

Annex VIII to CLP – On the UFI and preparing a poison centre notification in IUCLID

Obligations of Article 45 of the CLP Regulation. Annex
VIII to CLP

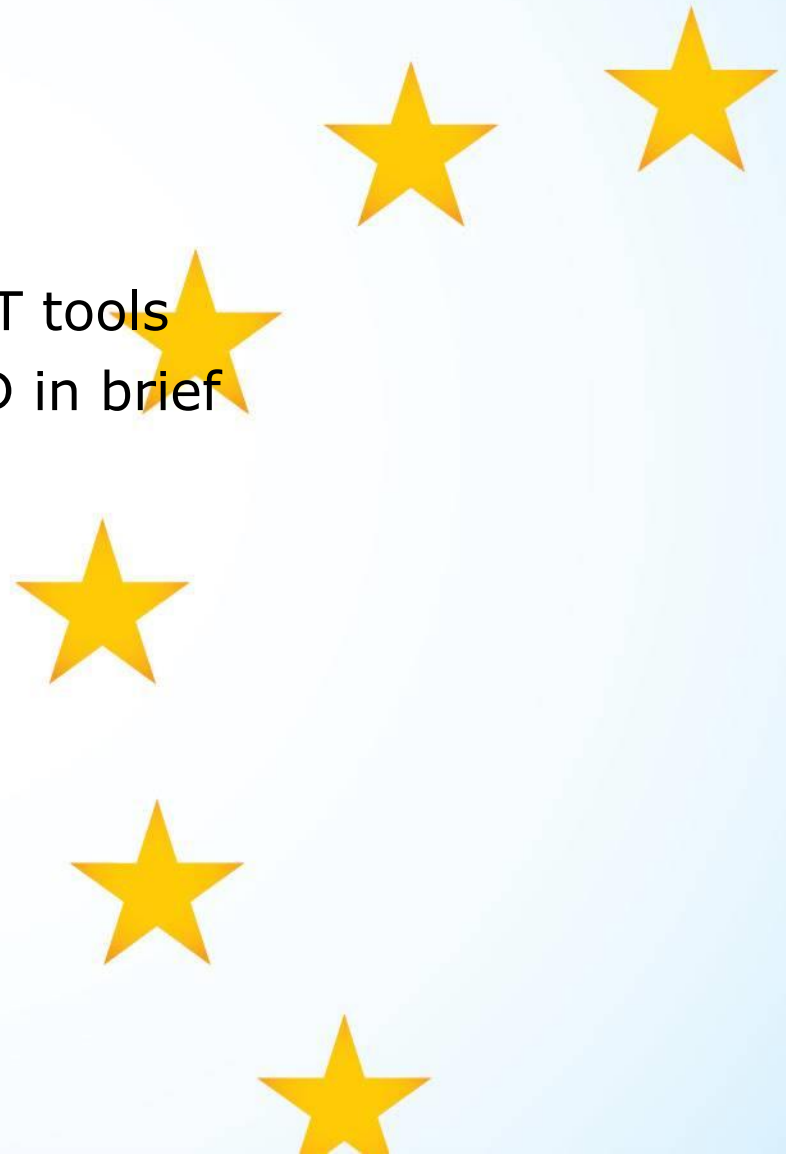
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Regulatory recap





Poison centre notifications – ‘PCN’

- ‘PCN’ obligation since 2009: Article 45 CLP
- Duty holders EU/EEA downstream users & importers
- Scope: mixtures classified for human health or physical hazards placed on the market
- Annex VIII published 2017: comply with harmonised
 - information requirements in all Member States
 - preparation of data in harmonised format

Timelines for compliance

- Compliance with Annex VIII for 'new' mixtures according to the use type of the mixture.



https://www.youtube.com/watch?time_continue=14&v=-7f88r6Dk0Y&feature=emb_logo

- Up until compliance date, national obligations apply
- Transition period for notified mixtures ends 1 January 2025
 - earlier if change required to existing notification

2nd Amendment of Annex VIII

- 'Workability' amendment following identification of generic and sector specific issues.
- Solutions sought to balance the need for information required and administrative burden/difficulty to comply
- Construction products, bespoke paints, fuels, interchangeable component groups



Navigating the PCN format and IT tools



ECHA tools for industry

- UFI generator
- Harmonised 'XML' PCN submission format
- European product categorisation system
- Scientific guidance and technical support
- Tools to support preparation and submission

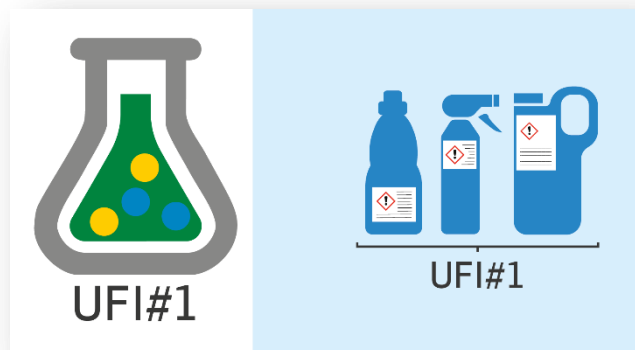


Closer look at the UFI



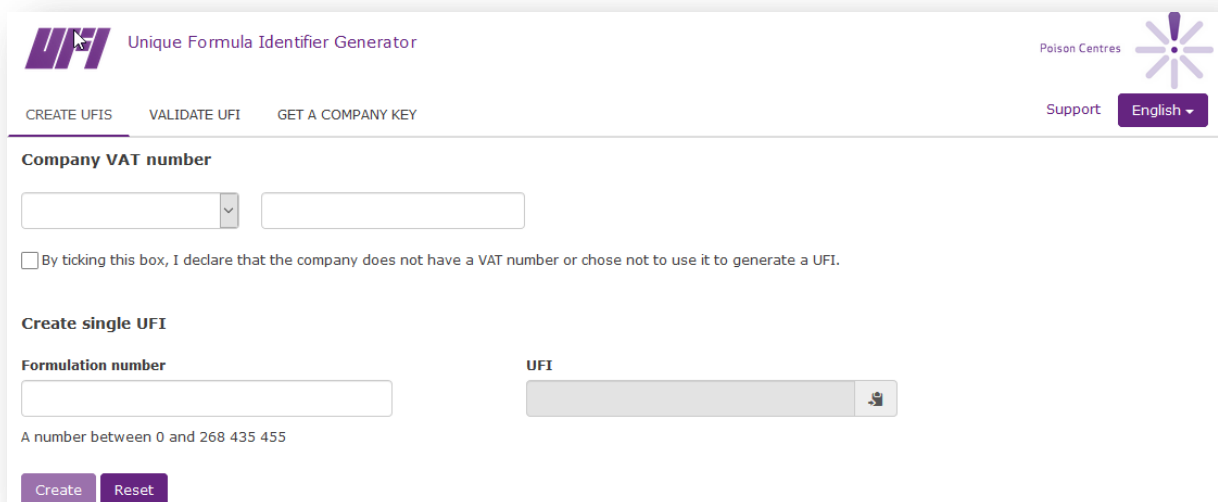
The UFI code - recap

- Unique formula identifier assigned to a mixture composition
- Included in submission & product **UFI: VDU1-414F-1003-1862**
- Printed on or affixed to label e.g. sticker
- Clearly visible and legible
- Indelibly marked and firmly attached (if a sticker is used)



Generating a UFI

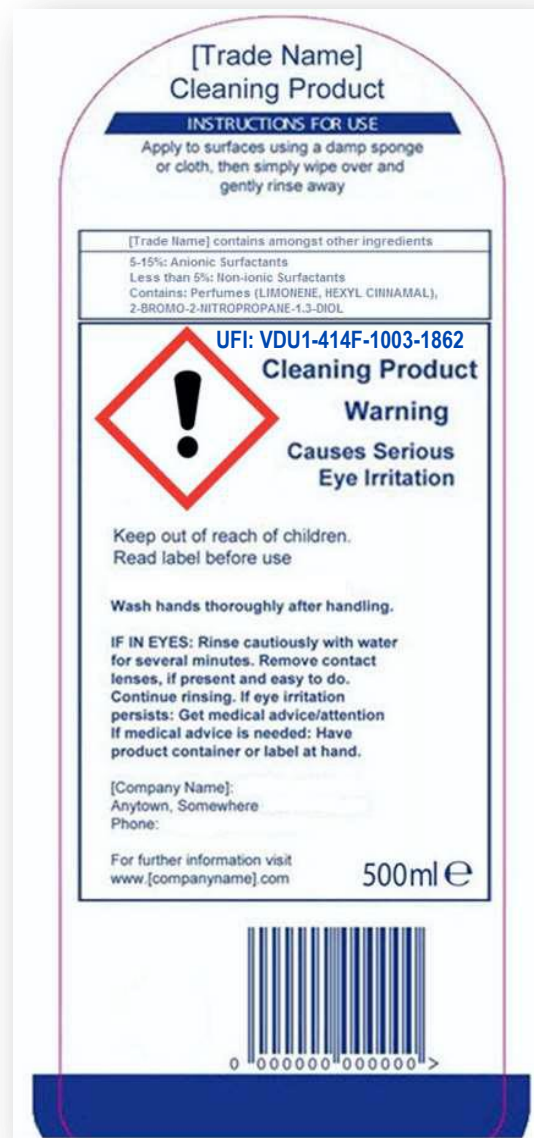
- Industry obligation to generate UFI
- Online UFI Generator tool, or, UFI algorithm implemented in own system
- Input parameters
 - VAT number (not mandatory, alternatives available)
 - internal formulation number (number between 0 and 268,435,455)



The screenshot shows the 'Unique Formula Identifier Generator' web interface. At the top left is the UFI logo and the title 'Unique Formula Identifier Generator'. On the top right, there are links for 'Poison Centres' and 'Support', along with a language dropdown menu set to 'English'. Below the header, there are three navigation tabs: 'CREATE UFIS', 'VALIDATE UFI', and 'GET A COMPANY KEY'. The main content area is titled 'Company VAT number' and contains a dropdown menu and a text input field. Below this is a checkbox with the text: 'By ticking this box, I declare that the company does not have a VAT number or chose not to use it to generate a UFI.' Underneath, there is a section for 'Create single UFI' with two input fields: 'Formulation number' and 'UFI'. The 'Formulation number' field has a note below it: 'A number between 0 and 268 435 455'. At the bottom left of the form are 'Create' and 'Reset' buttons.

Where on the label?

- No fixed rules concerning the positioning of the UFI on the label, it can be either:
 - a) section for 'supplemental information' or be placed
 - b) in proximity of the product name or trade name.
- Possible to place **outside the label** on the inner packaging, but, must be located with obligatory CLP label elements such as the product identifiers or hazard information



Specific derogations

- For **mixtures used on industrial sites** the UFI can be alternatively included in the Safety Data Sheet (SDS; Section 1.1)
- For **unpackaged mixtures** the UFI is an information requirement in Section 1.1 SDS.
- 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.





Special case multi-components

- Each mixture requires it's own notification!
- Multi-component products have separate labels for each component – each with it's own UFI



Special case multi language label

- Several UFI codes per label **not** recommended
- Exceptional cases if multiple UFIs are used, **country code** should be used in proximity of the corresponding UFI code

