

Online session on the declaration of hazardous mixtures in Luxembourg

Wednesday 9th November 2022



LE GOUVERNEMENT DU GRAND-DUCHÉ DE LUXEMBOURG Ministère de l'Environnement, du Climat et du Développement durable





Introduction

Laurène Chochois REACH&CLP Helpdesk Luxembourg Luxembourg Institute of Science and Technology

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LE GOUVERNEMENT DU GRAND-DUCHÉ DE LUXEMBOUR(Ministère de l'Économie





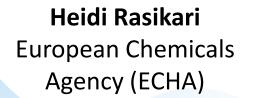
| 14:00 | Opening Laurène Chochois, REACH&CLP Helpdesk Luxembourg, Luxembourg Institute of Science and Technology (LIST) |
|-------|--|
| 14:10 | Annex VIII CLP – Declaration of hazardous mixtures to Poison Centre Ghaya Rziga, REACH&CLP Helpdesk Luxembourg, Luxembourg Institute of Science and Technology (LIST) |
| 14:40 | Questions & Answers |
| 14:50 | Poison centre notifications through the Belgian Poison Centre national system Laurène Chochois, REACH&CLP Helpdesk Luxembourg, Luxembourg Institute of Science and Technology (LIST) |
| 15:15 | Poison centre notifications through the ECHA Submission Portal Heidi Rasikari, European Chemicals Agency (ECHA) |
| 16:00 | Questions & Answers |
| 16:10 | How the data from mixtures declaration are managed in the Belgian Poison Centre system François Wuyts, IT coordinator, Brussels Poison Centre |
| 16:20 | Questions & Answers |
| 16:25 | Closing remarks Laurène Chochois, REACH&CLP Helpdesk Luxembourg, Luxembourg Institute of Science and Technology (LIST) |
| 16:30 | End |



Speakers







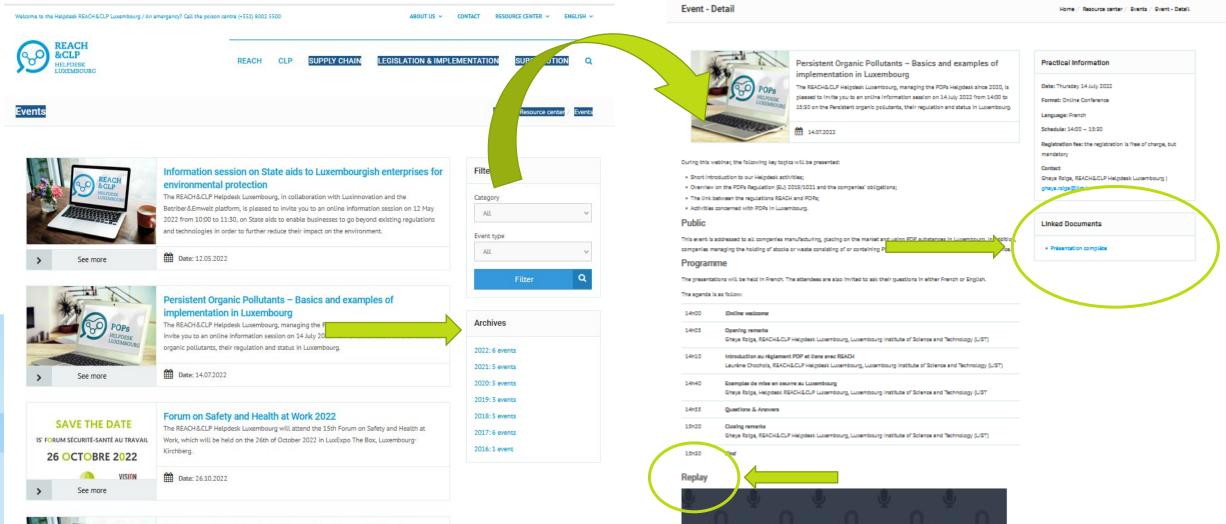
François Wuyts IT coordinator Brussels Poisons Centre Ghaya Rziga REACH&CLP Helpdesk Luxembourg Institute of Science and Technology (LIST)



REACH&CLP Helpdesk Luxembourg Institute of Science and Technology (LIST)



You wish to find our past events?





Newsletters

| | Welcome to the Helpdesk REACH&CLP Luxembourg / An emergency? Call the poison centre (+352) 8002 5500 ABOUT US ~ | | Stay up-to-date with REACH & CLP activities and subscribe to the monthly newsletter of the Luxembourg Helpdesk! ! | ✓ Subscribe |
|---|--|--|---|---------------------------------|
| | Newsletter | Home / Resource center, Assietter | 1 | |
| | The Helpdesk Luxembourg publishes a monthly newsletter to keep you informed on the latest news, events and information related to REACH & CLP. Interested in subscribing? Do not hesitate to fill in the form below. Note that generic email addresses (info@) are not valid, only personal emails are taken into account. | See also Archives - Monthly newsletter > | | |
| | Subscribe to our newsletter | Archives - SVHC Alert | Do you want to be kept inform on t | he latest news on |
| | First name * * indicates required | Archives - Thematic newsletters | REACH and CLP? | |
| | Last Name * | | Do not hesitate to suscribe to our mo | nthly newsletter! |
| | Email Address * | | | |
| | Company * | | | 2 |
| | | Do γοι | have a critical substance for which a | |
| | Country* | regulat | cory follow-up is needed? | |
| (| Which newsletter do you want to receive? | Do n | ot hesitate to suscribe to our « SVHC | |
| 1 | C REACH&CLP Helpdesk monthly newsletter SVHC alert' newsletter Select the newsletter(s) | | Alert » newsletter | P P |
| | Language preference you wish to receive | | | · Curd |
| | French German | | | |
| | | | | |



Help us to identify your needs and improve our services!

| Q_O &CLP haza | e session on the declaration of rdous mixtures in Luxembourg dnesday, 9 th November 2022 | LEXXMAGUNG Institute of scores And technology |
|--|---|---|
| | Satisfaction Survey | |
| | form in addet to help us to ensure the qual vents. Please put filled-in form in the respect | |
| | Company: | |
| | Rating Scale | |
| 1: very poor 2: poor 3: satisfact | | cellent N/A: not applicable |
| | 1 2 | 3 4 5 6 N/A |
| Global quality | | 3 4 3 0 N/A |
| Overall satisfaction | | |
| Quality of the program (cla | topics) | |
| Teaching methods | | |
| Presentation of the information | | |
| Moderation/handling of discussions (Q | (3) | |
| Scientific quality | | · · · · · |
| Quality of the content presented | | |
| Command of the subject | | |
| Professional content | | |
| Illustrations and exercises linked to the sul | bject | <u>i </u> |
| Added value in your job | | |
| Logistical organization | | |
| Welcome, Networking Lunch, break | | |
| Room and material | | |
| 2 – Which are the presentations that you p | fiformation session (Explain)? referred most (Explain)? | |
| 2 | | |
| 8 – Which are the presentations that you a | annelated the least (Evaluate) | |
| | | |
| | | |
| 2 | | |
| | formation content | |
| 4 – What were your expectations of this in | formation session? | |
| What were your expectations of this in An update of the state of the art | | Increase your knowledge |
| An update of the state of the art | Readily applicable solutions | Increase your knowledge Other: |
| | Readily applicable solutions | |





Thank you for answering the survey!



