Poison Centre Notification (PCN) & Its Implications on SDS

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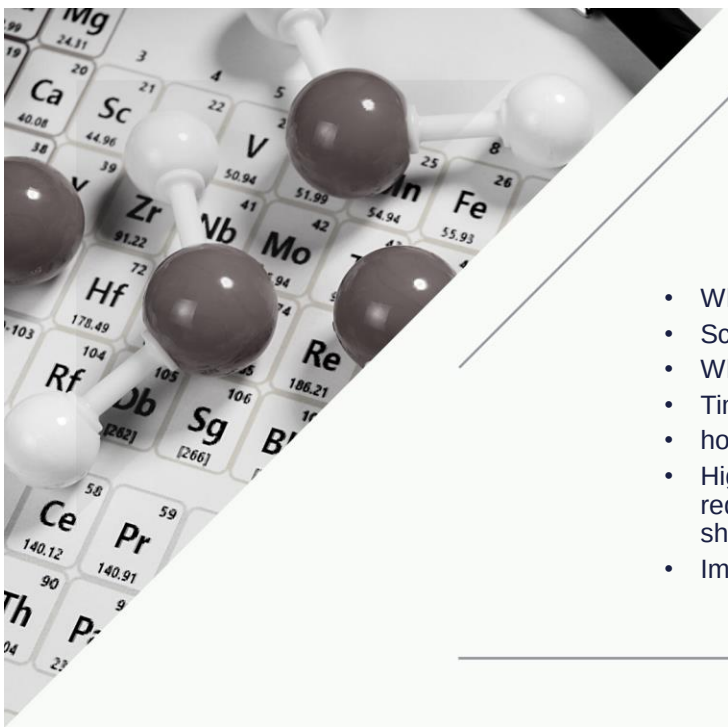
1



Summary of Topics

- What is Poison Centre Notification (PCN)
- Scope of PCN
- What are the obligations within PCN
- Timelines for compliance
- how to start preparing notifications
- Highlight harmonised information requirements beyond the safety data sheet
- Implications on SDS

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2

What is Poison Centre Notification?

Article 45 of the Classification, labelling & Packaging (CLP) Regulation:

companies placing hazardous mixtures on the market are obliged to provide information about certain hazardous mixtures to the relevant national bodies.

Annex VIII to the CLP Regulation (adopted in March 2017)

harmonised requirements for poison centre notifications (PCN) applicable as of 1 January 2021*

European Chemicals Agency (ECHA)

Tools, guidance and support

https://poisoncentres.echa.europa.eu/

3

3

CLP Regulation – Annex VIII

- Harmonisation of information requirements for certain hazardous mixtures in all EU Member States
- Preparation of data in a harmonised submission format (.xml)
- For use by poison centres for the purposes of making an emergency health response

4

4

What mixtures are in scope?

- Mixtures classified for human health or physical effects
- Does NOT include mixtures:
  - classified only for environmental effects/gases under pressure/or explosives
  - used in scientific research & development
  - not covered by CLP Regulation

5

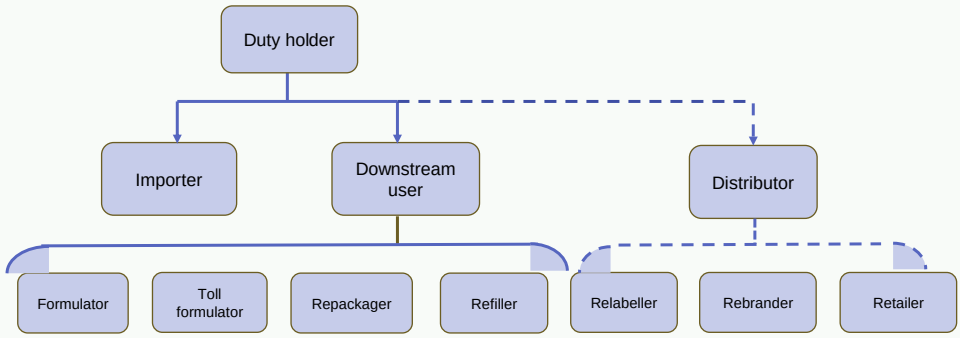
Exemptions in PCN

- Mixtures not covered by CLP Article 2:
  - medicinal products
  - veterinary medicinal products
  - cosmetic products
  - medical devices which are invasive or used in direct physical contact with the human body
  - food or feeding stuffs including when they are used as food additives or flavourings in foodstuffs, additives in feeding stuffs or in animal nutrition.
- Mixtures used for Research and & Development
- Mixtures classified only for environmental effects
- Mixtures classified only for gases under pressure and/or explosives (unstable explosives and Division 1.1 to 1.6).