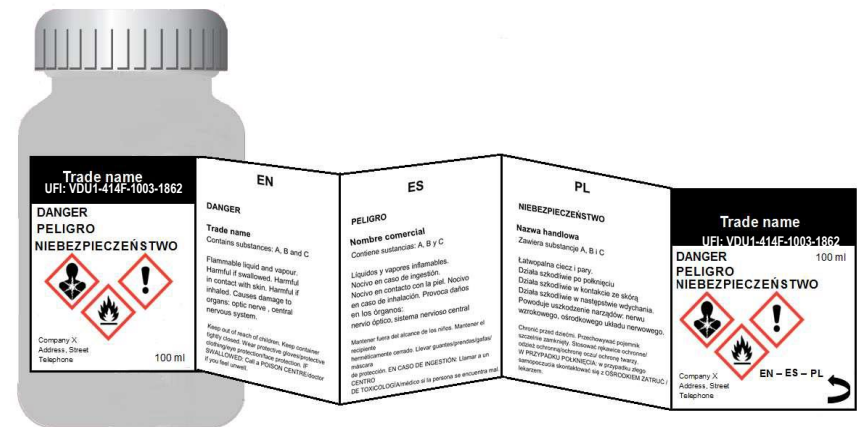
PAINTCO SATIN WHITE		Product code 123456						
UFI: VDU1-414F-1003-1862								
Krasvaste zijdeglanslack - Couche de finition satinée résistante à l'abrasion - Scratch-resistant satin finish								
	<table border="1"> <tr> <td>NL:</td> <td>X Straat, 9999 YZ Stad, Tel. 49 (0) 0000 0000 00</td> </tr> <tr> <td>BE:</td> <td>Rue Y, B-9999 Ville, Tel. 49 (0) 0000 0000 00</td> </tr> <tr> <td>GB:</td> <td>Z Street, Town XY99 9YZ, Tel. 49 (0) 0000 0000 00</td> </tr> </table>		NL:	X Straat, 9999 YZ Stad, Tel. 49 (0) 0000 0000 00	BE:	Rue Y, B-9999 Ville, Tel. 49 (0) 0000 0000 00	GB:	Z Street, Town XY99 9YZ, Tel. 49 (0) 0000 0000 00
	NL:	X Straat, 9999 YZ Stad, Tel. 49 (0) 0000 0000 00						
BE:	Rue Y, B-9999 Ville, Tel. 49 (0) 0000 0000 00							
GB:	Z Street, Town XY99 9YZ, Tel. 49 (0) 0000 0000 00							
<p>Waarschuwing. Ontvlambare vloeistof en damp. Buiten het bereik van kinderen houden. Verwijderd houden van warmte, hete oppervlakken, vonken, open vuur en andere ontstekingsbronnen. Niet roken. Inhoud/verpakking afvoeren naar een inzamelpunt bij de gemeente. Bij het inwinnen van medisch advies, de verpakking of het etiket ter beschikking houden.</p> <p>Attention. Liquide et vapeurs inflammables. Tenir hors de portée des enfants. Tenir à l'écart de la chaleur, des surfaces chaudes, des étincelles, des flammes nues et de toute autre source d'inflammation. Ne pas fumer. Eliminer le contenu /récipient au point de collecte municipale. En cas de consultation d'un médecin, garder à disposition le récipient ou l'étiquette.</p> <p>Warning. Flammable liquid and vapour. Keep out of reach of children. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Dispose the contents/container at the municipal collection point. If medical advice is needed, have product container or label at hand.</p> <p>EU grenswaarde voor dit product (cat A/d): 300 g/l. Dit product bevat maximaal 300 g/l VOS. Valeur limite en UE pour ce produit (cat A/d): 300 g/l. Ce produit contient au maximum 300 g/l COV. EU limit for this product is (cat A/d): 300 g/l. This product contains max 300 g/l VOC.</p>								
	 EWC: 080111	1L						

Special case small packaging

- Inner packaging so small or awkward shape and not possible to place the UFI
- UFI should be placed in either
 - fold-out labels (advised to include UFI on front and back page)
 - tie-on tags, or
 - outer packaging

Guidance on labelling and packaging

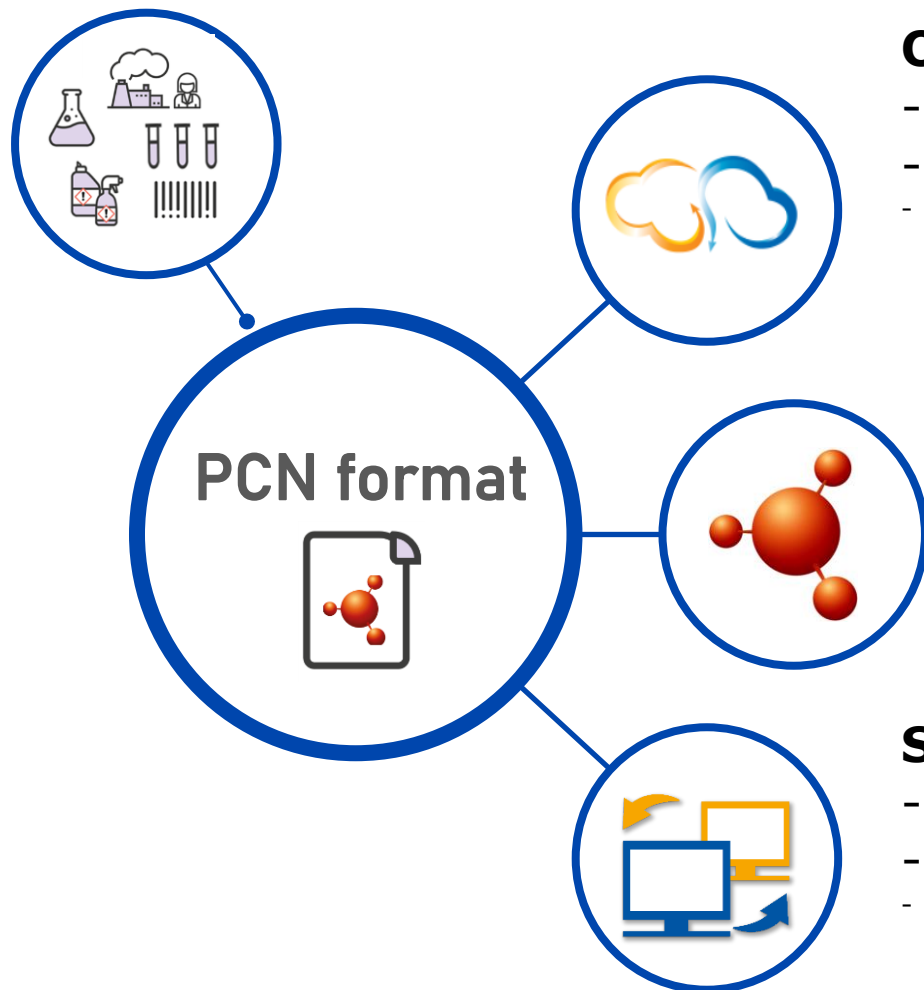
<https://echa.europa.eu/guidance-documents/guidance-on-clp>



Submission format and tools



Ways to prepare a PCN notification



Online in IUCLID Cloud

- Maintained by ECHA
- Secure data storage
- <https://echa.europa.eu/support/dossier-submission-tools/echa-cloud-services>

Offline in IUCLID 6

- Downloaded from IUCLID website
- Desktop and server versions
- <https://iuclid6.echa.europa.eu/>

System-to-system service

- Prepared in company's system
- Automated & bulk approach
- <https://poisoncentres.echa.europa.eu/system-to-system-service>

Ways to submit a PCN notification



ECHA Submission portal

- A centralised tool for preparing, submitting and managing submissions
- Supports multimarket submissions
- <https://poisoncentres.echa.europa.eu/echa-submission-portal>

System-to-system service

- Automatic & bulk submission of dossiers
- Request to access the service
http://comments.echa.europa.eu/comments/cms/Contact_S2S.aspx

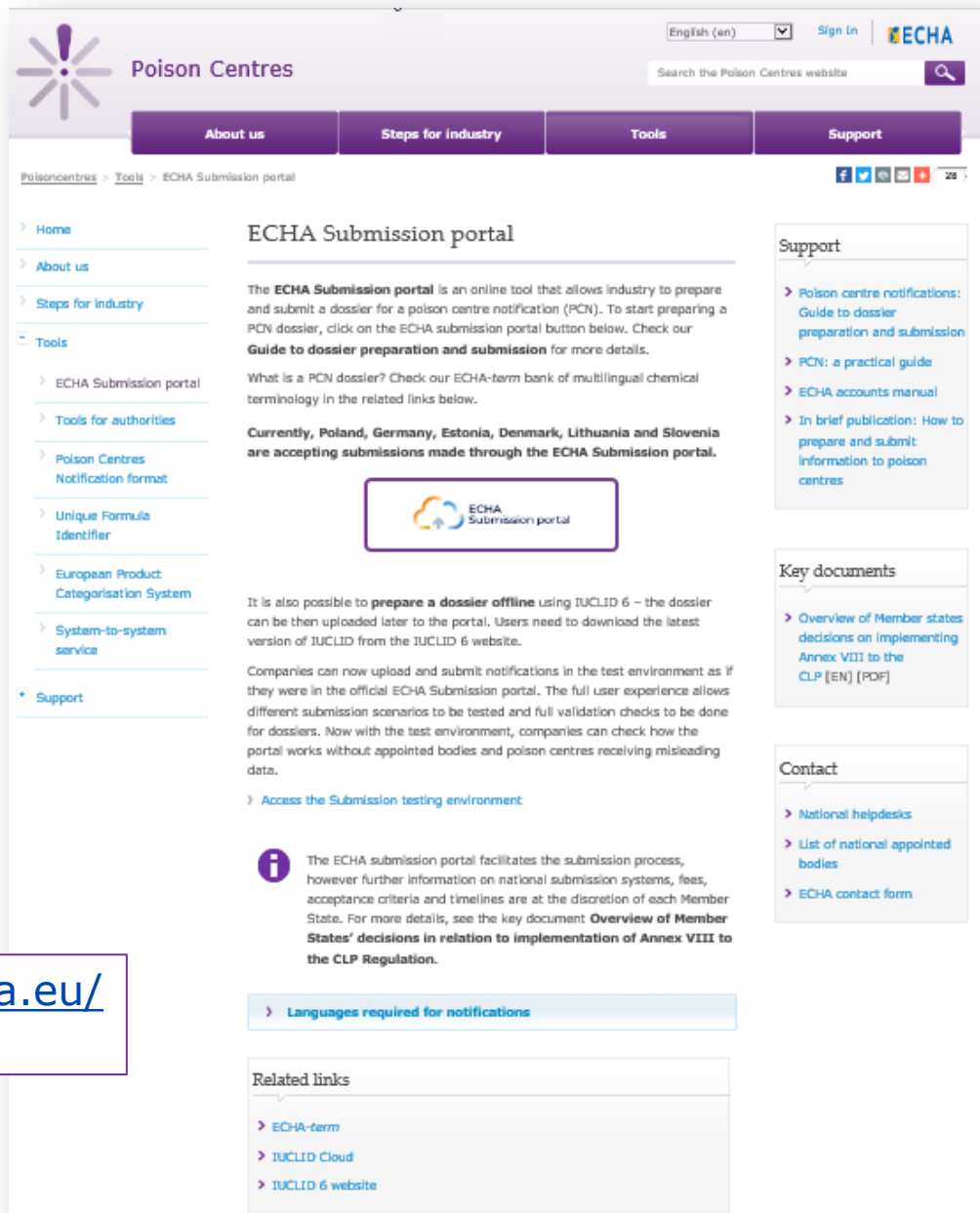
National systems

- Some will remain available, most rely on the ECHA Submission portal
- Harmonised format from Annex VIII
- <https://poisoncentres.echa.europa.eu/appointed-bodies>

Portal page

- Access to the Portal
- Lists which countries are accepting portal notifications
- Link to the submission testing environment
- Comprehensive support material!

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



The screenshot shows the ECHA Submission portal website. The header includes the ECHA logo, a language selector set to English (en), a Sign In button, and a search bar. The main navigation bar has tabs for About us, Steps for industry, Tools, and Support. The page title is "Poison Centres" and the breadcrumb trail is "Poisoncentres > Tools > ECHA Submission portal".

The left sidebar contains a navigation menu with the following items:

- > Home
- > About us
- > Steps for industry
- Tools
 - > ECHA Submission portal
 - > Tools for authorities
 - > Poison Centres Notification format
 - > Unique Formula Identifier
 - > European Product Categorisation System
 - > System-to-system service
- + Support

The main content area is titled "ECHA Submission portal". It contains the following text:

The **ECHA Submission portal** is an online tool that allows industry to prepare and submit a dossier for a poison centre notification (PCN). To start preparing a PCN dossier, click on the ECHA submission portal button below. Check our **Guide to dossier preparation and submission** for more details.

What is a PCN dossier? Check our ECHA-term bank of multilingual chemical terminology in the related links below.

Currently, Poland, Germany, Estonia, Denmark, Lithuania and Slovenia are accepting submissions made through the ECHA Submission portal.

Below this text is a button labeled "ECHA Submission portal".

It is also possible to **prepare a dossier offline** using IUCLID 6 – the dossier can be then uploaded later to the portal. Users need to download the latest version of IUCLID from the IUCLID 6 website.

Companies can now upload and submit notifications in the test environment as if they were in the official ECHA Submission portal. The full user experience allows different submission scenarios to be tested and full validation checks to be done for dossiers. Now with the test environment, companies can check how the portal works without appointed bodies and poison centres receiving misleading data.

> [Access the Submission testing environment](#)

i The ECHA submission portal facilitates the submission process, however further information on national submission systems, fees, acceptance criteria and timelines are at the discretion of each Member State. For more details, see the key document **Overview of Member States' decisions in relation to implementation of Annex VIII to the CLP Regulation**.

