

# Notifying hazardous mixtures to the National Poisons Information Centre: How, what and why?

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[www.poisons.ie](http://www.poisons.ie)

Facebook: @NPICireland



- ▶ What we do
- ▶ Why we need information on your products
- ▶ Harmonised information requirements
- ▶ NPIC information requirements
- ▶ Current notification systems
  - Mixtures for consumer or professional use
  - Mixtures for industrial use
- ▶ Fees

# National Poisons Information Centre of Ireland

- ▶ Based in Beaumont Hospital, Dublin
- ▶ Telephone information service
- ▶ Monitor trends in poisoning
- ▶ Public education – poison prevention
- ▶ Appointed body for CLP Article 45 and Article 9(3) of the Detergent Regulations
  - *Chemicals (Amendment) Act 2010*



# National Poisons Information Centre of Ireland

Doctors and healthcare professionals  
01 837 9964 / 01 809 2566

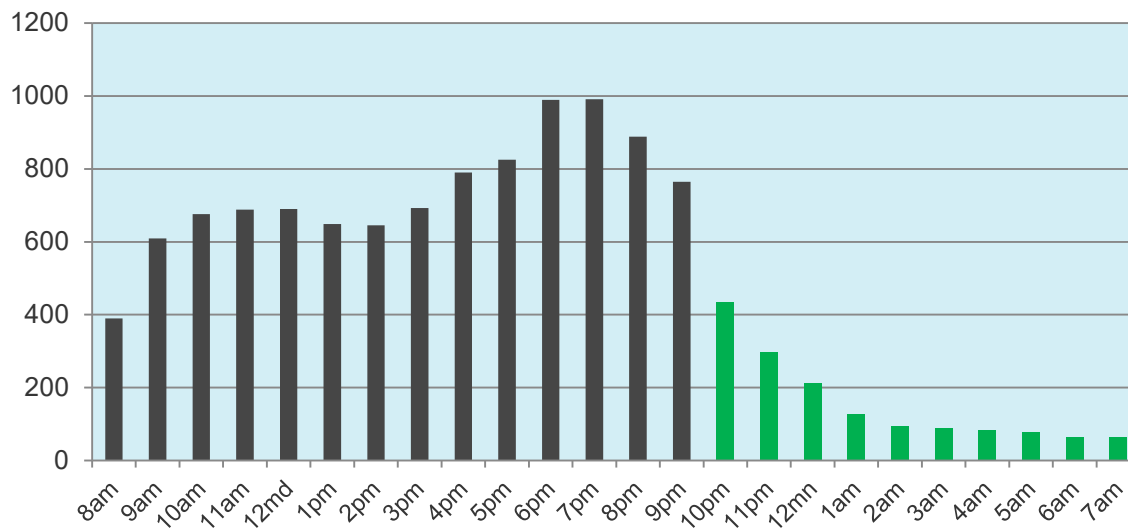
- ▶ 24-hour telephone information service
- ▶ Toxicity, features and management of poisoning
  - Toxic dose
  - Symptoms and signs of poisoning
  - Observation period
  - Specific treatment / investigations
  - Discharge criteria

