Implementing Annex VIII for EU Poison Centers

By: Alec Dierenfield & Nichelle Rubash

Definition

Annex VIII amendment to Regulation EC No 1272/2008 creates a standardized submission process, and common way to access and utilize information pertaining to hazardous mixtures sold in the EU.

Why does it exist

Current requirements for reporting product composition differ widely between each country, creating an unnecessary burden for companies selling their products in several or all EU countries. A standardized submission method across all countries will greatly decrease the cost for such companies. The new submission process will also provide all EU poison center responders with the same medical information, leading to more efficient and objective medical responses.

- The regulation leads to a standardized method of providing information on product composition.
- EU responders will also have the same medical information available.
- UFI allows responders to exactly identify the product and its composition.
- This leads to a more efficient and objective medical response.
- It also reduces unnecessary over-treatment which is often given to be on the safe side.

Products and Chemicals it applies to

Applies to:

- Mixtures with a health or physical hazard classification
- Biocides
- Detergent and Cleaning Agents

Exempt:

- Mixtures solely for research and development
- Any products/chemicals exempt from CLP
- Explosives and Non-Hazardous gases

Deadlines

Materials need to be in compliance based on their intended use by the following dates:

- Consumer Use: January 1st, 2020
- Professional Use: January 1st, 2021
- Industrial Use: January 1st, 2024

Submission Overview

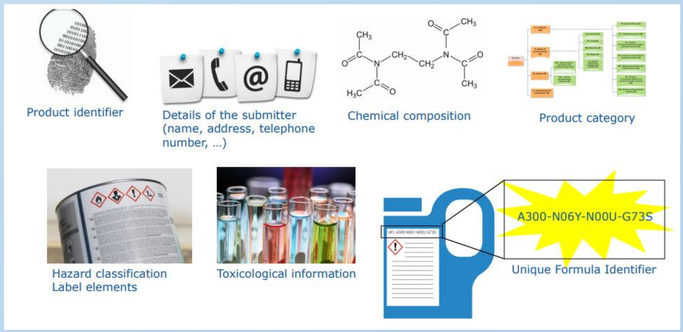
When an Importer or Downstream user, wants to sell a hazardous mixture in the EU, they must submit an application to applicable member states or the EU with the following information:

- Product Identifier (e.g.: UPC Code)
- Details of Submission company (Phone number, Address etc.)
- Exact Chemical composition (including hazardous and large percentage non-hazardous components); Industrial mixtures have a reduced submission
- Formulation components (with SDS documents or UFI)
- Product Category
- Hazard Classification Label
- Toxicology Information (Physical and Health hazards)
- Unique Formulation Identifier (16 digit code generated by EU that is unique to each mixture)

Unique Formulation Identifier (UFI)

The UFI is a 16-character alphanumeric code that will print on the product label. It is generated electronically when submitting. The UFI creates a unique link between a product and its poison center information. The requirements for needing a UFI are:

- A UFI is required for all hazardous formulations.
- A UFI is recommended for formulations classified as Not Hazardous or Hazardous only to the Environment but is not required.
- A new UFI needs to be created if there is change in the health hazards or a change in composition (see *Resubmission* and *Mixture in a Mixture*)

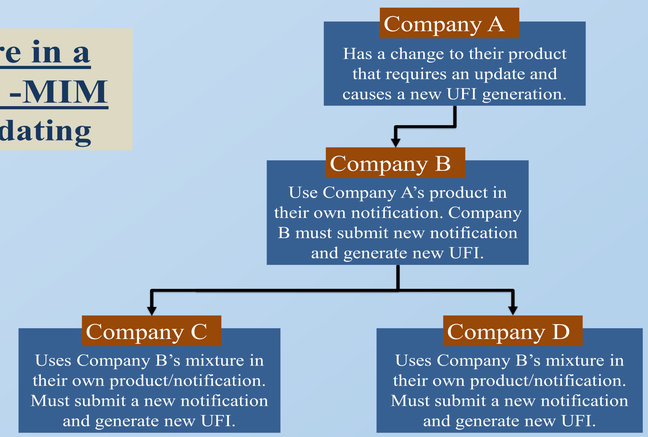


Resubmission

If there are changes to an already submitted product, a new submission must be done before it can be placed on the market. Those changes that would require a resubmission are:

- A change to the UFI
- Change to Physical or Health Hazard Classification
- New toxicology information
- Addition or removal of component
- Changes to concentration of component

Mixture in a mixture -MIM UFI updating



Steps to be ready

- Know where you are placing your product on the market and corresponding deadlines
- Create an internal system to track composition and hazard changes
- Get Compliant Raw Material (RM) SDS documents or RM UFIs
- Enter all composition components in IUCLID
- Submit all in scope chemicals to Poison Centers before deadline
- Know if and how your product is being used downstream
- Submitter is required to create submission for new mixtures created by downstream distributors or retailors by mixing existing products together or by additives (e.g.: Mixing paints to create new colors)
- Also Note:
  - Regulation is not yet been finalized by ECHA
  - Reports say that ECHA's IT solutions are significantly behind schedule

Sources: http://ec.europa.eu/growth/sectors/chemicals/poison-centres/; https://poisoncentres.echa.europa.eu/
http://www.hibiscus-plc.co.uk/wp-content/uploads/2017/12/chemical-pic-01-1024x410.png; https://kaeltia.com/wp-content/uploads/2017/06/blogPoison-1-1024x379.png;