Preparation of notifications for poison centres according to Annex VIII CLP

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8th BfR User Conference on Product Notifications
Berlin, Germany

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CLP – Annex VIII


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II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) 2017/542
of 22 March 2017
amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures by adding an Annex on harmonised information relating to emergency health response
(Text with EEA relevance)

- New Annex published in March 2017
- Obligation for **importers and downstream users** placing hazardous mixtures on the market to notify national appointed bodies
- Phased deadlines by 1 January
  - 2020 for consumer use
  - 2021 for professional use
  - 2024 for industrial use
  - 2025 marks end of transition period
  - Before placing on the market (no data, no market)

1. What companies will need to notify?

2. Poison centres project – where are we?

3. Getting ready – how can industry prepare?

4. Questions and answers

What companies will need to notify?

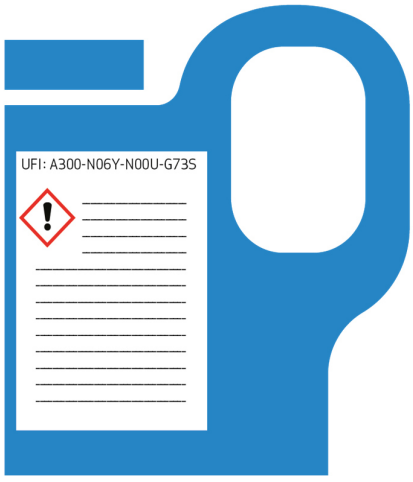
What companies will need to notify?

Unique Formula Identifier (UFI)

Unique Formula Identifier

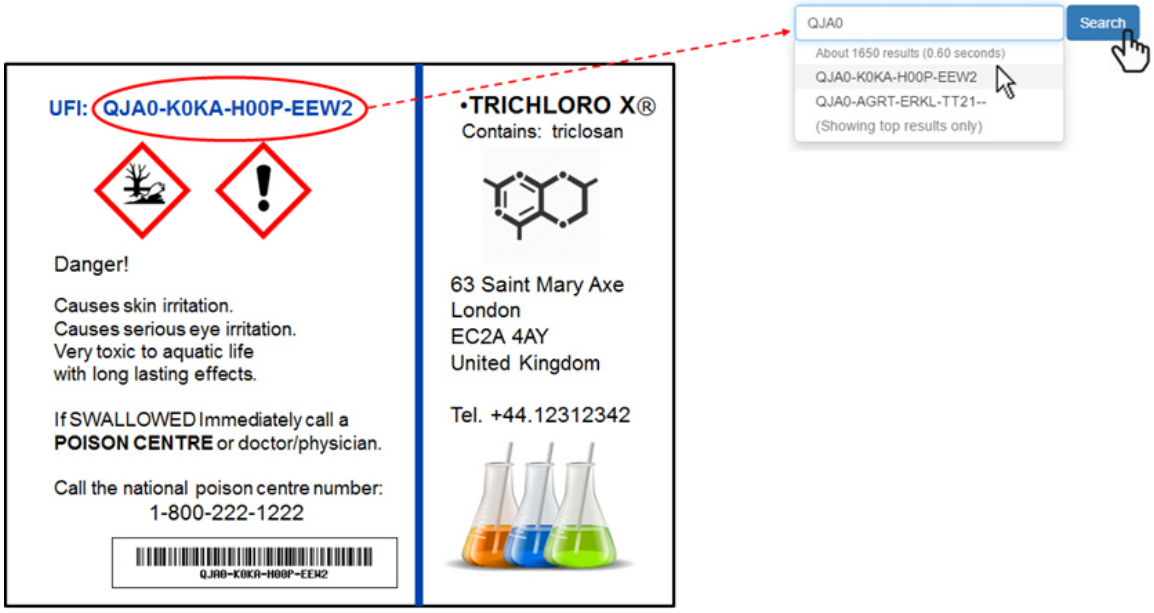
New notification requirement for product label