General public  
01 809 2166

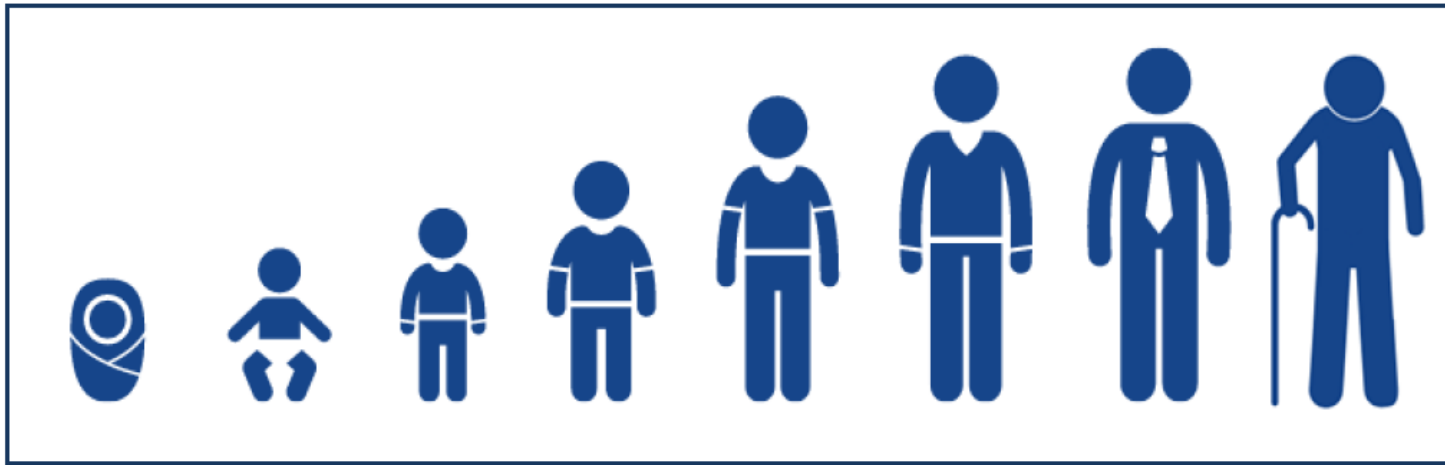
- ▶ Telephone information service 08:00–22:00
- ▶ First aid
- ▶ Triage e.g.
  - Go to hospital now
  - Go to hospital if these symptoms develop
  - No treatment needed

# National Poisons Information Centre of Ireland

- ▶ 11,835 enquiries in 2019
  - 11,516 human poisoning
  - 51% from general public, 46% from doctors and healthcare professionals



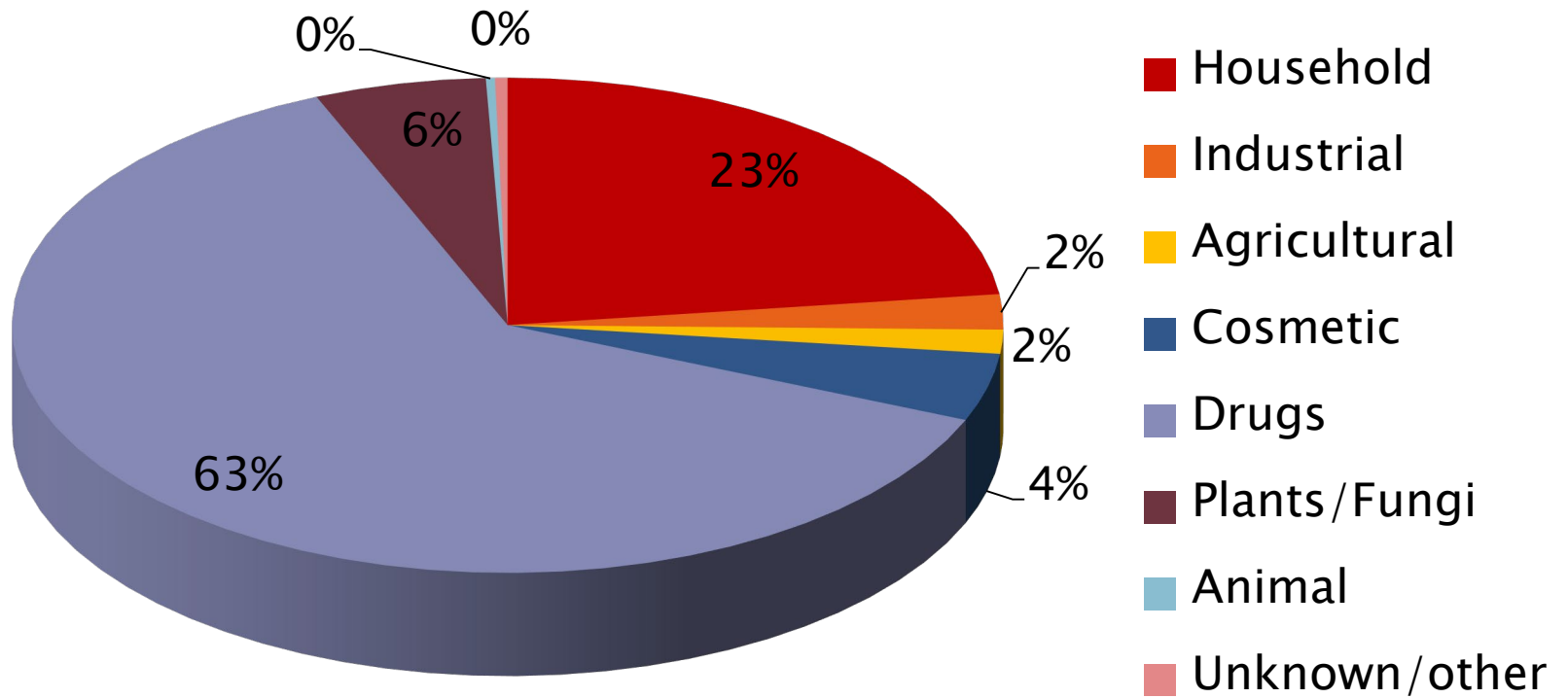
# National Poisons Information Centre of Ireland



