



**An Roinn Talmhaíochta,
Bia agus Mara**
Department of Agriculture,
Food and the Marine



Notifying Hazardous Mixtures to the
National Poisons Information Centre

Webinar
9th March 2021



**An Roinn Talmhaíochta,
Bia agus Mara**
Department of Agriculture,
Food and the Marine



Overview of the legal requirements and guidance on notifying hazardous chemical mixtures in accordance with Annex VIII of CLP

**Caroline Walsh, Inspector
Health and Safety Authority
9th March 2021**

Overview

- Legislative background
- Annex VIII – key obligations
- What information to notify
- About the UFI
- Support material



Poison Centres

Annex VIII- legislative background

CLP & REACH Regulations

- Direct acting in all Member States and EEA
- Relevant provisions:
 - **Title VI, Article 45** and Annex VIII (new) regarding poison centre notification
 - **Title IV, Article 31** and Annex II, Section 1.4 regarding emergency number
- In Ireland:
 - Notifying mixtures applies only to hazardous mixtures within the scope of CLP Article 45 including biocides and plant protection products
 - No requirement to notify mixtures which are outside the scope of Article 45, but this can be done voluntarily

Competent Authorities in Ireland



- Chemicals Act 2008 & 2010 covers the administration and enforcement of REACH and CLP in Ireland and appoints..
- Health and Safety Authority - CA for chemicals
- Department of Agriculture, Fisheries and the Marine - CA for biocides (BPR) and plant protection products (PPP) only
- Beaumont Hospital – National Poison Information Centre (NPIC) responsible body for CLP Article 45 only



An Roinn Talmhaíochta,
Bia agus Mara
Department of Agriculture,
Food and the Marine



CLP Article 45

- CLP Article 45 (1)

*“ Member States shall appoint a body ...
responsible for receiving information ...
for formulating preventative and curative measures ...
in the event of emergency health response, from importers and
downstream users placing mixtures on the market.*

*This information shall include the chemical composition of
mixtures placed on the market and classified as hazardous on
the basis of their health or physical effects...”*

REACH Annex II Section 1.4

- 1.4 Emergency phone number

*“References to emergency information services shall be provided. If an advisory body exists in the Member State where the substance or mixture is placed on the market (**this may be the body responsible for receiving information relating to health referred to in Article 45 of Regulation (EC) No 1272/2008**), its telephone number shall be given and can suffice....”*

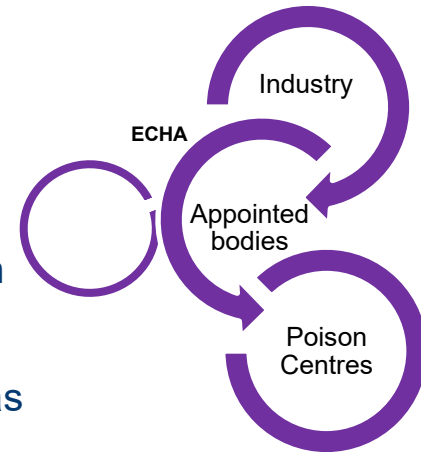
What you need to do...

- If you place hazardous chemical products, including biocides, plant protection products and detergents, within the scope of CLP Article 45, on the Irish market ? E.g. paint, adhesive, cleaning products...
- There are two steps you must take to ensure compliance with REACH and CLP:
 - I. *Notify the hazardous chemical product to the NPIC
 - II. **Include the NPIC emergency number in Section 1.4 of the SDS, following notification and payment of a fee
- *Since 1st January 2021 the process for notification to the NPIC has changed....
- ** Including NPIC number can be done when next updating SDS..

Annex VIII- key obligations

Annex VIII to CLP

- Annex VIII Harmonised information relating to emergency health response and preventative measures
- Adopted March 2017, two amendments, (Oct 2019, March 2020) due to editorial and workability issues
- Provides for harmonisation of information at EU level
- Introduces a Poison Centre Information (PCN) format which harmonises the submission information requirements
- ECHA provides the tools for data preparation and transfer as well as submission process
- Stepwise compliance dates depending on the use type of the mixture, i.e. consumer, professional or industrial use.



