New legal requirements for submission of product information to Poisons Centres in EU Member States

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The Netherlands
Different product notification procedures in EU

- Product information requirements
- Notification forms
- Methods of electronic notification

HARMONISATION!
Discussion on product information requirements

First phase 2009-2010
- EAPCCT Guidelines
- Workshop on the harmonisation of information for Poisons Centres

Second phase (2011-2012)
- Stakeholder discussions
- Review cf. article 45(4)

Third phase (2013-2015)
- CARACAL (draft legal text)

Fourth phase (2016)
- REACH committee
Draft Annex VIII on product notification

Information requirements
Product identifier
• Complete trade name(s) of the product
• Unique Formula Identifier (UFI)
• Other identifiers
Contact details of the submitter
Contact details for rapid access (24/7)

Classification of mixture and label elements
• Hazard class and category
• Hazard pictograms codes
• Signal word
• Hazard statements codes
• Precautionary statements codes

Toxicological information
• as in Section 11 of Safety Data Sheet

Additional Information on the mixture
• Colour
• pH
• Physical state (solid, liquid, gas)
• Packaging (type and size)
• Intended use (Product Categorisation Code)
• Consumer, professional, industrial use

Composition
• Chemical name of the substance
• CAS number, EC number
• Hazard class and category
• UFI (mixture in mixture)
• Concentration (exact or range)

Blue: not on SDS or less detailed
Composition – components in mixture

The following components shall be indicated:

- classified for health or physical hazards:
  - all components in concentration ≥ 0.1%
  - identified components in concentration < 0.1%

  Excluding e.g.: impurities/additives of a substance

- not classified for health or physical hazards:
  - all components in concentration ≥ 1%
Composition – concentration of component

**CLP Regulation (EC) No 1272/2008**

### Health hazard classes

<table>
<thead>
<tr>
<th>Hazardity</th>
<th>Categories</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute toxicity Oral</td>
<td>1 3 4</td>
</tr>
<tr>
<td>Acute toxicity Dermal</td>
<td>1 3 4</td>
</tr>
<tr>
<td>Acute toxicity Inhalation</td>
<td>1 3 4</td>
</tr>
<tr>
<td>STOT* - single exp</td>
<td>1 2 3</td>
</tr>
<tr>
<td>STOT* - repeated exp</td>
<td>1 2</td>
</tr>
<tr>
<td>Aspiration hazard</td>
<td>1</td>
</tr>
<tr>
<td>Skin corrosion/irritation</td>
<td>1 2</td>
</tr>
<tr>
<td>Eye damage/irritation</td>
<td>2</td>
</tr>
<tr>
<td>Respiratory sensitisation</td>
<td>1</td>
</tr>
<tr>
<td>Skin sensitisation</td>
<td>1 2</td>
</tr>
<tr>
<td>Carcinogenicity</td>
<td>1 2</td>
</tr>
<tr>
<td>Mutagenicity</td>
<td>2</td>
</tr>
<tr>
<td>Reproductive toxicity</td>
<td>2</td>
</tr>
</tbody>
</table>

* Specific Target Organ Toxicity

1. **Hazardous components of major concern for emergency health response:**
   - Exact concentration
   - Alternatively: narrow ranges

2. **All other components:**
   - Wider ranges
Hazardous components of major concern for emergency health response

Example:
Exact concentration 26%
Falls in > 25 - ≤ 100 range
Allowed # of units: 5

Can be notified as:
21-26%, 22-27%, 23-28 %, 24-29%, 25-30%, 26-31%
but also 25-27% or even 26%

• Sufficient for adequate risk assessment
• Sufficient confidentiality
• Reduce renotification after small changes in ingredient concentration
For all other components in the mixture:

<table>
<thead>
<tr>
<th>Exact concentration (%)</th>
<th>Maximum width of the concentration range:</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥ 25 - &lt; 100</td>
<td>- 20 % units</td>
</tr>
<tr>
<td>≥ 10 - &lt; 25</td>
<td>- 10 % units</td>
</tr>
<tr>
<td>≥ 1 - &lt; 10</td>
<td>- 3 % units</td>
</tr>
<tr>
<td>≥ 0 - &lt; 1</td>
<td>- 1 % units</td>
</tr>
</tbody>
</table>