> [Languages required for notifications](#)

The right sidebar contains the following sections:

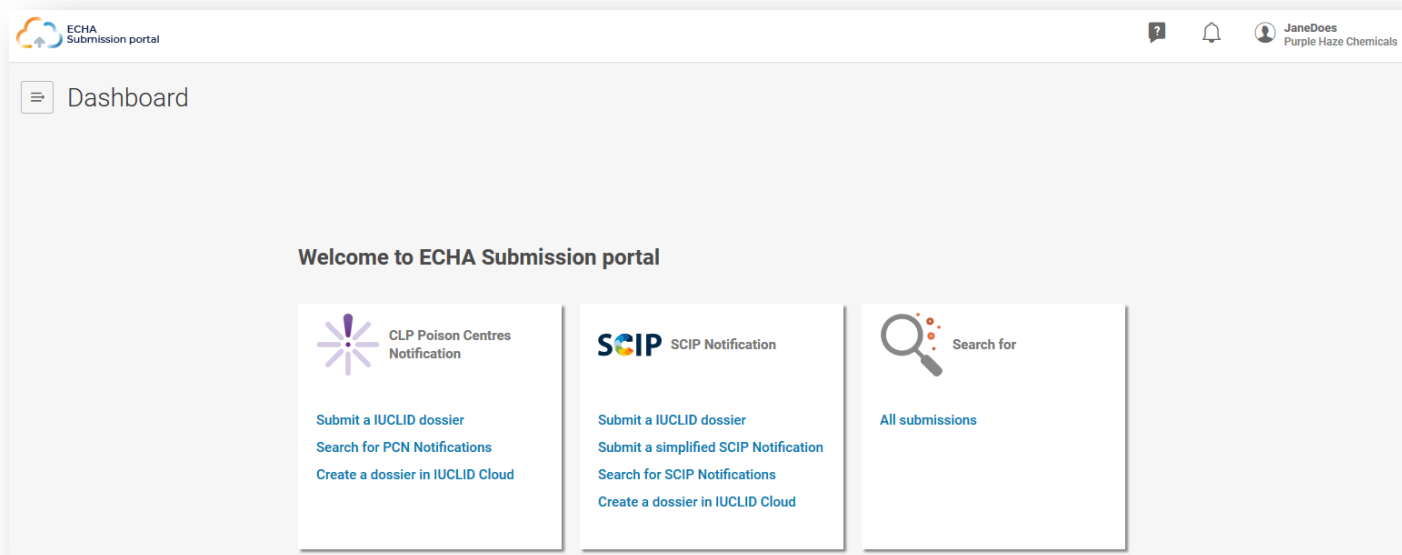
- Support**
 - > [Poison centre notifications: Guide to dossier preparation and submission](#)
 - > [PCN: a practical guide](#)
 - > [ECHA accounts manual](#)
 - > [In brief publication: How to prepare and submit information to poison centres](#)
- Key documents**
 - > [Overview of Member states decisions on implementing Annex VIII to the CLP \(EN\) \[PDF\]](#)
- Contact**
 - > [National helpdesks](#)
 - > [List of national appointed bodies](#)
 - > [ECHA contact form](#)

At the bottom, there is a "Related links" section with the following items:

- > [ECHA-term](#)
- > [IUCLID Cloud](#)
- > [IUCLID 6 website](#)

Portal - dashboard

- PCN users and SCIP notification users
- Create a dossier in IUCLID cloud
- Submit online
- Search submissions



The screenshot shows the ECHA Submission portal dashboard. At the top left, it says "ECHA Submission portal". On the top right, there are icons for help, notifications, and a user profile for "JaneDoes Purple Haze Chemicals". Below the header, there is a "Dashboard" link. The main content area is titled "Welcome to ECHA Submission portal" and features three main action cards:

- CLP Poison Centres Notification**: Includes links for "Submit a IUCLID dossier", "Search for PCN Notifications", and "Create a dossier in IUCLID Cloud".
- SCIP Notification**: Includes links for "Submit a IUCLID dossier", "Submit a simplified SCIP Notification", "Search for SCIP Notifications", and "Create a dossier in IUCLID Cloud".
- Search for**: Includes a link for "All submissions".

Accessing ECHA's IT applications



Getting access to ECHA's IT applications



Full details in **ECHA Accounts manual** at https://www.echa.europa.eu/documents/10162/21721613/echa_accounts_en.pdf/



Creating an ECHA Account

- An ECHA account allows you to login to all of ECHAs IT applications.
- One username/one password to access REACH-IT, R4BP 3, ePIC, ECHA cloud services and the ECHA Submission portal
- To create an ECHA Account, go to the login page at <https://idp-industry.echa.europa.eu/idp/>
- Provide name/contact details, e-mail confirmation

VERIFY YOUR EMAIL ADDRESS
Follow the steps below to verify your email address

A confirmation email with a verification link has been sent to XXXX.XXXXX@echa.europa.eu. Please click on the verification link in order to verify your email address and be able to login.

[Go to Login](#)



Assign a legal entity

- Assign a legal entity to the account by adding details about the company
- Each legal entity is assigned a UUID number which is mandatory the dossier
- Consistency check of UUID between the dossier and in the portal upon submission

INDUSTRY LEGAL ENTITY CREATION

Do you need access to REACH-IT, R4BP 3, ePIC, ECHA Cloud Services, ECHA Submission Portal for Industry?

Please associate your account with a legal entity.

A Legal Entity (LE) may represent anything between a complex business structure and a simple organised business, for example, a corporation, a company, or a single person. By creating a LE the associated users will be able to access ECHA's IT tools.



If your legal entity has already been registered, to associate this account with that legal entity, please communicate the username [\[redacted\]](#) and email address [\[redacted\]](#) to the legal entity manager

Create a New Legal Entity



User roles

- Define the users and their roles
 - 'Legal entity manager'
 - Submission portal manager
 - IUCLID full access
- Consultants can work on behalf of a company when appointed as a 'foreign user'

Purple Haze Chemicals

LEGAL ENTITY USERS [+ Create new user](#) [Add foreign user](#)

View the list of users associated with the Legal Entity

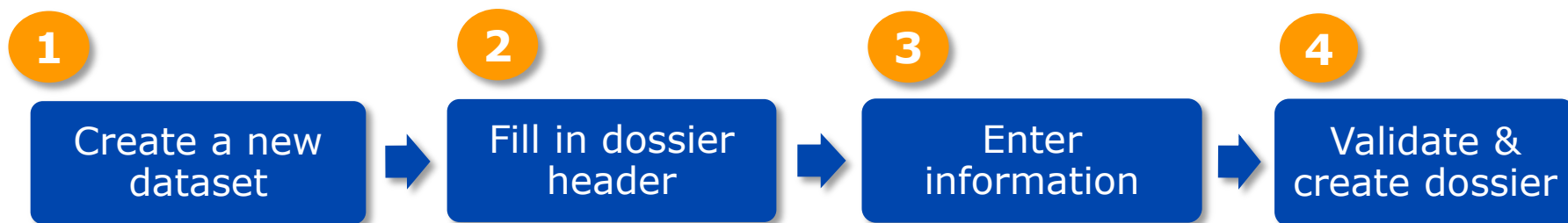
Sort by
Username Search

Username	Name	Email	User roles	Status	Actions
JaneDoes	Jane Does		LE Manager IUCLID Beta Full Access IUCLID Full Access REACH Manager Submission Portal Manager	Active	↻

Create a dossier in IUCLID



Dossier creation overview

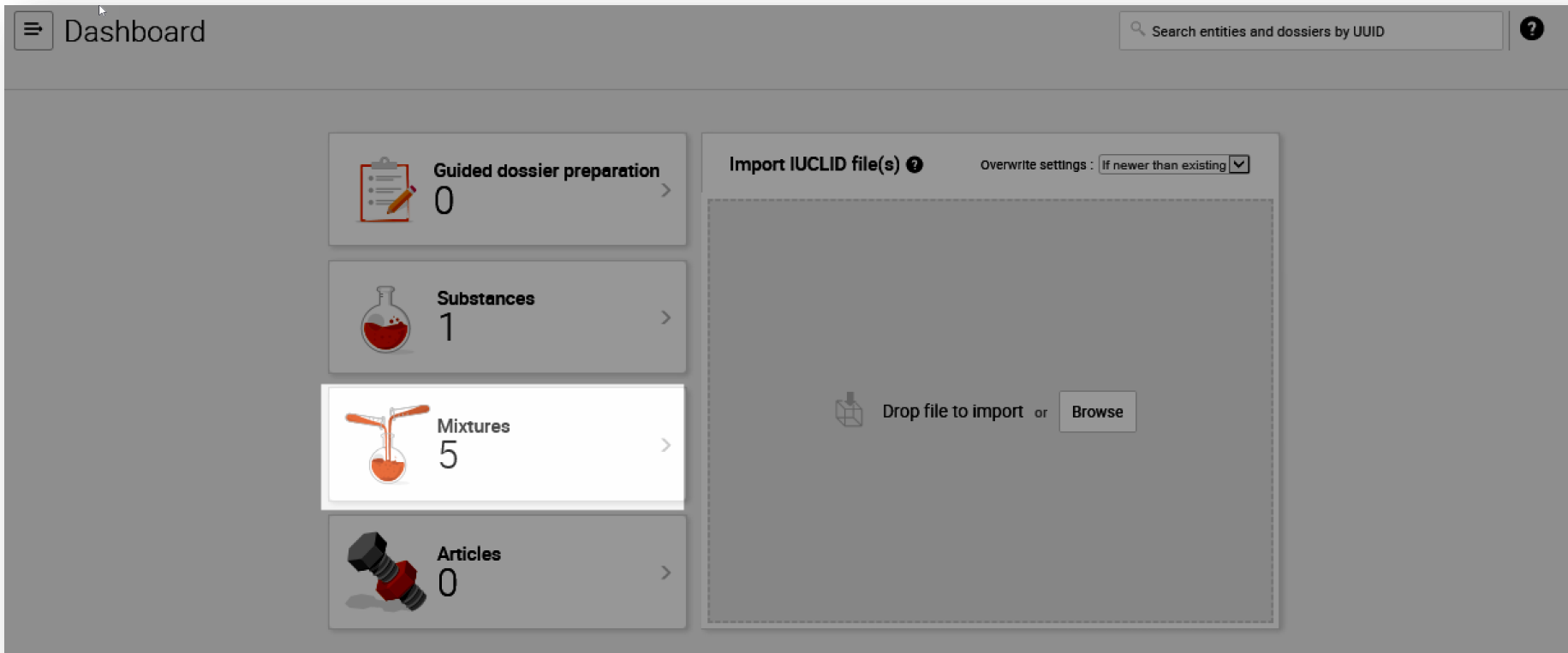


Step by step instructions in **PCN practical guide** at https://poisoncentres.echa.europa.eu/documents/22284544/22295820/pcn_practical_guide_en.pdf/

Create a dataset



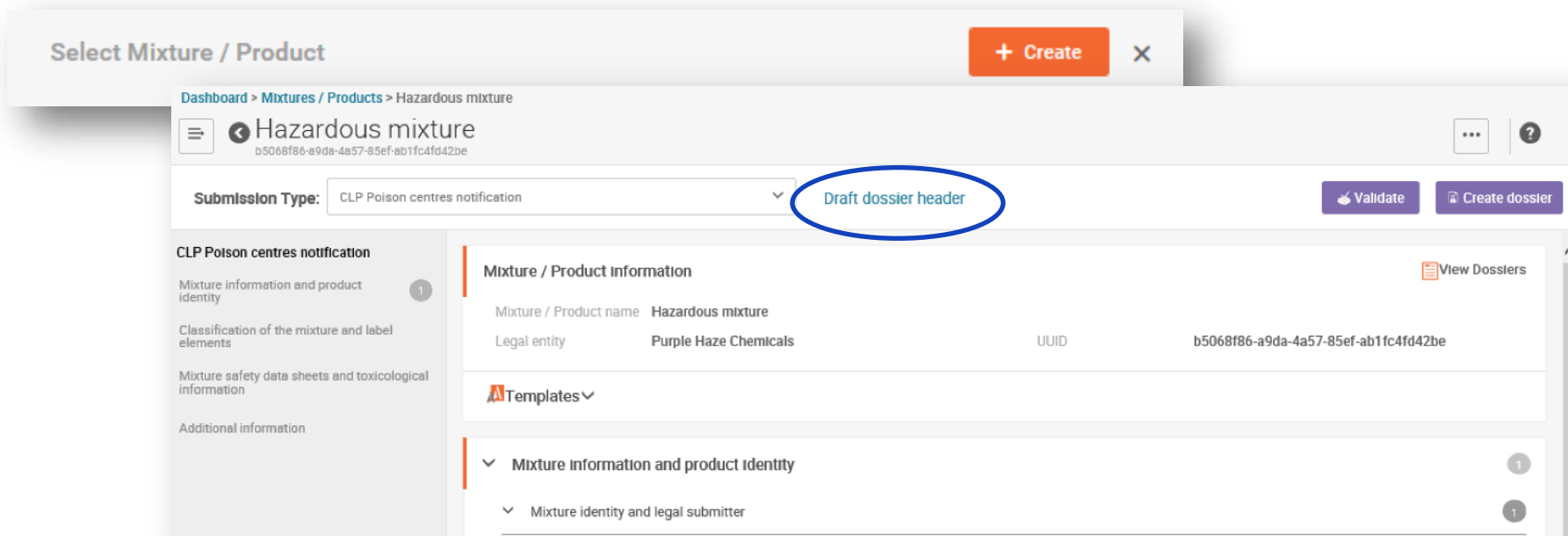
IUCLID dashboard



The screenshot shows the IUCLID dashboard interface. At the top left, there is a "Dashboard" label with a hamburger menu icon. At the top right, there is a search bar with the text "Search entities and dossiers by UUID" and a help icon. The main content area is divided into two columns. The left column contains four summary cards: "Guided dossier preparation" with 0 items, "Substances" with 1 item, "Mixtures" with 5 items (highlighted in white), and "Articles" with 0 items. The right column is titled "Import IUCLID file(s)" and includes an "Overwrite settings" dropdown menu set to "if newer than existing". Below this is a large dashed box for file import, with a "Drop file to import" instruction and a "Browse" button.

