Online information session

Getting prepared to notify your hazardous mixtures according to Annex VIII CLP

ECHA Poison Centre Team

11 December 2018
11.00 - 13.00 Helsinki time
With you today

Daniele Ape  
Daniel Sompolski  
Heidi Rasikari

Online panelists: Mercedes Viñas, Vasileios Tsifoutis, Claudia Rimondo, Sari Jaanu, Jakob Aahauge, Stefan Supanic, and Erika Burai
To ask a question

• Use the Q&A panel at any time

• We will answer as many questions of general interest as we can today

• Specific questions or questions after the event to echa.europa.eu/contact
Recording available
poisoncentres.echa.europa.eu/

Have you categorised your hazardous mixtures?
11 December 2018
If you are an importer or a downstream user of hazardous mixtures, it is time to get familiar with the European product categorisation system (EuPCS) and categorise your mixtures.

News

24 July 2018
New study on workability issues
A new study initiated by the European Commission addresses concerns raised by stakeholders on the workability of new requirements for the notification of information on hazardous chemical mixtures for emergency health response.

29 June 2018
Guide for European Product Categorisation System published
A new European Product Categorisation System (EuPCS) practical guide for industry has been published.
Today’s objectives

• Offer advice to industry on how to start preparing notifications already now

• Highlight harmonised information requirements beyond the safety data sheet

• Inform about expected timelines regarding the Guidance and IT tools for preparation and submission

• Opportunity to ask questions on regulatory matters related to Annex VIII of the CLP Regulation
Getting prepared to notify your hazardous mixtures according to Annex VIII
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
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
Who has to submit information?

- Importers and downstream users placing hazardous mixtures on the market.

*Distributors are not considered duty holders – Member States challenging the role of distributors ‘placing on the market’ – open issue discussions ongoing
Timelines for compliance

- Notifications must comply with the harmonised requirements according to the use type of the mixture
  - 1 January 2020: consumer uses
  - 1 January 2021: professional uses
  - 1 January 2024: industrial use only

- Transition period for existing products ends 1 January 2025
  - unless change made to existing notification between relevant deadline and end of transition period
Harmonised requirements in a nutshell

- **Submission format** – Poison Centre Notification (PCN) format, IUCLID compatible, structured fields for information
- **Submitter details** – name, address... - consistent with the label
- **Mixture information** - C&L, tox info, composition, pH, physical state
- **Product information** - trade name, packaging, uses, colour
- **Unique formula identifier** – e.g. YV9K-3J9A-G209-C2T7, UFI makes a link between the product and the submitted mixture information
Beyond the safety data sheet – adapting existing or including new data
Review toxicological information

- Toxicological information from SDS section 11
  - Free text in all required languages
  - Check quality - no references to other sections
Obtain the full composition

• Hazardous components
• Non-hazardous components
  • not normally detailed in the SDS
  • establish improved information exchange in supply chain

• Check the formulation of any mixtures in mixtures (MiMs)
  • Best case scenario – report information on all substances
  • In other cases, possible to use the UFI notified by your MiM supplier, provided you also list all the known components
Assign concentrations to all components

https://poisoncentres.echa.europa.eu/components-of-major-concern

- Exact concentrations or concentration ranges allowed

- If ranges are used, check the maximum width allowed (see Tables 1 & 2 of Annex VIII)

- Components that are not classified for physical and health effects need only be declared at concentrations ≥1%
Consider exceptions...