6

Obligations under Article 45 & 4(10) CLP

- Stipulates general obligations to comply also for distributors
- *'Substances and mixtures shall not be placed on the market unless they comply with this Regulation'.*



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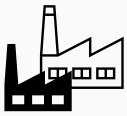
Who can submit information?

For example, EU based:

Legal entities on behalf of duty holders, such as consultant, mother company, i.e. 'Foreign user'



Importers or downstream users of mixtures out of scope i.e. a voluntary submission

Legal representative of non-EU suppliers can also make a submissions through the EU legal entity

8

8

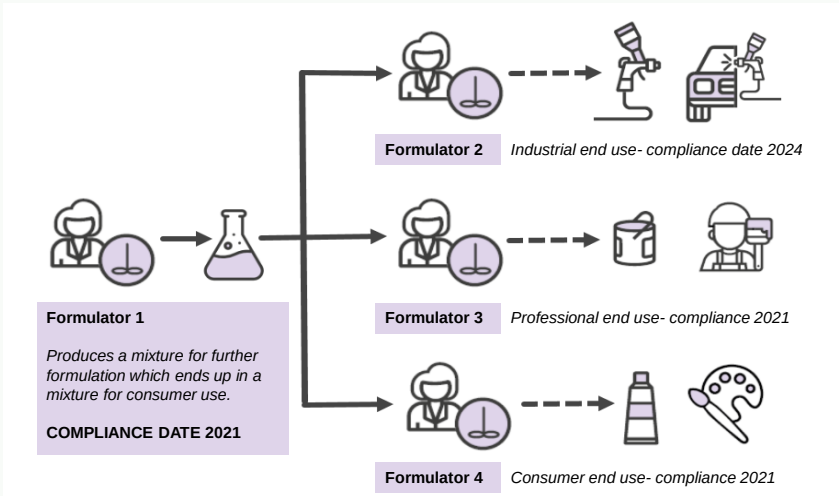
Timelines for compliance

- Notifications must comply with the harmonised requirements according to the use type of the mixture
- Transition period for existing products ends 1 January 2025
- unless change made to existing notification between relevant deadline and end of transition period

*This deadline has been recently extended

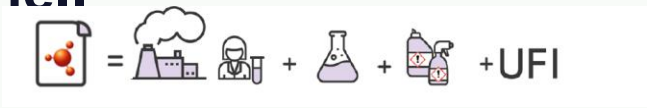
9

Compliance date depends on end use



10

Harmonised requirements in a nutshell



- Submission format –Poison Centre Notification (PCN) format, IUCLID compatible, structured fields for information
- Submitter details –name, address etc. -consistent with the label
- Product information -trade name, packaging, uses, colour
- Mixture information -C&L, toxinfo, composition, pH, physical state
- Unique formula identifier –e.g. YV9K-3J9A-G209-C2T7,
- Unique formula identifier(UFI) makes a link between the product and the submitted mixture information

11

Mixture information

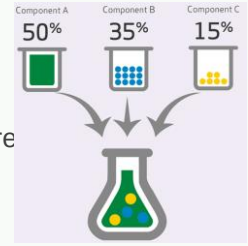
- All the complete trade name or names of the mixture/product as they appear on the label.
- Toxicological information as required in Section 11 of the Safety Data Sheet* in all languages required by the prospective Member States.
- Hazard classification and labelling information
  - Hazard class and category, hazard pictogram codes, signal word, hazard and precautionary statement codes
- Physico-chemical properties i.e. colour, pH and physical state.

* The SDS is not an information requirement and cannot replacement the toxicological information required.

12

Mixture composition

- Details of all mixture component (substances and **MiMs**) concentrations to 100%:
  - Classified components when in concentrations ≥0.1%
  - Not classified components when in concentrations ≥1%
- Product identifiers
  - Substance chemical names, CAS/EC numbers, IUPAC, INCI where applicable (in accordance with Article 18(2) CLP).
  - MiM trade name, UFI where applicable



- Hazard classification of components (labelling information not required).

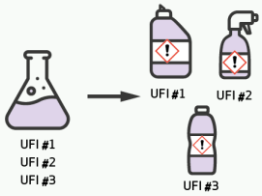
The SDS is not an information requirement and cannot replace the toxicological information required.

13

UFI and other identifiers of the mixture/product

- At least one unique formula identifier (UFI) must be assigned to the mixture being placed on the market.
- Note that one mixture composition may have multiple UFIs assigned to it which may correspond to different products (with the same mixture composition).

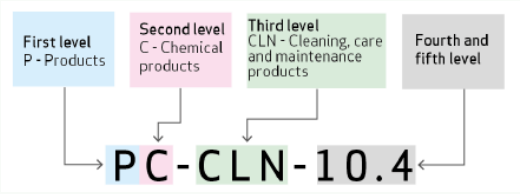
Other identifiers may be optionally included by the submitter, for example, previous national notification numbers.