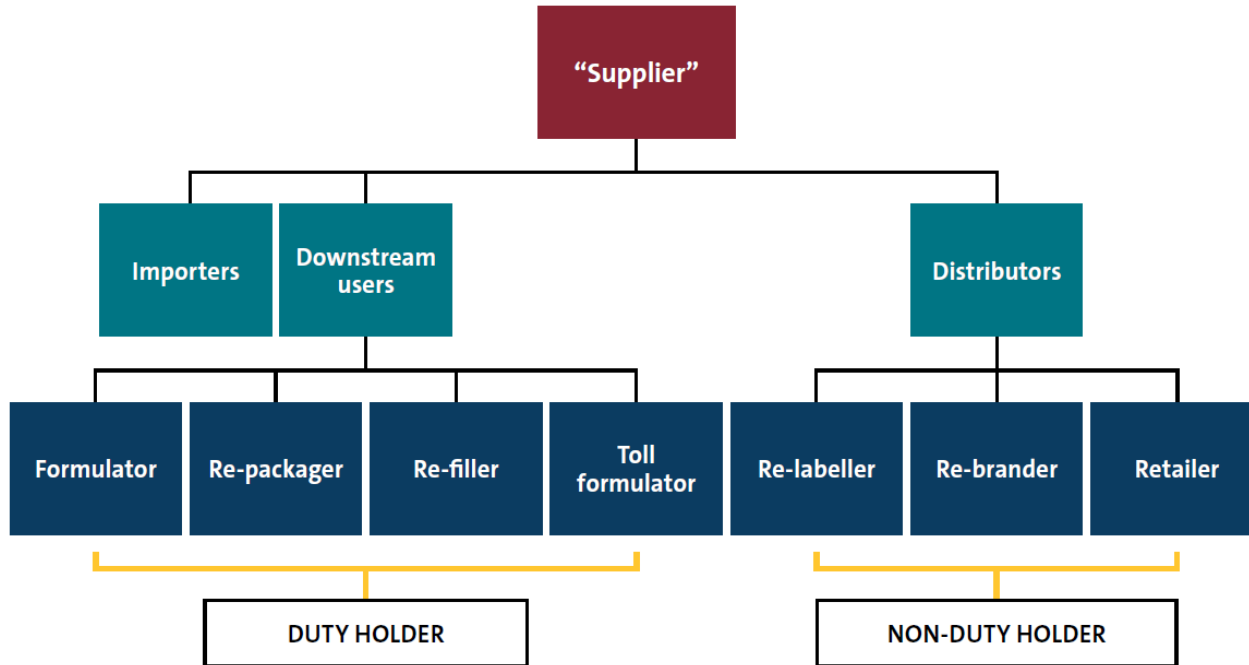
What chemicals should be notified

- A chemical product must be notified to the poisons centre in Ireland when all of the following conditions are met:
 - **It is a mixture**, as defined by CLP Article 2(8) ii: ‘a mixture or solution composed of two or more substances’; includes mixtures combined with articles e.g. candles, air fresheners, ink cartridges
 - **It is classified as hazardous**, on the basis of its health or physical effects, as stated in CLP Article 45(1) ; and Annex VIII, Part A, Section 2.2; and
 - **It is placed on the Irish market.** CLP Article 2(18) defines ‘placing on the market’ as ‘supplying or making available, whether in return for payment or free of charge, to a third party. Import shall be deemed to be placing on the market.’”

What chemicals are not notified

- Substances
 - - Mixtures not covered by CLP
 - - Mixtures classified only for environmental effects
 - - Mixtures used for R&D; PPORDs
 - - Gases under pressure
 - - Explosives (unstable explosives and divisions 1.1 to 1.6)
- *These can be notified voluntarily to the NPIC*