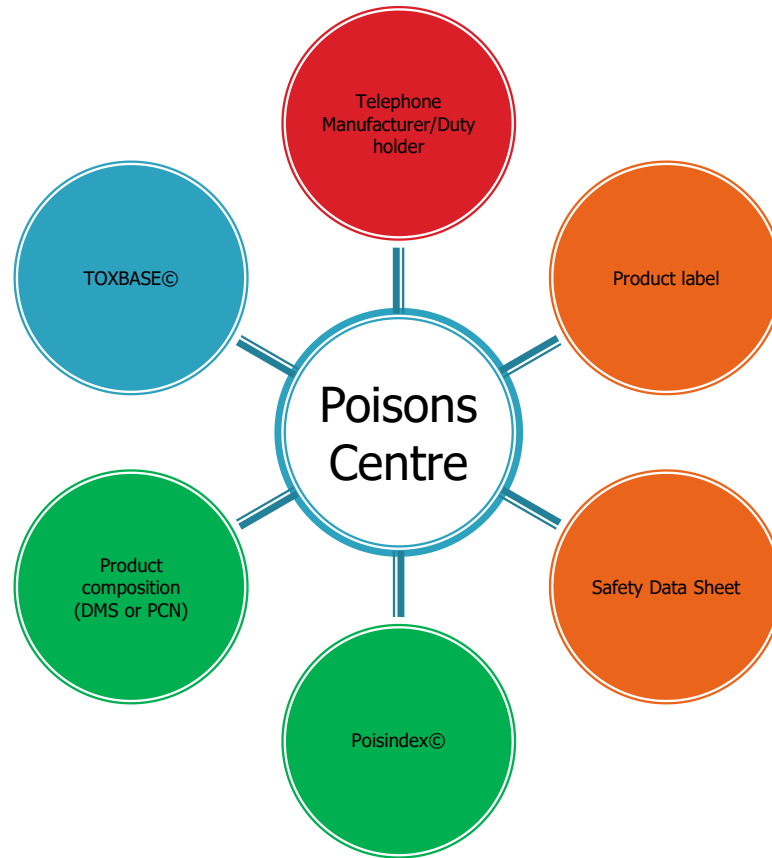
<1 yr	1-4yr	5-9yr	10-14yr	15-19yr	20-49yr	50-59yr	>70yr
7.3%	45.1%	7.2%	3.5%	4.6%	13.8%	5.7%	4.6% *

\*8.2% age was not defined

# Agent categories 2019



# Sources of information used by the NPIC





## Liquid detergent capsules (Liquitabs)

[Printable version](#)

Updated 1/2019

### Type of Product

### **Type of Product**

### Synonyms

A capsule of concentrated fabric washing liquid in a water soluble polyvinyl alcohol membrane.