Unique 16 character code in 4 blocks



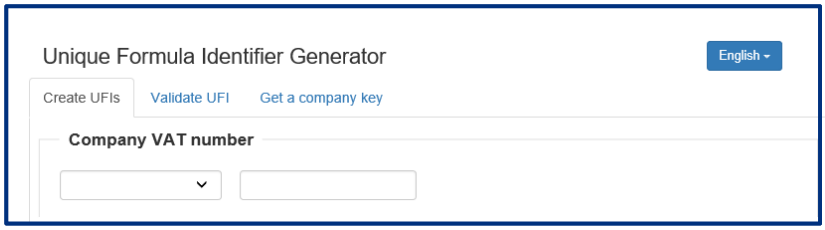
UFI code links the notified mixture **composition** information to a specific product on the market

Relevance of UFI for poison centres



Current status

- Final version of UFI Generator and algorithm (with developers guide) available poisoncentres.echa.europa.eu/



- Single or multiple generation of UFIs
- Available in all EU languages

What companies will need to notify?

Unique Formula Identifier (UFI)

Details of the submitter

Details of the submitter

Details of the submitter

- Company name
- Address
- Phone number
- Email address

- Information consistent with the label

What companies will need to notify?

Unique Formula Identifier (UFI)

Details of the submitter

Details of product

Details of the product

- Trade name
- Physical state
- Colour
- pH
- Packaging type and size
- Use (consumer, professional, industrial)

What companies will need to notify?

Unique Formula Identifier (UFI)

