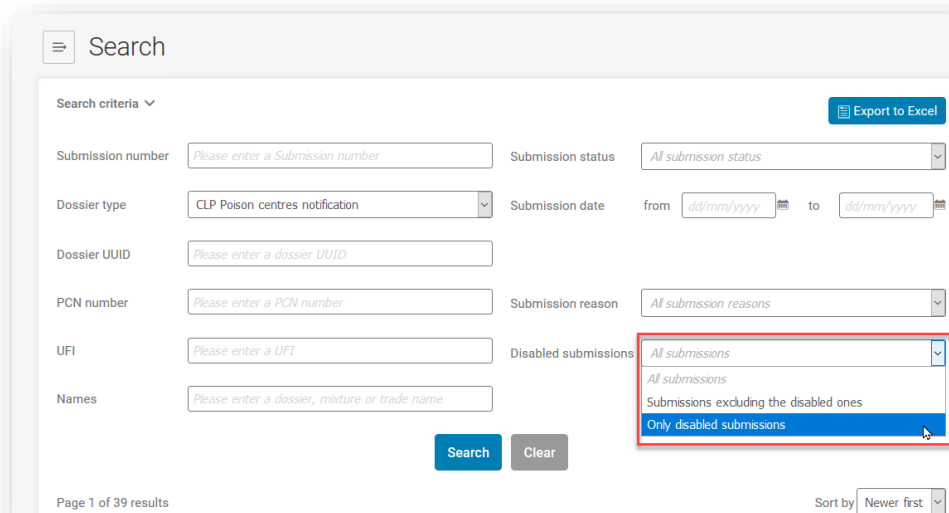
Once the request to Disable submission [Submission number] has been initiated, a submission number for the request will also be generated.



Disabled submissions are marked accordingly as 'Disabled' in the Submission status (depicted by the circle-backslash symbol), however, note that they will remain visible and accessible by Appointed Bodies and poison centres.



To track your disabled submissions in the ECHA Submission portal, you can use the search functionality to filter via 'Disabled', or by searching with the 'Submission number' of the request.



The information about disabled submissions is visible in two Submission reports.

- i) **the Submission report of the successfully disabled submission:** 'Disabled' (text or symbol) will appear in the Submission status; Submission events; Submission graph; and Submission history.

Go to search
Submission status: Succeeded ▲ Disabled ⓧ
[View Validation report](#)

Dossier type: CLP Poison centres notification
 Submitted by: Jane Does
 Submission number: RMH091863-18
 Submitted IUCLID version: 6_6

Submitted by: Jane Does
 Purple Haze Chemicals
 ECHA-f428c44e-79b3-4f7f-a72b-78e7ceda3be4

Submission information

PCN number [b8f2c447-8955-4169-a20f-743af3a0c3dc](#)
 Mixture name Group submission - detergents
 Dossier name GS first test
 Dossier UUID 115b6fe8-5e03-4360-8092-db53d488e730
 File name 115b6fe8-5e03-4360-8092-db53d488e730.i6z
 Reason for submission The submission is an update
 Type of submission Group submission

Product information

Use type Consumer, Professional

Recipients (Member States - market placement)

Finland
Germany

Submission events

07/10/2021 15:19 Dossier submitted
 07/10/2021 15:19 Dossier passed validation checks
 07/10/2021 15:20 Dossier received by DE
 07/10/2021 15:20 Dossier received by EL
13/12/2021 10:39 Submission disabled

Submission graph

PCN number
b8f2c447-8955-4169-a20f-743af3a0c3dc

| | | | |
|------------------|------------------------------|---|---|
| 07/10/2021 13:47 | RMH604581-10 | ▲ | |
| 07/10/2021 15:19 | RMH091863-18 | ▲ | ⓧ |
| 13/12/2021 10:39 | RMH378890-97 | ✔ | |

Submission history

For PCN number [b8f2c447-8955-4169-a20f-743af3a0c3dc](#)

Showing 1 to 3 of 3 submissions

| Submission Date | Submission Number | | Submission Status |
|------------------|--------------------------------|---|-------------------|
| 13/12/2021 10:39 | ● RMH378890-97 | ✔ | |
| 07/10/2021 15:19 | ⓧ RMH091863-18 | ▲ | ⓧ |
| 07/10/2021 13:47 | ● RMH604581-10 | ▲ | |

- ii) **the Submission report of the 'Request to disable'**: The Submission status will appear as 'Succeeded' if the request to disable was successfully processed; Submission information will indicate the referenced submission for disabling and the 'Reason for disabling' (as selected from the picklist); Submission events, Submission graph and Submission history will refer to the disabled submission.