### Ingredients

### **Synonyms**

Liquid laundry detergent capsules  
Liquid detergent capsules  
Liquid laundry pods  
Liquid sachets  
Liquid tablets  
Liquigel capsules

### Toxicity

### Alert

### Features

### Management

### **Ingredients**

### Additional Information

**Contents vary widely between different brands and manufacturers so wherever possible please consult the exact entry.**


# Why notify?

- ▶ Immediate access to accurate and up to date information if poisoning/exposure occurs
- ▶ Prepare treatment guidelines in advance of exposure
- ▶ Rapid identification of an exposure which is likely to result in serious effects to health
  - Referral for urgent medical attention
  - Rapid access to treatment guidelines
- ▶ Rapid recognition of an exposure which is unlikely to result in serious effects to health
  - Prevents unnecessary emergency department attendances and hospital admissions
- ▶ Information for medical emergencies available outside company office hours (evenings, weekends, public holidays).

# Why notify?

## ▶ Product label

Contains amongst other ingredients: Less than 5% Non-ionic Surfactants, **Methanol**, Benzalkonium Chloride, Concentrated Perfume, 2-Methyl Undecanal, Citronellol, DL-Limonene (Racemic), Butylphenyl Methyl-Propional, Alpha-Isomethyl Ionone, 1-(2,6,6-Trimethyl-Cyclohexa-1, 3-Dienyl)-2-Buten-1-One




UK NPIS 0344 892 0111 Ireland NPIC (01) 809 2566

### Methanol

[Printable version](#)  
Updated 12/2016

Type of Product	<b>Type of Product</b> Solvent, antifreeze, windscreen wash.
Synonyms	<b>Synonyms</b> Methyl alcohol, carbinol, wood alcohol, wood spirit
Toxicity	CAS 67-56-1 UN 1230
Features	<b>Toxicity</b> Highly toxic. Methanol is an alcohol and will cause features of intoxication. Its main toxicity is secondary to metabolism to formaldehyde and formic acid. It is these metabolic products that are responsible for the most serious toxic features including metabolic acidosis and blindness. Ocular toxicity results from formic acid accumulation and is made worse by acidosis.
Management	
Additional Information	
NPIS Use Only	
Links	

 **HIGHLY TOXIC SUBSTANCE**

All patients who have ingested any amount of this product should be referred to an Emergency Department.  
Consider discussion with NPIS: In the UK NPIS **0344 892 0111** / in Ireland NPIC **(01) 809 2566**.

# Why notify?

## ▶ SDS

SECTION 3: Composition/information on ingredients						
3.2. Mixtures						
EC 1272/2008						
Chemical Name	Index No.	CAS No.	EC No.	REACH Registration Number	Conc. (%w/w)	Classification
Benzalkonium Chloride		68424-85-1			1 - 10%	Met. Corr. 1: H290; Acute Tox. 4: H302; Skin Corr. 1A: H314; Aquatic Chronic 1: H410;
Organic Alcohol	603-001-00-X	67-56-1	200-659-6		1 - 10%	Flam. Liq. 2: H225; Acute Tox. 3: H331; Acute Tox. 3: H301; STOT SE 1: H370;

[echa.europa.eu](http://echa.europa.eu) > [registration-dossier](#) > [registered-dossier](#) ▼

### [Methanol - Registration Dossier - ECHA](#)

Display Name: Methanol; EC Number: 200-659-6; EC Name: Methanol; CAS Number: 67-56-1;

Molecular formula: CH4O; IUPAC Name: methanol ...

## ▶ Duty holder

Hi Patricia

Apologies I have sent you the older MSDS see attached the new one.

Just to confirm it is Ethanol used in [REDACTED] and it is lower that 3%.

Hi,

Just to follow up on your call,

Just to confirm it is less than 3% of Ethanol

Thanks,

# What are the information requirements?

- ▶ Mixtures for consumer or professional use
  - Annex VIII applies since 1<sup>st</sup> January 2021
- ▶ Mixtures for use at industrial sites only
  - NPIC product information form
  - OR
  - Annex VIII submission
- ▶ **NB** Mixtures for industrial use that are reformulated further down in the supply chain and ends up in a consumer or professional use product
  - Annex VIII applies (obligation to comply with CLP)

# Annex VIII Information Requirements



+



+



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## Contact details

Submitter details  
Contact point if person having further relevant information is other than the submitter  
Emergency contact

## Mixture information

Product/mixture identifier  
Toxicological information  
Hazard classification and labelling information  
Physico-chemical properties