Who has to notify



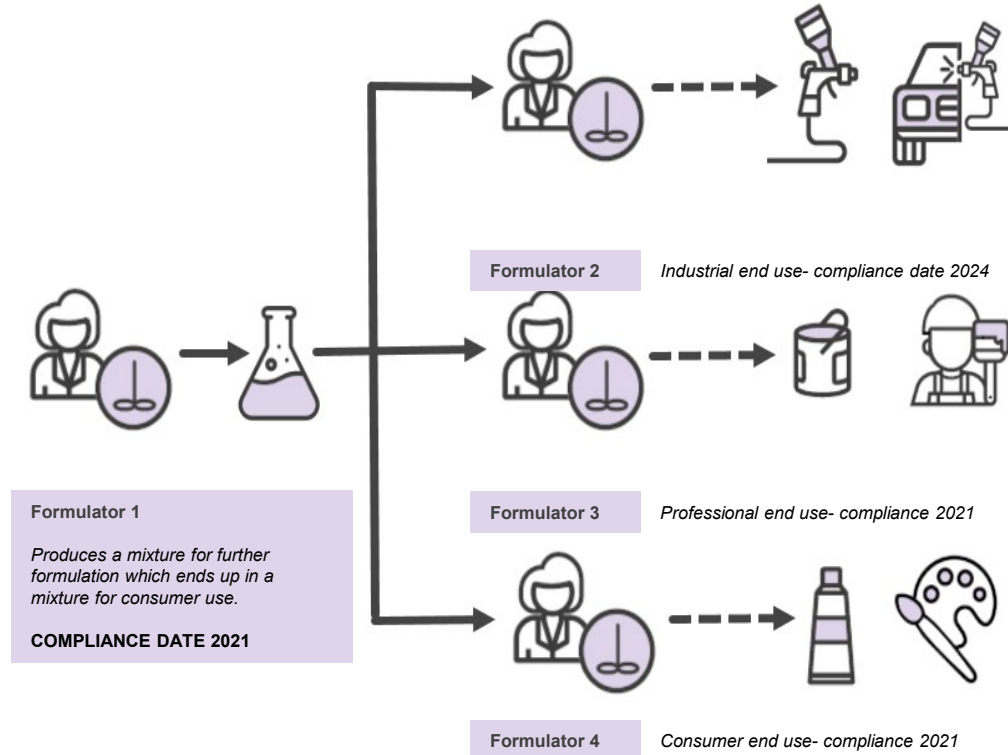
The role of the distributor

- Relabelling, rebranding and retailing activities may lead to potential information gaps if information is not shared in the supply chain
- Distributors wishing to place a product on the market where poison centres do not have all the relevant information for that product have two options
 - Inform the upstream supplier who may include the relevant information in their own submission.
 - Make their own Annex VIII submission

Compliance dates

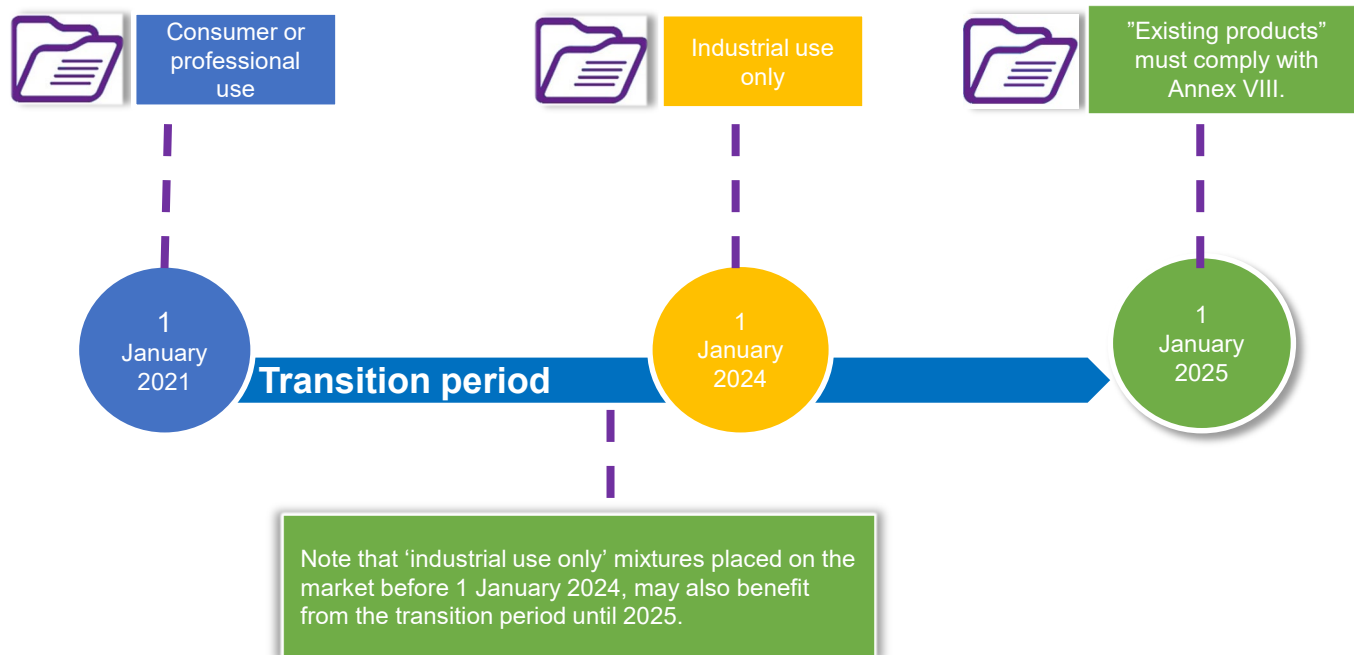
- For 'new' mixtures not already notified – notification is always before placing on the market.
- Different dates for compliance depend on the use type of the mixture:
 - 1 January 2021: consumer or professional use
 - 1 January 2024: industrial use*
- *Before this date, mixtures continue to be subject to existing national requirements but can use PCN (voluntarily)