Details of the submitter

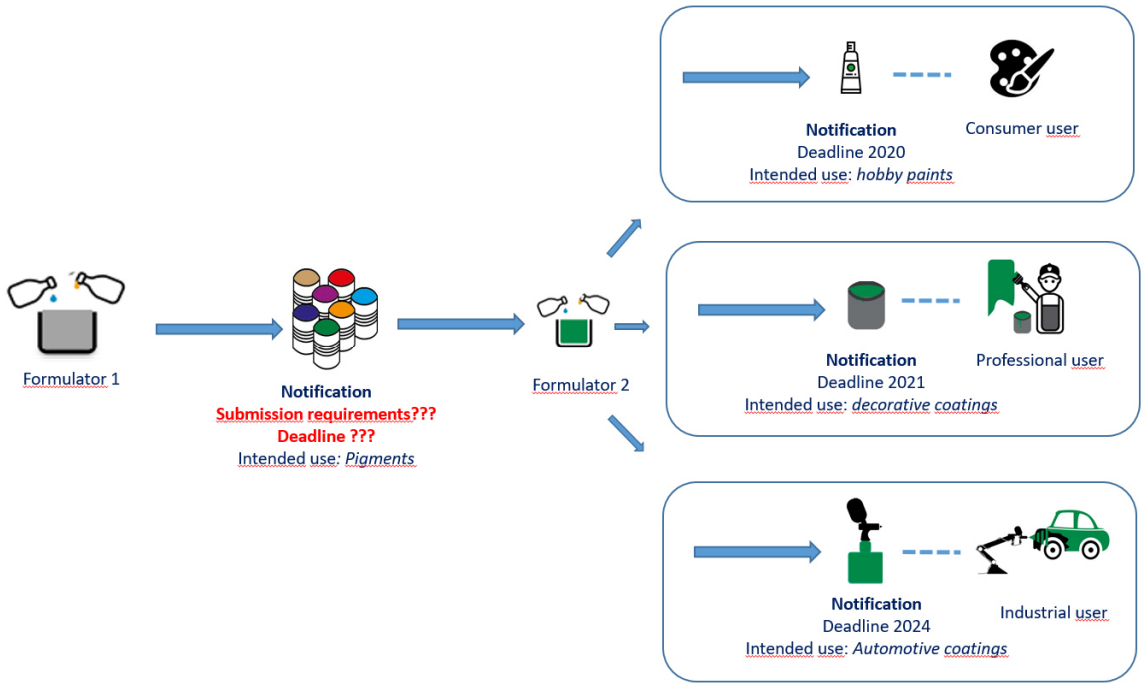
Details of product

Product category

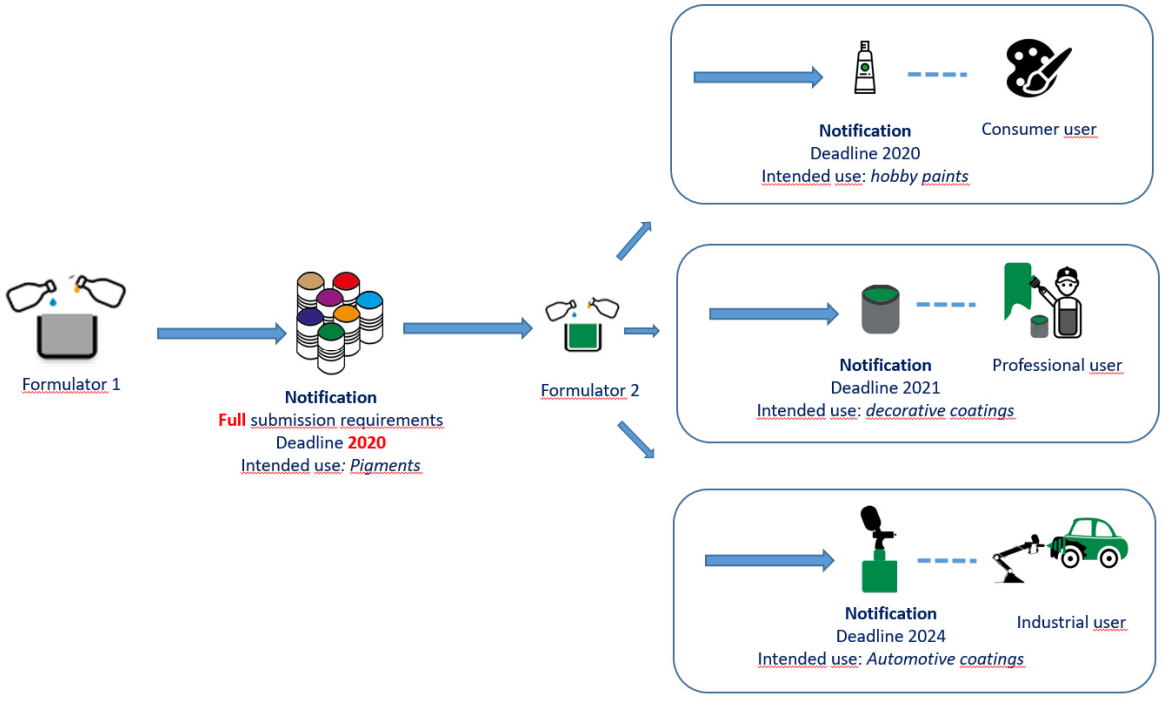
Product categorisation - key principles and purpose

- Product category mandatory in industry notifications
- Single selection based on main intended use
- Supports appointed bodies at EU level
  - reporting/statistical analysis of poisoning incidents
  - identification of risks & proposing risk management measures
- Used by poison centres e.g. for 'backtracking' and registering cases in incidents

Intended use and end user

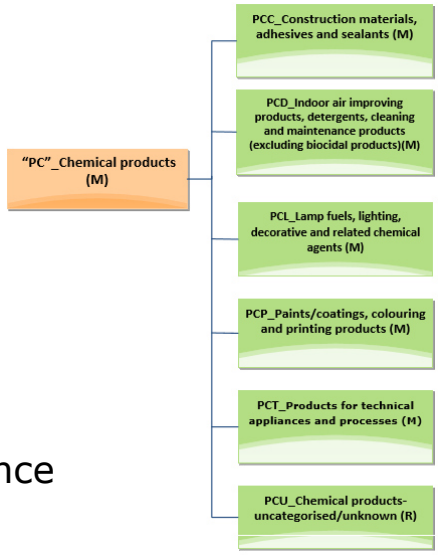


Intended use and end user



Current status

- Draft EU PCS published in March 2017
- Final version 1.0 by December 2017
- Active participation from working group
- Development of practical EU PCS manual
- Process for EU PCS update and maintenance currently being developed



What companies will need to notify?

