Product Stewardship - Poison Centers Notifications - (to be updated)

Poison Centers Notifications

Poison centers provide **medical advice** to citizens and healthcare professionals on health emergencies arising from exposure to hazardous chemicals or to other toxic agents, such as medicines, plants, bites and stings. Poison centers in the EU answer calls for **support daily and around the clock** . On average over a year, EU poison centers answer 600 000 support requests, half linked to accidental exposures that imply children.

What about regulatory requirements?

Under the **CLP Regulation (Article 45)**, companies importing or placing hazardous mixtures on the European market have an obligation to provide **information about these mixtures** to the **relevant national appointed bodies**. Appointed bodies make then this information available to **poison centers** so that they can provide rapid medical advice in the event of an emergency.

REACH regulation (Annex II) precise that the emergency phone number of the company and/or relevant official advisory body (this may be the body responsible for receiving information relating to health, which is referred to in Article 17 of Directive 1999/45/EC) must be indicated in **section *1.4 Emergency telephone* of the Safety Data Sheet (SDS)** with an obligation to specify if this phone number is available only during office hours.

Until now the absence of harmonization regarding the information that should be provided to the appointed bodies has led to inconsistencies in the information available to medical personnel in cases of poisoning or accidental exposure incidents in the different EU Member States...

Useful Links

Regulations/guidance

- Regulation 2020/1677 (CLP Annex VIII)
- Regulation 2020/878 (REACH Annex II)
- Guidance on harmonized information relating to health emergency response - Annex VIII to CLP
- Delegated Act Amending Annex VIII of CLP **(broken link)**
- Overview of Poison centers notification requirements and contact information per Member State prepared and provided by CEFIC **(broken link)**
- Overview of Member States decisions in relation to implementation of Annex VIII to CLP Regulation **(broken link)**

Websites:

- Poison Centres ECHA website

Regulation - What is new?

The notification dates for consumer goods has been delayed until the 1st of January 2021 aligned with the date of notification for professional mixtures.

On March, 22nd 2017, European Comission adopted regulation n°2017/542 modifying CLP regulation adding an annex (**Annex VIII**) that aims to **harmonize** information provided to the appointed bodies in terms of **content** and **format** .

Besides, the ECHA has created a **Central portal** ("free for fees") **for notification submission** (but not mandatory, Member states can choose to continue to use national portal with associated national fees - list of states not yet published-)*

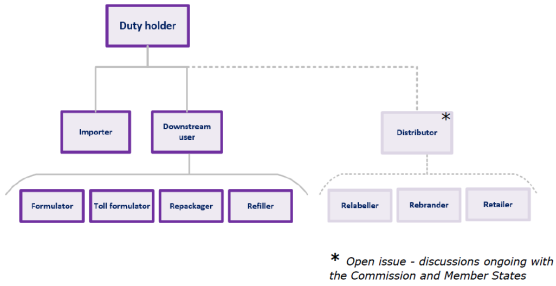
For more details please refer to "MS readiness Update in Aug 2019 v 1.2. for Annex VIII" document at the following link* **(broken link)

Who has to submit information?

=> Importers and downstream users placing hazardous mixtures on the European market

What mixtures are in the scope?

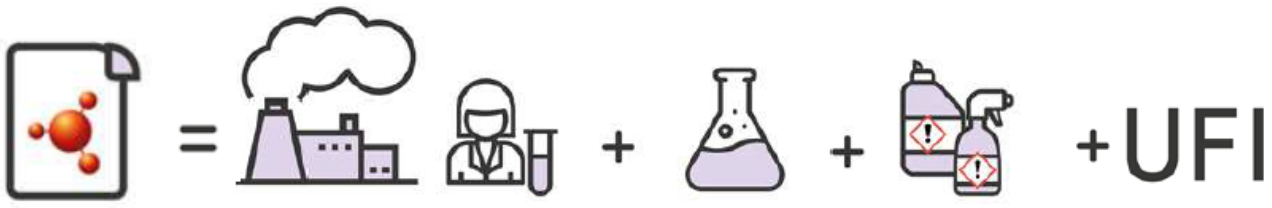
=>Mixtures classified for **Human health** and/or **Physical hazards**

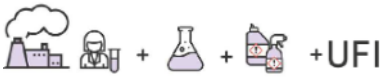


Exempted mixtures:

- only classified for environmental effects
- only classified as Gases under pressure or explosives (unstable explosives and divisions 1.1 to 1.6)
- used in scientific reasearch and development
- not covered by CLP regulation

Harmonised requirements (notification format + content)





Harmonised submission format:

Poison Centre Notification (PCN) format, IUCLID compatible, structured fields for information

