POISON CENTRE NOTIFICATIONS

Instructions and info sheet for preparing in IUCLID dataset view mode

Safer Chemicals Conference

02 June 2020

Contents

1. General outline

Welcome to the training session!

This session covers how to create an initial and update dossier for a poison centre notification using the dataset view mode.
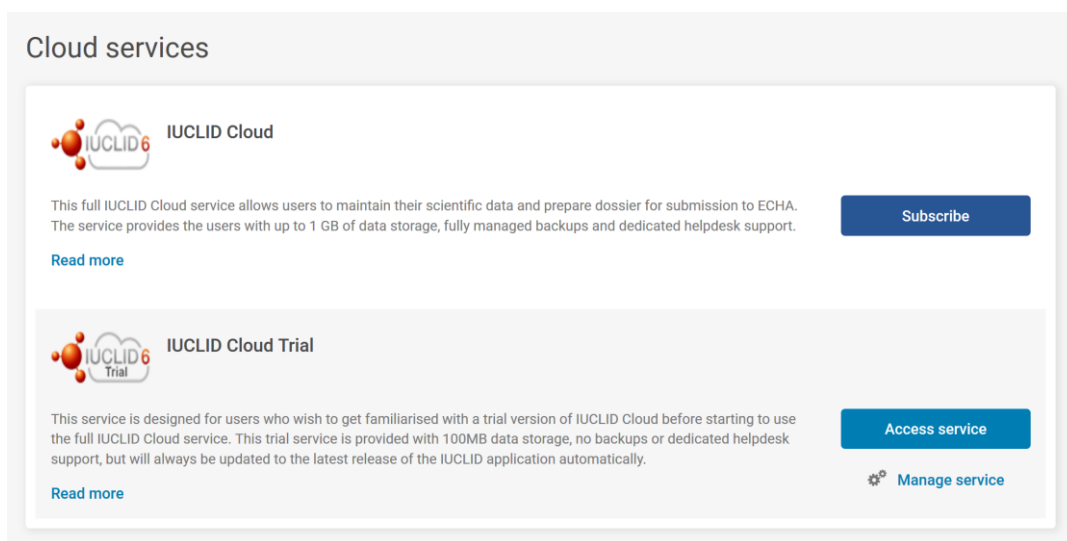
These instructions are based on example data for the purposes of explaining various procedures and functionalities and do not in any way represent real existing data.

Working environment
Data preparation using

- IUCLID 6 offline, downloaded from the IUCLID website (https://iuclid6.echa.europa.eu/)

- ECHA Cloud services online (active subscription required https://ecs.echa.europa.eu/cloud/home.html)

! Select **IUCLID Cloud trial service** to avoid mixing text data with production data.

Method of working
Follow the online demonstration and use these instructions (containing a pre-prepared PCN preview report in Annex 1), you will find all the information you need to guide you through this four-part training session.

? If you have any questions, you can submit them to the ECHA Helpdesk using the form https://comments.echa.europa.eu/comments_cms/Contact_CLP.aspx

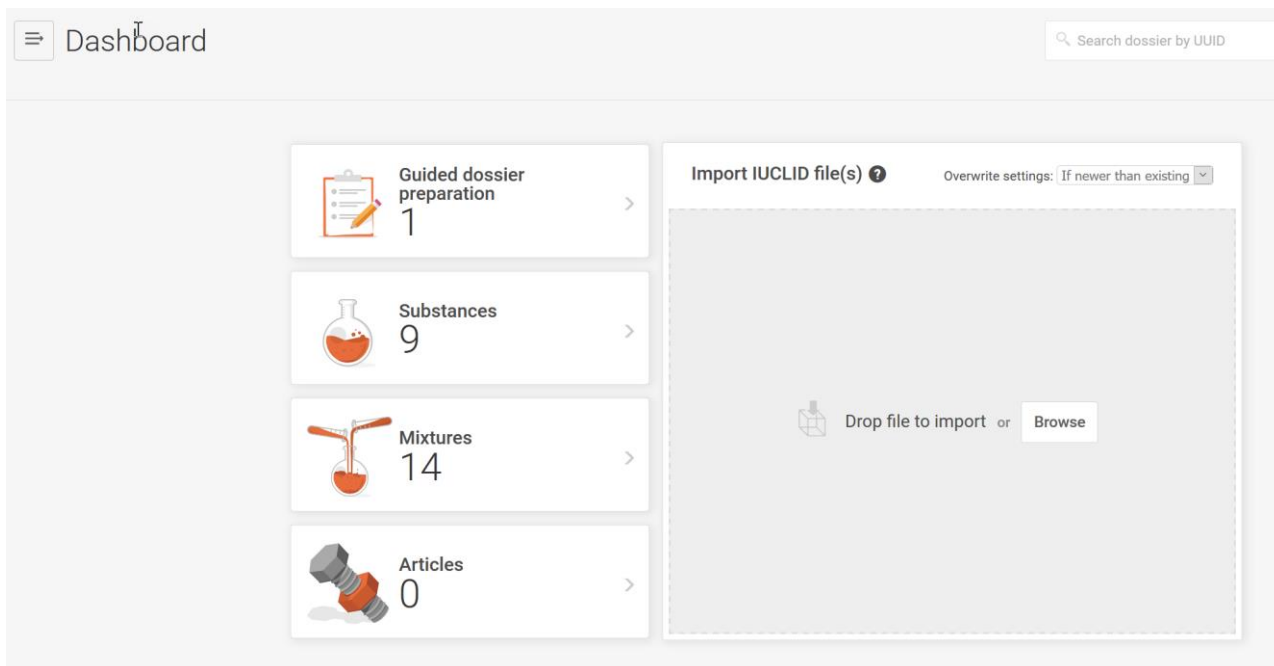## 2. Additional information before you begin

About the mixture and notification

The notification will cover standard information requirements and be prepared for two different Member States i.e. a multimarket submission. One initial notification will be prepared, followed by a simple update.

The mixture contains two substance components, and one mixture in mixture component (MiM). The full MiM composition is not known.

The dashboard

The IUCLID dashboard hosts the substances and mixtures widgets from which you will create your substance, mixture in mixture, and final mixture/product datasets and dossier from. These instructions do not cover the Guided dossier preparation, nor the Articles widgets.
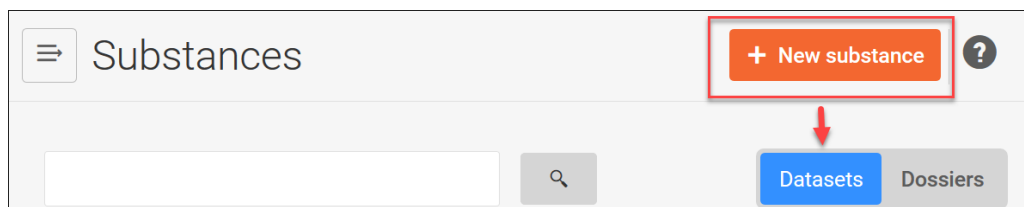
Creating and customising a dataset

From the substances widget on the dashboard, you arrive at the substances listings. Select New substance to create a new substance dataset (see screenshot below)

Similarly, from the Mixtures widget on the dashboard, you arrive at the mixture listings. Note it is possible to toggle between the listed datasets and dossiers. Select New mixture/product to create either a mixture in mixture dataset, or a mixture/product dataset (i.e. the final mixture).
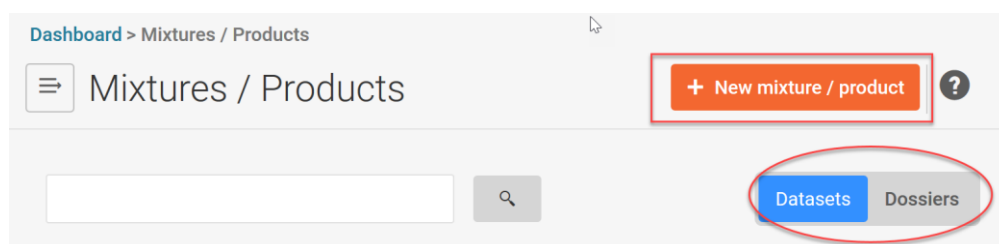
Each dataset needs a name before it can be opened and information entered.

The dataset can be customised for 'CLP poison centre notifications' by selecting from the Submission type picklist the relevant type i.e. for substance information; mixture in mixture information, and final mixture/product information.

To enter information, you will need to create new documents, and in some cases New items.
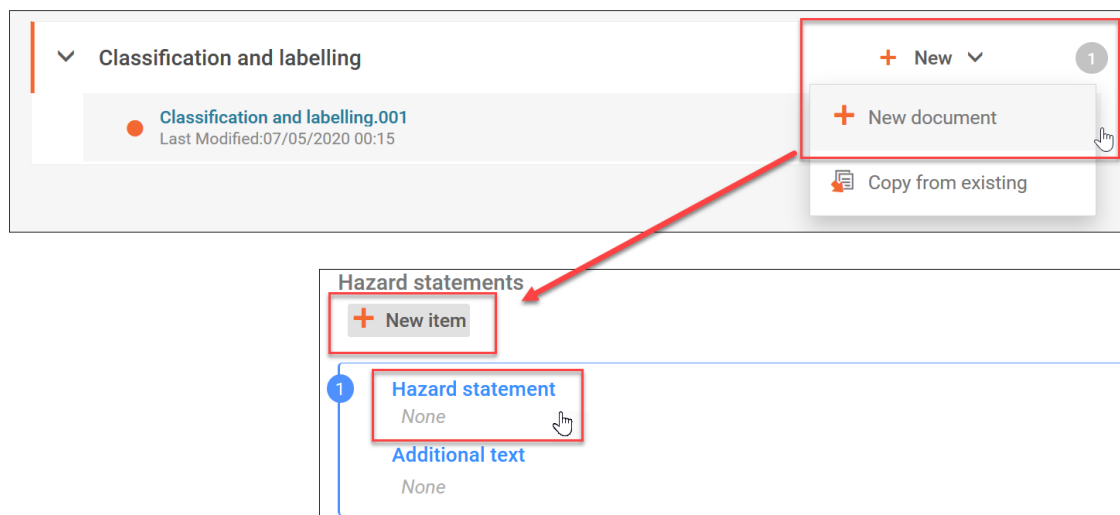
Classification and labelling

IUCLID shares documents such as the classification and labelling, for the substance, mixture in mixture, and mixture/product datasets across numerous legislations. For this reason, the labelling information fields will appear in the substance and mixture in mixture dataset even though it is not required for the components.