14

Product information

- Use type of the mixture, or a combination of the three considering the end use:
  - consumer
  - professional
  - industrial
- A product category based on the main intended use selected from the European Product Categorisation System (EuPCS).



- Individual packaging types and their sizes. No ranges are permitted.

15

15

Beyond the safety data sheet (SDS) –adapting existing or including new data

16

16

Review toxicological information

- Toxicological information as required in Section 11 of the Safety Data Sheet in accordance with Annex II to REACH.
- The information is required as free text in the national language* required by the Member state where the mixture will be placed on the market.
- Multimarket submissions must include this information in every language.
- Check quality of the information in Section 11, i.e. no references to other sections of the Safety Data Sheet should be made.

* Or other languages permitted by the Member State e.g. English.

17

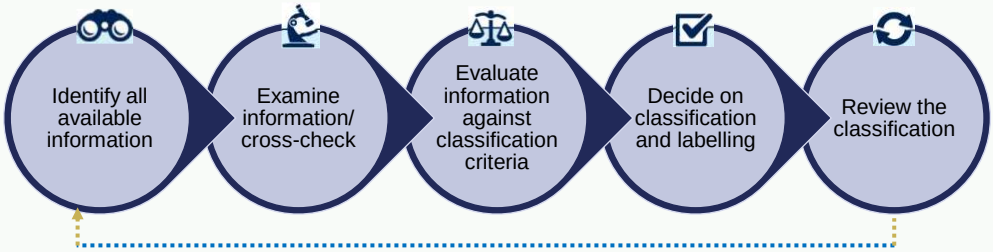
Assign concentrations to all components

- All components (substances and mixtures) of the mixture must be declared including:
  - the hazardous components
  - non-hazardous components**
- Exact concentrations or concentration ranges allowed
- The allowed range width depends on the concentration and hazard category reported in Annex VIII.
- If the concentration changes or if it goes beyond the allowed limits, then a notification update is required.

**** These components are not normally detailed in the Safety Data Sheet.**

18

Steps to classify a mixture



Consider what information you actually have available.

Is the information you have relevant and reliable?

Proceed hazard by hazard

Classify and label with appropriate label element

New information is generated all the time – keep up to date!

19

Declaring components of 'major concern'

When mixture components are classified for at least one of the hazard categories listed below, their concentrations in a mixture should 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.

Hazard classification

As an alternative to providing a concentration as an exact percentage, a concentration range may be submitted in accordance with Table 1 in Part B of Annex VIII (Table 1 below).

Where the exact concentration is higher than 1 %, the upper and lower limits of the concentration bands may be rounded to a maximum of one decimal; where the exact concentration is lower than or equal to 1 %, a maximum of two decimals may be used.

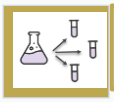
Table 1: Concentration ranges applicable to hazardous components of major concern for emergency health response (substances or MiMs)

Concentration range of component contained in the mixture (%)	Maximum width of concentration range to be used in the submission
≥ 25 - < 100	5 % units
≥ 10 - < 25	3 % units
≥ 1 - < 10	1 % units
≥ 0.1 - < 1	0.3 % units
> 0 - < 0,1	0.1 % units

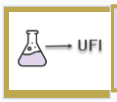
20

Declaring mixture-in-mixture components

- Check the formulation of any **mixtures in mixtures (MiMs)** and report each component's identity and concentration according to the information available.



Full composition is known from MiM supplier
Report information on all substances at the final mixture level. Aggregate where relevant.



Full composition of the MiM is not known
Report the UFI of the MiM provided it has been already notified in the relevant Member State.

No MiM UFI or MiM not notified in the relevant Member State
List the compositional information from the SDS along with the MiM supplier information.