[Go to search](#)

Submission status: Succeeded ✓

Dossier type: CLP Poison centres notification Submitted by: Jane Does
 Submission number: RMH378890-97 Purple Haze Chemicals
 Submitted IUCLID version: N/A ECHA-f428c44e-79b3-4f7f-a72b-78e7ceda3be4

Submission information

PCN number [b8f2c447-8955-4169-a20f-743af3a0c3dc](#)

Referenced submission [RMH091863-18](#)

Reason for submission Request to disable the Referenced submission

Reason for disable Submitted dossier contains test data

Recipients (Member States - market placement)

Finland
Germany

Submission events

13/12/2021 10:39 Dossier submitted
 13/12/2021 10:39 Dossier passed validation checks
 13/12/2021 10:41 Dossier disabled in FI
 13/12/2021 10:41 Dossier disabled in DE

Submission graph

PCN number [b8f2c447-8955-4169-a20f-743af3a0c3dc](#)

10/10/2021 13:47 [RMH604581-10](#) ▲

10/10/2021 15:19 [RMH091863-18](#) ▲ Ⓞ

12/12/2021 10:39 [RMH378890-97](#) ✓

Submission history

For PCN number [b8f2c447-8955-4169-a20f-743af3a0c3dc](#)

Showing 1 to 3 of 3 submissions

| Submission Date | Submission Number | Submission Status |
|------------------|--------------------------------|-------------------|
| 13/12/2021 10:39 | ● RMH378890-97 | ✓ |
| 07/10/2021 15:19 | ⚙ RMH091863-18 | ▲ Ⓞ |
| 07/10/2021 13:47 | ⦿ RMH604581-10 | ▲ |

< **1** > Items/page ▼

Appendix 1. Instructions: establishing a foreign user

The following is an example of how to set up a 'Foreign user' in ECHA Accounts.

A foreign user is essentially an external user (i.e. a third party) 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. Check the specific user roles in IUCLID and the ECHA Submission portal which define the user access level in [section 2.3](#).

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.

| Username | Name | Email | User roles | Status | Actions |
|----------|-----------|------------|---|--------|---------|
| JaneDoes | Jane Does | [redacted] | 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 username and UUID provided by the consultant that was sent to her.

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)

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



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 holders 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 parts of the ECHA Accounts interface. On the left, the 'LEGAL ENTITY USERS' section shows a table of users associated with the legal entity 'Purple Haze Chemicals'. On the right, the 'USER INFORMATION' section provides details for the user 'John Smith'.

| Username | Name | Email | User roles | Status | Action |
|--------------|------------|------------|---|--------|-----------|
| JaneDoes | Jane Does | [Redacted] | LE Manager IUCLID Beta Full Access IUCLID Full Access REACH Manager Submission Portal Manager | Active | [Refresh] |
| SafeConsults | John Smith | [Redacted] | IUCLID Full Access IUCLID Trial Full Access Submission Portal Manager | Active | [Delete] |