Harmonized content requirements:

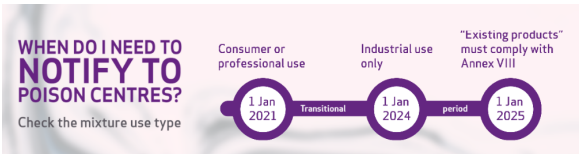
- Submitter details - name, address... - consistent with label
- Mixture information - C&L, tox info, full composition, pH, physical state
- Product information - label elements, packaging sizes, uses (consumer /professional/industrial, product category (defined by ECHA)
- UFI = Unique formula identifier (obtained via UFI generator tool) - eg YV9K-3J9A-G209-C2TZ
  UFI makes a link between the product and the submitted mixture information

ECHA Central submission portal:

- Online through the portal
- Offline using IUCLID
- System-to-system integration => do your notification in Solvay's WP1 system and automatic sending to the ECHA central database

Deadlines and key dates:

There was a change in the regulatory deadline for consumer goods. All professional and consumer products should be notified by the 1st of January. All industrial products by the 1st of January 2024.



Solvay (to modify) strategy: tool implementation in SAP EHS coordinated by Hazcom

1. Communicate to GBUs
2. Implement the tool of the 3rd party partner OPESUS in Solvay's WP1 - Go-Live September 2020

3. Update the labels to include UFI number
4. Train and accompany the GBU's on the usage of the new tool and doing the first notifications

Training Materials

>> Refer to Poison Center Notification training. **(broken link)**

FAQ

The exact composition of the product with all ingredients concentration - including non hazardous components - is required. Indeed it is considered that, in some cases, non-hazardous components may be also harmful if e.g. digested in large amounts or if synergistic effects occur.

The regulation provides different provisions for mixture components (substances and MiM) that are considered of 'major' concern and 'other' components:

- **Components of major concern for emergency health response**:

When mixture components are classified in accordance with this Regulation for at least one of the hazard categories listed below, their concentration in a mixture must be **expressed as exact percentages**, in descending order by mass or volume:
— acute toxicity, Category 1, 2 or 3
— specific target organ toxicity (Single exposure, Category 1 or 2)
— specific target organ toxicity (Repeated exposure, Category 1 or 2)
— skin corrosion, Category 1, 1A, 1B or 1C
— serious eye damage, Category 1
As an alternative to providing concentrations as exact percentages, **a range of percentages** may be submitted in accordance with Table 1 in Part B of Annex VIII (reported in Table below), in descending order by mass or volume.

Concentration range of the hazardous component contained in the mixture (%)	Maximum width of the concentration range to be used in the submission
≥ 25 - < 100	5% units
≥ 10 - < 25	3% units
≥ 1 - < 10	1% unit
≥ 0,1 - < 1	0,3% units
> 0 - < 0,1	0,1% units

- **Other Hazardous components and components not classified as hazardous:**

The concentration of components classified for hazard classes not listed above or components not classified as hazardous should be expressed, in accordance with Table 2 in Part B of Annex VIII (reported in Table below), **as concentration ranges** in descending order by mass or volume. **As an alternative**, the exact concentration can be provided.

Concentration range of the component contained in the mixture (%)	Maximum width of the concentration range to be used in the submission
≥ 25 - < 100	20% units
≥ 10 - < 25	10% units
≥ 1 - < 10	3% units
> 0 - <1	1% unit

The **UFI (Unique Formula Identifier)** is a unique 16-digit alphanumeric code (example: ***E600-30P1-S00Y-5079***) that **unambiguously links the submitted information on a mixture** (and hence information relevant for the treatment of patients) **to a specific product placed on the market**.

All products for which submission is made with the **same UFI** need to share the **same composition**. However, different UFIs can be used for the same mixture (for marketing and/or confidentiality reasons: country-specific product names, different brands in different price segments, customer-specific product names...) as long as those UFIs have been submitted to the appointed bodies.

The UFI **must be printed on or affixed to the label** of the hazardous mixture for which submission obligations apply. In case of mixtures which are unpackaged or mixtures with industrial uses only, the UFI shall be indicated in Section 1.1 of the SDS (in other cases on voluntary basis).

Companies are responsible for the generation and management of the UFI for their mixtures. A software application (the UFI generator) has been developed to allow industry to generate
UFIs. The UFI of a specific mixture is based on the value added tax (VAT) number of a company and a formulation number assigned by the company to this specific mixture.