A recent development for the C&L document is the Calculate labelling function which calculates labelling information based on the classification entries included in the previous section.

PART 1 - Substance dataset creation

A dataset must be created for each substance component plus each substance component of a mixture in mixture (MiM). Every substance must be linked to a reference substance and the classification information provided.

For this demonstration, refer to the PCN Preview report for the example data to assist you with the identification of the training mixture components.

This section will cover:

✓ Creating a PCN customised substance dataset
✓ Creating / downloading a reference substance
✓ Linking a reference substance to the substance dataset

For the purpose of this exercise, your mixture consists of three components;

1. Perfume substance #1 - a generic product identifier (GPI)
2. Substance #2 – a substance component (not classified)
3. MiM #1 - one mixture in mixture component containing two known substances, substance#3 and substance#4, and one unknown substance:
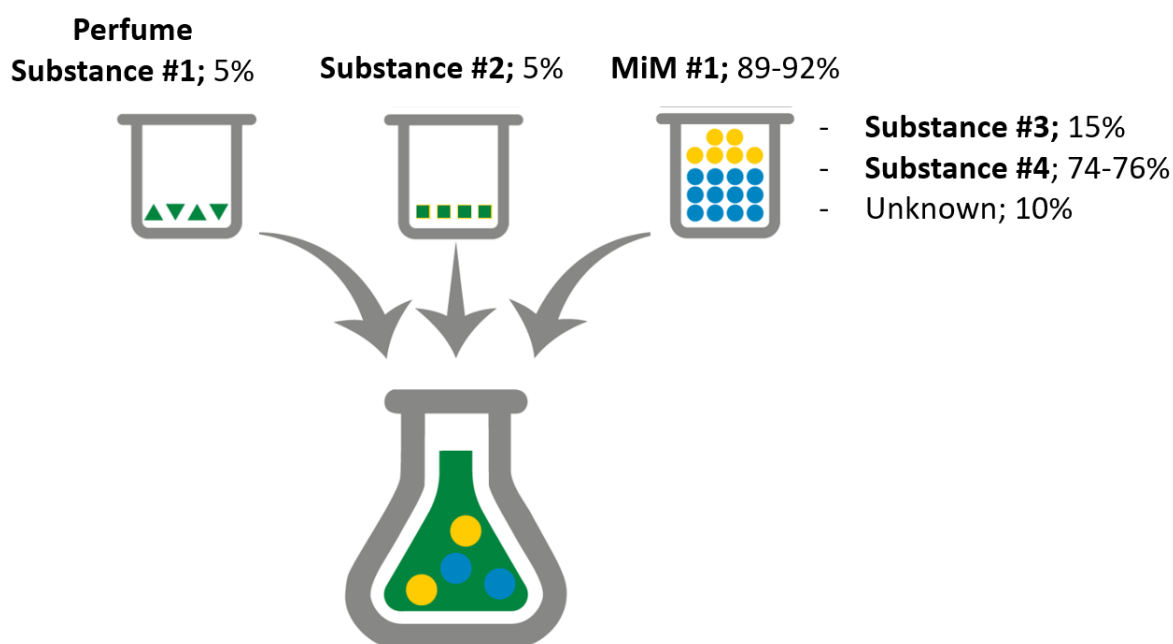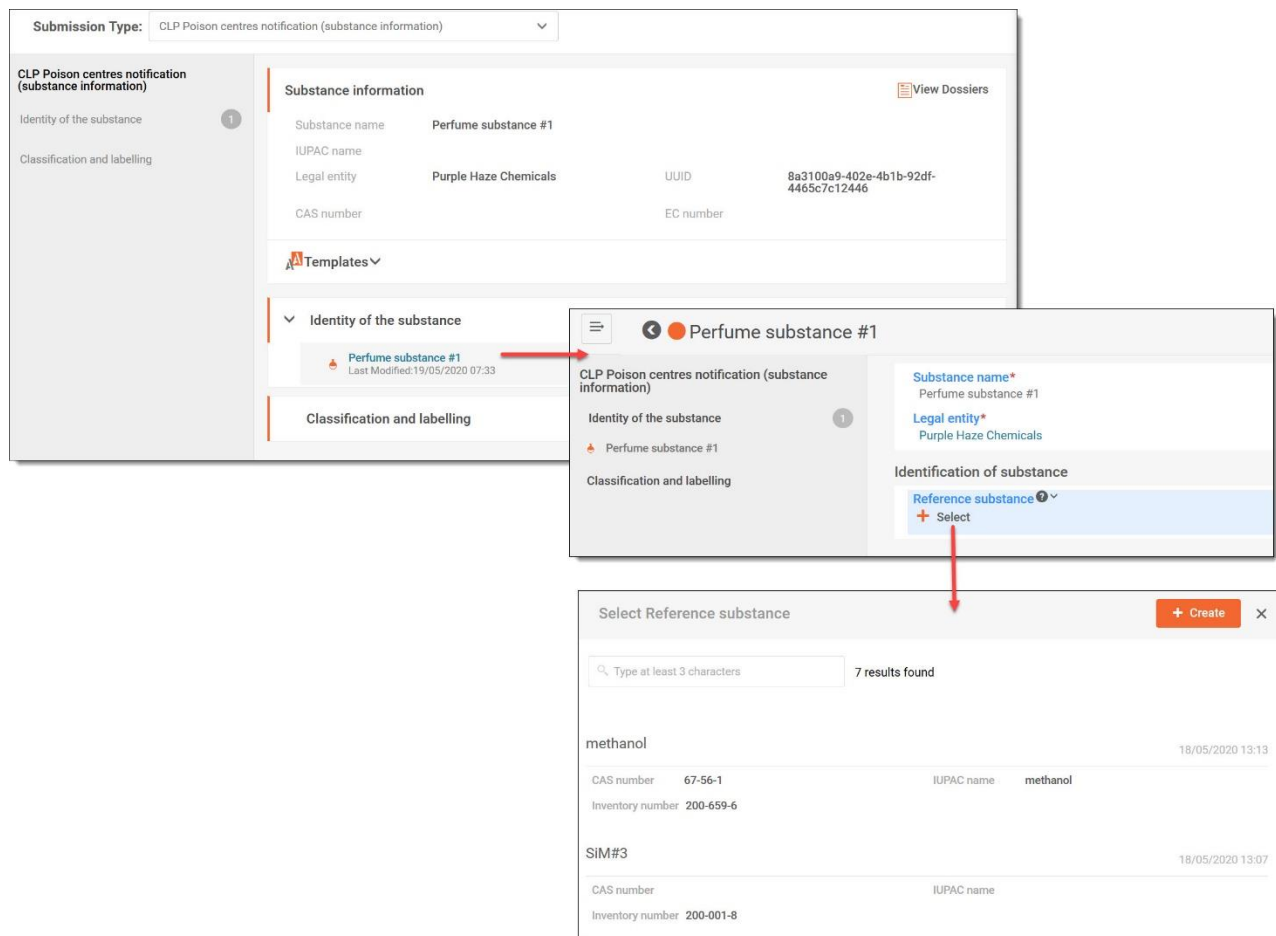
Perfume Substance #1; 5% **Substance #2;** 5% **MiM #1;** 89-92%
- **Substance #3;** 15%
- **Substance #4**; 74-76%
- Unknown; 10%

Exercise: Create individual substance datasets for each of the four substances in your mixture and link each to a valid reference substance.

Steps:

1. To create a substance dataset, select Substances from the dashboard and create a click on New substance dataset.

2. Give the dataset a name, e.g. Perfume Substance#1. Select Create and open the document

3. Customise the document by selecting CLP poison centre notification (substance information) from the Submission type list.

