

Poison Centre Notifications Handbook

May 2023

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LEGAL NOTICE

This document aims to assist national helpdesks and users with their 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 regards to the use that may be made of the information contained in this document.

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| Version 0 | First edition | May 2022 |
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If you have questions or comments in relation to this document, please send them by using the information request form. The information request form can be accessed via the Contact ECHA page at: <http://echa.europa.eu/contact>

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1. Introduction



Companies placing hazardous mixtures on the market are obliged to provide information about certain hazardous mixtures to the relevant national appointed bodies, according to Article 45 of the CLP Regulation. The national appointed bodies make this information available to poison centres so that they can give advice to the citizens or medical personnel in the event of an emergency.

Annex VIII to the CLP Regulation, adopted in March 2017, defines the harmonised requirements for poison centre notifications (PCN) applicable as of 1 January 2021.

There are two sides to be considered when providing support: understanding the regulatory aspects and how to submit the information. This document provides a map of all the available information on both sides so you can quickly find the source of information needed to reply to the question you receive.

Whenever the material is already translated, the following icon appears: . The links will then lead to the website from where the different versions can be downloaded, and not directly to the document.

Links: [Understanding CLP – ECHA \(europa.eu\)](#) 

[About us – Poison Centres \(europa.eu\)](#) 

Legislation: [Annex VIII CLP](#) 

2. Regulatory aspects

The aim of this first part is to present and explain all the regulatory aspects in relation to PCN obligations.

2.1. Steps for Industry

This section provides an easy and stepwise approach for Industry to comply with their duties, articulated on seven steps. Each one includes links to further information. The seven steps are:

1. Know your obligations.
2. Know the standard information requirements.
3. Know your portfolio.
4. Generate your UFI's.
5. Adapt your data.
6. Prepare your submission.
7. Keep the information up to date.

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Link: [Steps for industry - Poison Centres \(europa.eu\)](https://europa.eu)

2.1.1. Who and What

Who: duty holders under Article 45 are defined as importers and downstream users placing hazardous mixtures on the market. In all cases, the obligation lies with the EU legal entity, which means that a non-EU supplier of the mixture cannot replace the EU-based duty holder.

What: obligation to provide specific information on companies' mixtures to appointed bodies. It applies to mixtures placed on the market that are classified for human health or physical hazards.

Exemptions: mixtures considered hazardous only due to environmental hazards; radioactive mixtures; mixtures subject to customs supervision; mixtures used in scientific research and development; medicinal and veterinary products, cosmetic products, medical devices and food and feeding stuffs; and mixtures only classified as gases under pressure and explosives.



Links: [Know your obligations - Poison Centres \(europa.eu\)](https://europa.eu)

[List of national appointed bodies](#)

[ECHA webinar: Getting prepared to notify your hazardous mixtures](#)

[Leaflet: Poison Centres - Notifying hazardous mixtures as of 2021](#)

2.1.2. Standard Information Requirements

The harmonisation of information requirements means that the existing national requirements across the EU have been replaced by one set of information requirements and one format of data submission: the PCN format. The main sets of information requirements are:

| Unique formula identifier (UFI) | Full chemical composition | Classification and labelling |
|---------------------------------|---------------------------|--------------------------------------------------------------------------------------------------------------------------|
| Toxicological information | Product category | Information identifying the submitter, the product and whether the mixture has consumer, professional or industrial uses |



Link: [Know the standard information requirements - Poison Centres \(europa.eu\)](https://europa.eu)



[In Brief: Information requirements for poison centres notifications](#)

2.1.3. Knowing the Portfolio

It is time for the companies to look at their product portfolio:

- Identify which products have been previously notified and the countries where they are on the market.

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- Establish the use type, or types, of each product: Consumer or professional (compliance date January 2021) or Industrial (compliance date January 2024).
- Pay attention: limited, group or voluntary submissions are possible.

Link: [Know your portfolio - Poison Centres \(europa.eu\)](#) 

2.1.4. Generating UFI

The unique formula identifier (UFI) is a unique code that will be required both in the submission of information and on the label, or in some cases the packaging, of the products that contain a hazardous mixture.

The condition for assigning a UFI is that all products labelled with the same UFI need to share the same mixture composition.