New UFI has to be created when there is:

- change of components (addition, substitution or deletion of one or more components)
- a change in concentration beyond the concentration range provided in the original submission
- a change in concentration beyond the limits allowed for exactly declared concentrations

As defined in Annex VIII, mixture components can include other mixtures, referred to as mixtures in mixtures (MiM). By default, duty holders need to submit information on the full composition of the MiM supplied. If the supplier (for confidential reason) does not want to provide you the composition information, the MiM's UFI can instead be indicated in the submission together with the known MiM's components (at least those found in the SDS).
A harmonized European product categorization system (EuPCS) maintained by ECHA is used to describe the intended use of a mixture for which information according to Annex VIII has to be submitted (section 3.4 of part A of Annex VIII).

When making a submission for a hazardous mixture, duty holders **must assign a product category** which best defines the intended use of the product(s). The same principle is followed in the case of mixtures that may fit multiple product categories, for example, a 2-in-1 laundry detergent also containing a stain removal agent: it is the responsibility of the notifier to **select the main intended use**, which in this case, the main intended use would likely be a laundry detergent.

An EuPCS practical guide has been published to support categorizing products according to their main intended use.
Annex VIII part B, section 2.3, specifies that the submission has to include the information on the toxicological effects of the mixture or its components that is required in Section 11 of the SDS of the mixture. The information requirements for an SDS are specified in Annex II to the REACH Regulation. The information to be included in the submission thus has to include as a minimum all the relevant and available information on the toxicological health effects related to each of the health hazard classes covered by Annex I to CLP:
(a) acute toxicity;
(b) skin corrosion/irritation;
(c) serious eye damage/irritation;
(d) respiratory or skin sensitization;
(e) germ cell mutagenicity;
(f) carcinogenicity;
(g) reproductive toxicity;
(h) STOT-single exposure;
(i) STOT-repeated exposure;
(j) aspiration hazard

For each of the above hazard classes the submission should include the information required for Section 11 of the SDS, which will allow the poison centers to provide adequate advice in case of exposure to the mixture. This could include, when available, the result of the test, reference to the species and test method used, and possibly information on the exposure period.

Annex VIII does not prescribe any specific structure for reporting such information. Considering that it is not possible to define in general terms what information is needed for the
purposes of this Annex, the full content of Section 11 of the SDS could be considered potentially relevant for the poison centers and emergency responders.
While performing a quality check of the submitted information, Member States' Appointed bodies may contact the submitter directly to request clarification for any deficient, unclear or conflicting information. The request must, however, be reasonable and necessary for the Appointed body to carry out its tasks under Article 45 of the CLP.
The importers and downstream users of hazardous mixtures placed on the market for industrial use only, have the possibility to opt for a 'limited submission' as an alternative to the general submission requirements.

In such cases, information on the composition of their industrial mixtures submitted to the appointed body may be limited to the information contained in the SDS. However, it must be ensured that additional detailed information on the composition of such mixtures is rapidly available on request, in the event of an emergency health incident.

The submitter who have chosen the 'limited submission' must, according to section 2.3 of Part A and section 1.3 of Part B of Annex VIII, provide in the submission the contact's details for
rapid access to 'additional detailed product information'.
Companies may sometimes have in their product portfolio, a high number of similar mixtures, which may only slightly differ in certain elements. Therefore Annex VIII allows to submit, under certain conditions, information for several mixtures with a single submission, which is called 'group submission'.
A group submission is possible if:

- all mixtures in the group contain the same composition except for certain perfumes and/or fragrances under specific condition, and for each of the components, the reported concentration or concentration range is the same;
- all mixtures in the group have the same classification for health and physical hazards; and
- all mixtures in the group belong to the same product category.

According to Section B.4.1 of Annex VIII, a submission update is required when:

- the name of the mixture (the product identifier, e.g. trade name/brand/identification of the mixture) or the UFI is changed, or
- the mixture classification for health or physical hazards changes, or
- relevant new toxicological information that is required in Section 11 of the safety data sheet becomes available on the hazardous properties of the mixture or its components,
  or
- the composition of the mixture is changed following:

a) Addition, substitution or deletion of one or more of the components that needs to be indicated, or
b) Change in the concentration range provided in the original submission; i.e. the concentration of a component of the mixture, is changed beyond the concentration range provided in Table 1 and 2 Annex VIII, or
c) Change in the exact concentration provided in the original mixture; i.e. the concentration of a component in the mixture is changed beyond the limits indicated
in Table 3 of Annex VIII

Note that whenever changes listed above occur, an update of the submitted information is required before the mixture, as changed, is placed on the market.
In principle, you need to make a submission to every Member State where you place on the market in the language of that Member State. How this will be done in practice depends on the final agreed structure of the IT system.

More questions? Contact EH&S and Substance Team.