4. Click on the blue hyperlinked name of the substance -> Click on Reference substance to create a link to the reference substance information
(see below for substances 1-4).

a) **Perfume substance # 1**- will be declared as a generic product identifier (GPI). GPI declaration can only be made under certain conditions, and when these conditions are fulfilled, linking to a reference substance is not mandatory.
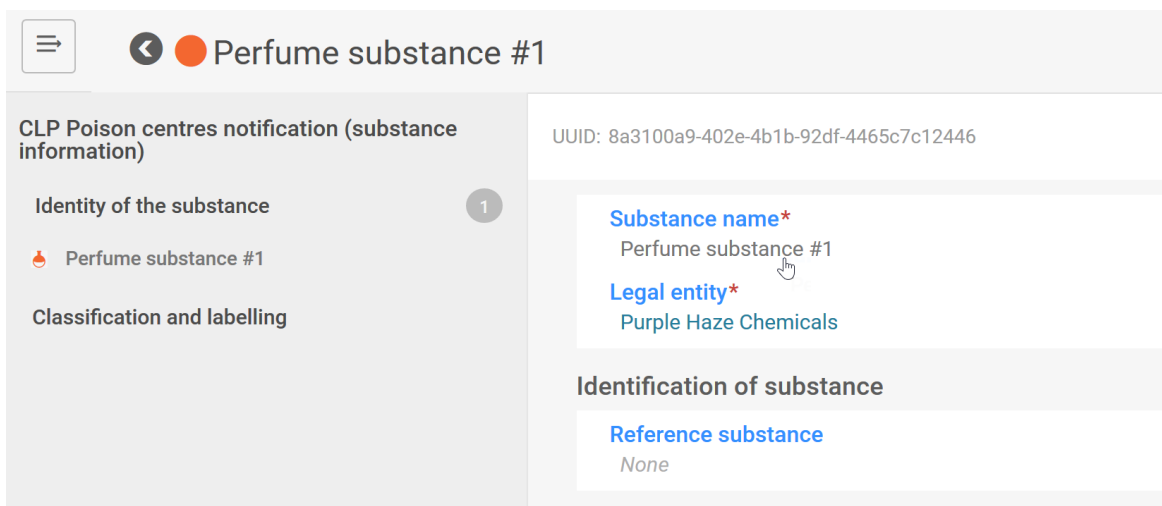
➔ Note that it is possible to modify the Substance name if preferred to another name that suits for the management of your data.
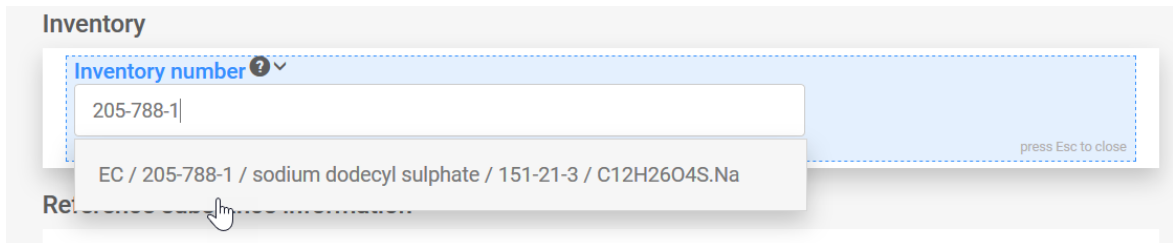
b) **Substance #2**- Select create from the Reference substance page and enter the substance identity information manually using 'IUPAC nomenclature'. This example uses *(rel)-10âH-trans-12î-(2-methylbut-2(E)-enoyl)-1â-(isobutanoyl)-6á,13î-dihydroxyclerodan-4(20),8(18)-dien-7,15-dione-15,16-oxide*
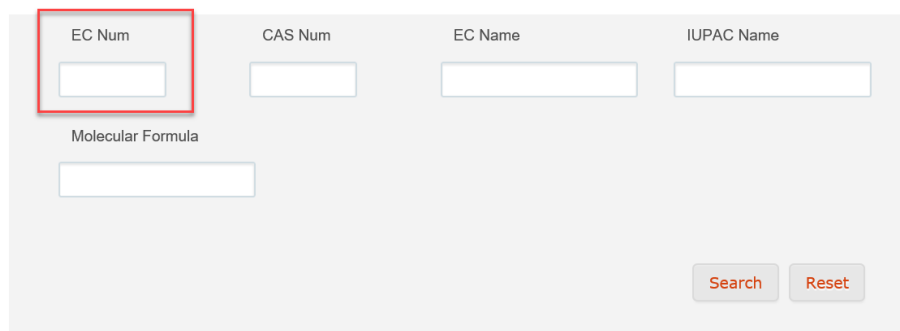
c) **Substance #3** – Select create from the Reference substance page and click on the Inventory field. Search by EC number for the relevant entry. This example uses EC 205-788-1
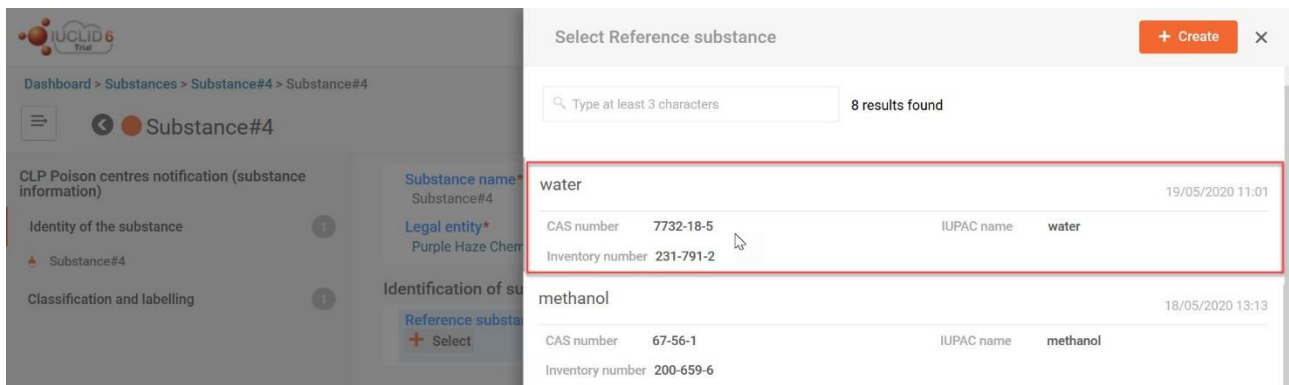
d) **Substance #4** – select an available reference substance from the list, which has been downloaded from the IUCLID website. This examples uses water; EC 231-791-2

➜ To download, go to the IUCLID website (https://iuclid6.echa.europa.eu/get-reference-substances), search (e.g. by EC number) and download the .i6z file of the relevant substance to your desktop. **TIP:** the reference substance should be saved as .i6z file so it can be imported in IUCLID - note that Internet Explorer, changes the file extension from .i6z to .zip.

➜ Import the substance into the import box on the main dashboard (see section 1 'The dashboard'). After successful import, it will appear in your list of existing Reference substances.

5. For each substance, you need to enter the Classification information in the C&L document (see section 1 'Classification and labelling').

   a) For substances that are not classified check the Not classified box.

   ➢ Perfume substance#1 and substance#4

   b) For substances that are classified, make a selection from the Hazard categories and statements drop down list

   ➢ Substance#2

      Skin Irrit. 2-H315: Causes skin irritation

   ➢ Substance#3
      Flam. Solid 2-H228: Flammable solid;
      Acute Tox. 4-H302: Harmful if swallowed;
      Skin Irrit. 2-H315: Causes skin irritation;
      Aquatic Chronic 3-H412: Harmful to aquatic life with long lasting effects.>
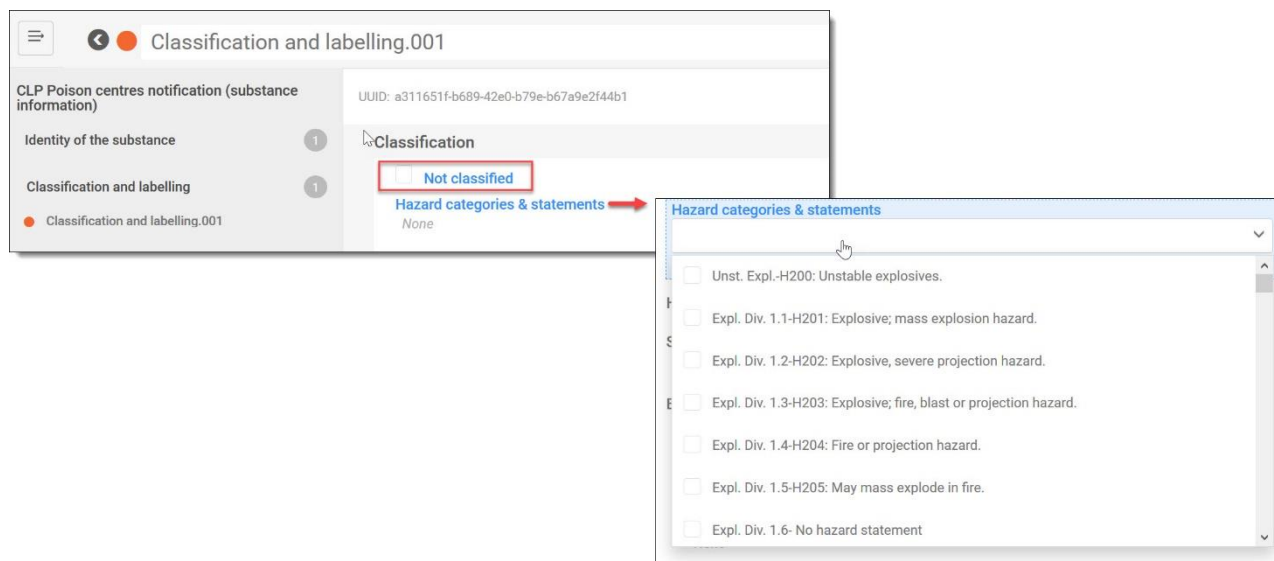
6. Labelling is optional for substances though you can utilise the 'Calculate' functionality (See section 2, Classification and labelling).

   ! When using the Calculate function, it is the notifiers responsibility to ensure correctness of the generated results. Therefore it is possible to make deletions or additions where needed.

PART 2 - Mixture in mixture (MiM) dataset creation 🍹

The MiM dataset contains a number of documents – the information you use to identify the MiM, will determine which documents and fields you are required to complete. For example to declare a MiM when the composition is not fully known there are three options:

    a) if UFI was previously notified to the relevant Appointed body

        –> UFI and **product identifier**

    b) if UFI is available but not previously notified to the relevant appointed body

        -> UFI, SDS composition, product identifier and **supplier's details**

    c) If no UFI is available

        -> SDS composition, product identifier and **supplier's details**

This exercise will cover:

✓ Creating a MiM dataset
✓ Correct declaration of MiM components

For the purpose of this exercise, the MiM UFI has been submitted to all EU Member State Appointed bodies.