Annex VIII CLP – Declaration of hazardous mixtures to Poison Centres

Ghaya Rziga REACH&CLP Helpdesk Luxembourg Luxembourg Institute of Science and Technology

Online session on the declaration of hazardous mixtures in Luxembourg 09 November 2022





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Declaration of hazardous mixtures









- Regulatory Basis
 - ✓ Article 45 CLP
 - ✓ Annex VIII CLP :
 - <u>Regulation (EU) 2017/542</u> amending CLP by adding an Annex on harmonised information relating to emergency health response
 - <u>Regulation (EU) 2020/11</u> amending CLP as regards information relating to emergency health response.
 - <u>Regulation (EU) 2020/1677</u> amending CLP to improve the workability of information requirements related to emergency health response



Declaration of hazardous mixtures





- What are the mixtures in scope?
 - ✓ Mixtures classified for human health or physical effects
 - ✓ Biocides and plant protection products may be concerned





Declaration of hazardous mixtures

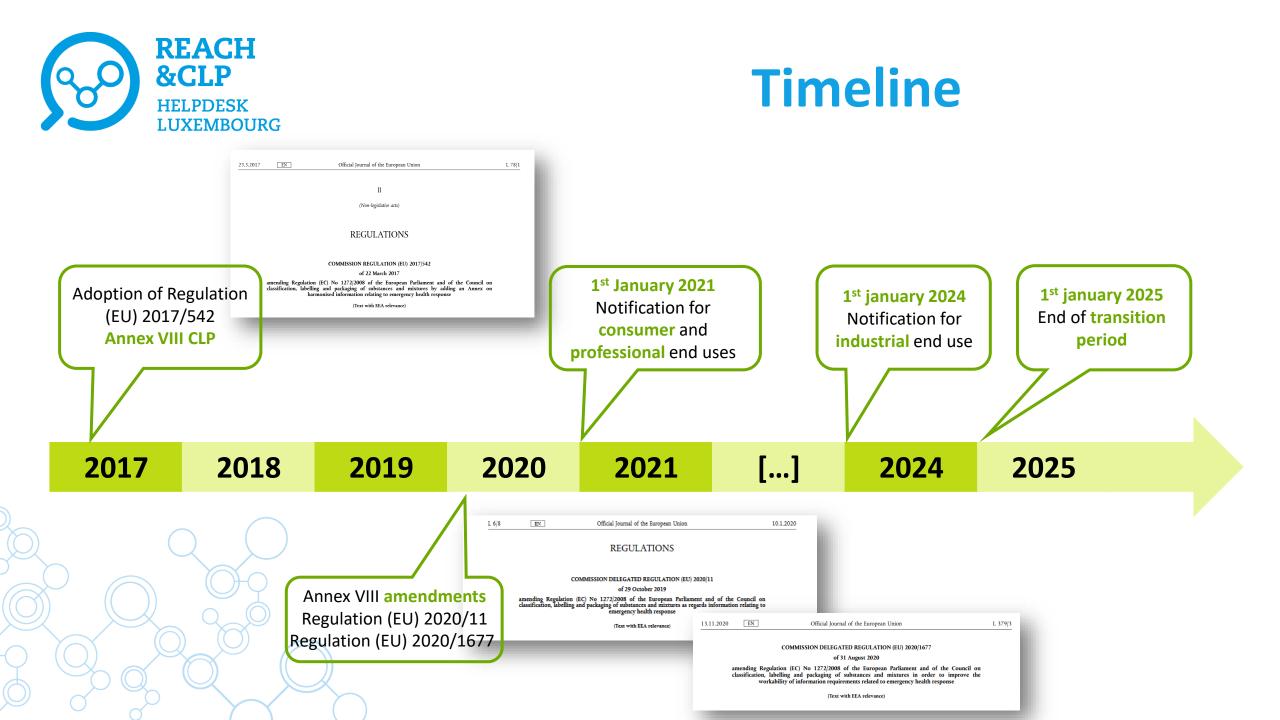








- Who is concerned?
 - ✓ Importers and downstream users placing hazardous mixtures on the market
 - Distributors (in particular rebranders/relabellers or companies distributing a mixture in another Member State)





What is the harmonised format?



Submitter Detailed information Consistent with label



Mixture C&L Tox. Information Full Chem. Composition pH, Physical state



Unique Formula

Identifier

16 character code



Product category (EuPCS) Trade name, colour Use types, intended uses

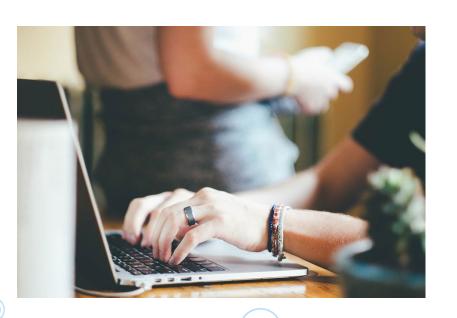


Harmonised Format

Poison centre notification







Information submission

- ECHA's harmonised PCN format
- Preparation:
 - ✓ Offline using a specific PCN interface in UICLID 6;
 - ✓ Online through IUCLID Cloud;
 - ✓ System-to-system integration.
- Submission:
 - ✓ Through the ECHA Submission portal;
 - Directly through the national submission systems of some Member States.

Majority of EU countries now accept poison centres notifications through ECHA's portal

→ Overview of Member States decisions in relation to implementation of Annex VIII to CLP Regulation (Poison Centre Notification) https://poisoncentres.echa.europa.eu/documents/22284544/27487986/msd_en.pdf/982d9115-58cb-75c8-80ae-8eb16f5c0009



Declaration in Luxembourg?

✓ Paquet REACH :

"The Minister responsible for Health is responsible for receiving the relevant information communicated by importers and downstream users who place mixtures on the market, in particular, for formulating preventative and curative measures, in particular in the event of an emergency health response."

✓ Since June 2015:
 Declaration to the Belgian Poison Centre

Since January 2022:
 Notifications can be made to the Belgian Poison Centre via the e-delivery system of the ECHA PCN portal using the IUCLID format in accordance with Annex VIII



Note: Notifications made via the national procedure do not have to be re-notified via the ECHA PCN portal and remain valid on 01/01/2025.



Declaration to the Belgian Poison Centre

- National procedure of the declaration to the Belgian Poison Centre:
 - Safety Data Sheet (SDS);
 CLP label;

for Luxembourg in French or German*

- Composition of the mixture; and
- ✓ Online declaration form (Excel format).
- No fees for declaration of products on the Luxembourg market.