Create a new mixture dataset

- Enter a name for the mixture dataset
- Specify 'working context' 'CLP poison centre notification'
- Open the draft dossier header



The screenshot shows the ECHA portal interface for creating a new mixture dataset. The main heading is "Select Mixture / Product" with a "+ Create" button and a close "X" button. Below this, the breadcrumb path is "Dashboard > Mixtures / Products > Hazardous mixture". The current page title is "Hazardous mixture" with a UUID "b5068f86-a9da-4a57-85ef-ab1fc4fd42be". The "Submission Type" is set to "CLP Poison centres notification", and the "Draft dossier header" option is highlighted with a blue circle. There are "Validate" and "Create dossier" buttons. The left sidebar shows a navigation menu with "CLP Poison centres notification" selected. The main content area displays "Mixture / Product information" with fields for "Mixture / Product name" (Hazardous mixture), "Legal entity" (Purple Haze Chemicals), and "UUID" (b5068f86-a9da-4a57-85ef-ab1fc4fd42be). Below this is a "Templates" section with a dropdown arrow. The bottom section shows a list of sections to be created, including "Mixture information and product Identity" and "Mixture identity and legal submitter", both with a "1" in a circle next to them.

Dossier header



Dossier header

- Contains the information that defines the validation rules
- Establishes the free text fields for certain sections in specific language
- NOTE- Submission type selection only if relevant
 - [Group](#) (not supported)
 - [Limited](#) (industrial use only)
 - [Voluntary](#) (for non-duty holders or mixtures out of scope)

← CLP Poison centres notification

Dossier name (given by user)
None

Dossier submission remark
None

Specific submissions

PCN number*
None
✘ PCN number field is mandatory.

Country (market placement)*
None
✘ Country (market placement) field is mandatory.

Language*
None
✘ Language field is mandatory.

Submission type

Limited submission (industrial use only)

Group submission

Voluntary submission

Notification type

Initial notification

New notification after a significant change of composition

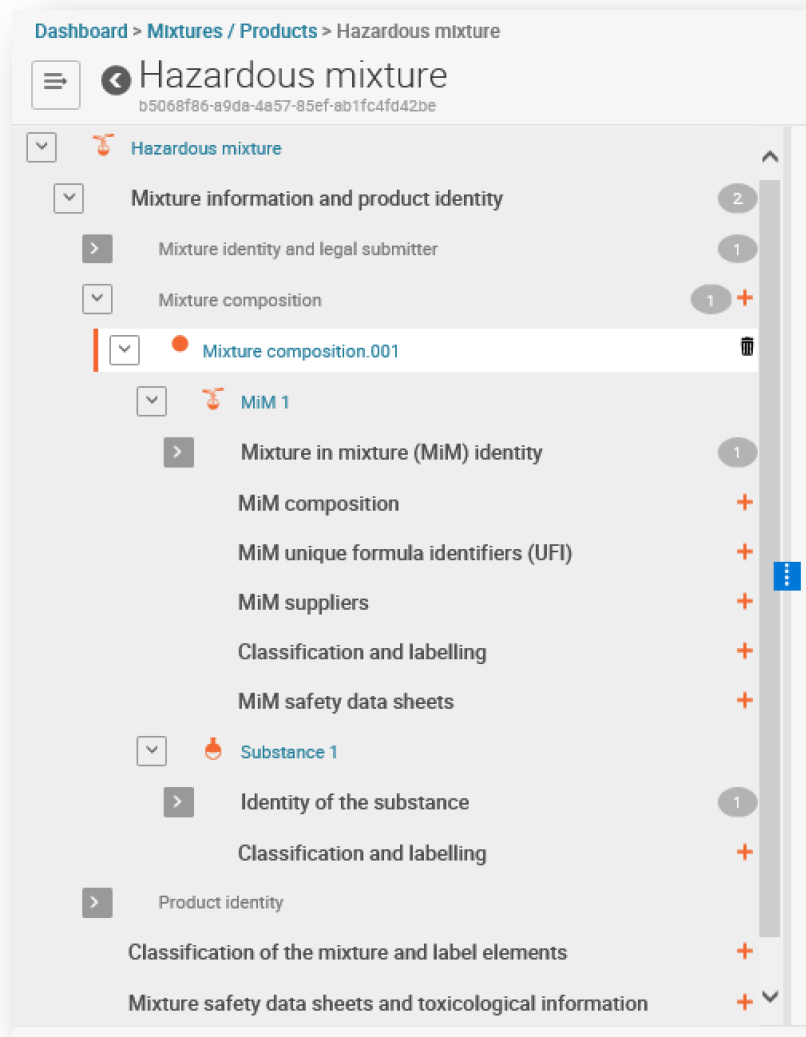
The submission is an update

Enter the required information



Enter information

- Navigation tree to move from dossier header to other sections
- Uses expandable and collapsible windows
- Create new 'document' + to enter information
- New support material for step by step in 'PCN practical guide' and video tutorial



The screenshot shows a web interface for a 'Hazardous mixture' dossier. The breadcrumb trail is 'Dashboard > Mixtures / Products > Hazardous mixture'. The main title is 'Hazardous mixture' with a unique identifier 'b5068f86-a9da-4a57-85ef-ab1fc4fd42be'. The navigation tree is as follows:

- Hazardous mixture
 - Mixture information and product identity (2)
 - Mixture identity and legal submitter (1)
 - Mixture composition (1 +)
 - Mixture composition.001 (highlighted)
 - MiM 1
 - Mixture in mixture (MiM) identity (1)
 - MiM composition (+)
 - MiM unique formula identifiers (UFI) (+)
 - MiM suppliers (+)
 - Classification and labelling (+)
 - MiM safety data sheets (+)
 - Substance 1
 - Identity of the substance (1)
 - Classification and labelling (+)
 - Product identity
 - Classification of the mixture and label elements (+)
 - Mixture safety data sheets and toxicological information (+)

Mixture composition document (i)

- All components (substances, mixture in mixtures) added in the mixture composition document
- Use checkboxes to flag 'special' components generic component identifiers, interchangeable component groups, standard formulas

Dashboard > Mixtures / Products > Hazardous mixture

Hazardous mixture
b5068f86-a9da-4a57-85ef-ab1fc4fd42be

Hazardous mixture

Mixture information and product identity (2)

- Mixture identity and legal submitter (1)
- Mixture composition (1) +
 - Mixture composition.001
- Product identity
- Classification of the mixture and label elements +
- Mixture safety data sheets and toxicological information +
- Additional information

Mixture composition.001
undefined: 0390eb34-7c48-470d-8914-0e383b34769f

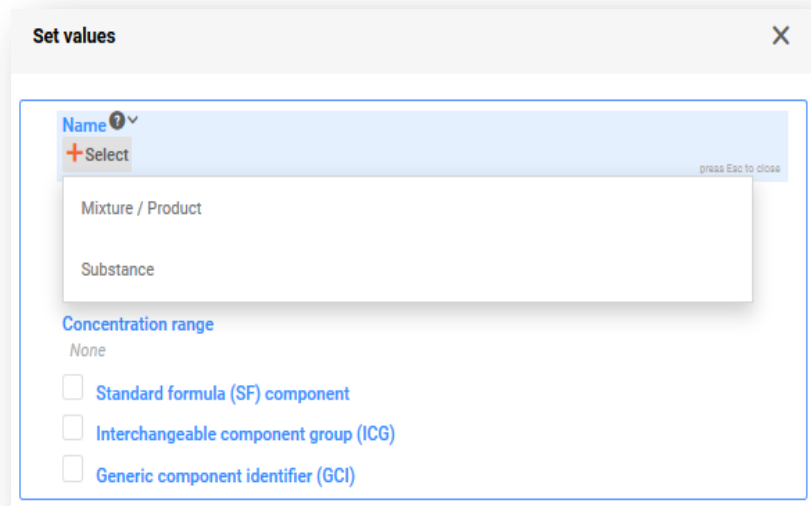
Components

+ New Item



#.	Name	Function	Typical con...	Concentrati...	Standard fo...	Interchange...	Generic co...	Action
1	None	None	None	None	<input type="checkbox"/> Standard formula (SF) component	<input type="checkbox"/> Interchangeable component group (ICG)	<input type="checkbox"/> Generic component identifier (GCI)	

Generic component identifier

- Recently renamed from 'Generic product identifier)
- Perfumes or colouring agents if they are **not classified for any health hazard**.
- Can be either substances or mixture in mixtures.
- Name & function
- Concentration
- GCI check box



Set values

Name  

+ Select press Esc to close

Mixture / Product

Substance

Concentration range

None

Standard formula (SF) component

Interchangeable component group (ICG)

Generic component identifier (GCI)

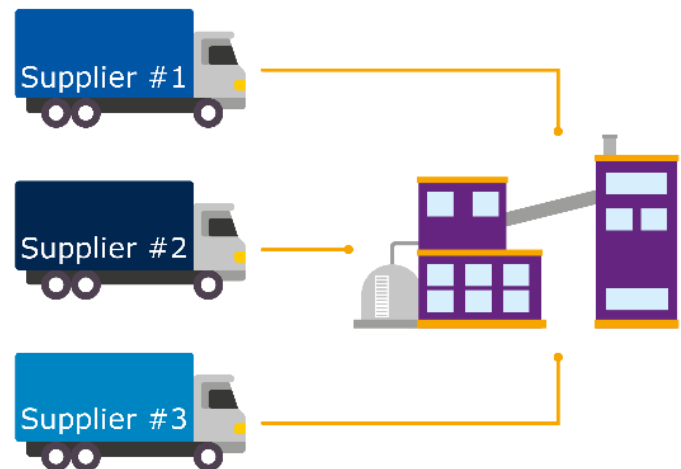
Standard formulas



- Certain **constructions products** that conform with composition corresponding to specific Standard Formulas (Part D Annex VIII) can be notified according to that formula's components and concentration.
- **Fuels** listed in Table 3 Annex VIII identified according to safety data sheet. They are technically handled as a Standard Formula.
- **In the PCN**, Standard Formula selected from the picklist and the components flagged in the notification. Alerts the system to apply different validation rule set. Validation rules for fuels differ from rules for construction products.

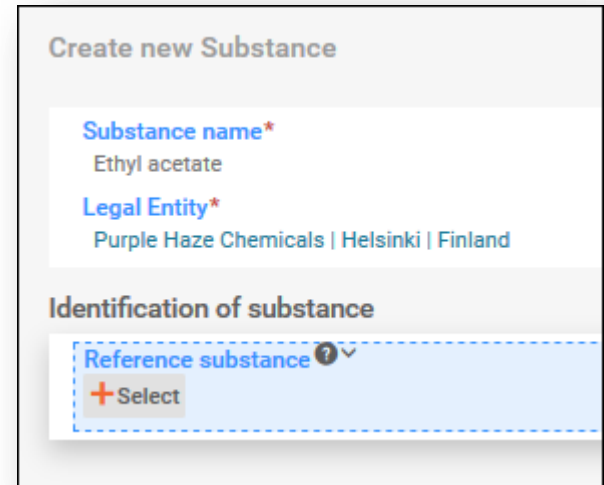
Interchangeable Component Groups

- **Cross sector** solution to address unknown mixture composition due to change in component(s), e.g. 'same' component, different suppliers.
- Consists of **interchangeable components** (fit certain criteria), where each can be used interchangeably in a mixture without altering its overall classification, hazard or emergency health response.
- **In the PCN**, an ICG is created as a mixture and interchangeable components (substances or mixtures) are added & flagged. The concentration is given to the group not the individual components



Reference substance

- Every substance component must be linked to a reference substance document
- Defines the identity of a substance
- Can be created on the spot or downloaded from the IUCLID website
- Reference substance documents can be selected for re-use once it is in the working environment.