Compliance date & end use



Mixtures transition to Annex VIII

- Mixtures already notified using existing system can avail of transition



Transition period

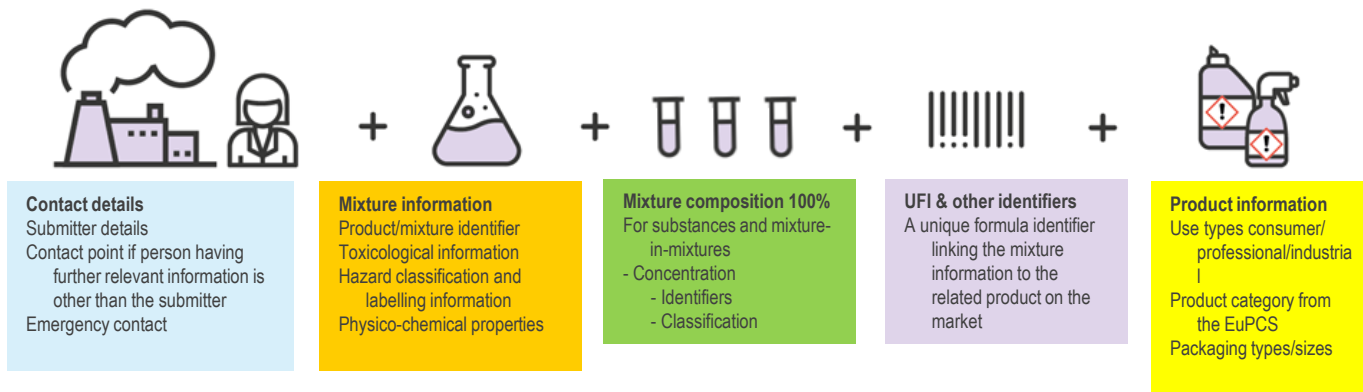
- For 'existing products' already notified, including biocides and plant protection products* and on the market there is a transition period until 1 January 2025.
- If there is a change** during the period from relevant compliance date to end of transition period then the notification has to be compliant with Annex VIII.
- **Such changes include either in the:
 - existing mixture composition*, or
 - product identifier (including UFI), or
 - toxicological properties.
- * If changes in composition occur to biocidal or plant protection products, they should also be notified to/applied for with the pesticide control division of DAFM directly.

Implications of Brexit on transition

- Transition to new Poison Centre Notification (PCN) system coincided with Brexit
- If you bought a product from GB before 31st December 2020- no duty to notify
- If you buy products from GB since 1st January 2021- duty to notify
- GB supplier has no duty under CLP to notify since 31st December 2020
- IE buyer is now an EU importer- with duty to notify
- Note: ECHA provide a solution to enable non-EU supplier, including GB, to notify using a EU legal entity (see ECHA guidance pages 51-53)

What information has to be notified

Information requirements



Contact details

- **‘Submitter details’** i.e. the legal entity responsible for the submission:
 - - *Name, address, telephone number and email*
- Where the submitter is not in possession of further information relevant for emergency health response, then the details of a **‘Contact point’** must be provided:
 - - *Name, address, telephone number and email*
- **‘Emergency contact’** only in the case of a limited submission where rapid access to additional product information must be provided 24hrs/day and 7days/week:
 - - *Name, telephone number, email address*

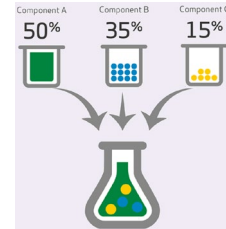
Mixture information

- 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
- Physical properties i.e. colour, pH and physical state.