The management of UFIs is the responsibility of the company. [Here](#)  it is possible to access the UFI generator. The published documentation includes the manual for software developers for creating and validating UFI.

Links: [ECHA animation: What is the UFI and what does it mean for your product labels?](#)
[What is a UFI](#)
[Creating and using your UFI](#)
[Managing your UFI](#)

[In Brief: The UFI and what it means for your product labels](#) 

[User guide for the UFI Generator](#) 
[UFI Developer's Manual](#)

[Guidance on labelling and packaging in accordance with CLP](#) 

[Generate your UFIs - Poison Centres \(europa.eu\)](#) 

2.1.5. Adapting the data

Companies need to perform a number of other tasks to have all the required information at hand and to be able to submit it for effective use by poison centres.

They must check the formulation and components of all their mixtures affected by their obligations. They can start assigning exact concentrations or appropriate concentration ranges distinguishing between components of major concern and other components.

Moreover, they have to pay attention to specific rules for Mixtures in Mixtures, to the toxicological information, to the UFI and any other relevant information such as product category, colour, packaging types and sizes.

Links: [Adapt your data - Poison Centres \(europa.eu\)](#) 


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[Declaring concentrations under Annex VIII to CLP Regulation](#) [EuPCS practical guide](#) [The European product categorisation system \(EuPCS\)](#) 

2.1.6. Preparing the submission

ECHA has established a harmonised PCN format for submitting the required information to poison centres. The format is available online. The ECHA Submission portal, available on ECHA's Poison Centres website, is an online tool to prepare and submit information according to the harmonised format. From here, the submissions are forwarded to the appointed bodies. It is important to check the Overview of Member States decisions to understand how they are preparing to receive the submissions.

ECHA has provided three different ways to prepare for the submission of information to poison centres: the IUCLID Cloud; specific PCN interface in IUCLID to work offline, and system-to-system (S2S) integration for advanced users.

Links: [Prepare your submission - Poison Centres \(europa.eu\)](#) 
[ECHA animation: Notifying hazardous mixtures to poison centres](#)

[In Brief: How to prepare and submit information to poison centres](#) 

[PCN: a practical guide](#) 

[Overview of Member States decisions on implementing Annex VIII to the CLP](#)

2.1.7. Keeping the information updated

The information contained in a submission made to an appointed body must accurately and always reflect the product on the market. Whenever the product changes in a way that concerns information requirements, this needs to be reflected in an update of the existing submission.

Links: [Keep the information up to date - Poison Centres \(europa.eu\)](#) 

2.2. Guidance

2.2.1. The Guidance on harmonised information relating to emergency health response

This document provides guidance on the provisions of Article 45 and Annex VIII to CLP. These

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concern the obligation to submit certain information on hazardous mixtures placed on the market, for emergency response reasons.

It is a comprehensive document that explains all aspects from the scope of Annex VIII to advice on how to handle UFI and labelling.



Links: [Guidance on CLP - ECHA \(europa.eu\)](#)

2.2.2. The Guidance on labelling and packaging in accordance with Regulation (EC) 1272/2008

This document provides guidance on how to label and package substances and mixtures in accordance with the CLP Regulation. It is a source of information valuable for the PCN.

Links: [Guidance on Labelling and Packaging](#)

3. IT tools

To provide help to industry and Member States' appointed bodies, ECHA has developed IT tools to support preparing, submitting and receiving information on hazardous mixtures.



3.1. ECHA accounts and EU login

If you use ECHA's tools, such as ECHA Submission portal or ECHA Cloud Services, you need an ECHA account. Having an ECHA account also allows you to subscribe to notifications, for example on a certain substance you are interested in.

This is a general service provided by ECHA, used for other regulations also.

Link: [ECHA accounts and EU Login - ECHA \(europa.eu\)](#)

3.2. ECHA submission portal

The ECHA Submission portal is an online tool that allows industry to prepare and submit a dossier for a PCN. It is also possible to prepare a dossier offline using IUCLID: the dossier can be uploaded later to the portal.

Links: [ECHA Submission portal](#)
[Direct access to the portal](#)
[Access the Submission testing environment](#)

3.3. PCN: a practical guide

It explains in detail all the steps to complete a successful submission. It contains screenshots and links to further support material.