Create new Substance

Substance name*
Ethyl acetate

Legal Entity*
Purple Haze Chemicals | Helsinki | Finland

Identification of substance

Reference substance ⓘ
+ Select

<https://iuclid6.echa.europa.eu/web/iuclid/get-reference-substances>

Validate and create



Validation rules

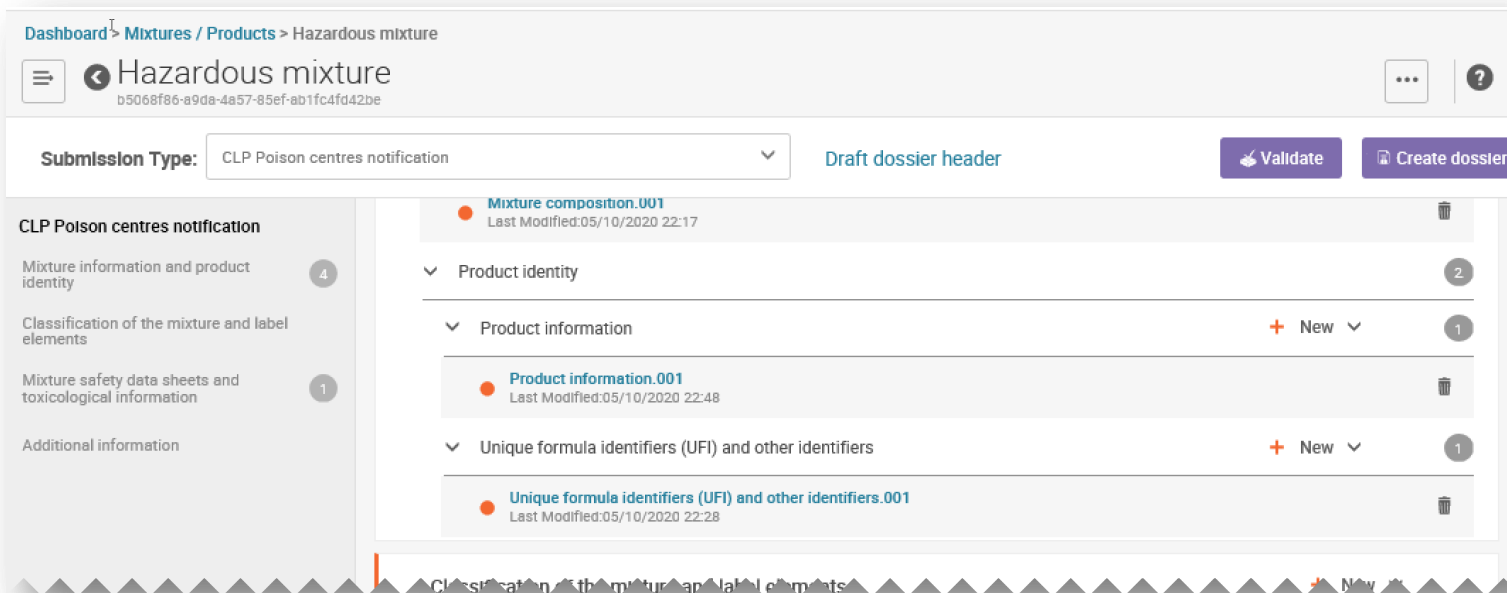
- Over 120 rules implemented in
 - Validation Assistant (before submission)
 - Portal Assistant (database check upon submission)
- List of validation rules available:
<https://poisoncentres.echa.europa.eu/poison-centres-notification-format>





The Validation assistant

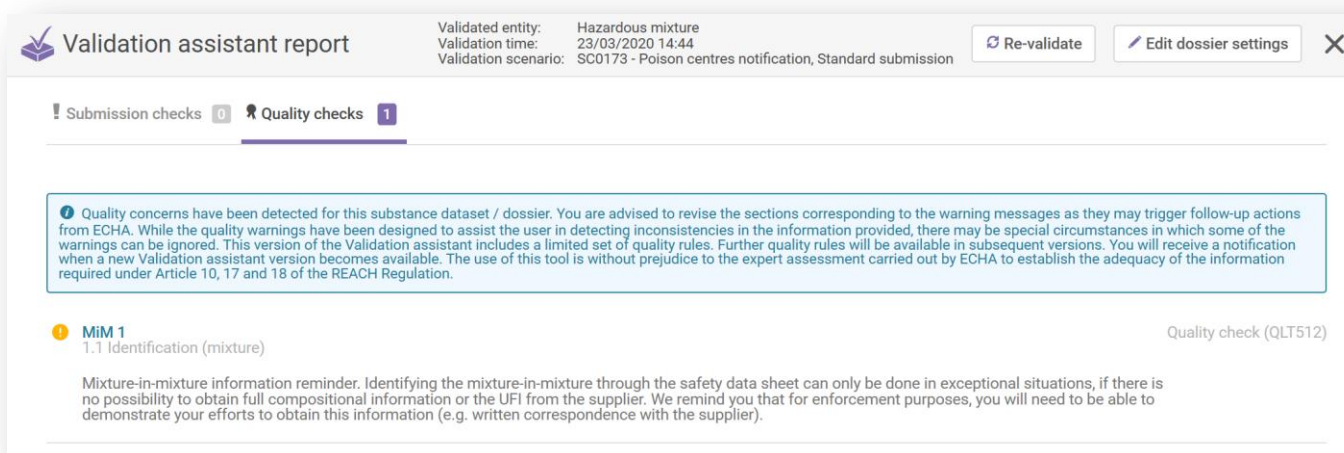
- Integrated into the preparation tools to check the included information before making a submission.
- Checks presence and quality of information, and internal dossier consistency



The screenshot shows the ECHA validation assistant interface for a hazardous mixture dossier. The breadcrumb navigation is "Dashboard > Mixtures / Products > Hazardous mixture". The page title is "Hazardous mixture" with a unique identifier "b5068f86-a9da-4a57-85ef-ab1fc4fd42be". The submission type is "CLP Poison centres notification". There are buttons for "Draft dossier header", "Validate", and "Create dossier". The main content area is divided into sections: "Mixture composition.001" (Last Modified: 05/10/2020 22:17), "Product identity" (2 items), "Product information" (1 item, with a "+ New" button), "Product information.001" (Last Modified: 05/10/2020 22:48), and "Unique formula identifiers (UFI) and other identifiers" (1 item, with a "+ New" button). Below this is "Unique formula identifiers (UFI) and other identifiers.001" (Last Modified: 05/10/2020 22:28). A sidebar on the left lists "CLP Poison centres notification" with sub-sections: "Mixture information and product identity" (4 items), "Classification of the mixture and label elements", "Mixture safety data sheets and toxicological information" (1 item), and "Additional information".

Validation report

- The validation report displays the outcome of the checks:
 - ✓ No failures (dossier will be accepted and forwarded to authorities)
 - ! Quality rules (dossier accepted but forwarded with the validation report highlighting potential deficiencies)
 - ✗ Failures (dossier will not be accepted by the system – fix errors – create and resubmit dossier)

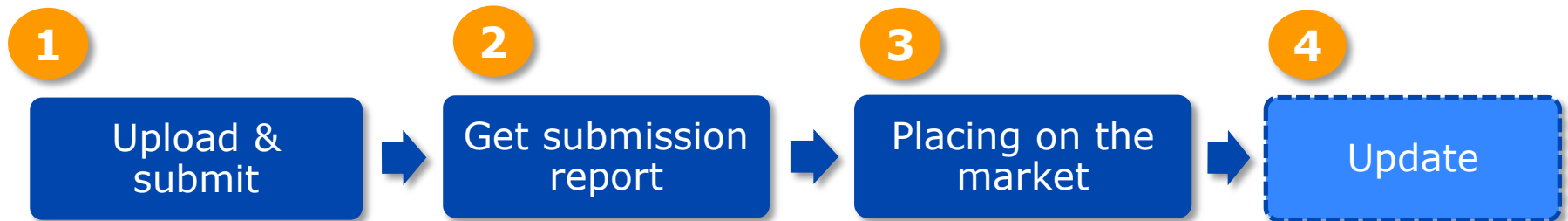


The screenshot shows the 'Validation assistant report' interface. At the top, it displays the validated entity as 'Hazardous mixture', the validation time as '23/03/2020 14:44', and the validation scenario as 'SC0173 - Poison centres notification, Standard submission'. There are buttons for 'Re-validate' and 'Edit dossier settings'. Below this, a summary bar shows 'Submission checks 0' and 'Quality checks 1'. A blue box contains a warning message: 'Quality concerns have been detected for this substance dataset / dossier. You are advised to revise the sections corresponding to the warning messages as they may trigger follow-up actions from ECHA. While the quality warnings have been designed to assist the user in detecting inconsistencies in the information provided, there may be special circumstances in which some of the warnings can be ignored. This version of the Validation assistant includes a limited set of quality rules. Further quality rules will be available in subsequent versions. You will receive a notification when a new Validation assistant version becomes available. The use of this tool is without prejudice to the expert assessment carried out by ECHA to establish the adequacy of the information required under Article 10, 17 and 18 of the REACH Regulation.' Below this, a specific quality check is listed: 'MiM 1 1.1 Identification (mixture) Quality check (QLT512)'. The text for this check reads: 'Mixture-in-mixture information reminder. Identifying the mixture-in-mixture through the safety data sheet can only be done in exceptional situations, if there is no possibility to obtain full compositional information or the UFI from the supplier. We remind you that for enforcement purposes, you will need to be able to demonstrate your efforts to obtain this information (e.g. written correspondence with the supplier).'