Example:
Exact concentration 50%
Falls in > 25 - ≤ 100 range
Allowed # of units: 20

Can be notified as:
40-60%, 50-70%, 30-50%, etc
Composition – requirements in EU countries

**COMPOSITION**

<table>
<thead>
<tr>
<th>SDS</th>
<th>Harmonisation</th>
</tr>
</thead>
<tbody>
<tr>
<td>🇫🇮</td>
<td>🇫🇮 🇩🇰 🇩🇪 🇫🇷</td>
</tr>
</tbody>
</table>

Thresholds for classified substances

Thresholds for *all* substances

Exact composition (no thresholds)

**CONCENTRATION**

<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>🇫🇮</td>
<td>🇪🇸 🇫🇷 🇨🇿 🇳🇱</td>
</tr>
</tbody>
</table>

No guidelines

Specified ranges

Exact concentration and specified ranges

Exact concentration
Unique Formula Identifier

Identification of the mixture is important!

- UFI changes with formula change
Electronic format

Large companies
IT-system

Small/Medium
Basic Application

Companies
SDS software

Product notification Portal? ECHA
Future European database?

Appointed bodies
IT-system

Import module
XML to PDF

Used as viewer

XML format

• Automatic format/quality check
• Better search options in database

Dr. Dieter Tox
Toxicology and classification
0032 475 123456

ECHA

Portal?
ECHA
XML format

Product notification Portal?

Basic Application

IT-system

Import module
XML to PDF

Used as viewer

Administrative information
Submitter information
Product information
Mixture information
Mixture components
Comments

* Country of placing on the market
* Submission type
  • Hazardous mixture
  • Non-hazardous mixture
* Submission reason
  • New mixture (initial submission)
  • Update
* Limited submission (industrial use only)
* Submission language(s)
Poisons Centres have to prepare!

Official publication of CLP Annex VIII expected in autumn 2016

Transition periods:
• Mixtures for consumer use: 2019
• Mixtures for professional use: 2020
• Mixtures for industrial use: 2023

Coming 3 years Poisons Centres have to prepare!
ECHA Poison Centres website

What is a poison centre?

Poison centres play an important role in the safe use of chemicals. They formulate preventive and curative measures in case of poisoning accidents. They provide medical advice to general consumers and physicians on health emergencies arising from exposure to hazardous chemicals or to other toxic agents.

Poison centres in the EU answer on average 600,000 calls for support each year. Roughly half of the cases are related to accidental exposures involving children.

Under Article 45 of the CLP Regulation, economic operators placing certain hazardous mixtures on the market have to provide information to national appointed bodies. This information is used by poison centres.

This website is established by the European Chemicals Agency to host the tools and format to support the submission of information by companies to the appointed bodies and poison centres.

Quick links

- List of national appointed bodies
- National helpdesks
- ECHA website
- CLP regulation
- DG GROWTH studies

News

5 April 2016
EU Commission is finalising its proposal for the harmonisation of information according to Art. 45 CLP

This is the result of a long process started in 2010 with the consultation of stakeholders, appointed bodies, poison centres and Member States competent authorities. The regulation is expected to be published in early autumn 2016.

https://poisoncentres.echa.europa.eu/
Thank you for your attention

Harmonisation!

"All for one - one for all"

DOUGLAS FAIRBANKS presents

"THE THREE MUSKETEERS"

Adaptation, Costuming, Research under EDWARD KNOBLOCK
Direction under FRED NIBLO
Photography under ARTHUR EDeson

Poisons Centres
Commission
Industry
Governmental authorities

UMC Utrecht
Nationaal Vergiftigingen Informatie Centrum
Scope of the legislation

Applies to:

- Mixtures classified as hazardous based on health or physical effects
  - including: biocidal and plant protection products
- excluding: ‘gases under pressure’ and ‘(unstable) explosives’
  (and not classified for any other hazard)

- Mixtures for consumer use, professional use and industrial use
- Reduced submission requirements mixture for industrial use only
  - REACH code SU3
  - Notification of SDS
  - Rapid access to detailed product information (24/7 telephone number)

Does not apply to:

- Mixtures for “Scientific Research & Development”