• Perfumes, fragrances and colouring agents may be generically identified (GPIs) if
  • They are not classified for any health hazard
  • Function and total concentration provided
  • Total concentration within thresholds

• Some submissions can contain limited compositional information if
  • Mixture has industrial use only
  • 24/7 phone service provided
Review product information

• Additional mapping may be required:
  • 33 packaging types available
  • 14 colours available

• Assess the use type(s) down the supply chain
  • Consumer
  • Professional
  • Industrial

• Select a product category according to the European product categorisation system
Assign product category

- Based on a single main intended use
- Select from 250 categories
- Descriptions/examples available
- Advice when more than one use
Generate and assign UFIs
poisoncentres.echa.europa.eu/ufi-generator

- A single UFI can only be assigned to one mixture composition
- To generate a UFI you need:
  - company VAT number
  - formulation number between 0 - 268 435 455
- Additional mapping of internal formulation codes/names (i.e. letters or special characters) may be required
- UFI generator tool available or you can implement a UFI generating algorithm in your own systems
Plan the relabelling of your products

• 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 only, 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
Follow guidance
poisoncentres.echa.europa.eu/guidance

- Draft version in last consultation step with Member States and EU Commission ongoing

- **Open issue** role of distributor → Under discussion: waiting for the outcome

- Expected publication of first final version early 2019

- Translations following outcome of ongoing discussion on distributors’ role
Dossier preparation and submission tools
Tools for preparation and submission

Guidance, support material & Helpdesk

ECHA TOOLS FOR PREPARATION

ECHA TOOLS FOR SUBMISSION

PCN PORTAL

Annex VIII CLP Regulation

INDUSTRY

Prepare

Submit

Receive

MEMBER STATES
Ways to prepare and submit 1/3

Online preparation in the PCN portal

• Guided dossier preparation tool for manual entering of data

• User friendly interface with step by step instructions and help

• ECHA Cloud service available to store dossier

• Dossier can be validated before submission to the PCN portal
Ways to prepare and submit 2/3

Offline preparation using IUCLID

- Additional option for companies preferring to enter data manually

- A new PCN user interface developed in IUCLID 6

- IUCLID dossier can be submitted to the PCN portal or to national submission systems

- Dossier validated before submission
Ways to prepare and submit 3/3

**System-to-system (S2S)**

- Most advanced dossier preparation and submission method
- Companies can directly prepare dossiers in PCN format in their own systems
- Submission occurs through automatic transfer to the PCN portal
- Supports companies with large portfolios
- Validations only possible after submission
PCN portal development – version 1

- Version 1 April 2019
- Features for industry
  - Online dossier preparation tool
  - Submission and search functionality
- Features for Member States
  - Secure mechanism to download notifications (security model in place)
PCN portal development - version 2

- Version 2 November 2019
- Features for industry
  - S2S automated submission
  - Improved user interface – multilingualism, online help...
- Features for Member States
  - S2S automated receipt in own database
  - Searchable database available for all MS to search notifications
Need support?  
poisoncentres.echa.europa.eu/steps-for-industry

Steps for industry

Under the new Annex VIII to the CLP Regulation, importers and downstream users placing hazardous mixtures on the market will have to provide specific information on their mixtures to appointed bodies. The annex also introduces a new harmonised format for notifications. The information will be used by poison centres for emergency health response purposes in case of incidents involving these mixtures.

The following pages aim to provide support to industry regarding their new obligations. The advice is based on the most current information available – however, this may be subject to change in the future. The specific Guidance on this topic is expected to be finalised at the end of 2018.

1. Know your obligations

- Know your obligations
- Know the standard information requirements
- Know your portfolio
- Generate your UFIs
- Adapt your data
- Prepare your submission
- Keep the information up to date
Q&A session

Daniele Ape
Daniel Sompolski
Heidi Rasikari
The webinar has ended

Thank you for joining us

We continue to answer your questions via the Q&A panel until:
13:00 Helsinki time

If you don't receive an answer by then, contact us:
echa.europa.eu/contact
Thank you!

Subscribe to our news at echa.europa.eu/subscribe

Follow us on Twitter @EU_ECHA

Follow us on Facebook Facebook.com/EUECHA
Recordings published

On our YouTube channel:
YouTube.com/Euchemicals

Material from previous webinars:
echa.europa.eu/support/training-material/webinars/