Identical products on the market in Belgium and in Luxembourg -> one declaration

* if in German, it is recommended to submit voluntarily also an English version



Useful links



REACH&CLP Helpdesk Luxembourg

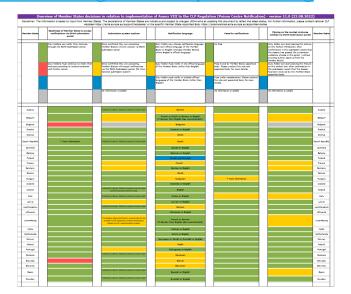
https://www.reach.lu/en/supply-chain/declaration-emergency-number/





Overview of Member States decisions in relation to implementation of Annex VIII to CLP Regulation (Poison Centre Notification) https://poisoncentres.echa.europa.eu/documents/1789887/5674408/ msd_en.pdf/982d9115-58cb-75c8-80ae-8eb16f5c0009

Belgian Poison centre: <u>https://www.centreantipoisons.be/entreprises/english/how-</u> declare/declarations-grand-duchy-luxembourg





Useful links





Poison centre website: <u>https://poisoncentres.echa.europa.eu/about-us</u>

Guidance on harmonised information relating to emergency health response –Annex VIII to CLP
<u>https://echa.europa.eu/documents/10162/13643/guidance on annex viii to clp en.pdf/412c5874-f8ec-cf52-fe1e-2fbe08fe2d11</u>

- The UFI and what it means for your product labels <u>https://poisoncentres.echa.europa.eu/documents/1789887/1803644/ufi what it means en.pdf/576a9a82-c352-b5b3-df73-e763da37e559</u>
- Information requirements for poison centres notifications <u>https://poisoncentres.echa.europa.eu/documents/1789887/1803644/information_requirements_in_brief_en.pdf/11835219-00f0-967a-1013-8179b1bffaa3</u>
- How to prepare and submit information to poison centres <u>https://poisoncentres.echa.europa.eu/prepare-and-submit-a-pcn</u>



Thank you for your attention!

Questions about REACH or CLP? Please contact us!



REACH&CLP Helpdesk Luxembourg Luxembourg Institute of Science and Technology (LIST) Environmental Research & Innovation Department (ERIN) 41, rue du Brill | L-4422 Belvaux | Luxembourg Email : <u>reach@list.lu</u> Tel. : (+ 352) 275 888-1



Poison centre notifications through the Belgian Poison Centre national system

Laurène Chochois REACH&CLP Helpdesk Luxembourg Luxembourg Institute of Science and Technology

Online session on the declaration of hazardous mixtures in Luxembourg 9th November 2022





VERNEMENT ND-DUCHÉ DE LUXEMBOURG e de l'Environnement, du Climat veloppement durable





To who to declare in Luxembourg?

✓ Paquet REACH :

"The Minister responsible for Health is responsible for receiving the relevant information communicated by importers and downstream users who place mixtures on the market, in particular, for formulating preventative and curative measures, in particular in the event of an emergency health response."

- ✓ Since June 2015:
 Declaration to the Brussels Poison Centre
- Since January 2022:
 Notifications can be made to the Belgian Poison Centre via the e-delivery system of the ECHA PCN portal using the IUCLID format in accordance with Annex VIII



| | Pourquoi déclarer? A qui | Accueil Entreprises In English How to declare? Declarations for the Grand Duchy of Luxembourg | | | | | | |
|----|---|---|--|--|--|--|--|--|
| | déclarer? Comment déclarer? | DECLARATIONS FOR THE GRAND DUCHY OF | | | | | | |
| | FAQ | LUXEMBOURG | | | | | | |
| | Contact service déclarations. | | | | | | | |
| | In English | Note related to the hazardous mixture notifications to Belgian Poison Centre | | | | | | |
| re | Why declare products and compositions? | From 01 January 2022, notifications of mixtures considered hazardous due to their health and physical effects can be made to the Belgian Poison Centre via the e-delivery system of the ECHA NCP portal. This | | | | | | |
| | How to declare? | by using the IUCLID format in accordance with Annex VIII of Commission Regulation (EU) 2017/542. More information via https://www.health.belgium.be/en/notification-poison-centre | | | | | | |
| | Notification of dangerous mixtures | Notifications made via the national procedure do not have to be re-notified via the ECHA NCP portal and remain valid on 01/01/2025. | | | | | | |
| | Notification of pesticides | | | | | | | |
| • | for agricultural use | | | | | | | |
| | Voluntary notifications | | | | | | | |
| | Notification of biocides | | | | | | | |
| | Declarations for the Grand Duchy of Luxembourg | Since June 2015, the public and the health professionals of the Grand Duchy of Luxembourg have access to the Belgian Poison Center via the free number (+352) 8002-5500. | | | | | | |
| | FAQ about declarations | In order to answer the calls adequately, the medical doctors of the Poison Centre need to have access to the | | | | | | |
| | Contact declarations | ingredients of the products on the Luxembourg market. | | | | | | |
| | | In application of the article 45 of the European regulation <u>UE 1272/2008</u> , the Belgian Poison Centre can receive th ingredients of dangerous mixtures, including biocides, on the Luxembourg market. | | | | | | |

Note: Notifications made via the national procedure do not have to be re-notified via the ECHA PCN portal and remain valid on 1st January 2025.



What does the declaration include?

| Identification | | | | Catégories | | | | Documents fournis (Noms des fichiers associés) | | | |
|-------------------------------|-------------|-------------------------------|---|--|-------------------------|-------------|---|--|---|-------------|---|
| énomination(s) commerciale(s) | UFI | Code interne à la firme | Usage exclusi- vement profes- sionnel | Mélange classé comme dangereux sur base du règlement (CE) n° 1272/2008 en raison de ses effets sur la santé ou de ses effets physiques. | Nouvelle déclaration | EU-PCS | Type de mélange: H:Ménage I:Industriel P:Peinture | Fiche de données de sécurité SDS visée à l'article 31 du réglement REACH | Composition chimique complète du mélange | Étiquette | |
| Obligatoire | Obligatoire | Facultatif | (O ou N) | (O ou N) | (O ou N) | Obligatoire | H,I ou P | Obligatoire | Obligatoire | Obligatoire | |
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Documents Safety data sheet, label and complete composition of the mixture

For Luxembourg:

SDS and label can be submitted in French or German.

Declaration form (EDS)

Excel file

✓ If SDS and label are submitted in German, it is recommended to submit voluntarily also an English version.



How to send the declaration?





By email:

depot@poisoncentre.be

(max. size for e-mail: 5Mb. You can send us your declaration in several mails if required)

By post (on CD/DVD/ USB):

Your CD/DVD/ USB must be sent at the following address:

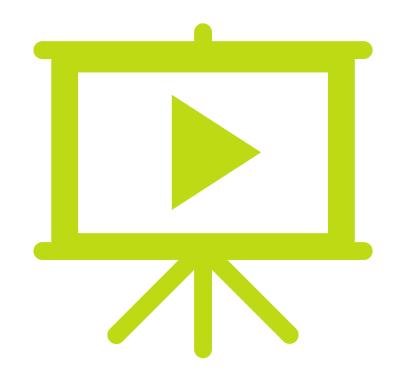
Centre Antipoisons

c/o Hôpital Militaire Reine Astrid Rue Bruyn 1, 1120 Brussel BELGIQUE



Practical demonstration

Poison centre notifications through the Belgian Poison Centre national system





Thank you for your attention

Do you have any question about REACH or CLP? Please contact us!