Mixture composition

- Details of all mixture component (substances and MiMs) concentrations to 100%:

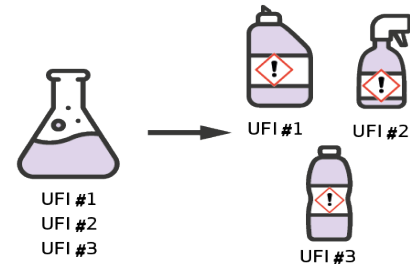
- Classified components when in concentrations $\geq 0.1\%$
- Not classified components when in concentrations $\geq 1\%$



- 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).

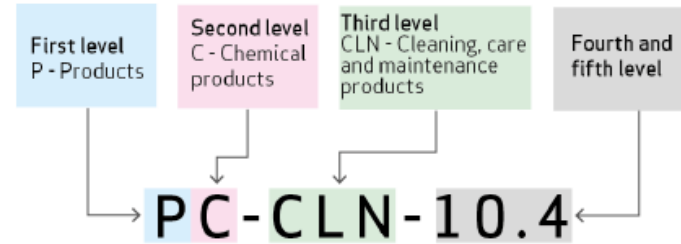
UFI and other identifiers

- 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.



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.



Exceptions to reporting standard information requirements

- The chemical identity and concentration of all components (substances and mixture in mixtures) needs to be fully declared, however, in certain circumstances you may optionally consider some exceptions:
 - Generic product identifiers (GPI)
 - Group submission
 - Limited submission
 - Voluntary submission

Generic product identifiers

- Perfumes and colouring agents may be generically identified (GPIs) *if*
 - They are not classified for any health hazard
 - Function is specified
 - Total concentration within thresholds:
 - 5% for the sum of perfumes;
 - 25% for the sum of colouring agents.
- Specifying a perfume or colouring agent as a 'GPI' can be used instead of the actual chemical identity of the relevant component(s).

Group submission

- Multiple mixtures of similar chemical composition may be grouped into a single submission *if*:
 - All the mixtures have the same classification for human health and physical hazards
 - All the mixtures have same mixture composition, differing only with regard to perfumes under specific conditions.
- It is not possible to group mixtures that are placed on the market by different duty holders.

Limited submission

- A limited submission refers to declaring the components (and their concentrations) limited to what is included in Section 3.2 of the Safety Data Sheet.
- A limited submission is only an option *if*:
 - The mixture is used on industrial sites only, and
 - 24/7 phone service to rapid access to additional information is provided in a language(s) of a Member State where the mixture is placed on the market.
- Contact details for rapid access could belong to the submitter or to an appointed third party i.e. a 'contact point'.
- All other information requirements must be included in the submission.

Voluntary submissions

- A voluntary submission can be made for mixtures out of the scope of Article 45/Annex VIII to CLP.
- Voluntary submissions may benefit:
 - industry by protecting confidential business information in the supply chain e.g. mixtures used in reformulation of other mixtures (MiMs).
 - poison centres to quickly reduce uncertainties in case of an incident.
- Most standard information requirements for voluntary submissions, including the UFI, apply.
- Note that placing the UFI on the label of products for which a voluntary submission is optional!



What about Unique Formula Identifier(UFI)

What is a UFI

- Code with a defined format
 - 16 digit alpha-numerical characters
 - Upper case letters
 - Separated by hyphen into 4 blocks
 - Each block identifies...
- **Name...use... composition...toxicological information**
- Example VDU1-414F-1003-18626.
- Generally rule is that a UFI is assigned to only one mixture composition
- It is flexible- it is possible to assign multiple UFI's to one mixture composition



UFI on the product label

- UFI must be included in the submission and clearly visible on the product label (printed or affixed).
- The UFI may also be provided on the packaging in close proximity to the label elements.
- The acronym 'UFI:' must precede the code to distinguish it from other codes.
- No specific requirements have been set, for instance, for position, font type or size but, inclusion requires planning so that it is easy to locate to assist with its communication to poison centres.
- Inclusion of UFIs on the label should be planned to coincide with the submission of information.

Specific UFI derogations

- The UFI is required on the label for all hazardous mixtures, however it can be alternatively included in the Safety Data Sheet (SDS; Section 1.1) for **mixtures used on industrial sites**.
- The UFI in the SDS is not an information requirement except for **unpackaged mixtures** (SDS; Section 1.1).
- For products that have **multiple packaging layers**, the UFI is only required on the inner packaging e.g. it is not required on the outer packaging or transport packaging.
- For **small or awkward sized packaging**, the UFI is allowed on the outer packaging in close proximity to the label.