Exercise: Create a MiM dataset and enter the information required to adequately identify the MiM component.

Steps:
1. Select Mixtures from the dashboard and create a new mixture/product dataset.

2. Give the MiM dataset a name and open the document

3. Customise the document by selecting CLP poison centre notification (mixture in mixture) from the Submission type list.

4. The following documents need to be created and completed using the data available in the PCN report. Note that not all are mandatorily required.

MiM composition

5. Add a new Document -> select new Component item
6. In the Name field, select Substance then specify Substance #3 and add the concentration (check PCN preview report).
7. Similarly, initiate another new Substance component item and specify Substance #4 and include the concentration (Check PCN report).

MiM UFI

8. Add a new Document -> select new UFI item
9. In the ID field, enter the UFI as provided by the supplier (check PCN report)

MiM suppliers

10. Add a new Document -> click on the Name field to select an existing legal entity or create a new one.
11. When creating a new one, enter as a minimum, all the relevant fields;

MiM classification

12. Add a new Document -> select either that the MiM is not classified or indicate the various hazard categories and statements.
13. The labelling information is not a requirement but can be added voluntarily.

MiM safety data sheets

The SDS is not a requirement but it is possible to add one in addition to the provided information above.

14. Add a new Document -> select new SDS item
15. A SDS file can be uploaded, the country and language specified.

PART 3 - Mixture/product (final) dataset creation

A mixture dataset must now be created for final mixture, bringing together all the previously created substance and MiM components plus including all relevant information about the final mixture and any associated products being placed on the market.

This exercise will cover:

✓ Creating and customising the dataset for the final mixture

✓ Specifying the notification in the dossier header

✓ Creating Endpoint study records and documents

✓ Linking the dataset substance and mixture components to the notification

✓ Specifying a GPI component

✓ Generating and adding a UFI

✓ Providing the mixture specific information

✓ Providing the product specific information

✓ Providing information in the multilingual fields

✓ Attaching documents

Exercise: Create a mixture/product dataset and enter the information required to adequately identify the mixture and it associated products

Steps:
1. Select Mixtures from the dashboard and create a new mixture/product dataset.

2. Give the final mixture dataset a name and open the document

3. Customise the document by selecting CLP poison centre notification from the Submission type list
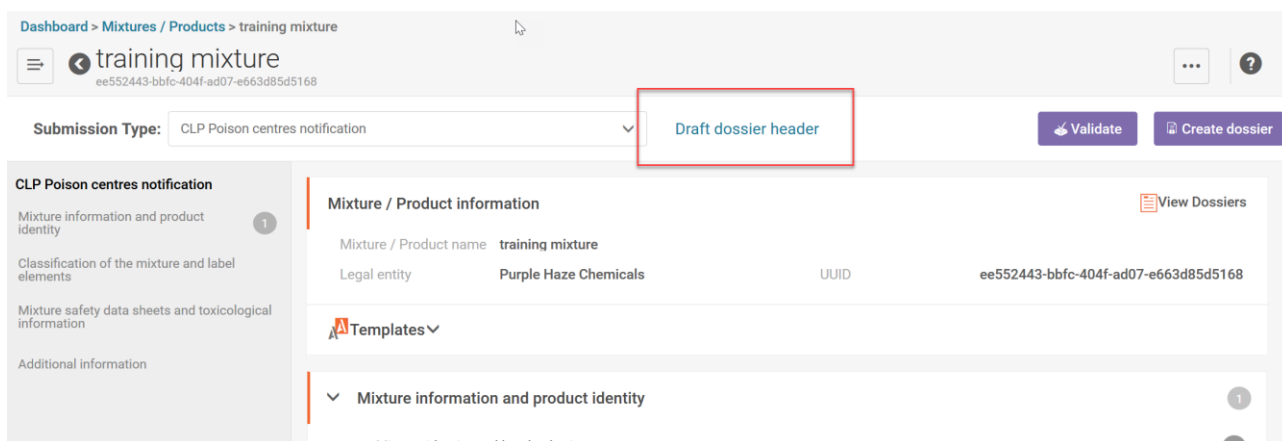
Dossier header

Before we begin entering information into the PCN customised dataset, we must first enter the details into the dossier header. The dossier header forms the submission context and assists the system to create certain e.g. multilingual or mandatory fields, and apply the validation rules accordingly. Note that not all information is mandatory to provide.

Exercise. Complete the dossier header according to the PCN report in the dossier header.

Steps:

1. Open the dossier header by clicking on Draft dossier header

2. Name your dossier and enter the relevant details for the submission.

Tip:

! When the dossier header is created, it is automatically aligned to a standard submission type. If the submission type differs from standard, then the appropriate selections need to be made (see screenshot below).

CLP Poison centres notification

Dossier name (given by user)
Training dossier 1

Dossier submission remark
None

Specific submissions

PCN number*

11ab682a-68b1-4f5c-8b14-da6b0611f3f1

36/255

Country (market placement)*
✓ Finland
✓ Sweden

Language*
✓ Finnish
✓ Swedish

Submission type

☐ **Limited submission (industrial use only)**

☐ **Group submission**

☐ **Voluntary submission**

Notification type

☐ **Initial notification**

☐ **New notification after a significant change of composition**

☐ **The submission is an update**

Specify the mixture components

You have already done the work identifying the components of your final mixture. In this part of the IUCLID dossier you need to make a link to all of them and enter the concentrations.

Exercise: Once you have created a new Mixture composition Endpoint study record, create a component document for each component (i.e. 1 substance and 1 MiM) and enter the corresponding information for each.

Steps:
1. Create a single mixture composition Endpoint study record (Not Endpoint study summary)
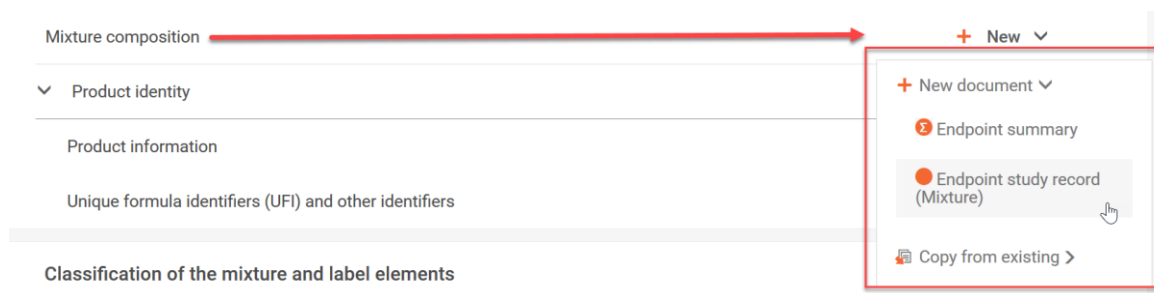
2. Link to the components by selecting New item, and in the Name field, select Substance (or Mixture/product) from the picklist (not reference substance).
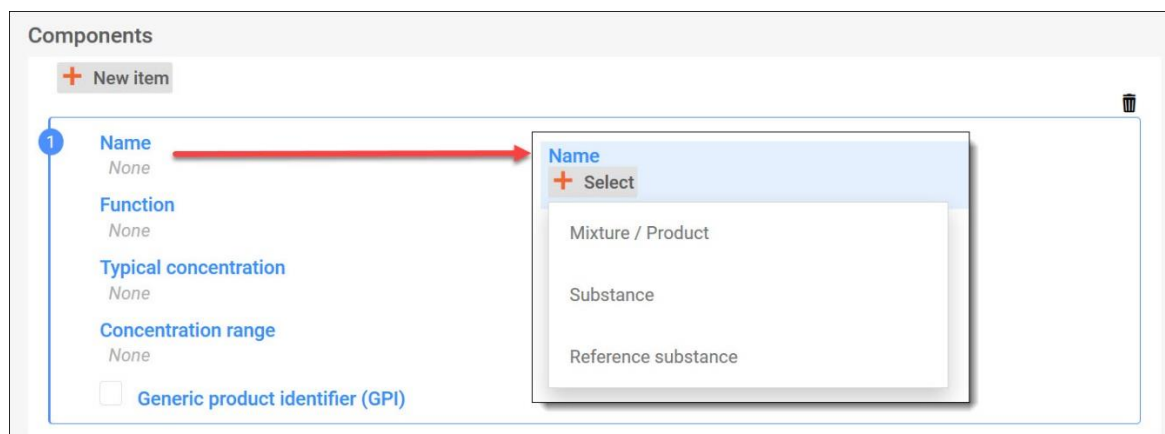
3. Select the component from the list of substances available.