REACH&CLP Helpdesk Luxembourg Luxembourg Institute of Science and Technology (LIST) Environmental Research & Innovation Department (ERIN) 41, rue du Brill | L-4422 Belvaux | Luxembourg Email: <u>reach@list.lu</u> Tel.: (+ 352) 275 888-1





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LE GOUVERNEMENT DU GRAND-DUCHÉ DE LUXEMBOUR(Ministère de l'Économie



Poison centre notifications through the ECHA Submission portal

Online session - Declaration of hazardous mixtures in Luxembourg

9 November 2022

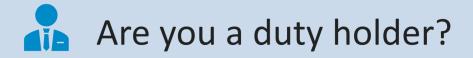
Heidi RASIKARI Poison Centre Team A3 Submission and processing European Chemicals Agency



Summary

- \rightarrow Getting started
- → Know the tools available
- \rightarrow Preparing a dataset and creating a dossier
- → Making a submission
- \rightarrow After submission
- → Support available

First things first - know your obligations



Is your mixture in scope?

- → EU importer and downstream user placing hazardous mixtures on the market Article 45
- → Distributors such as relabellers, rebranders and retailers, also have a role to avoid data gaps – Article 4(10)
- → 'Substances and mixtures shall not be placed on the market unless they comply with this Regulation'.

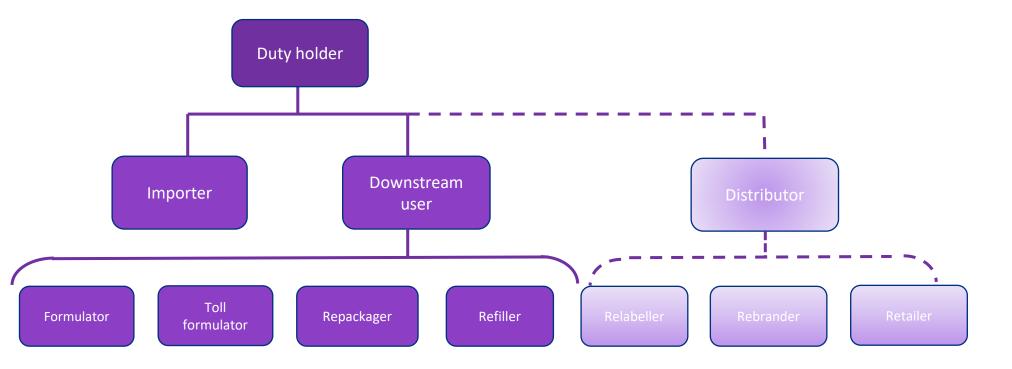
- → Mixtures classified for health and physical effects
- → List of exemptions e.g. exempt from CLP, classified for environment only, substances, articles, and more...
- → Mixture & article combination when the article acts as a carrier of a mixture, notify mixture accordingly. Check the Guidance!





Obligations under discussion!

CLP revision introducing targeted notification obligations e.g. when mixtures move between Member States or are re-labelled



Know the harmonised information requirements



Contact details Submitter details Contact point if person having further relevant information is other than the submitter Emergency contact for limited submission Mixture information Product/mixture identifier Toxicological information Hazard classification and labelling information Physico-chemical properties Mixture composition 100% For substances and mixture-inmixtures - 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



Where to next?

- → You identified the need to make a poison centre notification (PCN)
- → You have collected all the necessary data
- \rightarrow Now you want to put it together and make a dossier
- → To place mixture on the Luxembourg market, submit information to the relevant appointed body, there are two options:
 - Use the national system available for Belgium
 - Use the ECHA Submission portal



Our tools to support the preparation process

- → UFI Generator
- → European product categorisation system (EuPCS)
- → Harmonised PCN format
- → IUCLID
- → ECHA Cloud services
 - IUCLID Cloud (and validation assistant)
 - ECHA Submission portal



Unique Formula Identifier

- Industry obligation to generate UFI for the notification and product label
- Options are available to generate your UFI
 - using your VAT number & formulation number (recommended)
 - Prepare without VAT
- Tool and support available in official languages
- More here <u>https://poisoncentres.echa.europa.eu/ufi-generator</u>



How the UFI is used

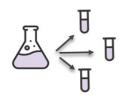
- → UFI concept created for poison centres
- → Makes a link between the product and the mixture information
- → Composition specific
- \rightarrow 1 UFI = 1 mixture composition
- → But!1 composition can have more UFIs
- → Companies can also use the UFI to protect confidential information about a mixture composition





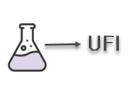
Declaring mixture-in-mixture components

→ Mixture-in-mixture (MiM) identity and concentration provided according to the information available



Full composition is known from MiM supplier Report information on all substances at the final mixture le

Report information on all substances at the final mixture level. Aggregate where relevant.



Full composition of the MiM is not known

FI Report the UFI of the MiM provided it has been already notified in the relevant Member State.



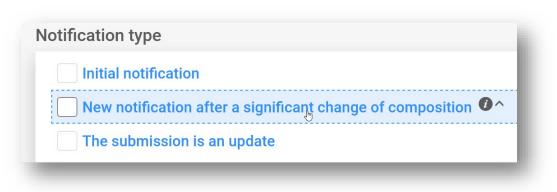
No MiM UFI or MiM not notified in the relevant Member State

Provide product identifier, list the compositional information from the SDS along with the MiM supplier information.



When is a new UFI needed?

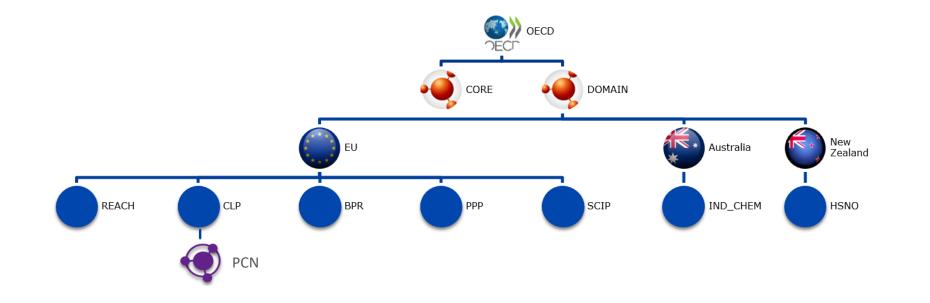
- → A new UFI must be generated (re-notified and re-labelled) when significant changes occur to the composition:
 - adding, substituting or deleting a component
 - change in concentration beyond the allowed variation
- → Not an update but a 'new notification' and indicated in dossier header to keep the link to the previous notification