Unique Formula Identifier (UFI)

Details of the submitter

Product category

Details of product

Toxicological information

Toxicological information

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity
Practical experience / human evidence: No data available
Animal data:

	Effect dose / concentration	Species	Method	Symptoms / delayed effects	Remark
Acute oral toxicity	LD50: >2000 mg/kg bw	Rat female	OECD 423	No adverse effect observed	Direct derivation of an ATE because of robust data
Acute dermal toxicity	LD50: >2000 mg/kg bw	Rat	OECD 402	No adverse effect observed	Direct derivation of an ATE because of robust data
Acute inhalation toxicity (vapour)	LC50: 62,300 mg/l	Rat male	OECD 403	No adverse effect observed	Direct derivation of an ATE because of robust data.

Other information: No data available
Assessment / Classification: Based on available data, the classification criteria are not met

Skin corrosion/irritation
Practical experience / human evidence: No data available
Acid-/Alkali reserve (buffer capacity for mixtures with extreme pH values)
Acidic reserve [g NaOH/100 g product]: not applicable
Alkaline reserve [g H2SO4/100 g product]: not applicable
Animal data:

Exposure time	Observation time	Species	Method	Result / evaluation	Remark
24 hours	72 hours	Albino rabbit	OECD 404	erythrema Scores: 2.3, reversible	

In-vitro skin test: data lacking
Other information: No data available
Assessment / Classification: Causes skin irritation

Serious eye damage/irritation
Practical experience / human evidence: No data available
Animal data:

Species	Method	Result/Evaluation	Remark
Albino rabbit	OECD 405	Conjunctival redness Scores: >= 2 Chemosis Scores: 1.5 Corneal opacity Scores: 1.7	

Other information: No data available
Assessment / Classification: Causes eye irritation

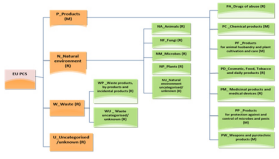
Sensitisation to the respiratory tract
Practical experience / human evidence: No data available
Other information: No data available
Assessment / Classification: Not classifiable due to data lacking

What companies will need to notify?

Unique Formula Identifier (UFI)

Details of the submitter

Details of product



Product category

Toxicological information

Hazard classification
Label elements

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Hazard classification
Label elements

- Classification of the mixture (health and physical hazards)

- Hazard pictogram codes
- Signal words
- Hazard statement codes
- Precautionary statement codes

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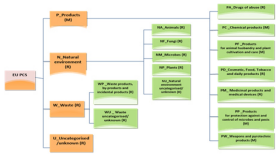
What companies will need to notify?

Unique Formula Identifier (UFI)

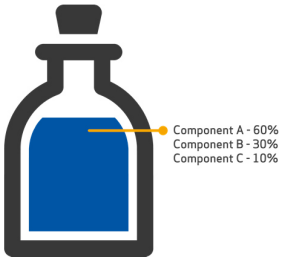
Details of the submitter

Details of product



Product category

Toxicological information

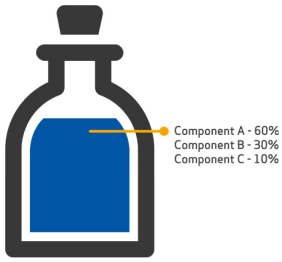


Full chemical composition

Hazard classification
Label elements

echa.europa.eu

Full chemical composition



- More information than normally present in SDS – need for more information exchange in supply chain
- All components must be indicated, also non-hazardous
- Exact concentrations or ranges
- Classification of components
- Generic components possible for perfumes, fragrances and colouring agents
- Mixtures in mixtures (MiM) possible via UFI to protect CBI