4. Add the information for the concentration according to the PCN preview report.

5. If the component is a generic product identifier, check the GPI box and the function becomes mandatory.
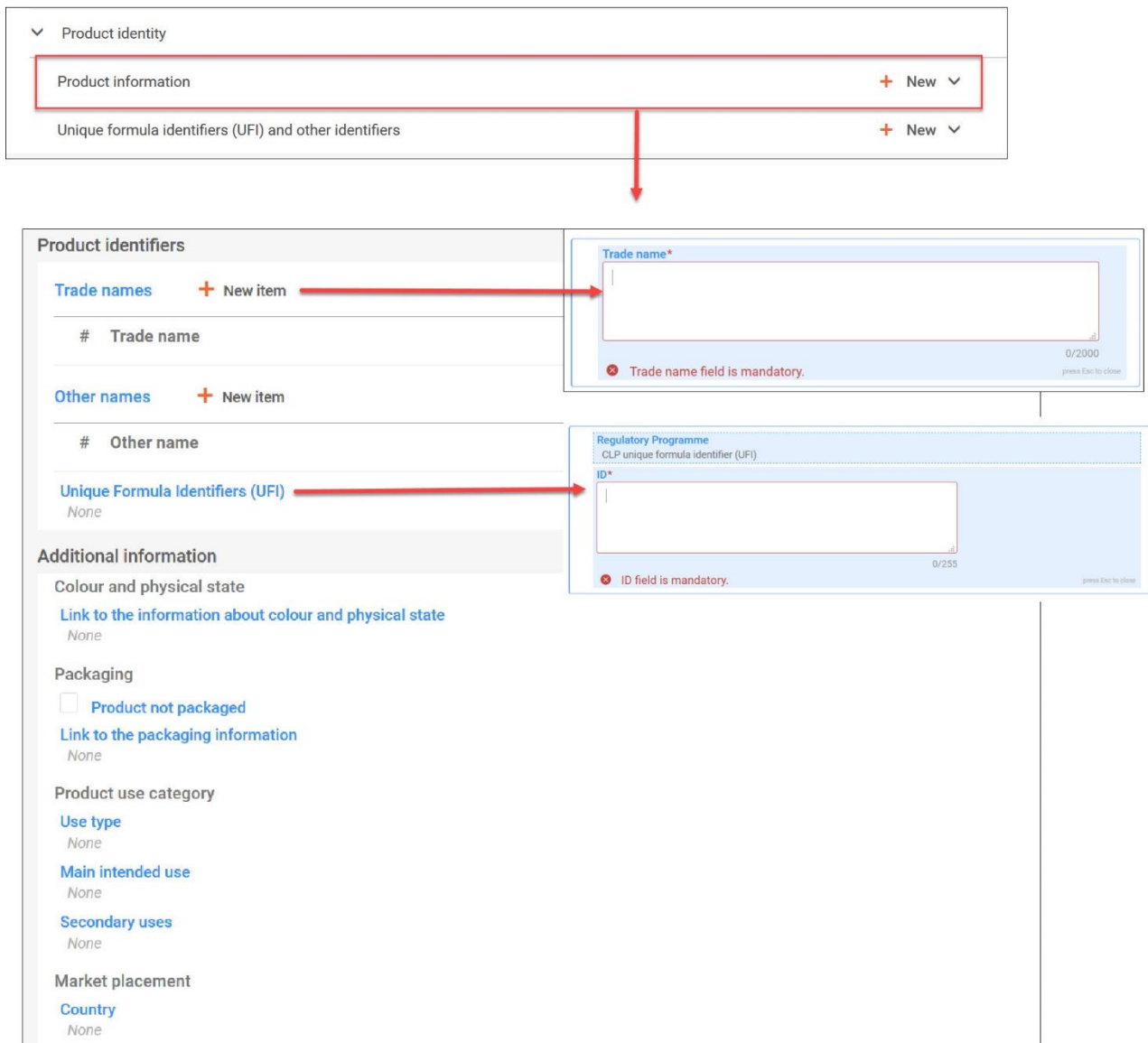
Complete the product identity and information

The product identity contains information about the product such as trade names, packaging and uses, plus information about the UFI assigned to it.

Before you begin - For this section, you will first need to create your own UFI using the UFI Generator https://ufi.echa.europa.eu/#/create). Select that you do not wish to provide the VAT number and enter a mock formulation number.

Exercise: Create a new Product information record and provide the relevant information, by entering the data, or making a selection from the picklists, that correspond to the information contained in the PCN preview report.

TIP: You will need to select the countries of market placement that match what you selected in the dossier header.

Complete the Classification and labelling information

The classification of the mixture and labelling document can be completed based on the information provided in the attached PCN preview report.

Exercise: Create a single C&L document (only one is permitted) and provide the information for the final mixture

Steps:

1. Create a new document for the C&L section
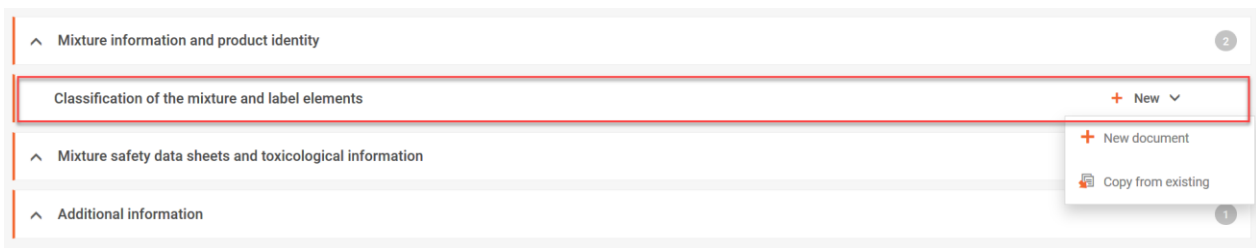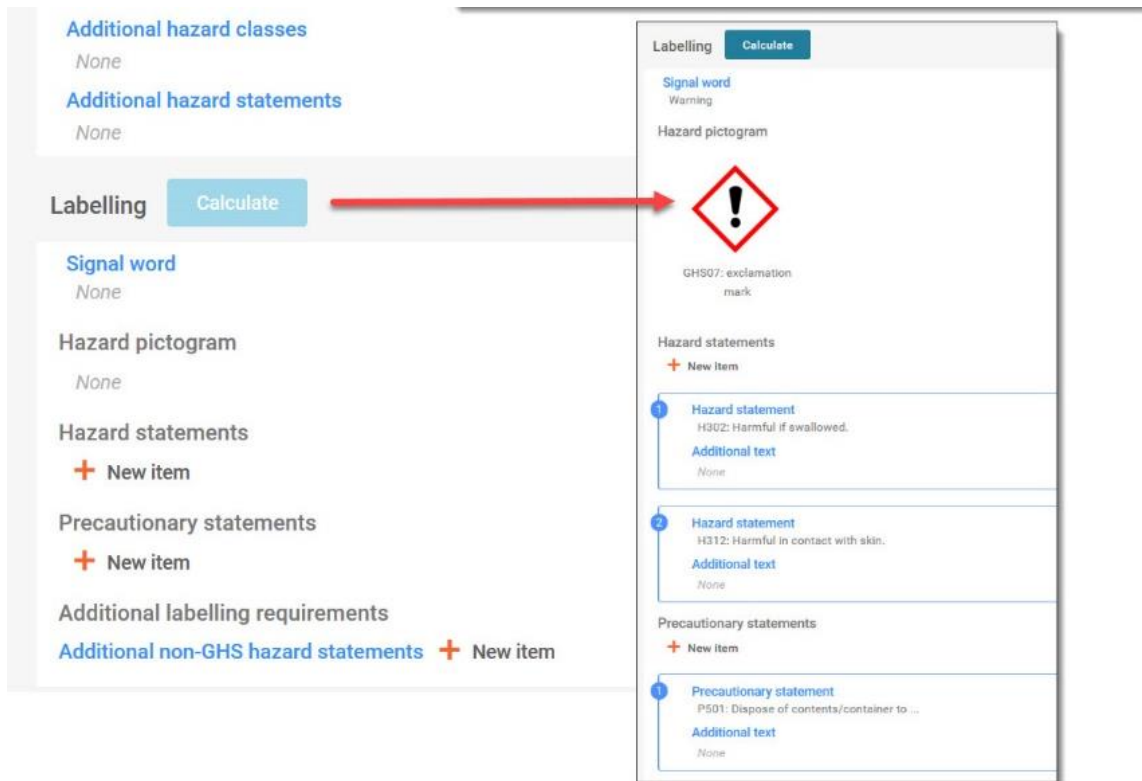
2. Click on the blue hyperlink Hazard categories and statements and make a selection from the picklist available according to your PCN preview report. You may optionally add any other relevant information (e.g., additional hazard classes, environmental hazards).
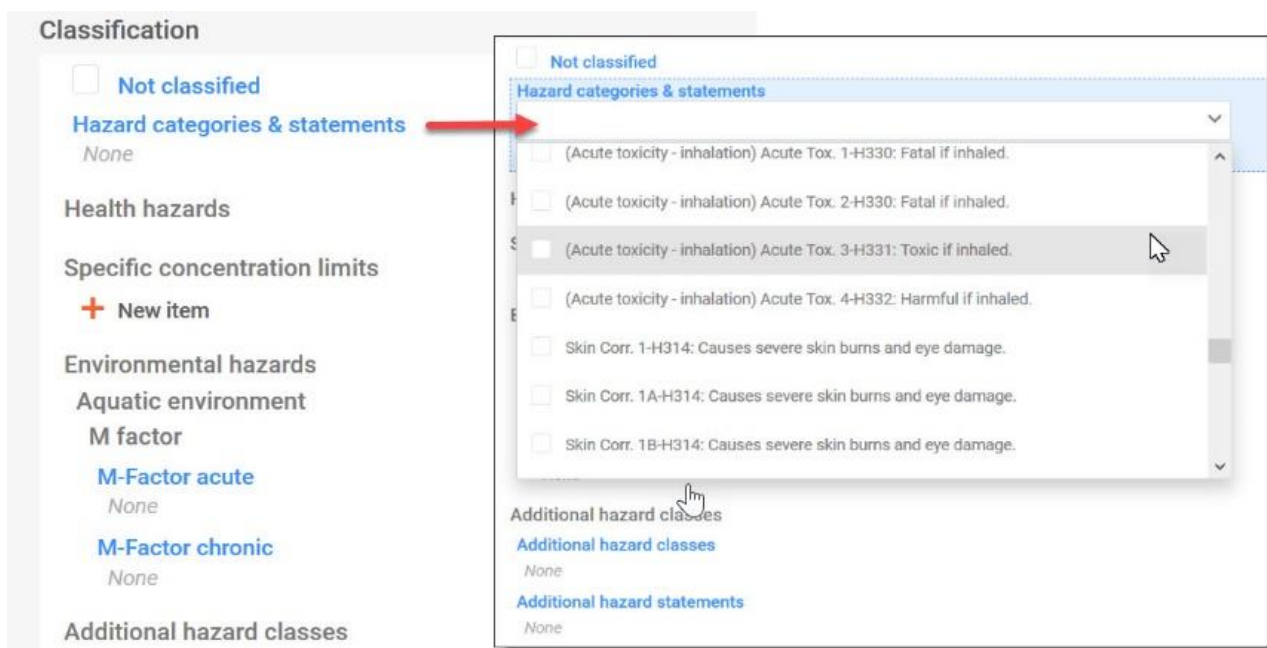
3. Use the Calculate function to automatically retrieve information– checking the information generated is the responsibility of the notifier.