Deadlines for UFI on label?

1st January
2021

- Consumer and Professional use products

1st January
2024

- Industrial use products

1st January
2025

- All products

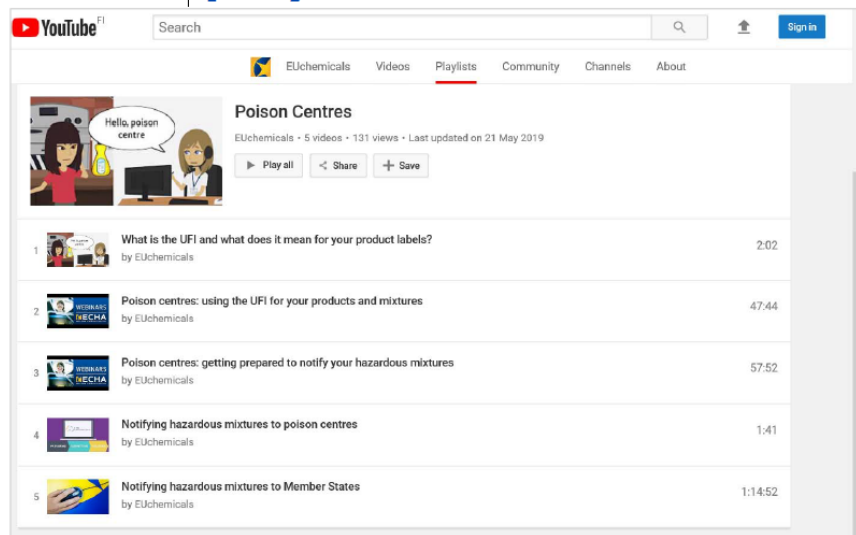


Poison centre notifications support material

ECHA YouTube

- Videos
- Webinars
- Supports






YouTube playlist



YouTube FI Search

EUchemicals Videos **Playlists** Community Channels About

Poison Centres
EUchemicals · 5 videos · 131 views · Last updated on 21 May 2019

1	 What is the UFI and what does it mean for your product labels? by EUchemicals	2:02
2	 Poison centres: using the UFI for your products and mixtures by EUchemicals	47:44
3	 Poison centres: getting prepared to notify your hazardous mixtures by EUchemicals	57:52
4	 Notifying hazardous mixtures to poison centres by EUchemicals	1:41
5	 Notifying hazardous mixtures to Member States by EUchemicals	1:14:52

<https://www.youtube.com/playlist?list=PLOGDACSD6qy-pVbXvKkxsIukZ3XAKOMy>

Poison centre training material



Poison Centres

English (en)

Sign In

ECHA

Search the Poison Centres website

About us

Steps for industry

Tools

Support

Poisoncentres > Support > e-Learning



> Home

> About us

> Steps for industry

> Tools

> Support

> Questions and Answers

> Guidance

> Helpdesks

> In Brief Publications

> National support

> e-Learning

e-Learning

This page offers a range of resources to get familiarised with preparing poison centre notifications as well as assistance for preparing a presentation on the Annex VIII obligations.

An extensive set of training slides on **Complying with Annex VIII - training the trainer** is available for you to select and use to suit your audience's needs.

Animations

Watch our latest introductory animation below, or visit our YouTube channel for our full range.

Understanding the compliance dates



Key documents

> [Complying with Annex VIII – training the trainer](#)

Related links

> [Poison centre YouTube channel](#)
> [IUCLID video tutorials](#)
> [ECHA webinars](#)

Training events

> [2020 Safer Chemicals - ECHA Conference](#)
> [2019 Safer Chemicals - ECHA Conference](#)

- <https://poisoncentres.echa.europa.eu/training-material>

Relevant ECHA Guidance



Guidance on harmonised information relating to emergency health response – Annex VIII to CLP

Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures

Version 2.0
July 2019

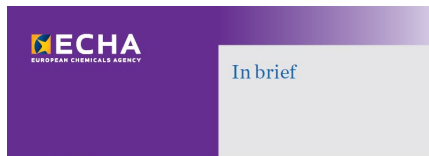


Guidance on labelling and packaging in accordance with Regulation (EC) No 1272/2008