- UFI linked to the mixture **composition**, not product/mixture
- New UFI (and new label) needed when:
  - adding, substituting or deleting a component
  - variation in concentration beyond the range specified
  - supplier changes UFI and it has impact on MiM

Annex VIII and ECHA's role

Annex VIII and ECHA's role

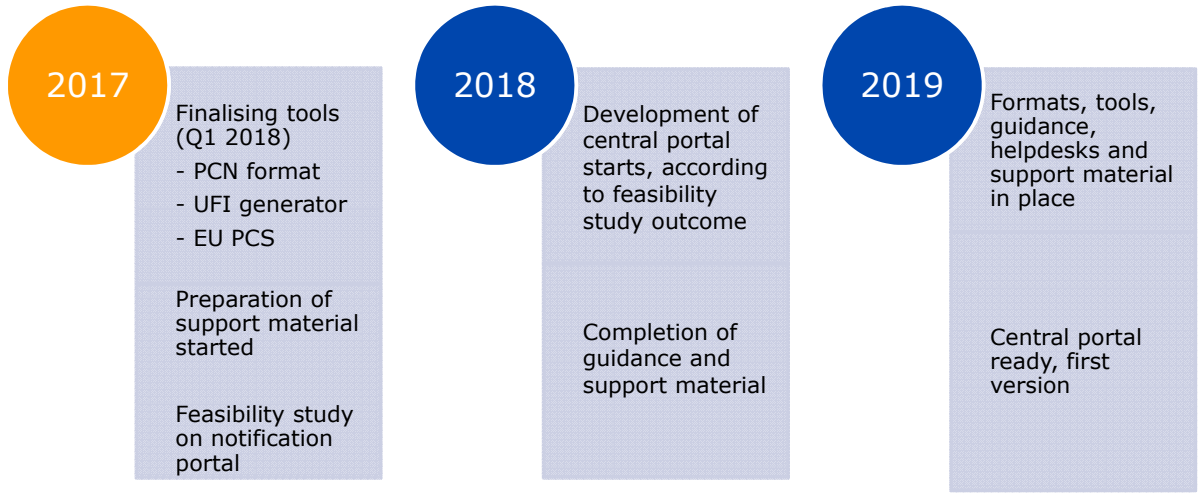
ECHA is here for you:

- Technical and scientific guidance and support
- Tools to facilitate submission of information

These include:

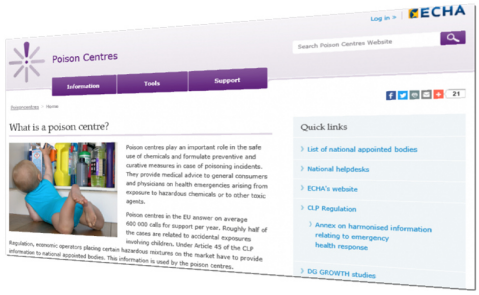
- Unique Formula Identifiers (UFI) generator
- Product categorisation system (PCS)
- Poison centres notification (PCN) format
- Development of a central notification portal?
- Guidance and support material

Timelines



Where are we?

- Poison Centres website is live poisoncentres.echa.europa.eu
- Outcome of the feasibility study on central notification portal



- ECHA/Stakeholder working groups in operation

Guidance	EU product categorisation system	IT tools

Guidance and support

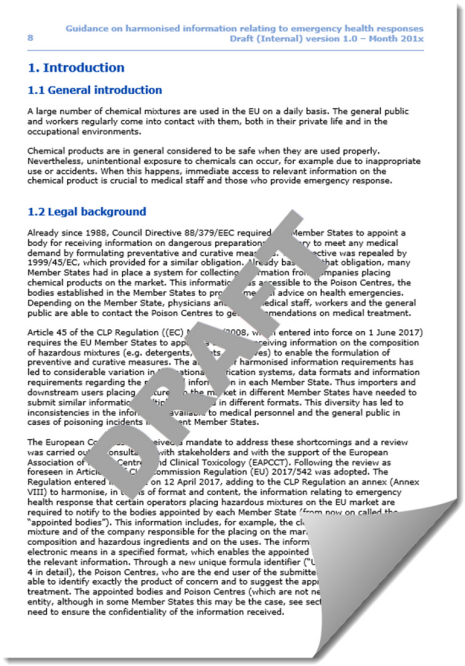
Guidance phase 1

Phase 1: drafting (on-going)