4. Check for free text fields which may require translating in all relevant languages, e.g.

Complete the toxicological information

Toxicological information is free text information and must be provided in all the relevant languages. Only one document is allowed for the toxicological senction.

Exercise:

Create the toxiclogical information document and complete all relevent multilingual fields using the PCN preview report as a reference source.

Steps:

1. Create a new document for the MSDS and toxicological sectiion
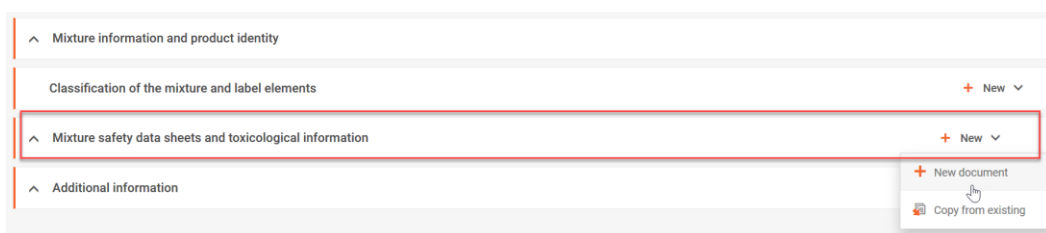
2. Click on the toxicological field and notice the multilingual fields that have been created. Enter some dummy data for both languages, or use copy/paste.

3. Add a mock SDS document by clicking on New item – then click on the created item to select and attach your file and complete the fields.
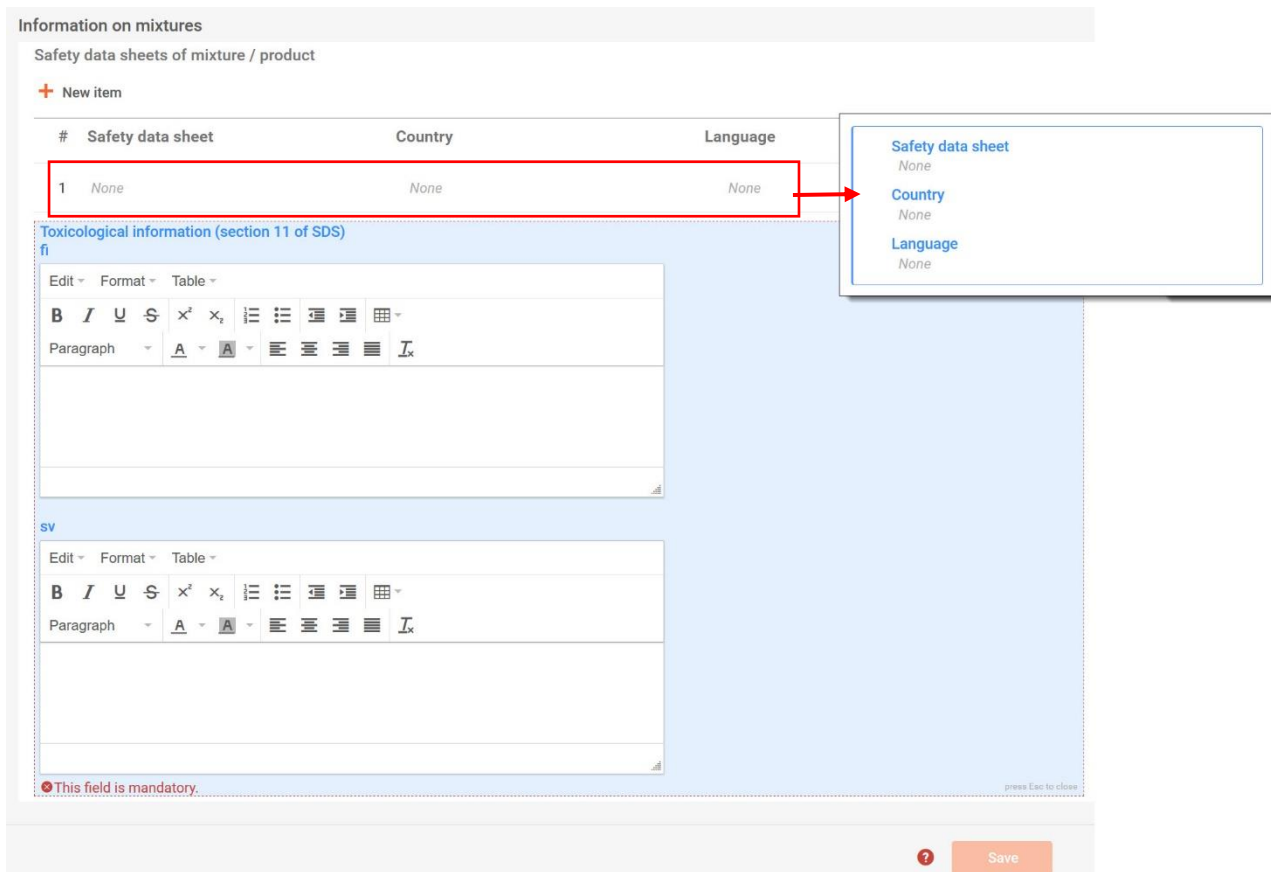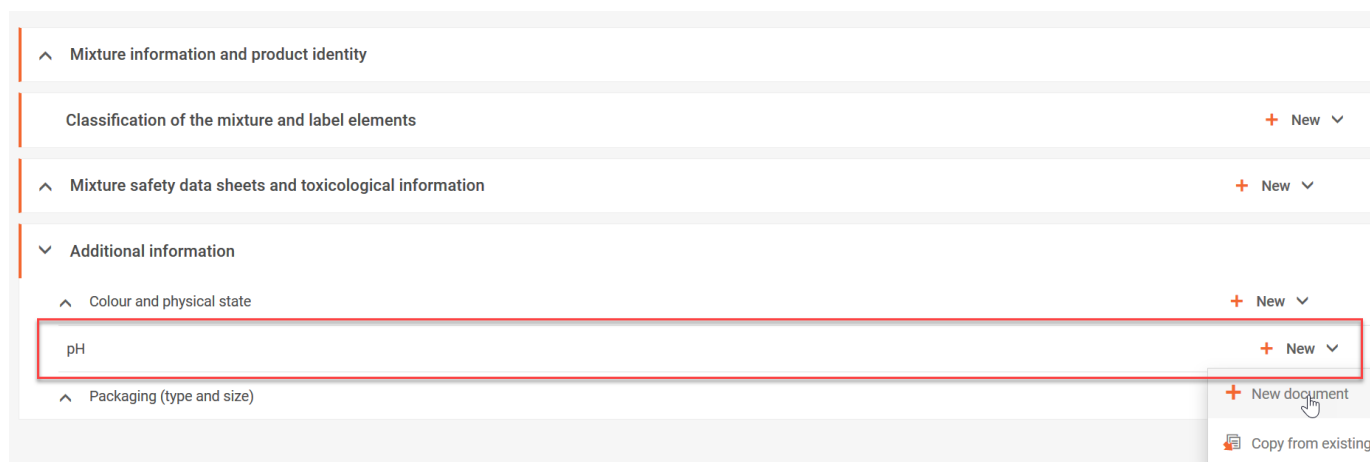
Additional information

This section contains a number of documents that were originally created already in the product identity section e.g. physical state and packaging type and size.

Exercise: Complete the pH information

Steps:

1. Create a new document for the pH

2. Enter the data for the pH and the Solution concentration.

For the purpose of the next part of the training session on validation and correction of failures – indicate here the value 'ca.' which will **trigger a validation rule failure**

3. Take note of the operators, ranges and decimal points used – see below for the various business and quality rules in place concerning the pH.
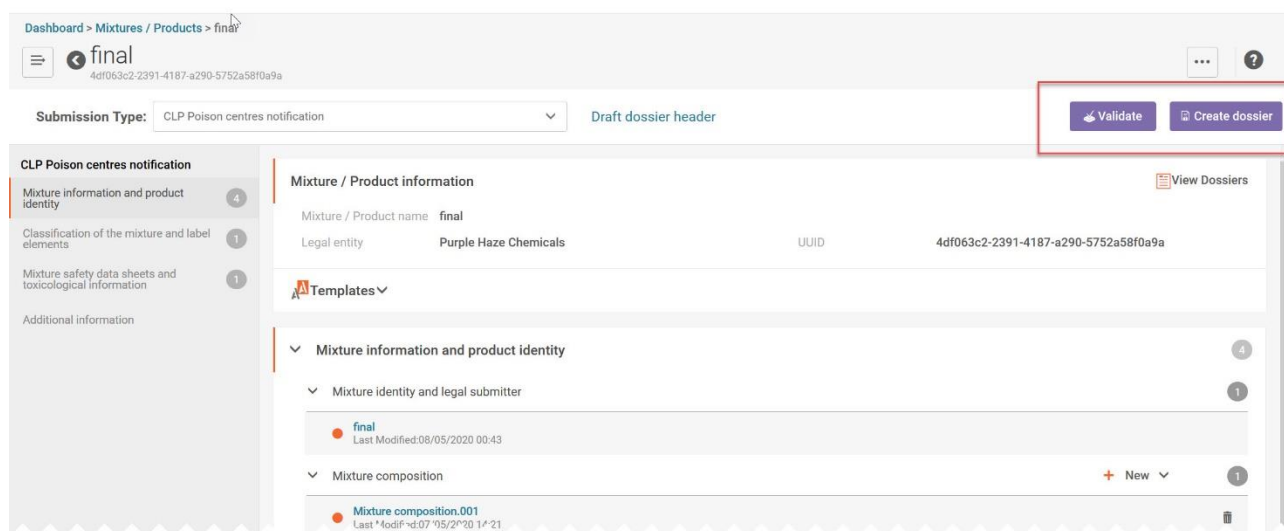
   All rules are listed in the validation rules annex (v.3.0) available from the PCN format support page https://poisoncentres.echa.europa.eu/poison-centres-notification-format.