PCN format

- → Harmonised format based on legal text an embedded in tools
- → PCN format is customised subset of the IUCLID format
- → Supports different legislations
- → The IUCLID core format/PCN format updated yearly in April





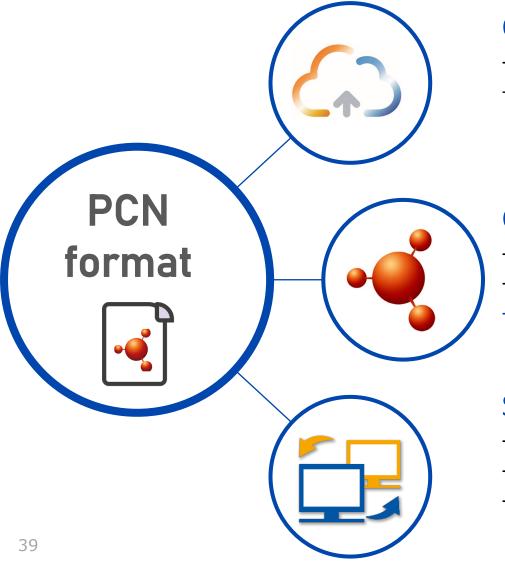
European Product Categorisation System (EuPCS)

- → List of product categories to select ONE main intended use
- → Secondary intended uses can be added voluntarily
- \rightarrow Basic distinction at the first level according to use
 - End-use (i.e. a final mixture) 'P' or
 - No end-use (i.e. for formulating other mixtures) 'F'
- \rightarrow Embedded in tools and exists outside the tool
- → Available in official languages
- \rightarrow Maintained by ECHA and subject to updates
- → Categories must be selected with care, as these are used by Appointed Bodies for reporting purposes

https://poisoncentres.echa.europa.eu/eu-product-categorisation-system



Putting it all together – options available



Online in IUCLID Cloud

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

Offline in IUCLID 6

- Downloaded from IUCLID website and maintained by the user
- Desktop and server versions
- https://iuclid6.echa.europa.eu/

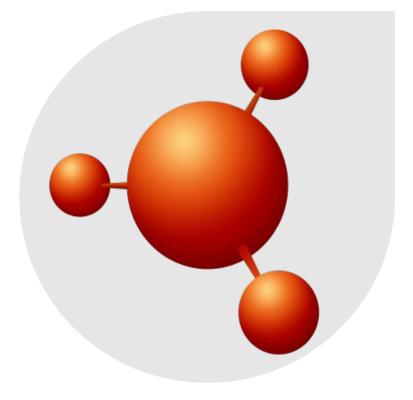
System-to-system service

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



Preparing information in IUCLID

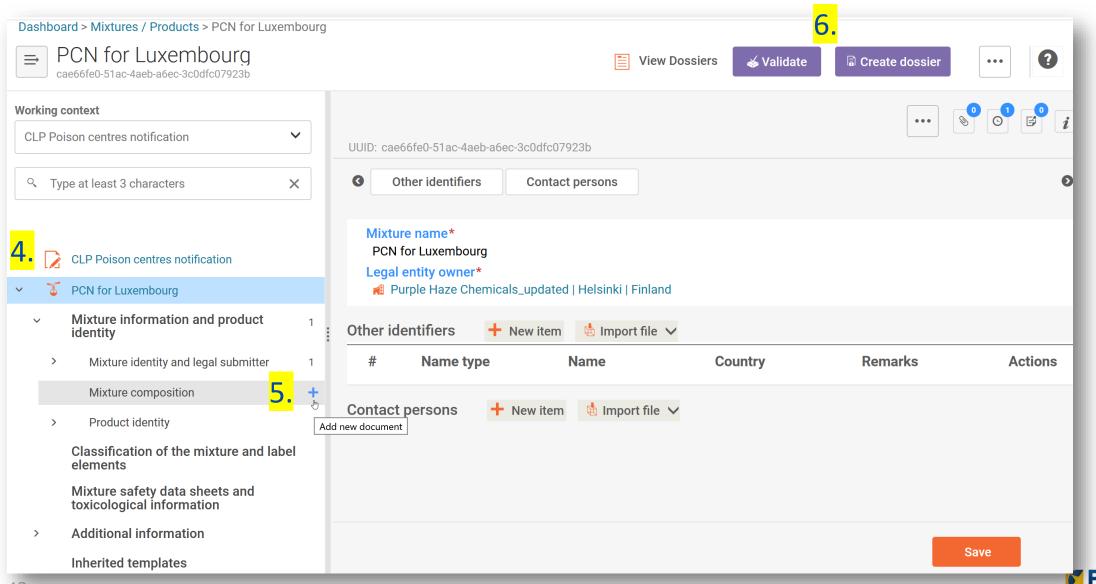
- → Interface same in online or offline preparation
- → User interface in EN but support available in official languages
 - IUCLID guide
 - PCN practical guide
- → Basic steps
 - Create an ECHA Account & legal identity
 - Access IUCLID instance
 - Enter information into editable datasets
 - Validate the contents and create the dossier
 - Make the submission
 - Check the post submission status





First steps in IUCLID – mixture dataset JaneDoes ? \square Purple Haze Chemicals 2 ⇒ Dashboard Search dossier, entities and documents by UUID Import IUCLID file(s) 🕢 Overwrite settings : If newer than existing v Substances JaneDoes ? 81 **Purple Haze Chemicals** Dashboard > Mixtures / Products ➡ Mixtures / Products 2 + New mixture / product New working context × Mixtures 43 Select working context Dossiers Datasets CORE Articles Advanced search Complete table of contents EU BPR Select/Deselect all 75 results found Newest first 🗸 BPR Active substance application (representative product) 25 Sort by V BPR Basic information (mixture) BPR Biocidal product authorisation ۲Ø mim 30/08/2022 15:27 ... BPR Summary of product characteristics (SPC) EU_CLP MiM Supplier Legal Entity CLP Interchangeable Component Group (ICG) THUR 102006d0 0000 1560 CLP PCN Standard formula component 2 C CLP Poison centres notification CLP Poison centres notification (mixture in mixture) EU PPP





Adding information

→ Picklist selections in English

| Not classified | |
|---|---|
| zard categories & statements Ø ^ | |
| | ~ |
| Unst. ExplH200: Unstable explosives. | ^ |
| Expl. Div. 1.1-H201: Explosive; mass explosion hazard. | |
| Expl. Div. 1.2-H202: Explosive, severe projection hazard. | |
| Expl. Div. 1.3-H203: Explosive; fire, blast or projection hazard. | |
| Expl. Div. 1.4-H204: Fire or projection hazard. | |
| Expl. Div. 1.5-H205: May mass explode in fire. | |