- Active involvement of authorities and industry via working group

  poisoncentres.echa.europa.eu/guidance

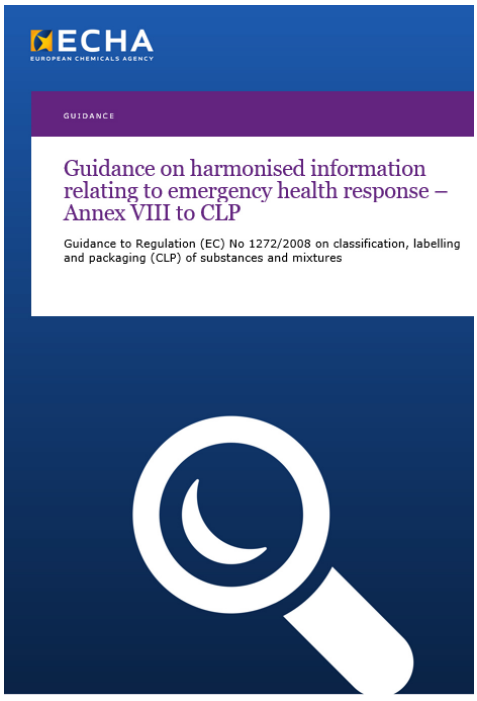
- Workshop on 5 Dec 2017
- First draft early 2018



Guidance phase 2

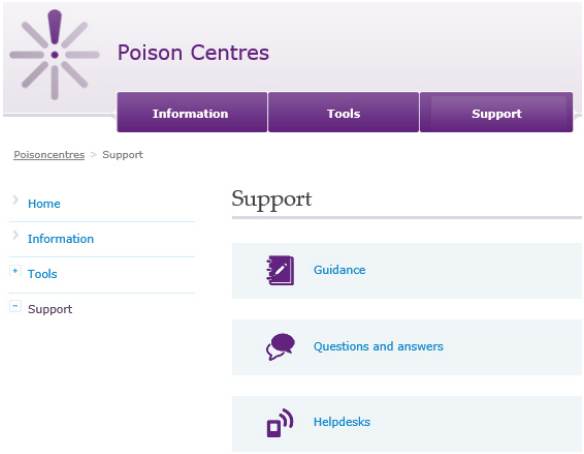
Phase 2: formal consultation with our partners

- Launch in Q1 2018
- Active participation of our accredited stakeholders
- Final Guidance v1.0 by end 2018



Support - current status

- >50 Q&As published
  visit our support page
- Targeted support for companies
  under development
- Training for national Helpdesks
  coming in 2018
- UFI factsheet
  coming soon



Get ready
How can industry prepare?

Know your obligations

- Are you importer or downstream user?
- Mixture hazardous? Exemptions?
- Deadlines? Transition period?
- Which countries?

Familiarise yourself with required information

- Full chemical composition
  - → enhanced communication in supply chain needed?
- UFI generation
  - → mapping company internal codes of mixtures
  - → planning re-labelling activities – can be done before the due time for notification
- Product categorisation according to PCS
- Section 11 of SDS
  - → improving quality or relevancy?
  - → language

Know your portfolio

- Uses: consumer, professional or industrial?
  - Note: consider uses downstream, not only your own
- Limited submission for industrial uses?
- Group submission for product 'families'?
- CBI important? Prepare to provide UFI to your customer (also possible for non-hazardous mixtures)
- Assign concentration (exact or ranges) to components of your mixtures

Get prepared

- Data management system needed?
- Process for monitoring and change management?
- Resources implication
- Redesign of labels
- Decision on preferred way of preparing information
- Decision on preferred way of submitting information

This is all done for…

Poison Centres

Questions and answers

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