21

Implications on SDS

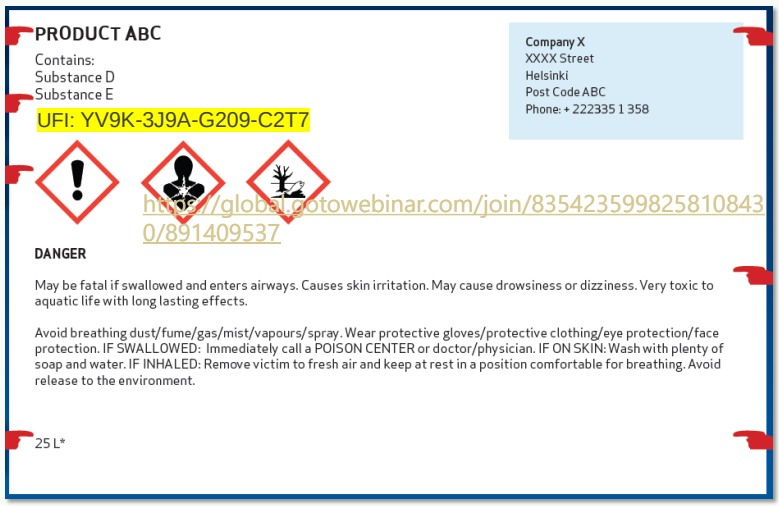
- The UFI is always to be included in the notification **as well as** on the label/packaging
- No rules on placement -redesign of label to incorporate this new element
- If the product is not packaged or has an industrial use or any other use, the UFI can be included in section 1.1 of the SDS
- Printing of UFIs on the label should be planned to coincide with the submission of information

22

Cont...

- In case of mixtures in mixture, if the composition details are not available then it is mandatory to give SDS and supplier information along with poison centre notification
- It is **mandatory** to have UFI on your SDS post from 1 Jan. 2021
- UFI should be from the actual notification done for PCN else it will be treated as dead/inactive UFI
- Mixture classification should be done correctly
- All data should be presented in SDS based on which the classification is done for mixtures
- M-factor or Specific Concentration Limits (SCL) are used that should also be mentioned in section 2 of SDS

Sample Label with UFI



Stepwise Actionable Points

GPC can:

- Do the pre-assessment of your mixtures- to know your PCN obligations
- Compile the data required for PCN notification
- Notification on behalf of your company

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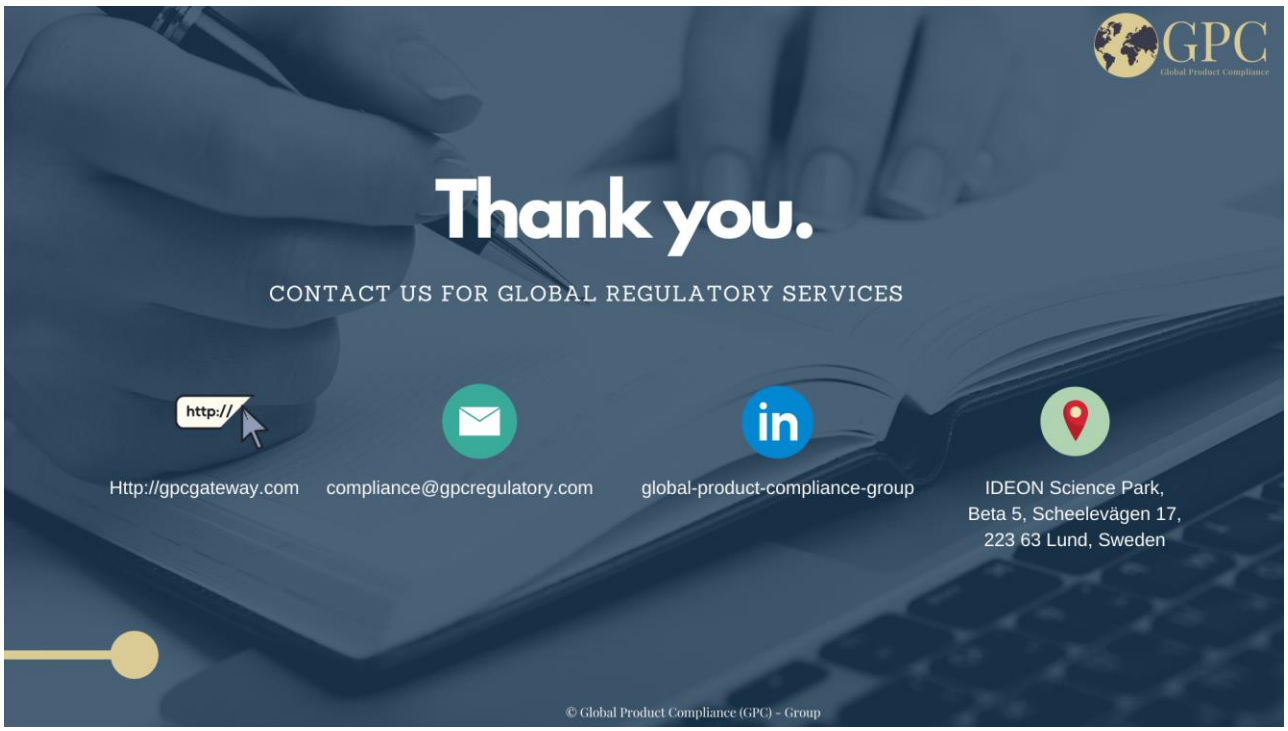
25

25



26