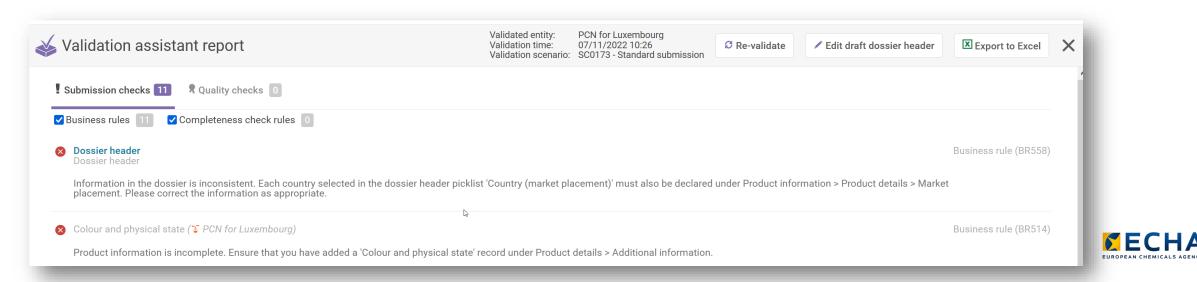
→ Free text fields must be in required language

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Validation checks

- \rightarrow Two types of checks in validation assistant
 - Submission check triggers a failure
 - Quality check triggers a warning
- → Rules are checked on the dataset (and content edited) before creating a dossier
- → Additional <u>Portal</u> rules checked on submission





→ Simple process!

→ Check the dossier header contents carefully first

| CLP Poison centres notification | Dossier name (given by user) Dossier submission remark Specific submissions | |
|---------------------------------|--|--|
| | PCN number* PCN number field is mandatory. Country (market placement)* Country (market placement) field is mandatory. Language* 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 | |

- → PCN number generated
- → Select markets
- → Select languages
- Submission type in special cicumstances
- Notification type mandatory



Submission channels

- → ECHA Submission portal hosts submissions for PCN, SCIP, and C&L notifications
- → Allows one PCN submission to multiple Member States (indicated in the dossier header)
- → 28/30 Member States currently accept PCN via ECHA portal
- → National systems possible for six Member States including Belgium
- \rightarrow Note that 80% submissions via S2S





Two ways to submit a IUCLID dossier through Portal

 \rightarrow Offline preparation

→ Online preparation

| ECHA Submission portal | | ? | JaneDoes Purple Haze Chemicals | |
|--|--|----------------------|-----------------------------------|------------------|
| ➡ Upload and submi | t | | | L |
| | | | | |
| | d your dossier for submission. Only i6z files are per nat currently only PCN, SCIP and PPP dossiers can or Browse Drop file to upload | | | J |
| Dashboard > Mixtures / Products > Initial sub (Heidi) Update of update submission 577e4a09-a820-443a-97e7-7c6d0ccdacc2 | n A 📑 View Dossiers 🏅 Go to source 🕇 | 🎸 Validate | Proceed to submission |] |
| | UUID: 577e4a09-a820-443a-97e7-7c6d0ccdacc2 | | Hide empty fields | 0 ¹ F |
| | Oossier Submission Type Dossier Subject | Specific submissions | Notification type | Ø |
| CLP Poison centres notification | Dossier Submission Type | | | |
| > 🏅 Initial sub (Heidi) | Dossier name (given by user) Update of update submission A Version | | | |



Outcome of a submission – submission report

- \rightarrow Details the status & context of the submission
- → Submission number: a unique identifier automatically assigned upon submission
- → Submission status
 - Successful submission
 - Successful, but contains warnings
 - Failed submission
- → Details of **submission events** when dossier has
 - Passed validation checks
 - Received by the appointed body
- → Submission history and links to related submissions
- → Note additional <u>Portal</u> rules checked upon submission



Submission report example

Submission report \Rightarrow **View Validation report** Go to search Submission status: Succeeded A **CLP** Poison centres notification Submitted by: Jane Does Dossier type: Submission number: RMH224595-10 **Purple Haze Chemicals** Submitted IUCLID version: 6 6 ECHA-f428c44e-79b3-4f7f-a72b-78e7ceda3be4 Submission information Recipients (Member States - market placement) 179f77eb-4304-4d89-a1d8-92d81fe54d3c Austria PCN number Finland Mixture name Initial submission H1 Dossier UUID fd48ac9e-750d-45fa-b6bf-902cb0fc68fc France fd48ac9e-750d-45fa-b6bf-902cb0fc68fc.i6z File name Submission events Reason for submission Initial notification Type of submission 09/03/2022 14:37 Dossier submitted Dossier passed validation checks Product information 09/03/2022 14:37 Dossier received by FI 09/03/2022 14:38 Dossier received by AT 09/03/2022 14:38 Consumer, Professional Use type Name(s) Lavender spritz Identifier(s) 0200-U0CW-500P-Q5F8



Keeping up to date

- Companies must ensure that the relvent appointed bodies have a valid and up to date notification at all times
- → Update information before placing on the market when
 - Change in identifier
 - Classification changes (for health or physical effects)
 - New toxicological information available
- → All updates are relevent for emergency health response, e.g. changes
 - in information such as the contact details of the submitter
 - to include new information e.g. packaging type or size,
 - to correct an error e.g. spelling mistakes
- → Sometimes a notification cannot be corrected -> disable a submission e.g. when you make a mistake in the concentration

Disable a submission vs. cease market

- → Possibility to 'disable' a submitted dossier
- → Feature in the ECHA Submission portal
- → Used in specific circumstances

- Possibility to indicate a ceased product from the market
- → Belongs to the PCN format
 - → Requires the submission of an updated dossier

| Go to search | Submission stat | tus: Succeeded 🤡 … 🗢 Disable submission |
|--|--|---|
| Dossier type: Submission number: Submitted IUCLID versi | CLP Poison centres notification RMH190287-16 on: 6_6 | Submitted by: Jane Does Purple Haze Chemicals ECHA-f428c44e-79b3-4f7f-a72b-78e7ceda3be4 |
| Submission inforn | nation | Recipients (Member States - market placement) |
| PCN number Mixture name Dossier UUID | 4684d25f-975c-4593-9deb-5f4245d033a9 Initial sub B 58261a98-36a4-4f27-b383-a2b3c4517100 | Finland Sweden |
| File name | <u>58261a98-36a4-4f27-b383-a2b3c4517100</u> <u>58261a98-36a4-4f27-b383-a2b</u> 3c4517100.i6z | Submission events |
| Reason for submission Reason for updating Type of submission | The submission is an update cease product from market | 07/03/2022 14:06 Dossier submitted 07/03/2022 14:06 Dossier passed validation checks |

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Available support channels and tools

Luxembourg specifics

- → Belgian Appointed Body is responsible for notifications placed on the market in Luxembourg
- → Member States overview document:
 - Note the language requirements for free text and if fees levied
 - Timing for placing on market (check submission report!)