Submitting the dossier



Dossier submission overview

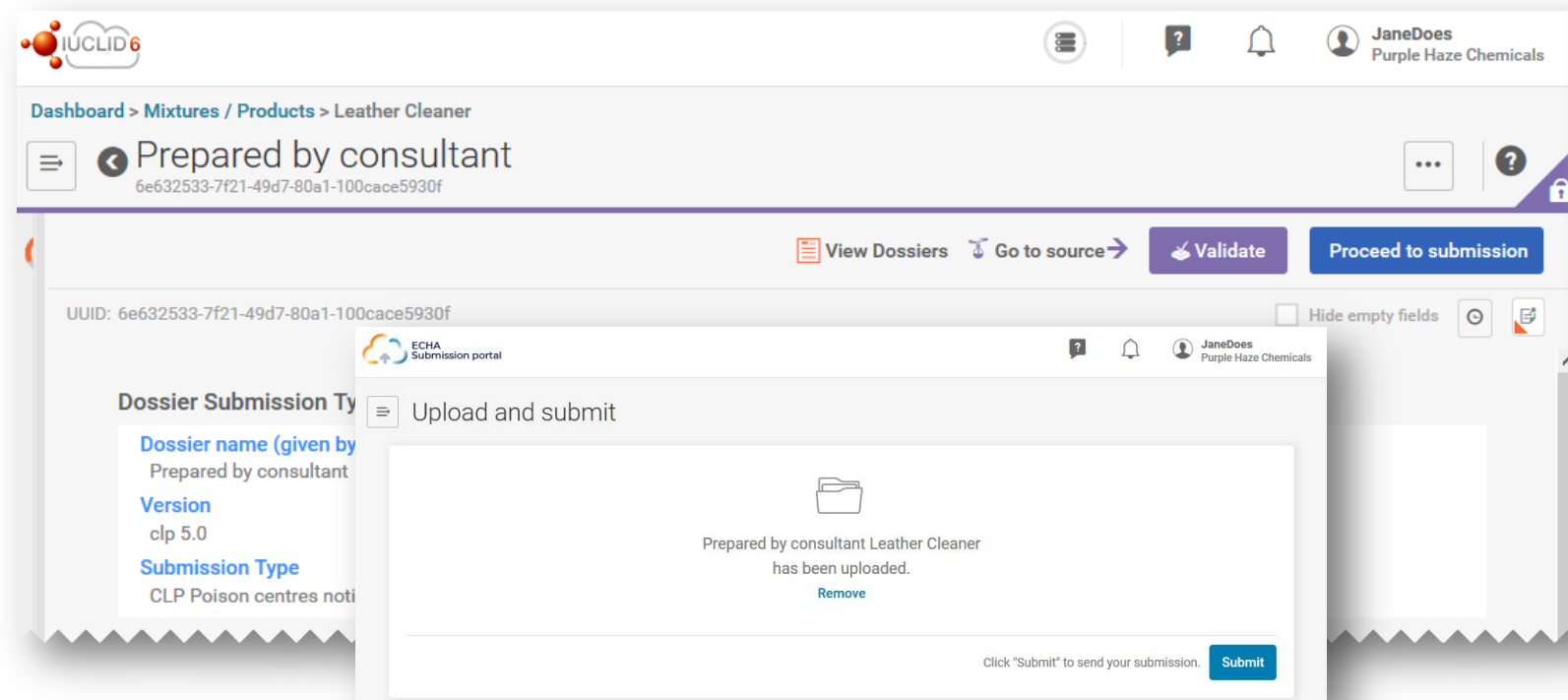


Upload and submit



Prepare and submit online

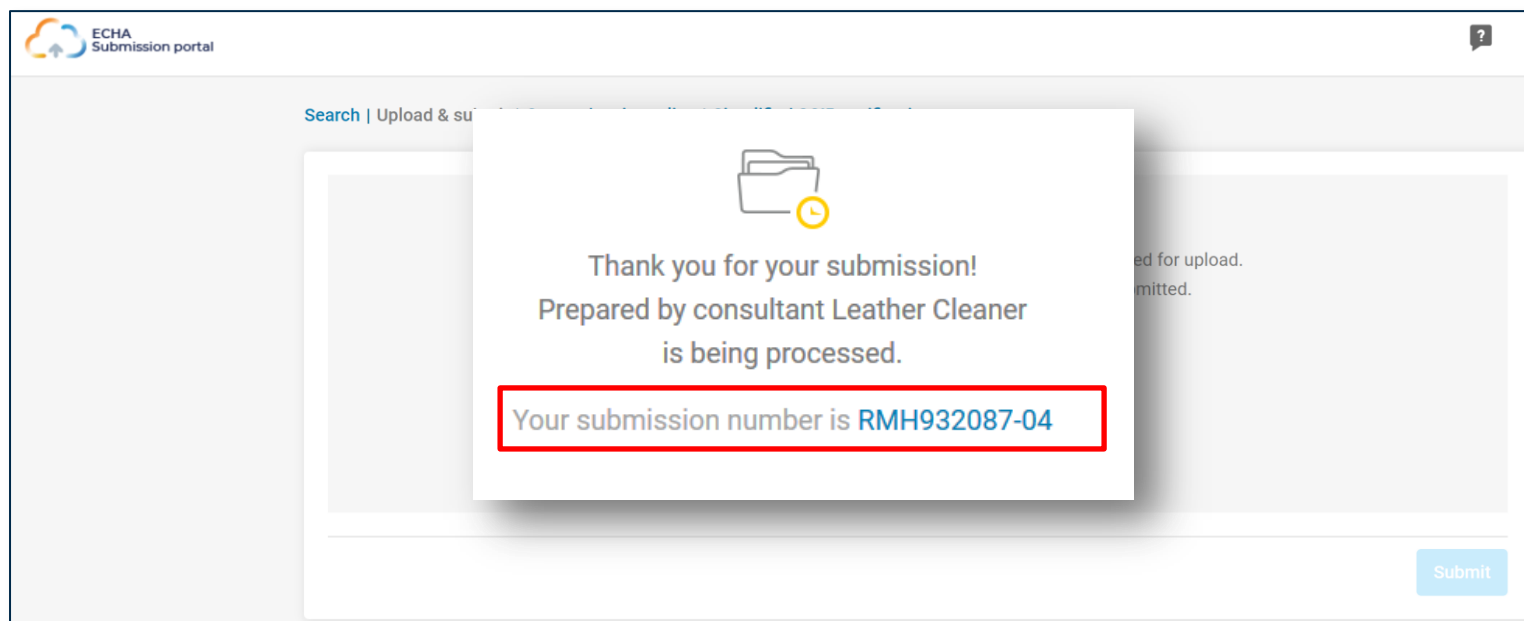
- After dossier created, proceed to submission.
- File automatically uploaded -> Submit!



The screenshot displays the ECHA IUCLID 6 submission portal. The user is logged in as JaneDoes, Purple Haze Chemicals. The breadcrumb trail is Dashboard > Mixtures / Products > Leather Cleaner. The dossier title is "Prepared by consultant" with the UUID 6e632533-7f21-49d7-80a1-100cace5930f. The interface includes buttons for "View Dossiers", "Go to source", "Validate", and "Proceed to submission". A modal window titled "ECHA Submission portal" is open, showing the "Upload and submit" step. The dossier name is "Prepared by consultant", the version is "clp 5.0", and the submission type is "CLP Poison centres noti". A message states "Prepared by consultant Leather Cleaner has been uploaded." with a "Remove" link. A "Submit" button is visible at the bottom of the modal, with a note: "Click 'Submit' to send your submission."

Manual upload and submit page

- Upload the dossier manually in import box
- Following successful submission, a submission number is assigned.
- Links to the submission report.

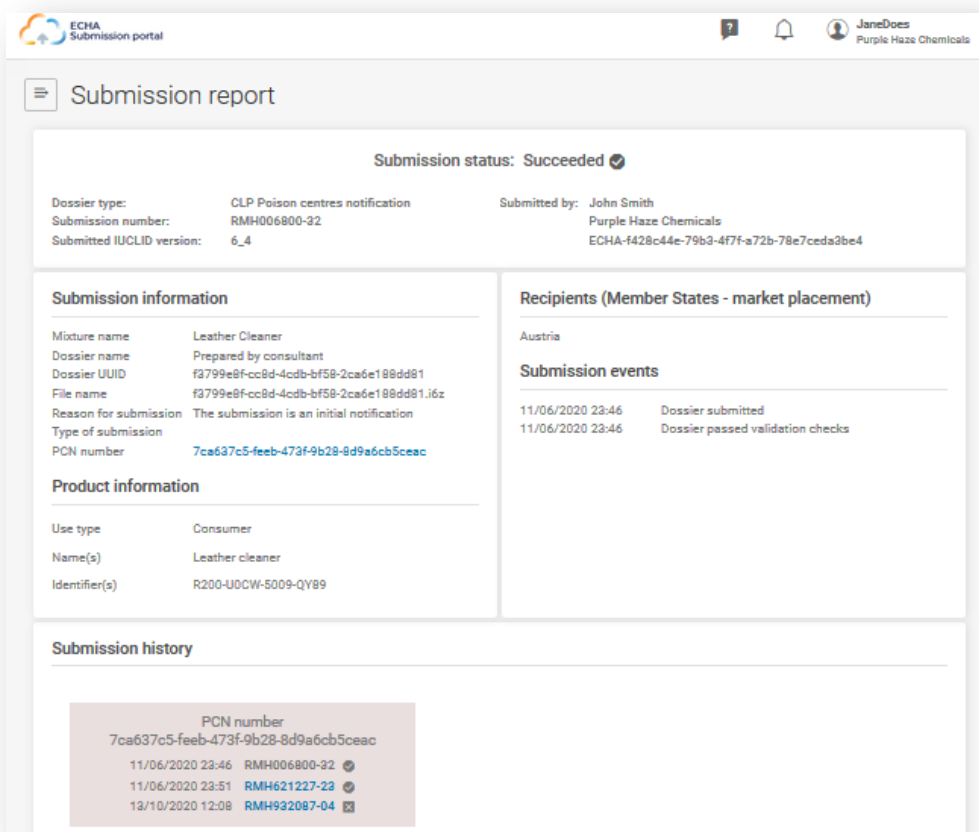


Submission report



Submission report

- Summary of the submission
- **Submission status** succeeded, succeeded with warnings or failed.
- **Submission** and **product information** – initial, update, name of the mixture etc. and **history** details
- Lists the Member States for **market placement**
- **Submission events** – critical to know to determine when to place on the market



ECHA Submission portal | JaneDoes Purple Haze Chemicals

Submission report

Submission status: Succeeded ✓

Dossier type:	CLP Poison centres notification	Submitted by:	John Smith
Submission number:	RMH006800-32		Purple Haze Chemicals
Submitted IUCLID version:	6_4		ECHA-f428c44e-79b3-477f-a72b-78e7ceda2be4





Submission information		Recipients (Member States - market placement)	
Mixture name	Leather Cleaner	Austria	
Dossier name	Prepared by consultant	Submission events	
Dossier UUID	f3799e8f-cc8d-4cdb-bf58-2ca6e188dd81	11/06/2020 23:46	Dossier submitted
File name	f3799e8f-cc8d-4cdb-bf58-2ca6e188dd81.i6z	11/06/2020 23:46	Dossier passed validation checks
Reason for submission	The submission is an initial notification		
Type of submission			
PCN number	7ca637c5-feeb-473f-9b28-8d9a6cb5ceac		

Product information	
Use type	Consumer
Name(s)	Leather cleaner
Identifier(s)	R200-U0CW-5009-QY89

Submission history

PCN number			
7ca637c5-feeb-473f-9b28-8d9a6cb5ceac			
11/06/2020 23:46	RMH006800-32	✓	
11/06/2020 23:51	RMH621227-23	✓	
12/10/2020 12:08	RMH922087-04	✗	

Search submissions





- Searching submissions by
 - A 'Sort by' functionality
 - Scrolling '<' or '>'
 - Entering search criteria
- Search results exported to Excel
- The submission number is links to the submission report
- Symbols to indicate if the submission is an initial  or update , or if it has a passed  or failed  status

☰ Search
Export to Excel

Search criteria ▾

Submission number	<input type="text" value="Please enter a Submission number"/>	Submission status	<input type="text" value="All submission status"/>
Dossier type	<input type="text" value="CLP Poison centres notification"/>	Submission date	from <input type="text" value="dd/mm/yyyy"/> to <input type="text" value="dd/mm/yyyy"/>
PCN number	<input type="text" value="Please enter a PCN number"/>	Submission reason	<input type="text" value="All submission reasons"/>
UFI	<input type="text" value="Please enter a UFI"/>		
Names	<input type="text" value="Please enter a dossier, mixture or trade name"/>		

Page 1 of 7 results Sort by

@	RMH269009-15 	19/10/2020 15:51		
PCN number	9b489e1c-93b8-44e4-b5c3-d02737d23b4d	UFI(s)	T200-U0CW-500A-Q671, F500-C029-F00T-DHT5	<input type="button" value="PCN"/>
Names	Dish washing liquid - initial, Dish washing liquid, Ultr...			
	Dossier type	CLP Poison centres notification		
@	RMH932087-04 	13/10/2020 12:08		
PCN number	7ca637c5-feeb-473f-9b28-8d9a6cb5ceac	UFI(s)	R200-U0CW-5009-QY89	<input type="button" value="PCN"/>
Names	Prepared by consultant, Leather Cleaner, Leather cle...			
	Dossier type	CLP Poison centres notification		
@	RMH621227-23 	11/06/2020 23:51		
PCN number	7ca637c5-feeb-473f-9b28-8d9a6cb5ceac	UFI(s)	R200-U0CW-5009-QY89	<input type="button" value="PCN"/>
Names	Prepared by consultant, Leather Cleaner, Leather cle...			
	Dossier type	CLP Poison centres notification		
@	RMH006800-32 	11/06/2020 23:46		
PCN number	7ca637c5-feeb-473f-9b28-8d9a6cb5ceac	UFI(s)	R200-U0CW-5009-QY89	<input type="button" value="PCN"/>
Names	Prepared by consultant, Leather Cleaner, Leather cle...			
	Dossier type	CLP Poison centres notification		

< 1 >
Items/page

Placing on the market



Member States – where are they now?

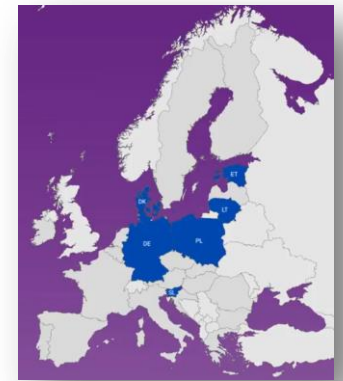
- Information received by Member States – updated when new information is received
 - Readiness and submission system options
 - Languages accepted
 - Fees charged
 - Timing for placing on the market

Overview of Member States decisions in relation to implementation of Annex VIII to the CLP Regulation (Poison Centre Notifications) - version 3.6 (18.08.2025)

Disclaimer: The information is based on input from Member States. The decisions of Member States are indicative and subject to changes. ECHA aims at updating this document to reflect the latest status. For further information, please contact national CLP Helpdesk: clp.helpdesk@echa.europa.eu

Member State	Readiness of Member State to accept notifications via ECHA submission system	Submission portal	Notification language	Fees for notifications	Placing on the market readiness notified via ECHA submission system	Member State
	Member State already connected to ECHA submission system and duty holders can start notifying their mixtures	Member State accepts notifications only via ECHA submission system	Duty holder may choose notification language between official language of the Member State or English (includes Member States where English is official language)	No fees	Duty holder can start placing mixture on the market immediately after confirmation of successful submission to the ECHA submission system (without awaiting approval from Member State)	
	Duty holder must continue to notify their mixture according to national legislation and procedures (e.g. for the literature 3.16.2020 for consumer and professional use mixtures). More information in column on the right concerns Member States connected to ECHA system	Member State accepts notifications via national submission system or ECHA submission system (duty holder has discretion of choice)	Duty holder must notify in one official language of the Member State (other than English)	Fees levied by Member State appointed body	Duty holder can start placing mixture on the market only after the Member State appointed body has downloaded the notification (information visible to duty holder in the submission report of ECHA system)	
			Duty holder must notify in multiple official languages of the Member State (other than English)	Fees under consideration		
		No information available		No information available	No information available	
Austria			German			
Belgium			French/Dutch or German/English			
Bulgaria			Bulgarian			
Croatia			Croatian or English			
Cyprus			Greek			
Czech Republic			Czech			
Denmark			Danish or English			
Estonia			Estonian or English			
Finland			Finnish and Swedish			
France			French			France
Germany			German or English			Germany
Greece			Greek			Greece
Hungary			Hungarian			Hungary

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



Considerations...

- Currently, not all countries are ready to accept harmonised notifications via the ECHA portal and national obligations apply
- Submissions made to Member States not accepting
 - are not considered as fulfilling legal requirements
 - remain in the database until Member State is connected and receiving
- Submission report indicates if '*Received by [country]*'
BUT
 - > check the Member States Overview to confirm if the Member State is connected and accepting the submitted notifications

Keeping up to date





Considerations

- Notification should be valid and up to date at all times.
- Updated notification is a revised version
- Update notification before changed mixture placed on the market
 - Change in mixture product identifier (including UFI)
 - Change in mixture classification
 - New toxicological data available
 - When changes in composition outside of the allowed ranges in Annex VIII
- Updated notification without undue delay e.g. new packaging type, change in emergency contact details, correction of error...

