

EUROPEAN NOTIFICATION SYSTEM FOR CHEMICALS

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TOPICS

- ▶ National Register for chemicals

- ▶ **European Notification System for chemicals**

- ▶ Management of an application for the authorisation of a biocidal product

POISON CENTRES NOTIFICATION FORMAT (PCN)

The Poison Centres Notification (PCN) format structures the information on hazardous mixtures classified for health or physical hazards to be submitted to the Member States.

This information has XML format based and defined by the requirements laid out in Annex VIII to the CLP Regulation. The information includes the **full chemical composition, toxicological information, relevant product and mixture details** including the **intended use (EuPCS)**, in addition to the label elements such as the unique formula identifier (**UFI**).

The PCN format, compatible with IUCLID, aims to harmonize and ensure the information available to poison centres in EU. Very useful information on PCN, data models and IUCLID format, are available on the ECHA website.

[Download Part A – Preparing a PCN dossier \(.pdf\)](#)

[Download Part B – Developers' guide to the IUCLID format \(.pdf\)](#)

THE UNIQUE FORMULA IDENTIFIER (UFI)

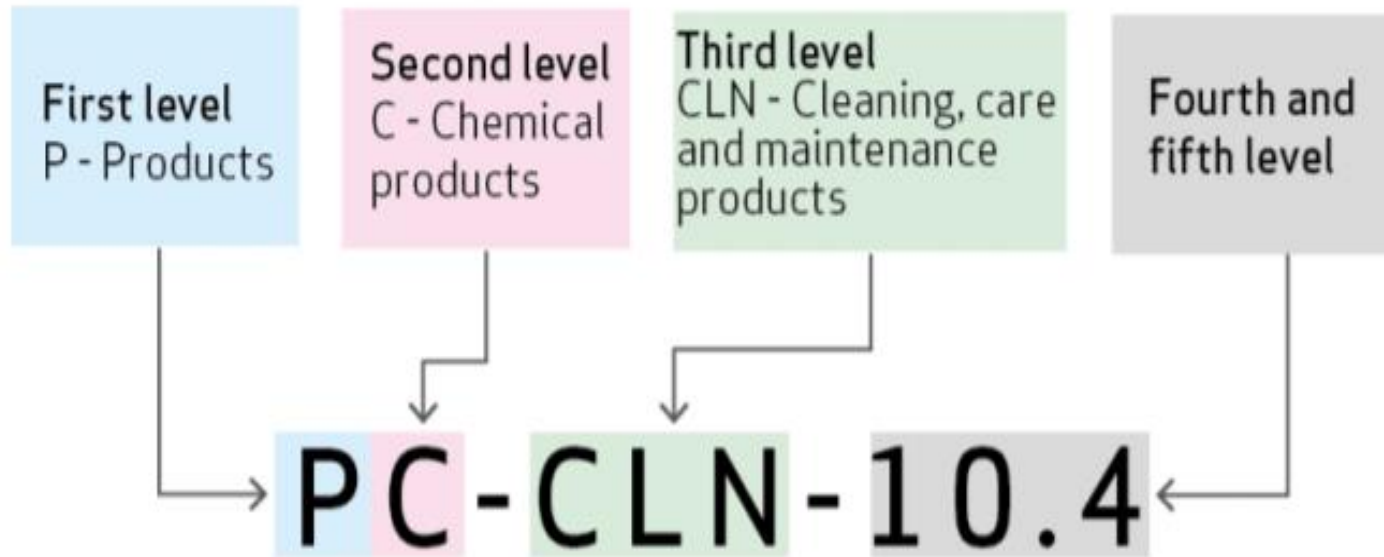
UFI establishes an unambiguous link between a mixture and the information submitted to Poison Centres, in order to identify the source of poisoning as basis for clinical toxicological risk assessment and to propose the right medical treatment.

CLP ANNEX therefore requires to print or affix a UFI on the label of a product and mention the UFI in the submission of information to Poison Centres.