USER INFORMATION
View and edit the user account details including email

GENERAL DETAILS

First Name
John

Last Name
Smith

Email
heidi.rasikari@echa.europa.eu

Phone

Username
SafeConsults

Creation Date
Jun 11, 2020

LEGAL ENTITY

Primary Legal Entity Name
SaferConsults

Primary Legal Entity UUID
ECHA-1fbcf2cc-b6c0-40af-8c84-65cf5cee2034

USER PROFILE

Roles

- IUCLID Full Access
- IUCLID Trial Full Access
- Submission Portal Manager

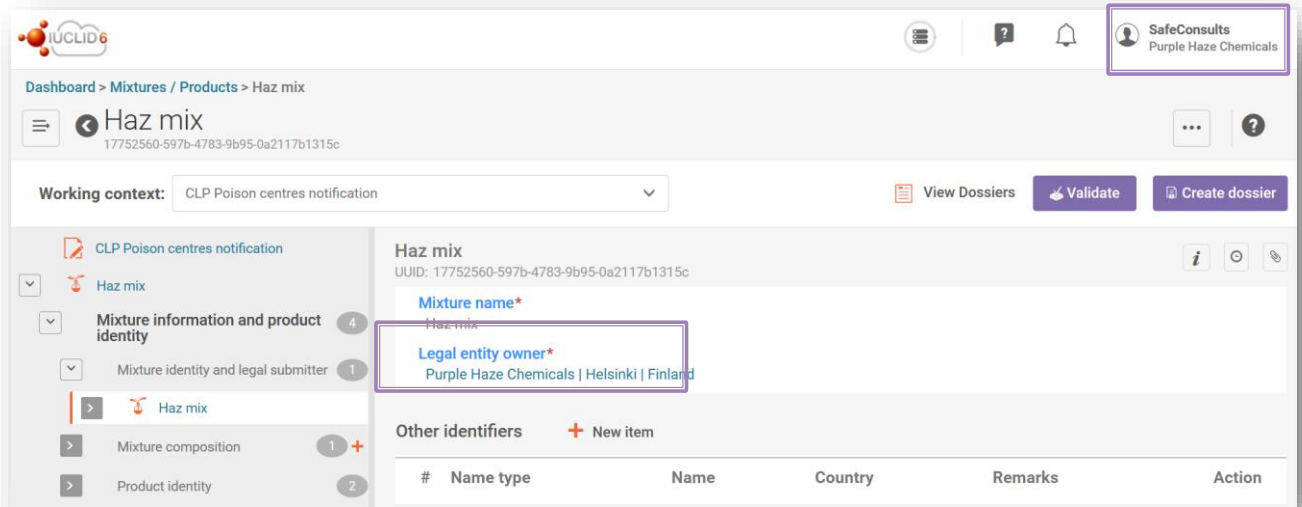
Step 4. The ECHA Cloud services and ECHA Submission portal share the same options in the top bar. From here, the consultant can select the legal entity on whose behalf to work on by selecting Switch legal entity. Note that the foreign user will only see the data relevant to the selected legal entity

The screenshot shows the top bar of the ECHA Accounts interface. The user is logged in as 'SaferConsults'. The 'Switch legal entity' dropdown menu is open, showing the current selection 'SaferConsults' and the option to switch to 'Purple Haze Chemicals'. A hand cursor is pointing at the 'Purple Haze Chemicals' option.

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.

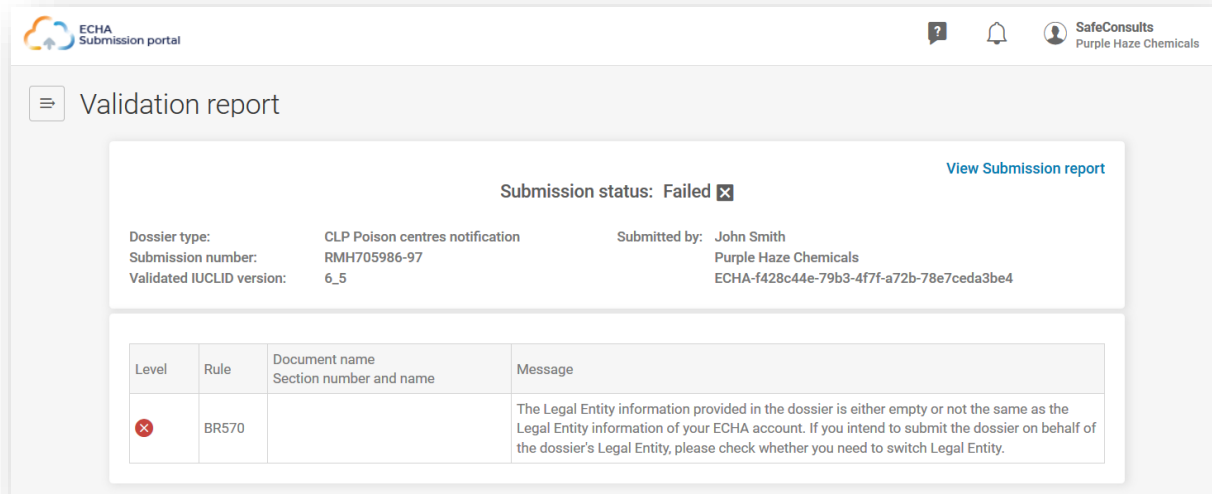
If a consultant is working for many customers, they can use this functionality to move from one customer's data to the other without having to log out and log in again.