Version 4.0
March 2019



Current *In brief* material



ECHA-18-B-02-EN

The UFI and what it means for your product labels

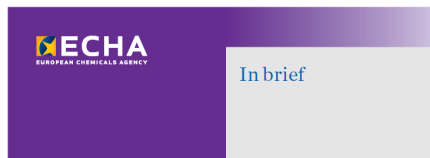
Key information to companies placing hazardous mixtures on the EEA¹ market



A new label element will appear on product labels from 2020 – a 16-character code called the unique formula identifier (UFI). By 2025, the UFI will be mandatory on the label of all products classified for health or physical hazards. Importers and downstream users placing such products on the market, will have to provide specific product information, including the UFI, to poison centres. Tools and support to generate the UFI are available on ECHA's Poison Centres website.

¹ European Economic Area – 28 Member States of the European Union and Norway, Iceland and Lichtenstein.

ANNANKATU 18, P.O. BOX 406, FI-00021 HELSINKI, FINLAND | ECHA.EUROPEA



ECHA-19-B-03-EN

Information requirements for poison centres notifications

Companies placing hazardous mixtures on the market have to submit information about these mixtures to specific bodies appointed by Member States. Poison centres use this information to give medical advice in the case of an emergency. The notification requirement applies from 1 January 2020. It is based on the Annex VIII to the Classification, Labelling and Packaging (CLP) Regulation.

WHO NEEDS TO MAKE A NOTIFICATION?

Notifications need to be submitted by importers and downstream users placing mixtures classified for human health or physical hazards on the market. The obligation covers mixtures for consumer, professional and industrial use.

WHAT FORMAT MUST BE USED?

Companies must provide the required information using the harmonised Poison Centres Notification (PCN) format. The format is XML-based and compatible with IUCLID.

WHAT INFORMATION IS REQUIRED?

The same set of information will be required by all Member States where the mixture is placed on the market.

Contact details – Name, full address, telephone number and email address of the importer or downstream user submitting the notification.

Trade name or names of the mixture – Where relevant, also brand names and variant names as they appear on the label.

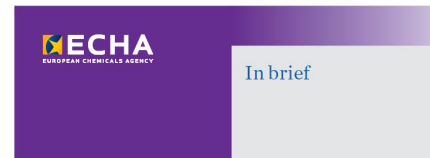
Packaging type and size – The packaging used to place the mixture on the market for consumer or professional use. The container type may be a bottle, a box or an aerosol can; for example. The size has to be given as the nominal volume or weight of the packaging.

Product category – The category according to the harmonised European product categorisation system (EUPCS). The selected category must match the main intended use of the product – which could be 'fertiliser', 'laundry detergent' or 'air care product' for example.

Unique formula identifier (UFI) – The code generated by means of the UFI Generator. For example, 1200-U00W-500A-Q2DA, has to be marked on the product label or packaging and included in the notification.

Hazard information – The human health and physical hazard classifications of the mixture.

ANNANKATU 18, P.O. BOX 406, FI-00021 HELSINKI, FINLAND | ECHA.EUROPEA



ECHA-18-B-05-EN

How to prepare and submit information to poison centres

Key information for companies submitting information on hazardous mixtures and for the Member State appointed bodies receiving the information.



The Poison Centres notification (PCN) portal is the online tool for industry to both prepare and submit information on hazardous mixtures that can be used by poison centres to help make an emergency health response.

The information to be submitted through the PCN portal is based on the harmonised PCN format which defines the information requirements established in Annex VIII to the CLP Regulation.

ANNANKATU 18, P.O. BOX 406, FI-00021 HELSINKI, FINLAND | ECHA.EUROPEA

Steps for industry

Step by step guide for industry on how to get started with their submissions is available on ECHA's Poison Centres website.

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

Know your obligations

Know your portfolio

Understand your
supply chain

Generate your UFI's

Collect your data

Prepare your
submission

Keep the information
up-to-date

IE supports

- NPIC: Chemicals Info (chemicalsinfo@beaumont.ie)
- HSA: Chemicals helpdesk chemicals@hsa.ie
- HSA/NPIC [information sheet](#) relating to notifying all chemical products
- BPR helpdesk biocides@agriculture.gov.ie
- DAFM [information note](#) relating to notifying biocidal and plant protection products
- ECHA helpdesk <https://echa.europa.eu/contact/clp>
- <https://poisoncentres.echa.europa.eu/appointed-bodies>



Thank you