PRODUCT CATEGORISATION SYSTEM

The intended use of a mixture shall be described in accordance with a harmonized product categorization system.

In order to best defines the intended use of a mixture to be placed on the market a product category must be assigned to the mixture.



EuPCS

1st level

2nd level

3rd level

(F)
Mixtures for further
formulation

(P)
Products

(PC)
Chemical Products
(excludes biocidal
products)

(PP)
Biocides and plant
protection products

- (PC-ADH) Adhesives and sealants
- (PC-AIR) Air care products
- (PC-ANI) Products for animals
- (PC-ART) Art materials (including chemical products used for decorative purposes)
- (PC-CLN) Cleaning, care and maintenance products
- (PC-COL) Colourants
- (PC-CON) Construction products
- (PC-DET) Detergents and auxiliaries for laundry and dishwashing
- (PC-ELQ) E-liquids and mixtures for electronic cigarettes
- (PC-FER) Fertilisers and fertilising products
- (PC-FUE) Fuels (and fuel additives)
- (PC-INK) Inks, toners and related printing materials
- (PC-PNT) Paints and coatings (and related auxiliaries)
- (PC-PYR) Pyrotechnic products
- (PC-TAT) Tattoo inks
- (PC-TEC) Products for chemical or technical processes
- (PP-BIO) Biocidal products
- (PP-PRD) Plant protection products (excludes biocidal products)

SUBMIT A NOTIFICATION

The main topic is:

How companies can notify their chemicals at EU Level?

IUCLID WEB APPLICATION

The screenshot displays the IUCLID 6 web application dashboard. At the top left, the text "IUCLID 6" is visible. The top right corner contains navigation icons: a hamburger menu, a question mark, a bell, and a user profile. Below this is a "Dashboard" header with a search bar labeled "Search dossier by UUID" and a help icon. The main content area is divided into two columns. The left column features three summary cards: "Guided dossier preparation" with 0 items, "Substances" with 9 items, and "Mixtures" with 2 items. The right column is titled "Import IUCLID file(s)" and includes an "Overwrite settings" dropdown menu set to "If newer than existing". Below the title is a large dashed box for file upload, with the text "Drop file to upload or Browse" and a "Browse" button.

IUCLID 6

Dashboard

Search dossier by UUID

Guided dossier preparation 0

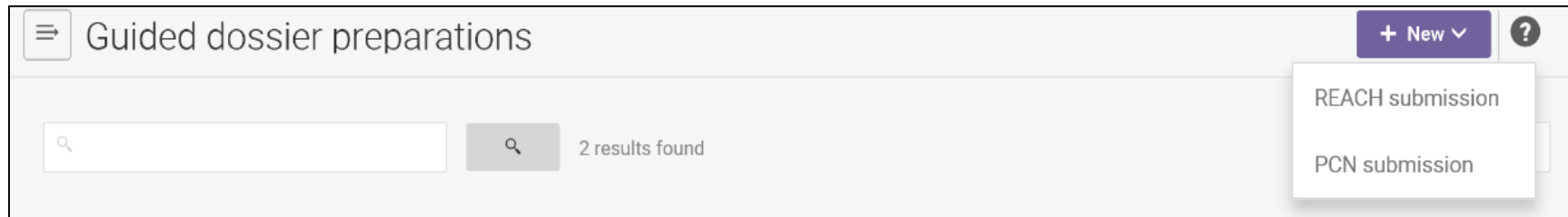
Substances 9

Mixtures 2

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

Drop file to upload or Browse

PCN SUBMISSION



By clicking on the button “New” it is possible to launch a new PCN submission and start a new guided dossier preparation.

DEFINITION OF THE DOSSIER CONTEXT

Guided dossier preparation for your Poison Centres Notification ✕

1 Specify your mixture

Let's get started by providing a name for your mixture and dossier!