## Mixture composition 100%

For substances and mixture-in-mixtures

- Concentration
- Identifiers
- Classification

## UFI & other identifiers

A unique formula identifier linking the mixture information to the related product on the market

## Product information

Use types consumer/professional/industrial  
Product category from the EuPCS  
Packaging types/sizes

# Unique Formula Identifier (UFI)

- ▶ **Unique formula identifier (UFI)**
  - new submission requirement
  - new label element
  - e.g. YV9K-3J9A-G209-C2T7.
- ▶ Unequivocal link between the information on a mixture and the corresponding product placed on the market
- ▶ Helps ensure that the appropriate emergency health response is quickly identified in the event of an incident

- ▶ Product not notified to NPIC
- ▶ Product label listed chemical x
- ▶ Safety data sheet supplied did not list chemical x

1. This product was modified in December 2017 to reduce the % inclusion of chemical x to below that which triggers classification and labelling of the product.
2. Product manufactured pre-December 2017 contained max 2.9% chemical x.
3. Product manufactured after December 2017 contains max 0.871% chemical x.



# Generating UFIs

- To ensure uniqueness of the UFI, the input parameters are company specific and non confidential:
  - The company's VAT number
  - Internal formulation number between 0 – 268 435 455.
- Concerning the VAT number:
  - Where confidentiality concerns exist, a VAT number can be replaced by 'company key' generated by the UFI generator tool.
  - In some cases, it may be necessary to determine which VAT number to use e.g. mother company's or toll formulator's.
- There are two ways to generate UFIs:
  - the UFI Generator tool for immediate generation.
  - implement the UFI generating algorithm (publically available) in the company's own systems.
- Further information available at <https://poisoncentres.echa.europa.eu/ufi-generator>

# NPIC information requirements

## Product identifiers

Trade name  
Other names, synonyms  
UFI if available  
Other identifiers e.g. PCS number

## Mixture composition 100%

All components  
- Concentration  
- Identifiers e.g. CAS, EC  
- UFI (MIMs)

## Mixture information

Toxicological information  
Classification of the mixture and label elements  
Physico-chemical properties (colour, pH, physical state)

## Product information

Use types consumer/professional/industrial  
Product category from the EuPCS  
Packaging types/sizes

## Contact details

Submitter details  
Importer/downstream user details (if different to submitter)

The image shows a two-page screenshot of the NPIC Product Notification Form. The form is titled "Product Notification Form" and is provided by POISONS INFORMATION CENTRE OF IRELAND. The first page (Page 1 of 2) contains sections for: Product identifiers (Trade name, Other names, synonyms, UFI, Other identifiers e.g. PCS number, company product code); Mixture composition (Chemical Name or Trade Name of component, Concentration, CAS number, EC number, UFI for Mixture-in-Mixture); Classification of the mixture and label elements (Hazard class, Hazard category, Hazard pictogram code, Signal word, Hazard statement codes, Precautionary statement codes); and Additional information on the mixture (Colour, pH, Physical state, Packaging type and size, Intended use). The second page (Page 2 of 2) contains sections for: Toxicological information (Description of the toxicity of the mixture or its components); Additional information on the mixture (Colour, pH, Physical state, Packaging type and size, Intended use); Contact details of submitter (Company Name, Address, Telephone, Email address, Contact Name, Position); and Contact details of importer or downstream user (Company Name, Address, Telephone, Email address, Contact Name, Position). The form includes numerous "Click here to enter text" and "Choose an item" prompts for user input.

# How to notify hazardous mixtures to the NPIC

- ▶ Notify mixtures for consumer or professional use via the ECHA PCN portal
- ▶ Notify mixtures for industrial use only directly to the NPIC **or** through the PCN portal
- ▶ **Note:** If your mixture for industrial use is reformulated further down in the supply chain and ends up in a consumer or professional use product, you must notify it via the ECHA PCN portal.

# ECHA PCN Portal

- ▶ <https://poisoncentres.echa.europa.eu/echa-submission-portal>
- ▶ Online tool that supports both industry and authority users in fulfilling their obligations under Article 45
- ▶ Industry: prepare and submit poison centre notification (PCN) dossiers containing information on hazardous mixtures to appointed bodies
- ▶ Makes the information available to appointed bodies for use by poison centres
- ▶ Facilitates the submission process
  - fees, acceptance criteria and acceptance timelines are at the discretion of each Member State.