| | 0 | vervi | ew of Member States deci | sions | in relation to implementat | tion o | of Annex VIII to the CLP Regu | latio | n (Poison Centre Notificati | on) · | version 11.0 (23.08.2022 |) | |
|--------|----------------|----------|---|-------|---|--------|--|-------|--|-------|---|----------------|----|
| | Disclaimer: Th | e inforr | | | | | ative and subject to changes. ECHA aims al specific Member State Appointed Body http | | | | | t national CLP | |
| | Member State | | Readiness of Member State to accept notifications via ECHA submission portal | | Submission system options | | Notification language | | Fees for notifications | | Placing on the market mixtures notified via ECHA Submission portal | Member State | |
| \neg | | | Puts helders and notify their originary | | Once confirmed they are accepting | | Putu helder mu chesse estitestes insures | | No fees | | Duty holder and shad also as the midure | | HI |
| | | | Duty holders can notify their mixtures through the ECHA Submission portal | | Once confirmed they are accepting, Member States will only accept via ECHA submission portal | | Duty holder may choose notification language between official language of the Member State or English (includes Member States where English is official language) | | no rees | | Duty holder can start placing the mixture on the market immediately after confirmation in the submission report that the dossier has passed the automated validation checks in the portal (without awaiting further approval from the Member State) | | |
| | | | Duty holders must continue to notify their mixtures according to national systems until further notice. | | Once confirmed they are accepting, Member States will accept notifications via the ECHA Submission portal, OR, their national submission system. | | Duty holder must notify in one offical language of the Member State (other than English) | | Fees levied by Member State appointed body. Please contact the relevant appointed body for more details. | | Duty holder can start placing the mixture on the market only after confirmation in the submission report that the dossier has been recieved by the Member State appointed body. | | |
| _ | | | | | | | | | | | | | HI |
| | Belgium | | | | | | French or Dutch or German or English (If German then English also recommended). | | | | | Belgium | |
| | Luxembourg | | | | The Belgian Appointed Bodyis responsible for the reception of all hazardous mixture declarations placed on the Luxembourgish market. | | French or German (If German then English also recommended) | | | | | Luxembourg | |

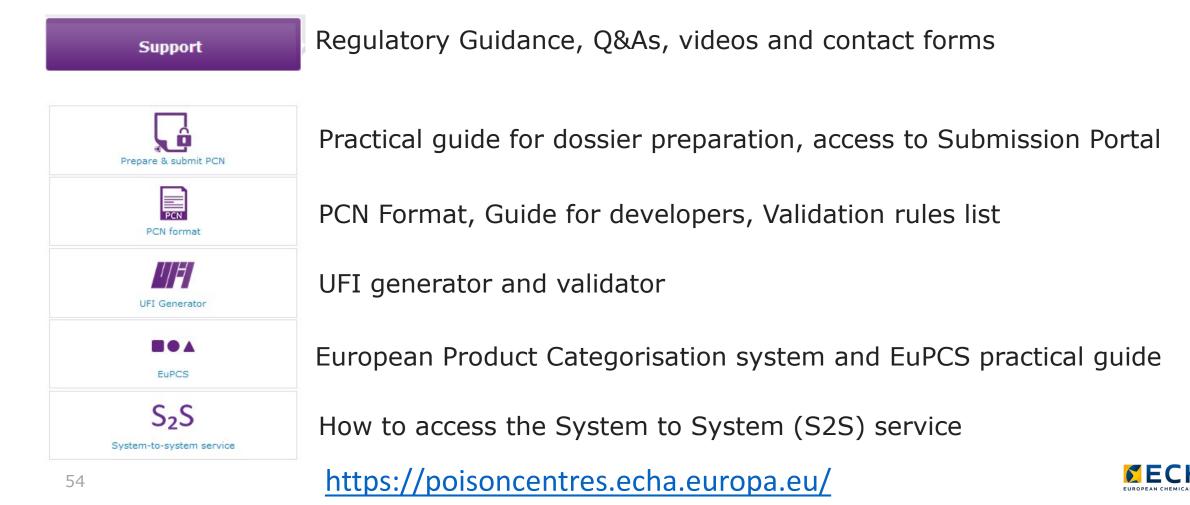
https://poisoncentres.echa.europa.eu/documents/1789887/5674408/msd_en.pdf/



The ECHA PC website

Main reference for companies





Support available in all EU languages

| Poison Centres | | francais (fr) V Ou Search Poison Ce | entres Website | 1. Mesures pour l'industrie 2. En vertu de l'annexe VIII du règlement CLP, les importateurs et les utilisateurs en aval qui mettent des mélanges dangereux sur le marché de l'IE d'avront fournit des informations spécifiques sur leurs mélanges autor spécifiques sur leurs spécifiques sur leurs mélanges autor spécifiques sur leurs mélanges autor spécifiques sur leurs spécifiques sur |
|-------------------------|--------------------------|--|----------------|--|
| Qui sommes-nous? | Mesures pour l'industrie | Outils | Support | pour les notifications. Les informations contenues dans les notifications seront utilisées par les centres antipiosen aux fins de la réponse à 3. apporter en cas d'urgence sanitaire lors d'incidents impliquant ces |
| Poisoncentres > Accueil | | | f 💙 🗟 🛨 🕄 344 | Connaître votre portefeuille mélanges. Ces pages fournissent une assistance au secteur industriel en ce qui concerne ses obligations en vertu de l'annexe VIII. Les conseils sont basés sur les derniè |
| | | | | |

ECHA

Notifications aux centres antipoison PCN: guide pratique Version 5.1 - juin 2022



Guide sur les informations harmonisées concernant la réponse à apporter en cas d'urgence sanitaire – Annexe VIII du règlement CLP

Orientations concernant le règlement (CE) nº 1272/2008 relatif à la classification, à l'étiquetage et à l'emballage des substances et des mélanges (règlement CLP)



Regulatory Guidance document

Practical Guide on dossier preparation



System-to-system support

 \rightarrow Submission service available for companies that want to use their own IT systems to submit regulatory information

→ S2S support pages available (not only PCN):

- General information on the service
- S2S service manual

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- Terms and Conditions
- Developers' Guide to the IUCLID format
- "Application programming interface" (API) specifications
- Specific news subscription

Our LinkedIn Groups



Three relevant groups managed directly by ECHA

- ECHA's poison centre notification group Annex VIII to CLP
- ECHA's system-to-system submission support network
- ECHA's IUCLID group
- \checkmark Updates and news
- ✓ Ask regulatory/technical questions & find answers to common problems
- ✓ Share experience and solutions with other members



Making contact with helpdesk!