Specify the mixture and the name of the dossier to be used for your Poison Centres Notification

Create a new mixture

Hazardous mixture

Specify the dossier name of your Poison Centres Notification

My hazardous mixture's name _ initial submission

Next

2 Dossier information

The information you provide in this step will determine what fields will be visible during the preparation of your dossier.

Check the submitter information

Submitter Information

Undefined Company Name

Define the dossier information

PCN number*

0/255

 PCN number field is mandatory.

Country (market placement)

Language

- Limited submission (industrial use only)
- Non hazardous mixture
- The submission is an initial notification
- The submission is a new notification after a significant change of composition
- The submission is an update

Reason for updating

Justification

 New item

No items added
 New item



Finish

STRUCTURE OF THE INFORMATION

1 Information to be completed

- Mixture Information
- Product information

Mixture Information

Here are the group of tasks that need to be completed to collect information about the identification of the mixture, its composition and other characteristics.

- Contact person(s) 2
- pH 1
Only values between -3 and +15 will be accepted, the pH value must be numerical only. No other characters allowed.
- Toxicological information 1
Toxicological information (free text field) must contain at least 200 characters. Non-compliance leads to failure, with an exception for voluntary submission.
- Mixture composition
- Unique formula identifiers (UFI) and other identifiers
- Classification and labelling information

TOXICOLOGICAL INFORMATION OF THE MIXTURE

← Toxicological information

1 SDS information (mixtures)

Information on mixtures

Safety data sheets of mixture / product

+ New item

No items added
+ New item

Toxicological information (section 11 of SDS)

fi

Edit Format Table

B *I* U ~~S~~ x^2 x_2

Paragraph A **A** *I*_x

sv

Edit Format Table

B *I* U ~~S~~ x^2 x_2

Paragraph A **A** *I*_x

MIXTURE COMPOSITION



◀ Mixture composition

Mixture components

+ Mixture component

No components have been added yet.

Substance components

+ Substance component

No components have been added yet.



← Mixture composition

Mixture components

[+Mixture component](#)

No components have been added yet.



Function and concentration
15/02/2019 15:59

1



Unique formula identifiers (UFI)



Mixture-in-mixture composition



Classification and labelling information of the mixture-in-mixture



Supplier



Mixture safety data sheets

Substance components

+ Substance component

+ New item

No components have been added yet.



