

Technical Insight - Poison Centre Notifications and UFI's

Background to CLP Regulation on Poison Centres

Article 45 of CLP relates to making information available to 'appointed bodies' or poison centres about hazardous mixtures.

Article 45 was implemented and adopted on 22nd March 2017; the Annex VIII to CLP as Commission Regulation (EU) 2017/542. It is available here: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32017R0542>

A Poison Centre Notification (PCN) must be made for each hazardous mixture before placing on the market in EU member state(s).

Deadlines for notification

The deadlines for notification depend on the use of your mixture, but also of any downstream product containing your mixture. The deadlines in Annex VIII are:

- Which hazardous mixtures are required to be notified? For Consumer use products (e.g. detergents and reed diffusers)– Jan 1st 2020 (**a draft amendment expects this to be delayed to Jan 1st 2021**)
- For Professional use products (e.g. paint, cleaning fluid) – Jan 1st 2021
- For Industrial use products (e.g. flavours for food, fragrances for cosmetics) – Jan 1st 2024

Which hazardous mixtures are required to be notified?

Mixtures which are classified with physical or health hazards under CLP must be notified before placing on the EU market. This applies even if the mixture is included in downstream products outside the scope of CLP Article 45 (e.g. cosmetics, pharmaceuticals, food).

What about R&D samples?

R&D samples are not required to be notified.

Requirements in brief

1. Obtain a Unique Formula Identifier (UFI) from ECHA for the hazardous mixture
2. Notify the poison centre of the EU member state and/or use the ECHA central portal to make a Poison Centre Notification (PCN)
3. Ensure the UFI is available on the product label for non-industrial use products
4. Ensure the UFI is available on the SDS for industrial use products
5. Update the poison centre notification if various criteria are met

What is Formpak doing to help?

1. The latest version of the CLP Safety Data Sheet and CLP Data Sheet Banded will show the UFI number in the appropriate section.
2. CLP labels can be modified to show the UFI number. Labels are typically customer specific. We can include the UFI number onto your specific labels upon request.
3. The UFI for your mixtures need to be added to Formpak. You can do this manually by adding the UFI number into the UFI property. If you want to add many UFI's for your mixtures in one go, it may be more convenient for us to help you with a mass upload.
4. We are working on new poison centre 'documents'. These will enable you to publish information in xml format directly from Formpak with the intention to make them available directly to the ECHA Central Portal.
5. The poison centre xml documents from Formpak will have versioning properties so you can manage change requirements and re-notify as required.
6. We will work on a notification tool to facilitate direct communication with the ECHA central portal. The ECHA portal to enable system to system communication is not expected to be available until the end of 2019.

More details

UFI's

UFIs may be generated singly or in multiples using a free to use online generation tool on the ECHA website. You are required to enter a company VAT number and a Formulation number and these calculate the UFI. The Formulation number can only include numerical digits.

Example:

Your internal formulation code will be formatted based on your own convention e.g. ABC-1234

You assign a numerical only poison centre Formulation code to ABD-1234 e.g.1234567

You enter your VAT number and Formulation code 1234567 and this combination generates a UFI e.g.GJC1-S7TH-AKFK-TR8P

NOTE: the same Formulation number and VAT number will generate the same UFI. This is an important point because there are requirements to generate a new UFI for the hazardous mixture if certain changes occur. For this reason, you should not use your internal codes or product codes as the poison centre Formulation number.

You may wish to link the poison centre formulation number to the UFI and your formulation code directly in Formpak. We can help with mass uploads if required.

Safety Data Sheets and Labels

Please contact us to arrange an update for your CLP Safety Data Sheet – this is provided without charge.

If you need to include the UFI on any specific labels, please let us know. A small charge is made for each label which is modified.

FAQ's

Do I need to notify mixtures with only environmental hazards or non-hazardous mixtures?

No

Is it all free?

ECHA will not charge for using the portal or for the generation of UFIs, however, some MS may charge for the notification. As of May 2019, 17 MS have indicated that they will not charge for notifications and 22 MS have indicated they will accept notifications via the portal, 3 of which will also accept direct submissions.

What happens if my formulation changes?

If components in your hazardous mixture are added, substituted or removed a new UFI is required. A new UFI is also required if there are changes in concentrations of components, beyond the concentration range or permitted variation range (if exact concentrations were reported).

What happens if my UFI changes?

If your UFI changes you need to update your submission. Your labels and / or Safety Data Sheet need to be updated to reflect the updated UFI.

What happens if the physical or health hazards or toxicological data for my mixture changes?

You need to update your submission if the physical or health hazards or toxicological data for your mixture changes.

If I've already notified my mixture to an EU MS Poison Centre under their existing system, do I need to re-notify under the new scheme?

Yes, but the deadline is much later, Jan 2025. However, if your mixture meets the requirements for an updated submission, this must be done according to the new scheme and deadlines.

Can I exclude the UFI from the product label?

For an Industrial Use mixture, the UFI is required on the Safety Data Sheet and does not need to be included on the label. You can optionally include the UFI on the label. The presence of the UFI on the label impacts in which section of the Safety Data Sheet the UFI appears.

Can I use the same UFI's for a group of mixtures which have the same classification for physical and health hazards?

A single UFI can be used for a group of mixtures (a group submission) if the mixtures have the same classification for physical and health hazards. In Annex VIII it also requires that the mixtures are in the same product category. However, a draft amendment removes this additional requirement.

Can I use different UFI's for the same hazardous mixture?

You can allocate several Formulation numbers to the same hazardous mixture and this will enable you to generate separate UFI's. This may be useful for commercial reasons, if you supply the same hazardous mixture to different customers.

FAQ's Continued....

What is a MIM?

You may be supplied with a mixture that is used within your hazardous mixture. A Mixture in Mixture is abbreviated to 'MIM'. In this case, your supplier can notify their own mixture and provide you with their UFI. When you notify your hazardous mixture, you can refer to their mixture in your notification and include the product identifier, concentration and UFI and information about the hazardous components.

The supplier of a MIM hasn't provided a UFI for their mixture. What do I do?

If the MIM is non-hazardous, the supplier has no legal obligation to notify, but they may optionally do so.

If the MIM is hazardous and does not have a UFI, you can still refer to their mixture in your notification and include the product identifier, concentration and additional information on hazardous components. In Annex VIII it requires that compositional information contained in the SDS of the MIM plus the SDS of the MIM is also provided, however a draft amendment removes the requirement to provide the SDS. You must also provide the name, email address and telephone number of the MIM supplier.

How do I notify my product which contains a MIM which has a UFI?

If your MIM has a UFI and has had information notified to a poison centre you should provide the product identifier, UFI, concentration of the MIM and information about the known mixture components from section 3 of the MIM supplier SDS.

I both buy and sell a hazardous mixture, which has UFI generated by my supplier. Can I pass on this UFI to my customer, or must I obtain a new UFI?

The responsibility to notify a Poison Centre is with importers and downstream users of hazardous mixtures. If you buy and do not alter a hazardous mixture and simply distribute it, it's possible you fulfil the role of 'Distributor'. Distributors are defined as 'Any natural or legal person established within the Community, including a retailer, who only stores and places on the market a substance, on its own or in a preparation, for third parties.' However, if you use a hazardous mixture e.g. you use the hazardous mixture in a product you make, then you meet the definition of a Downstream User. Currently there is nothing to stop a distributor passing on the UFI of hazardous mixtures. It's also permissible for a distributor to generate a separate UFI. The requirements are still under discussion at ECHA.

Further Q&A are available on the ECHA poison centre website:
<https://poisoncentres.echa.europa.eu/questions-and-answers>