Significant change in composition

- When changes in composition outside of the allowed ranges in Annex VIII = **new UFI!**

Didelį susirūpinimą keliantys komponentai

Kiti pavojingi komponentai

Sudėties pakeitimai ir UFI poveikis

Didelį susirūpinimą keliantys komponentai

Jeigu mišinių komponentai klasifikuojami bent pagal vieną iš toliau išvardytų pavojingumo kategorijų, reikėtų nurodyti tiksliai jų koncentracijos mišinyje procentinę dalį mažėjančia tvarka pagal masę arba tūrį:

- › ūmus toksiškumas, 1, 2 arba 3 kategorija;
- › specifinis toksiškumas konkrečiam organui – vienkartinis poveikis, 1 arba 2 kategorija;
- › specifinis toksiškumas konkrečiam organui – pakartotinis poveikis, 1 arba 2 kategorija;
- › odos esdinimas, 1, 1A, 1B ar 1C kategorija;
- › smarkus akių pažeidimas, 1 kategorija.

Vietoj tikslios koncentracijos galima nurodyti koncentracijos intervalą pagal VIII priedo B dalies 1 lentelę (žr. 1 lentelę).

Jei tikslī koncentracija didesnė kaip 1 %, viršutinės ir apatinės koncentracijos verčių intervalų ribos gali būti suapvalintos iki vienos dešimtosios; jei tikslī koncentracija mažesnė arba lygi 1 %, galima naudoti ne daugiau kaip dvi dešimtaines trupmenas.

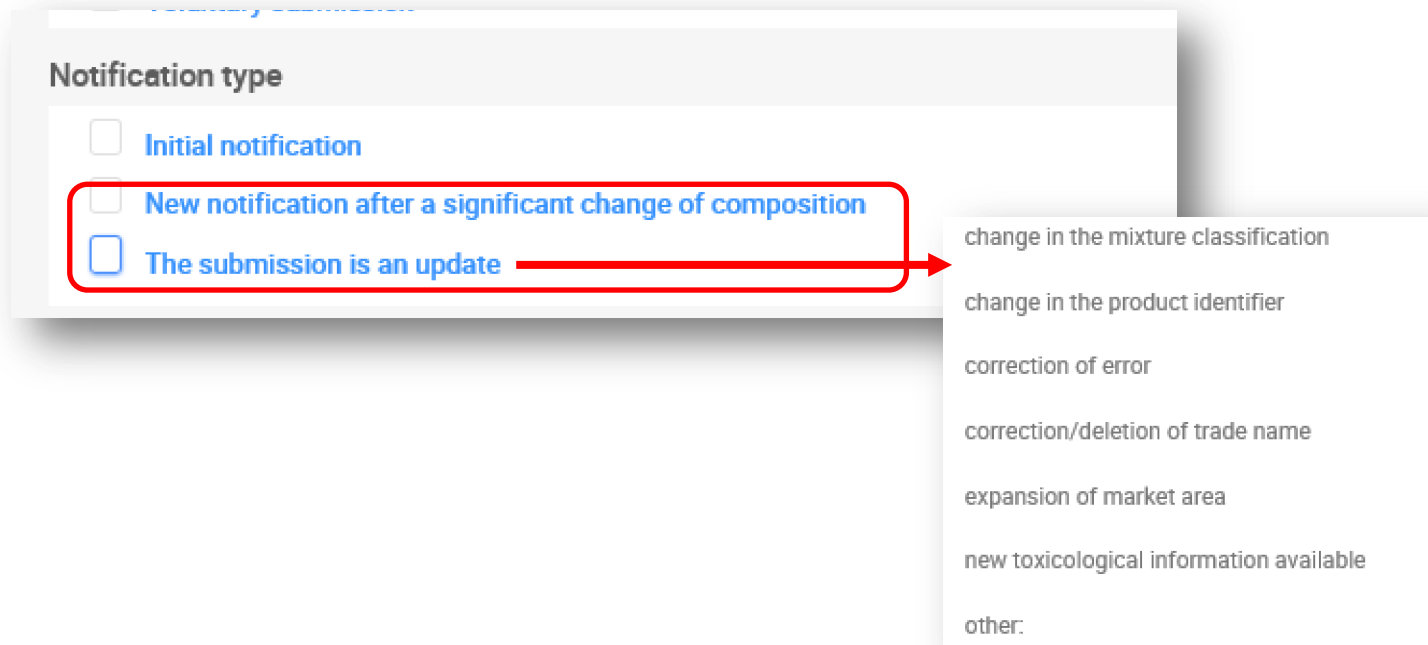
1 lentelė. Pavojingiems didelį susirūpinimą keliantiems komponentams taikomi koncentracijos intervalai atsižvelgiant į neatidėliotinas priemones, kurių reikia imtis ekstremaliose sveikatai situacijose (cheminės medžiagos arba mišiniuose naudojami mišiniai)

Mišinyje naudojamo komponento koncentracijos intervalas (%)	Didžiausios koncentracijos intervalo ribos, kurios turi būti naudojamos teikiant informaciją
≥ 25 - < 100	5 % vienetų
≥ 10 - < 25	3 % vienetų
≥ 1 - < 10	1 % vienetų
≥ 0,1 - < 1	0,3 % vienetų
> 0 - < 0,1	0,1 % vienetų

<https://poisoncentres.echa.europa.eu/lt/components-of-major-concern>

Indicating an update

- In the dossier header make relevant selection in the 'notification type'
- Updates require justification



Notification type

- Initial notification
- New notification after a significant change of composition
- The submission is an update

change in the mixture classification

change in the product identifier

correction of error

correction/deletion of trade name

expansion of market area

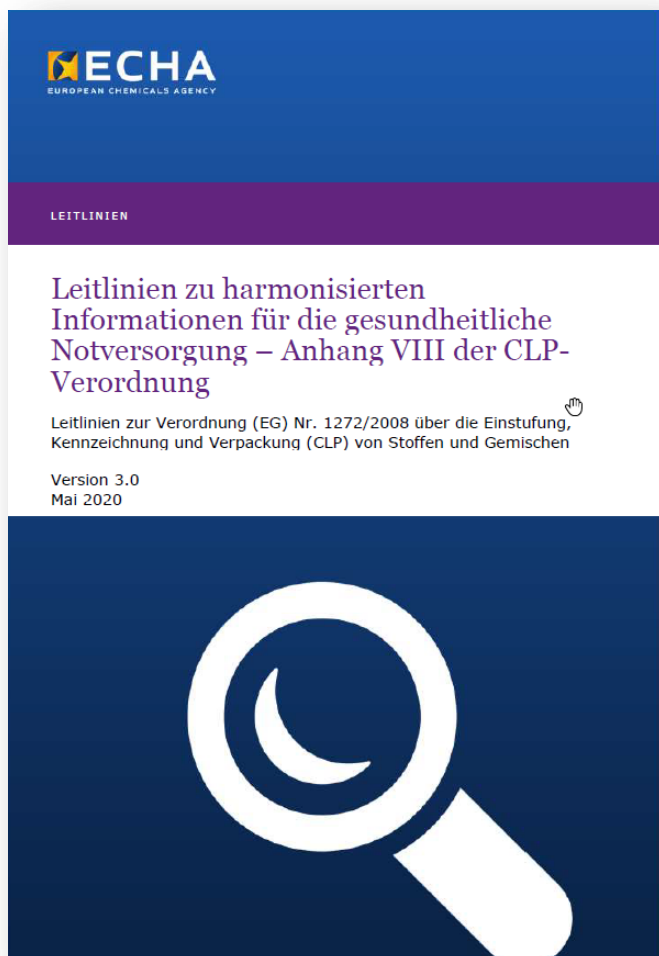
new toxicological information available

other:

Guidance & support

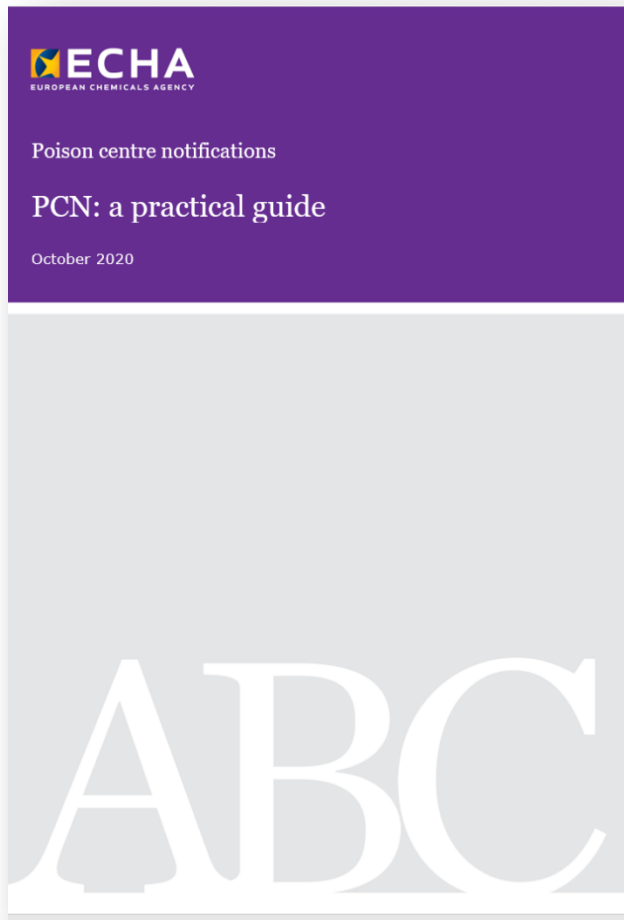


Relevant ECHA Guidance



- Annex VIII
 - V 3.0 - translated
 - V 4.0 - 2021
- Labelling and packaging
<https://echa.europa.eu/guidance-documents/guidance-on-clp>
- Substances in articles
- Safety Data Sheet
- Substance identity and naming
<https://echa.europa.eu/guidance-documents/guidance-on-reach>

PCN practical guide



- Recently updated
- Step by step how to:
 - access tools
 - prepare dossier
 - validate & create
 - generate preview report

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

e-Learning page

- For more visual support material:

- Animations
- Webinars
- Videos

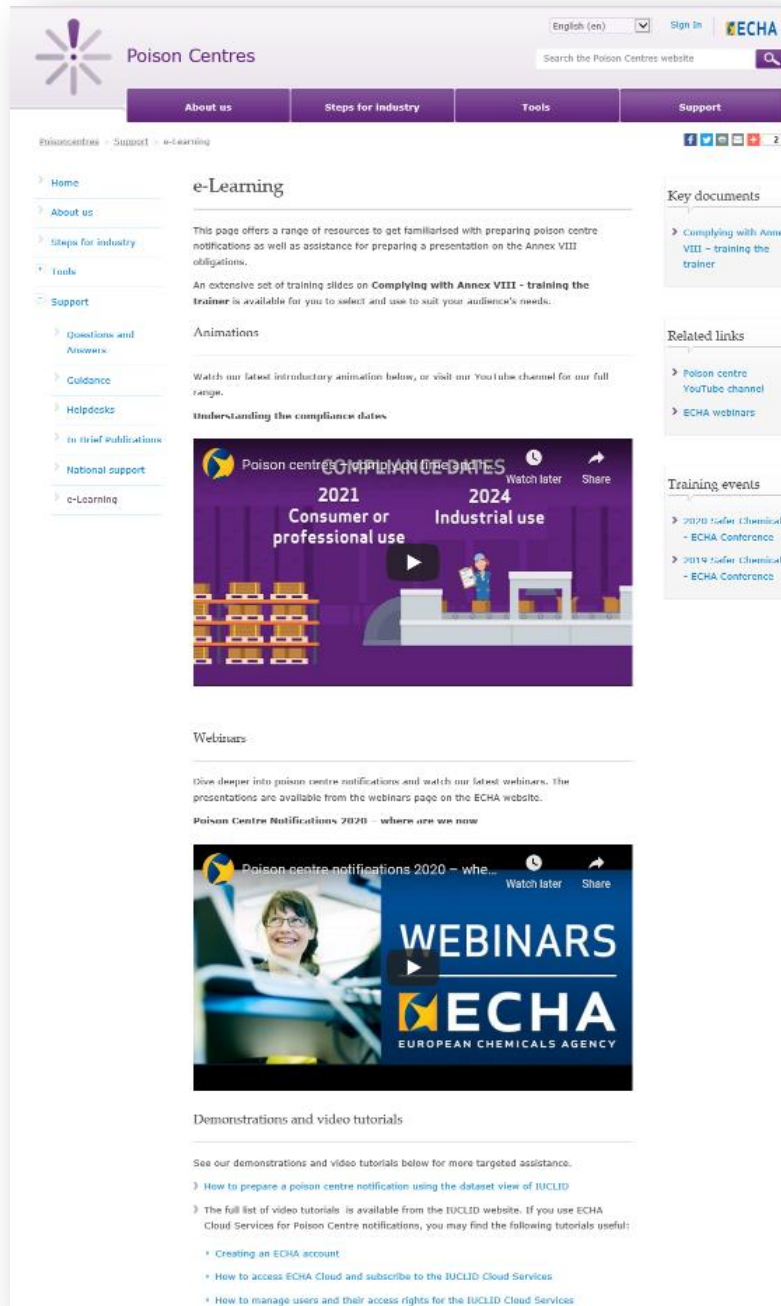
- **New video tutorials!**

[Step 1 - Creating a mixture dataset & checking the legal entity](#)