- National Helpdesk
- → First point of contact for regulatory support e.g. scope or obligations
 - https://echa.europa.eu/support/helpdesks

ECHA Helpdesk

- First point of contact for technical support e.g. regarding issues with submission such as validation rule failure
- <u>https://echa.europa.eu/contact/technical-support</u>



Thank you heidi.rasikari@echa.europa.eu echa.europa.eu/subscribe

Connect with us



echa.europa.eu/podcasts







@one_healthenv_eu







Conclusion

Laurène Chochois REACH&CLP Helpdesk Luxembourg Luxembourg Institute of Science and Technology

Online session on the declaration of hazardous mixtures in Luxembourg 9th November 2022





LE GOUVERNEMENT DU GRAND-DUCHÉ DE LUXEMBOURG Ministère de l'Environnement, du Climat et du Développement durable



LE GOUVERNEMENT DU GRAND-DUCHÉ DE LUXEMBOUR(Ministère de l'Économie

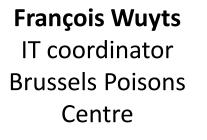


Speakers



Heidi Rasikari European Chemicals Agency (ECHA)





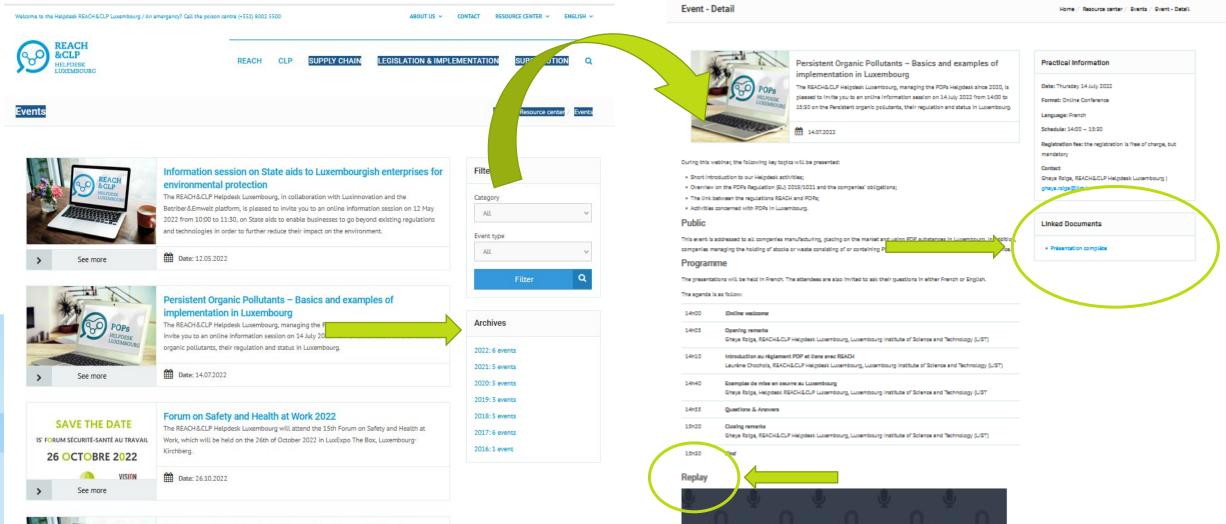
Ghaya Rziga REACH&CLP Helpdesk Luxembourg Institute of Science and Technology (LIST)



Laurène Chochois REACH&CLP Helpdesk Luxembourg Institute of Science and Technology (LIST)



You wish to find our past events?





Newsletters

| | Welcome to the Helpdesk REACH&CLP Luxembourg / An emergency? Call the poison centre (+352) 8002 5500 ABOUT US ~ | | Stay up-to-date with REACH & CLP activities and subscribe to the monthly newsletter of the Luxembourg Helpdesk! ! | ✓ Subscribe |
|---|--|--|---|---------------------------------|
| | Newsletter | Home / Resource center, Assletter | 1 | |
| | The Helpdesk Luxembourg publishes a monthly newsletter to keep you informed on the latest news, events and information related to REACH & CLP. Interested in subscribing? Do not hesitate to fill in the form below. Note that generic email addresses (info@) are not valid, only personal emails are taken into account. | See also Archives - Monthly newsletter > | | |
| | Subscribe to our newsletter | Archives - SVHC Alert | Do you want to be kept inform on t | he latest news on |
| | First name * * indicates required | Archives - Thematic newsletters | REACH and CLP? | |
| | Last Name * | | Do not hesitate to suscribe to our mo | nthly newsletter! |
| | Email Address * | | | |
| | Company * | | | 2 |
| | | Do γοι | have a critical substance for which a | |
| | Country* | regulat | cory follow-up is needed? | Ree 2 |
| (| Which newsletter do you want to receive? | Do n | ot hesitate to suscribe to our « SVHC | |
| 1 | C REACH&CLP Helpdesk monthly newsletter SVHC alert' newsletter Select the newsletter(s) | | Alert » newsletter | P P |
| | Language preference you wish to receive | | | · Curd |
| | French German | L | | |
| | | | | |



Help us to identify your needs and improve our services!

| HELPDESK | Online session on the declaration of hazardous mixtures in Luxembourg Wednesday, 9 th November 2022 | LUXEWBOURD INSTITUTE OF SCHWER AND TECHNOLOGY |
|---|--|---|
| | Satisfaction Survey | |
| | ration form <u>in order to</u> help us to ensure the quai ure events. Please put filled-in form in the respec | |
| | Company: | |
| | Rating Scale | |
| 1: very poor 2: poor 3: sati | | cellent N/A: not applicable |
| | 1 2 | .3 4 5 6 N/A |
| Global quality | 1 2 | 3 4 5 6 N/A |
| Overall satisfaction | | |
| Quality of the program (cla | topics) | |
| Teaching methods | | |
| Presentation of the information | | |
| Moderation/handling of discussions [| (a. <u>'s)</u> | |
| Scientific quality | | |
| Quality of the content presented | | |
| Command of the subject | | |
| Professional content | | |
| Illustrations and exercises linked to th | he subject | |
| Added value in your job | | |
| Logistical organization | | |
| Welcome, Networking Lunch, break | | |
| Room and material | | |
| | information session (Explain)? | |
| 2 – Which are the presentations that | you preferred most (Explain)? | |
| 2 – Which are the presentations that y 1 | | |
| 2 - Which are the presentations that y 2 - 2 - 2 | | |
| 2 - Which are the presentations that y 1 | you appreciated the least (Explain)? | |
| 2 - Which are the presentations that y 1 | you appreciated the least (Explain)? | |
| 2 - Which are the presentations that y 1 | you appreciated the least (Explain)? | |
| 2 | you appreciated the least (Explain)? | |
| 2 - Which are the presentations that y 1 | you appreciated the least (Explain)? his information session? t D Readily applicable solutions | Increase your knowledge |
| t - Which are the presentations that y 1 | you appreciated the least (Explain)? his information session? t D Readily applicable solutions | |





Thank you for answering the survey!



Other sources of information

- European chemicals agency: <u>http://echa.europa.eu/</u>
- Helpdesk Luxembourg: <u>www.reach.lu</u>
- German Helpdesk: <u>www.reach-clp-helpdesk.de</u>
- French Helpdesk: <u>http://helpdesk-reach-clp.ineris.fr/</u> And also: <u>www.inrs.fr</u>





Thank you for your attention

Do you have any question about REACH or CLP? Please contact us!

REACH&CLP Helpdesk Luxembourg Luxembourg Institute of Science and Technology (LIST) Environmental Research & Innovation Department (ERIN) 41, rue du Brill | L-4422 Belvaux | Luxembourg Email: <u>reach@list.lu</u> Tel.: (+ 352) 275 888-1





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THE END









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