pH		
BR512	Exactly one 'pH' record must be provided.	S, L
BR545	Either 'pH not relevant' must be selected or a pH value must be reported (one value or range).	S, L
BR524	Allowed pH values: -3=< pH =<15	All
BR615	Allowed pH qualifiers: one value cannot have qualifiers, range cannot have 'c.a.'.	All
QLT504	pH value must be indicated as an integer or specified to one decimal.	All
QLT501	Maximum pH value range width is 1 unit (when pH =<3 or >=10).	All
QLT510	Maximum pH value range width is 3 units (when pH 3 < pH <10).	All
BR585	If pH is relevant, 'Solution concentration' must be provided.	All

PART 4 - Validate the information, create a dossier and prepare an update

From the main mixture page you will find the Validate and Create dossier functions.

With over 120 validation rules in place validating your information is highly recommended to avoid business rules failure. That said, there are a number for rules that can only be checked in the system after submission

This exercise will cover:

✓ Validating information / correcting information

✓ Creating a dossier for an initial submission

✓ Viewing a dossier

✓ Generate a PCN preview report

Exercise: Validate your dossier ensuring there are NO business rule failures.

- If there are failures, proceed to correct them by returning to the specified document.

- If there are no failures, proceed to dossier creation.

Steps:

1. From the main page, first select Validate, and the dossier header will present itself for you to review and check.

2. If all the information is in order, click on Validate

3. Check and correct any failures. Business rule failures are listed by the section e.g. pH, and the code e.g. BR615 and an error message. In most cases, the failure messages contains a hyperlink back to the section to correct it.

If you indicated in the ca. value in the pH section, this will have triggered a failure – see below.
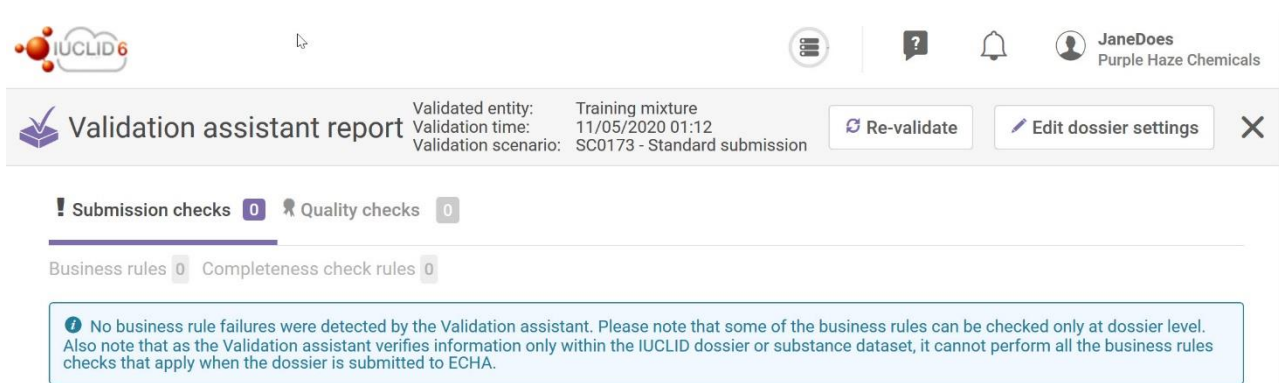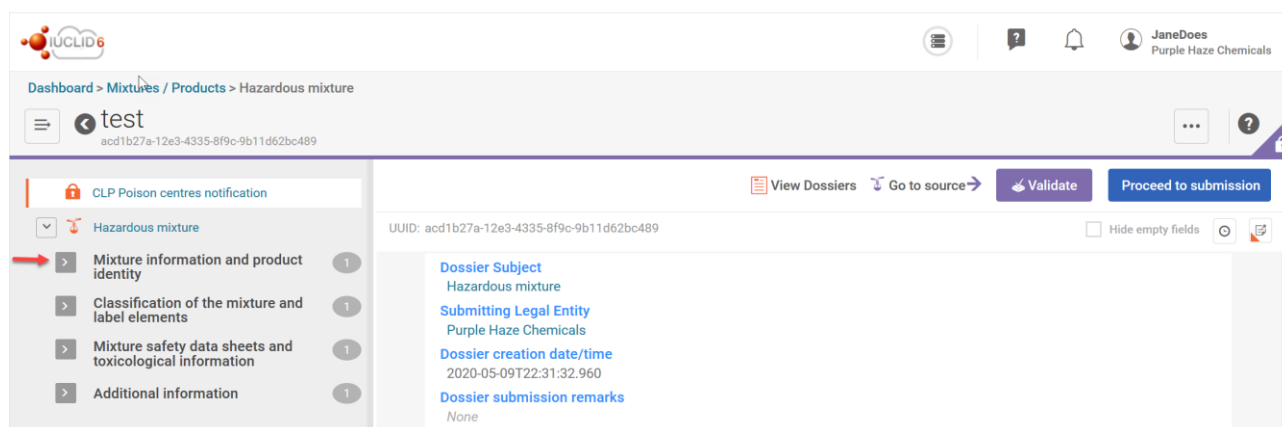
Note! Submitting a dossier that knowingly has failures will not be accepted by the ECHA Submission portal. Other rules, such as quality rules (QLT) will trigger a warning. Dossiers containing quality issues will be accepted by the system but will be alerted to the Appointed Body upon receiving the notification.

4. When the dossier has no reported errors, proceed to Create dossier by first clicking on the ✖ in the top right hand corner, then selecting 'Create dossier'

5. When your dossier has been successfully created, open it to view the contents in dossier view mode – ensure you click on the items to expand the view.

! IMPORTANT - If you are working in the Cloud Trial, the button Proceed to submission' will be disabled. This is to ensure that test dossiers do not get forwarded to the Member States' appointed bodies.