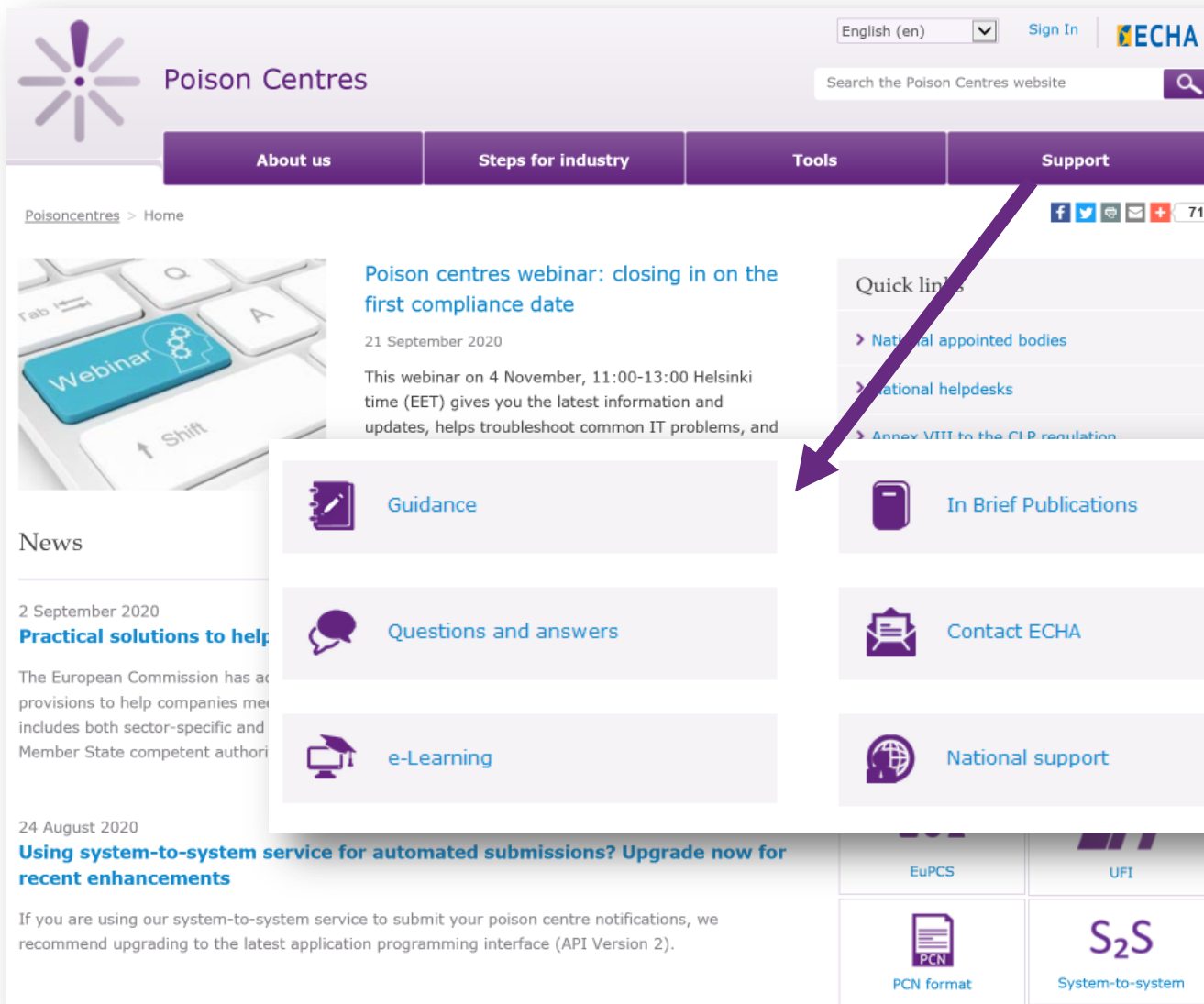
[Step 2 - Entering information in the mixture composition](#)

[Step 3 - Entering product and additional information](#)

[Step 4 - Explaining toxicological information and classification and labelling](#)



The screenshot shows the ECHA Poison Centres website's e-Learning section. The page has a purple header with the ECHA logo and navigation links: 'About us', 'Steps for Industry', 'Tools', and 'Support'. A search bar is located in the top right. The main content area is titled 'e-Learning' and includes a navigation sidebar on the left with links to Home, About us, Steps for Industry, Tools, Support, Questions and Answers, Guidance, Helpdesks, In brief publications, National support, and e-Learning. The main text describes resources for preparing poison centre notifications and mentions an extensive set of training slides on 'Complying with Annex VIII - training the trainer'. There are sections for 'Animations' and 'Webinars'. Two video thumbnails are visible: one for '2021 Consumer or professional use' and '2024 Industrial use' with a play button, and another for 'WEBINARS' featuring a woman and the ECHA logo. A 'Key documents' sidebar on the right lists 'Complying with Annex VIII - training the trainer'. A 'Training events' sidebar lists conferences from 2020 and 2019.



The screenshot shows the Poison Centres website interface. At the top, there is a language selector set to 'English (en)', a 'Sign In' button, and the ECHA logo. A search bar is located below the language selector. The main navigation bar includes 'About us', 'Steps for industry', 'Tools', and 'Support'. A secondary navigation bar contains social media icons for Facebook, Twitter, LinkedIn, YouTube, and a notification bell with '71' alerts.

The main content area features a featured article titled 'Poison centres webinar: closing in on the first compliance date' dated 21 September 2020. Below this is a 'News' section with two articles: 'Practical solutions to help...' dated 2 September 2020 and 'Using system-to-system service for automated submissions? Upgrade now for recent enhancements' dated 24 August 2020.

A navigation menu overlay is positioned in the center, containing the following items:

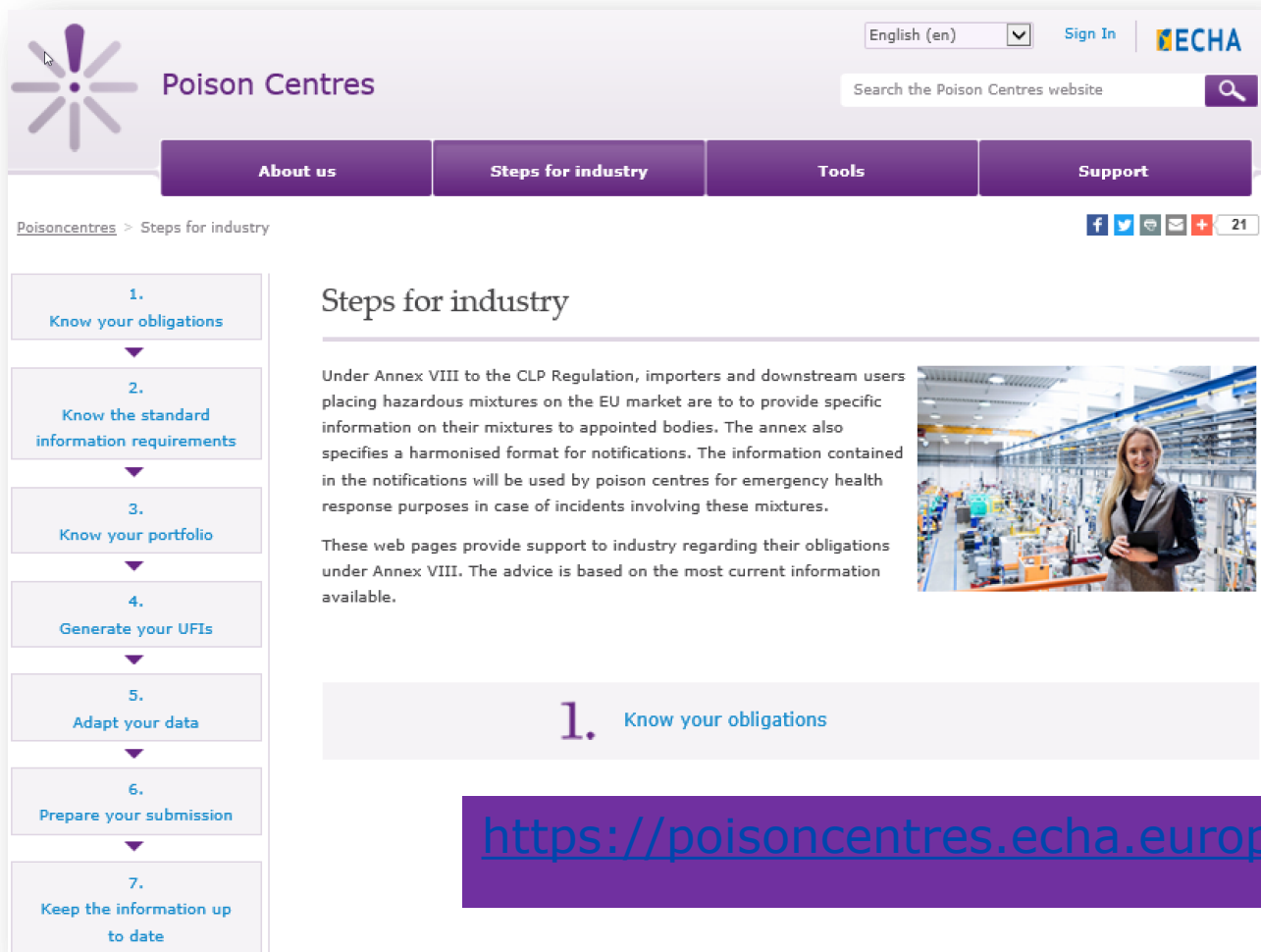
- Guidance
- Questions and answers
- e-Learning
- In Brief Publications
- Contact ECHA
- National support

At the bottom of the page, there are four service tiles: 'EuPCS', 'UFI', 'PCN format', and 'S₂S System-to-system'.

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


echa.europa.eu


Steps for industry




The screenshot shows the 'Poison Centres' website interface. At the top, there is a navigation bar with 'About us', 'Steps for industry', 'Tools', and 'Support'. A search bar and language selector are also present. The main content area is titled 'Steps for industry' and includes a list of seven steps on the left sidebar. The first step, '1. Know your obligations', is highlighted. The main text explains that under Annex VIII to the CLP Regulation, importers and downstream users must provide specific information on their mixtures to appointed bodies. A photograph of a woman in a laboratory setting is shown to the right of the text. A large purple box at the bottom of the page contains the URL: <https://poisoncentres.echa.europa.eu/>

Poison Centres

English (en) Sign In 

Search the Poison Centres website 


About us Steps for industry Tools Support

Poisoncentres > Steps for industry  21

Steps for industry

Under Annex VIII to the CLP Regulation, importers and downstream users placing hazardous mixtures on the EU market are to provide specific information on their mixtures to appointed bodies. The annex also specifies a harmonised format for notifications. The information contained in the notifications will be used by poison centres for emergency health response purposes in case of incidents involving these mixtures.

These web pages provide support to industry regarding their obligations under Annex VIII. The advice is based on the most current information available.



1. Know your obligations
2. Know the standard information requirements
3. Know your portfolio
4. Generate your UFI's
5. Adapt your data
6. Prepare your submission
7. Keep the information up to date

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

Connect with us on LinkedIn!

- Keep up to date with the latest news from the Poison Centre Team
- Post questions and join in on the community discussion



<https://www.linkedin.com/groups/12364138/>

Need more help?

- National Helpdesk
echa.europa.eu/support/helpdesks
- ECHA contact form
echa.europa.eu/contact/clp

Nacionalinės pagalbos tarnybos

Nacionalinės pagalbos tarnybos buvo įsteigtos kaip ryšių punktai, į kuriuos kreipiamasi pirmiausiai turint klausimų dėl BPR, CLP ir REACH reglamentų. Pagalbos tarnybų darbuotojai gali jums patarti jūsų kalba ir žino vietos sąlygas, o tai gali praversti siekiant laikytis šių reglamentų reikalavimų. Toliau rasite jų kontaktinius duomenis.

Lithuania

BPR helpdesk	National Public Health Centre under the Ministry of Health, Vilnius Department Kalvariju st. 153, LT-08221 Vilnius Telephone: +370 5 264 9678 Fax: +370 5 264 9664 Email: vilnius (at) nvsc.lt BPR website
CLP and REACH helpdesk	Environmental Protection Agency A. Juozapaviciaus str. 9, LT-09311 Vilnius Telephone: +370 5212 6094; +370 5212 6091 Fax: +370 70 66 2000 Email: reachdp (at) aaa.am.lt REACH and CLP website

Contact - CLP

Your request

Request type *

Annex VIII – Poison Centres

Topic *

Please select...

Thank you!

poisoncentres@echa.europa.eu

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