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



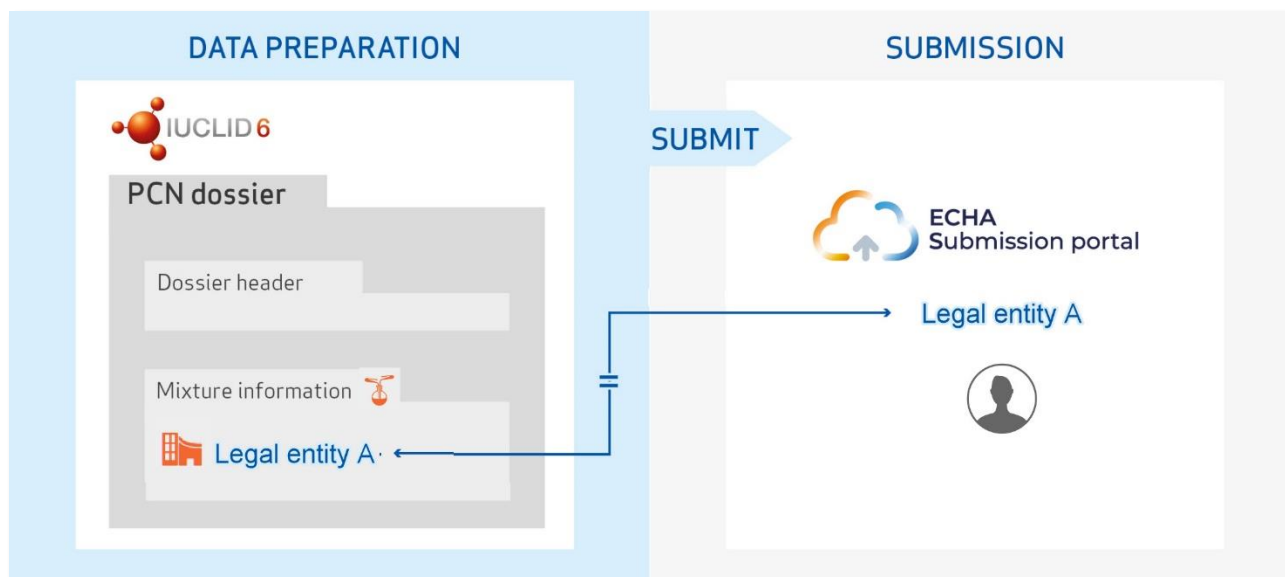
Where local installations of IUCLID are in use, the consultant initiates a notification and assigns it to the Duty Holders legal entity. The consultant switches to the legal entity of the Duty Holder in the ECHA Submission portal when the dossier is ready to be submitted.

⚠ 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.



Appendix 2. Troubleshooting BR570 and legal entity consistency

The Legal Entity UUID in the PCN dossier (indicated in the Mixture information and legal submitter section of IUCLID) must match the UUID number of the logged in user working in the ECHA Submission portal at the time of submission.



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 the notification process, it is essential that all parties 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 number in the PCN dossier. 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 1](#).

 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 second 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 UUIDs associated to the legal entities.

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

 Having two legal entities with the same name but different UUIDs 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.

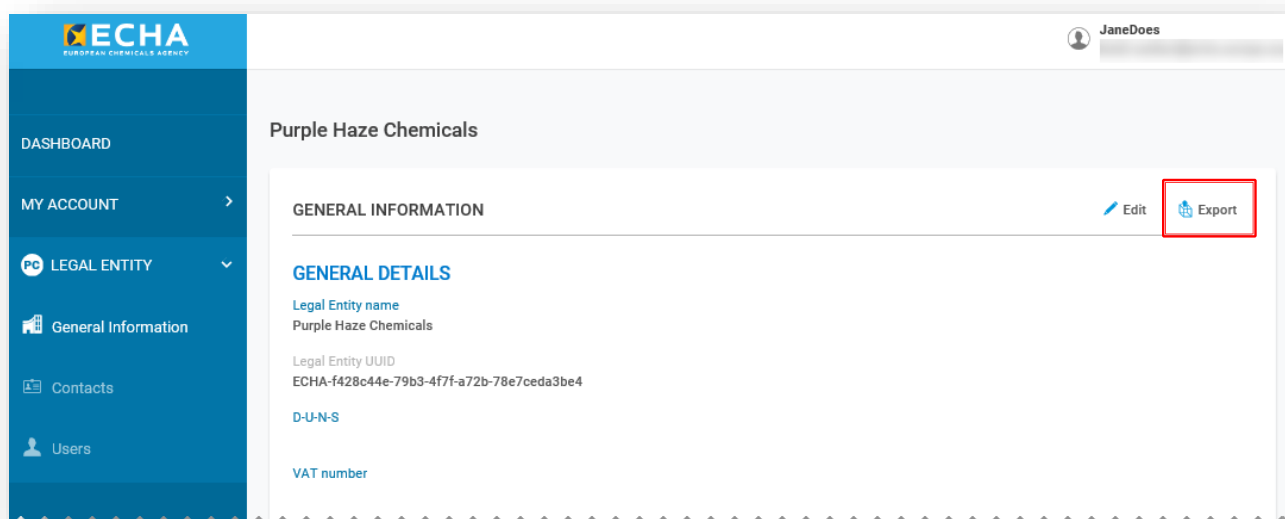
To add/update legal entity details into the IUCLID instance, the following steps are required:

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 submitters S2S keys.

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

- Consultant or other 3rd 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.

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 submitters legal entity (at the mixture level).
3. The third party submits the dossier in the ECHA Submission portal using the legal submitters S2S key.



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