6. To generate a PCN preview report, Click on '…' and select Generate report –>
    PCN Preview report.
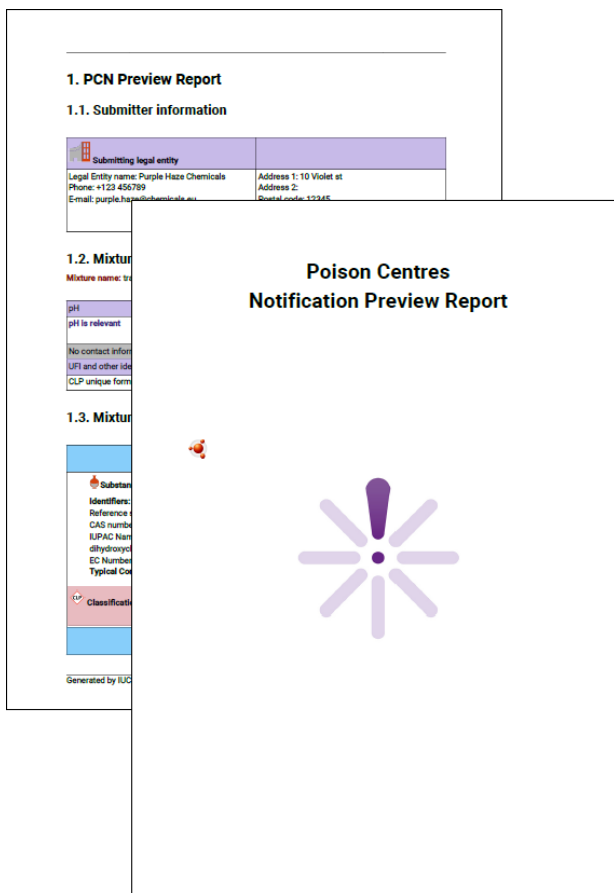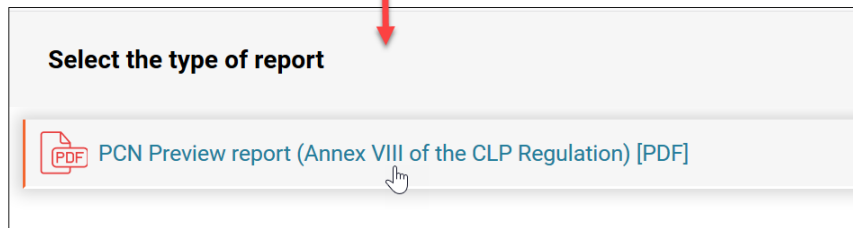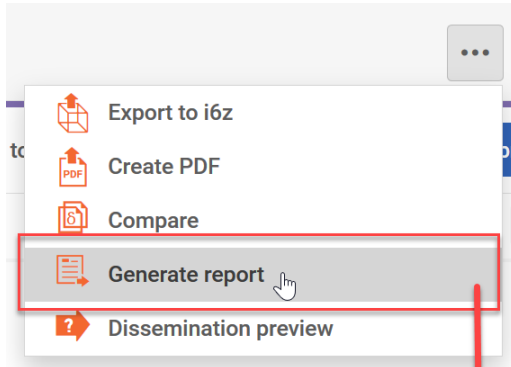
Now that a dossier with no reported failures has been prepared and created, we will look at how to proceed to update the dossier.
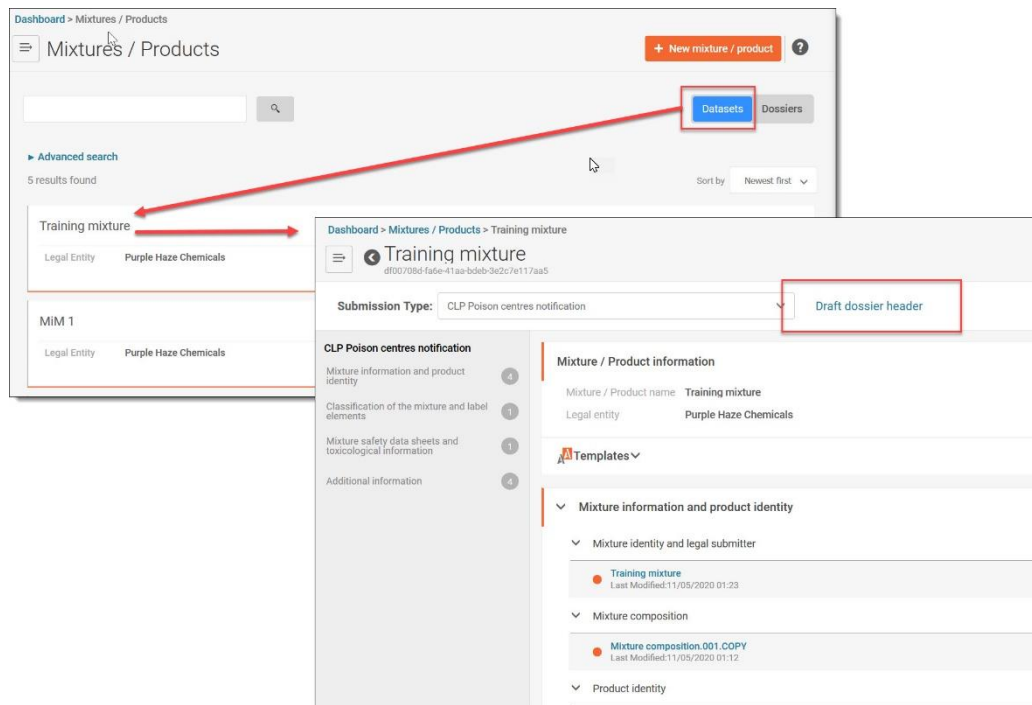
This exercise will cover:

✔ How to update the dossier header

✔ Creating an update dossier

Exercise: In this example we will look at how to make an update dossier to include an additional packaging type.

Steps:
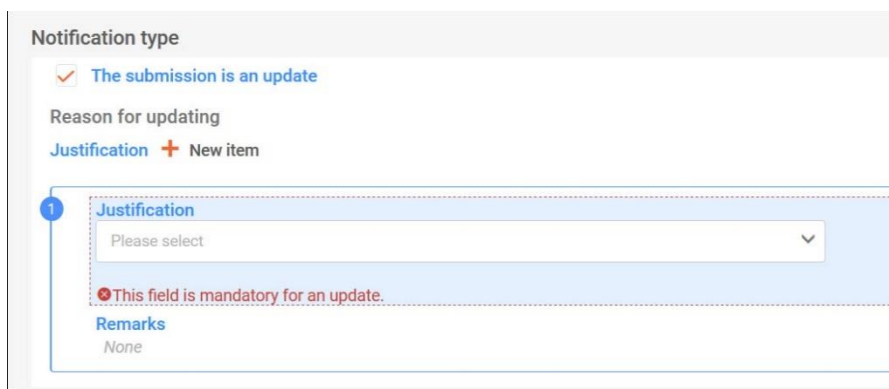
1. Back in the dataset list, select the mixture dataset you wish to update and click on Draft dossier header.

2. In the dossier header section,

- you may want to change the name of the dossier to help identify it.

- unclick 'Initial notification' and select 'Update' and provide the reason.

- e.g. Other: addition of a new packaging type.

3. Move from the dossier header to the dataset and make the necessary changes e.g. create a new packaging document and add the type and size of packaging.

4. Run the validation assistant until it is passes all business rules and create a dossier.

Annex I – PCN preview report

**Poison Centres
Notification Preview Report**

Table of Contents

1. PCN Preview Report

1.1. Submitter information

🏠 Submitting legal entity	
Legal Entity name: Purple Haze Chemicals Phone: +123 456789 E-mail: purple.haze@chemicals.eu	Address 1: 10 Violet st Address 2: Postal code: 12345 Town: Helsinki Country: Finland [FI]

1.2. Mixture information

Mixture name: Final mixture

pH	
pH is relevant	pH value: 6 - 7 Solution concentration (%): 100
Contact persons	
No emergency contact information provided	
Name: Smith, Jane Organisation: ChemTrack Contact type: dossier contact	Phone: +358 0400100100 Mobile phone: e-mail: Country: Finland [FI]
UFI and other identifiers	
CLP unique formula identifier (UFI)	C500-C029-F00U-DFXH

1.3. Mixture composition

Substance components
🧪 **Substance name:** Substance#2
Identifiers: Reference substance name: Substance #2 CAS number: IUPAC Name: (rel)-10âH-trans-12î-(2-methylbut-2(E)-enoyl)-1â-(isobutanoyl)-6á,13î-dihydroxyclerodan-4(20),8(18)-dien-7,15-dione-15,16-oxide EC Number: **Typical Concentration:** 5 % (v/v)
🔶 **Classification for substance component: Substance#2**
Classification and labelling according to CLP / GHS for health hazards

Hazard class	Hazard category	Hazard statement

Generated by IUCLID 6 v4.14.1 19/05/2020   1

| Skin corrosion / irritation: | Skin Irrit. 2 | H315: Causes skin irritation. |

Mixture in Mixture component (MiM)

MiM name: Mixture in mixture #1

CLP unique formula identifier (UFI): Q200-U0CW-500C-Q4CD

Concentration range: >89 - <92 % (v/v)

Substance components of the MiM: Mixture in mixture #1

Substance name: Substance#4 ()
Identifiers
Reference substance name: water
CAS number: 7732-18-5
IUPAC Name: water
EC Number: 231-791-2
Typical Concentration: 75 % (v/v)

Substance name: Substance#3 ()
Identifiers
Reference substance name: Substance#3
EC Number: 205-788-1
Typical Concentration: 15 % (v/v)

Supplier name: MiM 1 supplier

Company name: ChemSupplies **Town:** Lahti **Country:** Finland [FI]

Safety data sheet provided: Yes

- SDS.pdf

Classification for MiM component: Mixture in mixture #1

Classification and labelling according to CLP / GHS for physical hazards

Hazard class	Hazard category	Hazard statement
Flammable liquids:	Flam. Liquid 1	H224: Extremely flammable liquid and vapour.

Classification and labelling according to CLP / GHS for health hazards

Hazard class	Hazard category	Hazard statement
Skin corrosion / irritation:	Skin Irrit. 2	H315: Causes skin irritation.
Serious damage / eye irritation:	Eye Irrit. 2	H319: Causes serious eye irritation.

GPI components

Name of Generic Product Identifier for the Substance: Perfume GPI#1
Function: perfume

Typical Concentration: 5 % (v/v)

1.4. Product information

Trade name(s)	BeGone
UFI and other identifiers	CLP unique formula identifier (UFI): C500-C029-F00U-DFXH
Market placement:	Finland [FI] ; Sweden [SE]
Colour and physical state	Physical state at 20°C and 1013 hPa: liquid Colour: yellow Colour intensity: transparent
Packaging Is product packaged: Yes	Type of packaging: bottle Size of packaging in contact with the product (container size): 5 L Type of packaging: bottle Size of packaging in contact with the product (container size): 1 L
Product use category	Use type: Consumer ; Professional Main intended use: PP-PRD-1 Acaricides for plant protection

1.5. Labelling

Signal word: Warning

Hazard pictogram:	Hazard statement:	Precautionary statement:
GHS07: exclamation mark	H315: Causes skin irritation. H319: Causes serious eye irritation.	P362+P364: Take off contaminated clothing and wash it before reuse. P332+P313: If skin irritation occurs: Get medical advice/ attention. P321: Specific treatment (see ... on this label). P302+P352: IF ON SKIN: Wash with plenty of water/... P280: Wear protective gloves/protective clothing/ eye protection/face protection/hearing protection/... P264: Wash ... thoroughly after handling. [fi] kädet; [sv]

			händer;
			P337+P313: If eye irritation persists: Get medical advice/ attention.
			P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Additional labelling requirements (CLP supplemental hazard statement)			
Additional labelling			

1.6. Classification

Classification and labelling according to CLP / GHS for health hazards		
Hazard class	**Hazard category**	**Hazard statement**
Skin corrosion / irritation:	Skin Irrit. 2	H315: Causes skin irritation.
Serious damage / eye irritation:	Eye Irrit. 2	H319: Causes serious eye irritation.

1.7. Toxicological information

Toxicological information (section 11 of SDS):
[fi]
Field content is not in a valid XML format and thus ignored!
[sv]
Field content is not in a valid XML format and thus ignored!

Thanks a lot for your attention ☺

You made it right to the end!