# Tools to prepare a notification



## ONLINE PREPARATION

- Online using IUCLID Cloud available in the ECHA Submission portal.
- PCN specific template available since April 2019.
- Consists mostly of structured fields using e.g. picklists.
- Free text fields must be provided in all languages e.g. toxicological information.
- Maintained, backed-up, updated by ECHA.
- Data securely stored in ECHA Cloud.
- Validation assistant to check dossier information before submitting .
- Notification preview report for user .

<https://poisoncentres.echa.europa.eu/echa-submission-portal>



## OFFLINE PREPARATION

- Offline using IUCLID 6 downloaded from the IUCLID website.
- New web interface available visually the same as in IUCLID Cloud.
- Multi-lingual fields for toxicological information not supported.
- Validation assistant and notification preview report available.
- Installed and maintained locally by users.
- Server version available for multi-user companies.

<https://iuclid6.echa.europa.eu/>



## SYSTEM PREPARATION

- System preparation uses the PCN format to prepare IUCLID compatible dossiers in a company's own system.
- The format is made available as a set of XML schema definition files
- System preparation is subject to PCN format updates which need to be maintained by users.
- Allows a more automated approach for companies to prepare and submit.

<https://poisoncentres.echa.europa.eu/poison-centres-notification-format>

# Tools to submit a notification



## ECHA Submission portal

- Available since April 2019- interface only in English.
- Multimarket submissions possible.
- Check which countries are connected and accepting submissions via the Portal\* before making any submissions.
- Dossiers are submitted directly in the portal or downloaded and saved locally for later submission.
- The dossiers will be stored centrally in the portal and accessible by authority users following strict security requirements.

<https://poisoncentres.echa.europa.eu/echa-submission-portal>



## System to System (S2S)

- Available since October 2019.
- Automatic transfer of dossiers created in company's own system to the ECHA Submission portal.
- The data in the notification will only be validated when it is submitted and any inconsistencies in the dossier will be highlighted through the portal.
- Industry need to submit a request to ECHA before access to this functionality can be granted.

<https://poisoncentres.echa.europa.eu/system-to-system-service>



## National submission systems

- Still in place until each Member State specifies otherwise.
- While all Member States must adhere to harmonised submission format, it is at their discretion how the information shall be submitted.
- Industry advised to consult with the national appointed body for further details for the use of national submission systems .

<https://poisoncentres.echa.europa.eu/appointed-bodies>

\*'Overview of Member States' decisions on implementing Annex VIII to the CLP' table:

<https://poisoncentres.echa.europa.eu/echa-submission-portal>

# PCN Portal submission report



Search | Upload & submit | Create dossier of

**Validation succeeded ✓** – the submission has passed the validation checks and the dossier has been dispatched and available to Member States for download.  
**Validation succeeded !** – the submission has passed the validation checks with warnings. A validation report listing potential deficiencies will be available for the submitter and the receiving Member State.  
**Validation failed X** – the dossier has failed the validation checks and has not been forwarded to the relevant Member State(s). A validation report listing the deficiencies is available for the submitter and a new submission must be made. .

Submission status: **Validation succeeded ✓**

Dossier Type: CLP Poison centres notification  
Submission number: RMH631802-25

Submitted by: **Jane Doe**  
**EcoChem**  
ECHA-c169b4c2-3ab3-45d2-940e-374a359a6a81

## Dossier header

Mixture name BR574 Initial 2  
Dossier name  
Dossier UUID 685fe617-95c5-41f0-97cd-2a8de89fccfb  
Filename BR574 Initial 2.i6z  
The submission is an initial notification  
PCN number 5de66d80-8d9f-4864-af2b-a1319349aed2

## Dossier information

Trade name 1  
1S53-21TS-N00N-GPTJ

## Recipients (Member States - market placement)

Austria

## Submission Events

21/02/2019 15:20	Dossier submitted
21/02/2019 15:20	Dossier passed validation checks
21/02/2019 15:20	Dossier available to MS for download
22/02/2019 10:20	Dossier downloaded by MS

The submission number is automatically assigned by the system.