Function and concentration
15/02/2019 16:00

1

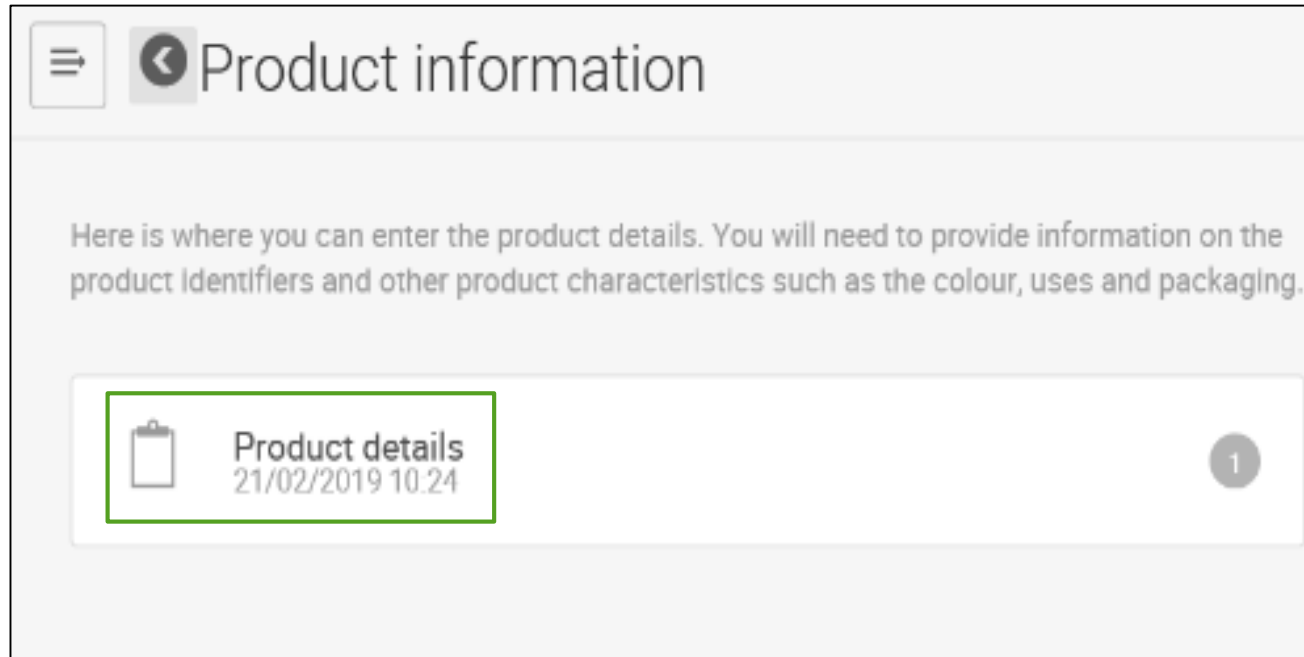
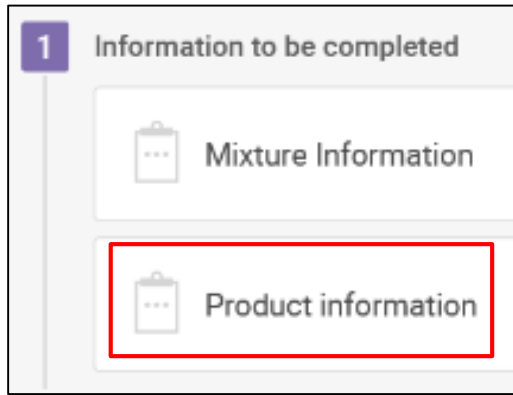


Substance identification
15/02/2019 16:00

1



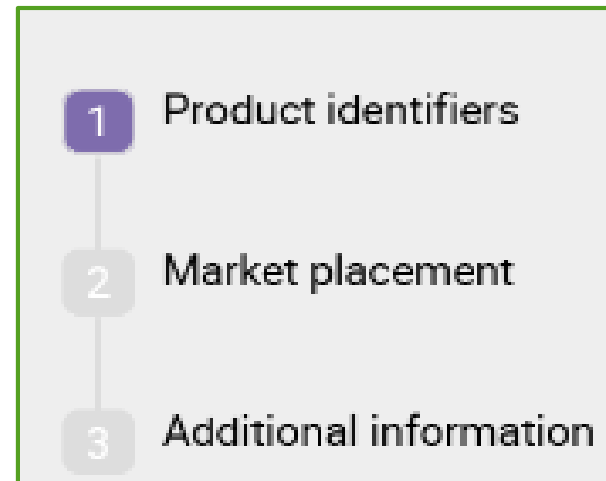
Classification and labelling information of the substance



Product identifiers (Trade name(s), Other name(s), UFI and other identifiers);

Market placement;

Additional information (colour and physical state, packaging, product use category).




2 Finalize your dossier

 Validate

 Create dossier

When all the information have been added it is possible to validate the dossier by the validation assistant, in order to get the validation report which indicates the mistakes in the dossier preparation.

 **Product information Trade names, (1)**
Product information is incomplete. At least one 'Trade name' must be provided under Product details > Product identifiers.

[Validation report](#)

When all the mistakes are corrected, the dossier can be created.

2 Finalize your dossier

 Validate

 Create dossier

 Preview notification

Thank you!

SOURCES

ECHA WEBSITE: <https://echa.europa.eu>

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

ECHA POISON CENTRES NOTIFICATION WEBSITE: <https://poisoncentres.echa.europa.eu>

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