Link: [PCN: a practical guide](#)

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3.4. The PCN format

The PCN format aims to structure the information on hazardous mixtures classified for health or physical hazards available to poison centres in cases of poisoning incidents in the EU. The format is XML-based and defined by the harmonised requirements laid out in Annex VIII to the CLP Regulation. At the page indicated below it is possible to find examples of Poison Centre Notifications and the list of validation rules.

Links: [Poison Centres Notification format - Poison Centres \(europa.eu\)](#)
[Download the PCN format: Version 4.0](#)

3.5. IUCLID 6 website

IUCLID (International Uniform Chemical Information Database) is a software application to record, store, maintain and exchange data on intrinsic and hazard properties of chemical substances. It is a key software application for both regulatory bodies and the chemical industry. It hosts the database application used for the PCN too.

Link: [IUCLID website](#)

3.6. The European product categorisation system (EuPCS)

This system is used to describe 'the intended use of a mixture' for which a submission has to be made. Examples of intended uses include the use as an adhesive, as a decorative paint, or as a dishwashing detergent. The EuPCS in Excel and PDF format are available in the EuPCS section, as well as the practical guide.

Link: [European Product Categorisation System - Poison Centres \(europa.eu\)](#)



3.7. ECHA Cloud services

ECHA Cloud Services is a secure online platform used to distribute ECHA's IT applications into a private cloud environment. The service is built within ECHA's IT infrastructure and the use of encrypted communication. Regular security audits and updates of all the components make sure that the cloud data is safe and cannot be accessed by anyone else. Provided by ECHA, their functionalities are prioritised according to the needs of small and medium-sized enterprises

(SMEs). Introduction and support material can be found [here](#).



3.8. System-to-system

The system-to-system service (S2S) is available to support industry who wish to prepare and submit a PCN dossier in a more automated way. Under the S2S service, a company can create a PCN dossier directly in their own systems, using the IUCLID-compatible poison centre notification format.

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Link: [System-to-system service - Poison Centres \(europa.eu\)](#)

4. Support

This section contains general support material to help companies understand and comply with their obligations relating to placing hazardous mixtures on the market.

4.1. e-Learning

This page offers a range of resources to get familiarised with preparing poison centre notifications as well as assistance for preparing a presentation on the Annex VIII obligations and latest developments of the tools. Some videos are linked directly here, other are available in the **YouTube channel** or in the **Webinar section of the main ECHA web site**.

Link: [e-Learning - Poison Centres](#)

4.2. In Brief Publications

The In brief publications provide an informative but condensed series of information targeting specific obligations under Annex VIII.

Link: [In Brief Publications - Poison Centres \(europa.eu\)](#) 

- The UFI and what it means for your product labels
- Information requirements for poison centres notifications
- How to prepare and submit information to poison centres

4.3. National support

National helpdesks have been established as the first point of contact for regulatory questions for CLP. It is possible to contact also the nationally appointed bodies for direct inquiries in relation to the submission of information for the purpose of emergency health response. This page also includes the Overview of Member States decisions on implementing Annex VIII to the CLP.

Links: [National Helpdesks - ECHA \(europa.eu\)](#)

[National support](#)

5. Question and Answers

This section contains the most asked questions on the obligations relating to placing hazardous mixtures on the market.

The answers can be found in the link below, under the corresponding reported question. These can help to understand some specific points of Industry's duties covering both regulatory and IT issues.

In addition, at this page, the section **"This week in Helpdesk"** is available; it contains documents which deal with a bit more detail some matters, such as the UFI in SDS, how to notify

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microorganisms or how to work with a toll formulator (see list below).

Link: [Poison centre Q&As](#)

Documents of “This week in Helpdesk”:

[Submitting before the compliance date \(corrigendum\)](#)

[Toll formulators and PCN](#)

[EU importers/UK suppliers \(corrigendum\)](#)

[Legal submitters & foreign users](#)

[Generic product identifiers](#)

[UUID Numbers](#)

[UFI in the SDS](#)

[Micro-organisms](#)

[Polymers](#)

5.1. Duty holders and Annex VIII scope

- Who has the duty to submit?
- If I import a product in one Member State but do not sell it on the market in that Member State, am I obliged to submit information there?
- Are companies from the UK covered by this obligation?
- What mixtures are in scope?
- What about non-hazardous mixtures which are subject to supplemental labelling requirements?
- Are aqueous solutions of substances in scope of Articles 45 of CLP?
- What if my mixture also falls under another legislation?
- How long is a company liable for a notification?
- How should multi-component products be notified under Annex VIII?