The dossier header describes the submission context and also displays the PCN number for the notification. The PCN number is a link displaying all the submissions related to that number.

The dossier information contains the trade name(s) and the UFI(s) for the mixture.

The receiving Member States for the notification are listed here.

The time stamped events in the submission process. The event when a dossier has been downloaded by the Member State will also be shown here.

# PCN Portal submission report

- ▶ **Validation succeeded ✓** – the submission has passed the validation checks and the dossier has been dispatched and available to Member States.
  - Biocidal and plant protection products must also be registered with the Department of Agriculture.
  - Other products – No further action needed before placing mixture on the market in Ireland.
- ▶ **Validation succeeded !** – the submission has passed the validation checks with warnings. A validation report listing potential deficiencies will be available for the submitter and the receiving Member State.
  - Mixture can be placed on the market in Ireland.
  - Review submission and correct deficiencies without delay.
- ▶ **Validation failed X** – the dossier has failed the validation checks and has not been forwarded to the relevant Member State(s). A validation report listing the deficiencies is available for the submitter and a new submission must be made.
  - Mixture cannot be placed on the market.



# PCN Portal – Support & guidance

- ▶ ECHA Poison Centres site  
<https://poisoncentres.echa.europa.eu/>
- ▶ ECHA – Steps for Industry  
<https://poisoncentres.echa.europa.eu/steps-for-industry>
- ▶ ECHA YouTube channel  
<https://www.youtube.com/playlist?list=PLOPGDACSD6qy-pVbXvKkxslukZ3XAKOMy>
- ▶ Guidance on harmonised information relating to health emergency response – Annex VIII to CLP  
<https://echa.europa.eu/guidance-documents/guidance-on-clp>
- ▶ Support at <https://poisoncentres.echa.europa.eu/support>

# Submission to the NPIC

- ▶ Mixtures for industrial use only
- ▶ Submit the required information before you place the mixture on the market
- ▶ Complete the NPIC product information form
  - One form per product
  - Save form using product name as used on label
- ▶ Email to [chemicalsinfo@beaumont.ie](mailto:chemicalsinfo@beaumont.ie) or post to the NPIC on USB
- ▶ If emailing .zip files let us know in a separate email

# Transition period

- ▶ Consumer and professional use
  - Notifications send directly to the NPIC before 1 January 2021 will remain valid until 1 January 2025 or until certain changes are made to the product
    - e.g. changes to the mixture composition, toxicological properties or product identifiers
  - Updates will require a new notification via the PCN portal.
  - If the mixture/product remains unchanged until 1 January 2025, you must then make a new submission in the harmonised format via the PCN portal
  - If the mixture/product is discontinued before the end of the transition period, you do not need to make a new submission

# Transition period

## ▶ Industrial use

- Notifications send directly to the NPIC before 1 January 2024 will remain valid until 1 January 2025 or until certain changes are made to the product
  - e.g. changes to the mixture composition, toxicological properties or product identifiers
- Updates will require a new notification via the PCN portal
- If the mixture/product remains unchanged until 1 January 2025, you must then make a new submission in the harmonised format via the PCN portal
- If the mixture/product is discontinued before the end of the transition period, you do not need to make a new submission

# Fees

- ▶ No fee for submitting a notification via PCN Portal or directly to the NPIC
  
- ▶ Annual retainer charged to permit use of the NPIC telephone number in section 1.4 of the safety data sheet
  1. Notify mixture(s)/product(s)
  2. Contact NPIC at [chemicalsinfo@beaumont.ie](mailto:chemicalsinfo@beaumont.ie)
  3. Sign Agreement & Indemnity
  4. Pay annual retainer
    - €650 per annum per company
    - €200 if less than 10 products placed on the market
    - No additional fee for biocidal or plant protection products

# Further information

- ▶ See also

<https://www.poisons.ie/Manufacturers/Product-Registration>

- ▶ FAQs

<https://www.poisons.ie/docs/poisoncentrenotificationireland.pdf>

- ▶ Email [chemicalsinfo@beaumont.ie](mailto:chemicalsinfo@beaumont.ie) if still have questions