5.2. Workability solutions – second amendment of Annex VIII

- When can I use the Interchangeable Component Group (ICG) solution and how can it help me?
- Can we use an interchangeable component group for a mixture which contains similar components (same CAS, same composition, same technical function) coming from different suppliers?
- When can I use the Standard Formulas solution and how it can help me?
- Can I identify a MiM component as a standard formula?
- What are bespoke paints and why do they benefit from Article 45 exemptions?
- Who can in practice benefit from the exemption for bespoke paints? What does “limited amount” mean?

5.3. Information requirements and confidentiality

- Which information do I need to submit?
- How can I obtain information on the composition of mixtures I am importing, if the non-EU supplier does not want to disclose it?
- Can a Member State request additional information besides what is contained in the agreed harmonised format?
- There is a possibility for limited submission for industrial use if I provide a 24/7 telephone service. What does 24/7 mean, and what languages need to be covered?
- As a supplier, how can I avoid disclosing the composition of my mixture to my customer who uses it as a co-formulant in their product?

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5.4. Compliance dates

- I have previously notified in one Member State and can benefit from the transition period. Does this mean I can benefit also in other Member States?
- When do I need to submit information according to the new rules?
- Can industry start using the harmonised information requirements before the relevant compliance dates?
- Do I need to relabel all my mixtures (for adding the UFI) before the relevant compliance date?
- Do I need to re-submit information on the products I previously notified under the existing system?

5.5. Unique Formula Identifier (UFI) and labelling

- Can companies generate UFIs and already place them on the label now?
- Can different UFIs be used for a single mixture that is placed on the market with different trade names and possibly by different companies?
- The UFI is generated based on the VAT number of the company. Does it mean that if a legal entity changes (due to a split or merger) new UFIs will need to be generated?
- Is it possible that the exact same UFI could be generated by two unrelated companies? How about related companies, e.g., multi-nationals with several subsidiaries?
- Is a company obliged to use their VAT number to generate the UFI? Modified in October 2020
- I'm a private label formulator of a mixture and I have several customers for this mixture. How should the UFI codes for the different customers be managed?
- Am I obliged to put the UFI on the label of my product? What about on the packaging?
- Are there any guidelines for the UFI?
- Does the UFI need to be on both the intermediate packaging and outer label?

5.6. Mixture in mixture (MiM) components

- How do I declare the components of the MiM in my final mixture?
- If a supplier informs me that their UFI has changed, do I need to update my submission?
- I am formulating a mixture using a non-hazardous mixture from another supplier. How do I get the compositional information on this mixture (my MiM) for my submission?
- The mixture I formulate is meant for industrial use, therefore I can opt for a limited submission. What if the mixture ends up as a MiM in a consumer product?
- I have two suppliers for the same MiM, which I alternatively use for the formulation of my final mixture (according to the availability). Can I include the information for these two MiMs (SDS for example and UFI code) in the same submission?

5.7. Tools for preparing and submitting notifications

- What are the differences between online and offline preparation of PCN dossiers?
- When can we use the ECHA Submission portal to start submitting?
- I have submitted my dossier but the Member State is not yet receiving notifications via the portal – what will happen to my notification?
- Will Member States keep their own national submission systems?
- Is it possible to make one submission which is then valid for all Member States?
- As a duty holder, can another company, for example a consultant, submit information on my behalf?
- Who will see the information submitted?
- Who performs validation checks on the information contained in my dossier? Modified in October 2020
- Before submitting, can I see the same validation report that the Appointed Body will

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- receive from the portal when downloading notifications?
- What will happen to the information previously submitted under the national systems? Will it be migrated to the new database?

5.8. Fees and language requirements

- What information must I provide in the relevant languages of the notification?
- Will Member States charge fees for Annex VIII submissions?
- Does the ECHA Submission portal support invoicing from the appointed body?
- Can I prepare the notification in my preferred language, which upon submission through the portal, would then be converted into the language of the receiving Member State?