



Declaration of dangerous products in
Luxembourg

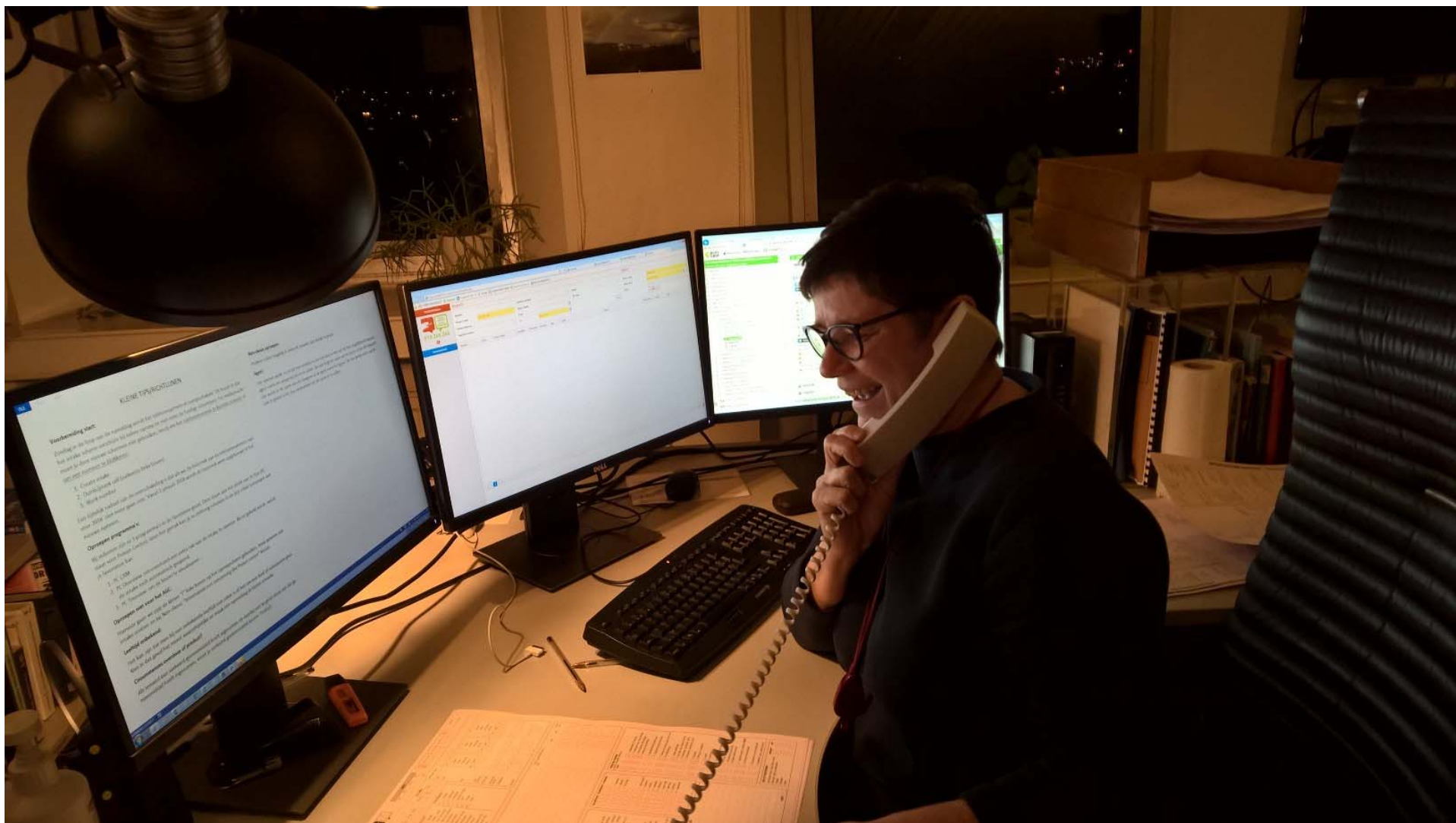
Current status and future developments at the
Belgian Poison Centre?



December 12th, 2019

François Wuyts





Renewal IT platform



Intake





070 245 245

Intake Number I-399

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✖

Intake

Reporters

Reporter 1

Agents

Agent 1

Circumstances

Victims

Victim 1

Symptoms

Treatments

Examin

Sources / Remarks

Announcements

General

Name

Phone / email 1231

Anonymous

Language NL FR GE EN Other

Reporter type

Public

Doctors

Other professions

Reporter country

Country Belgium Luxembourg

Place

Postalcode

City

Reporter location

Agriculture, horticulture

Hospital, clinic Emergency

Mobile Intervention Unit

Public pool

Reporter Remarks

Agents

Agent relation

Combination

Combination quantity

Agent 1

Characteristics

Quote

Exact agent name

Categories

Ways of exposure

Aspiration

Extravasation

Nasal

Rectal

Agent Remarks

Web Application for fast input of phone calls



Renewal IT platform

- Direct input of incoming calls
 - integration of application with telephony and product databases
 - Use of a hierarchical categorisation system

- Building of 7 product databases according to data schema available allowing automatic import



New system

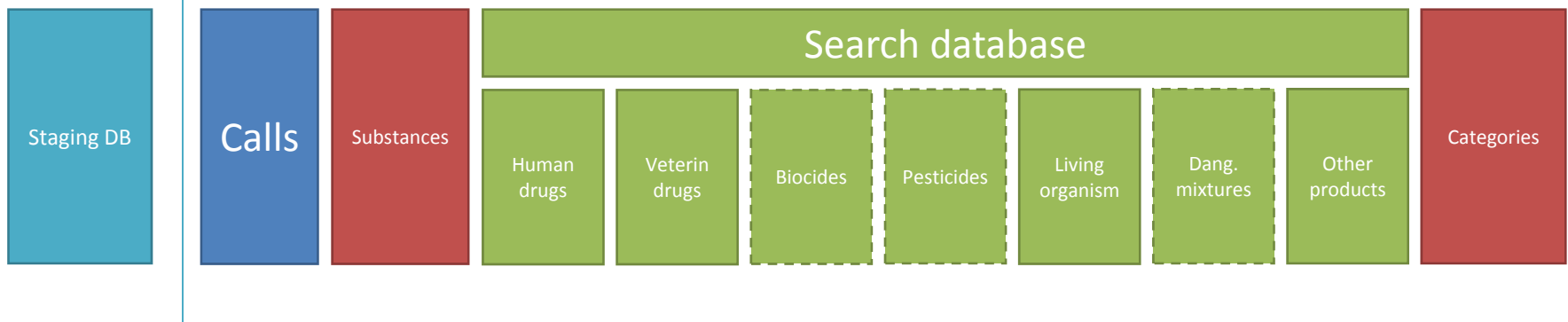


MS CRM

Intake

Application Layer

Data Layer



- New system built on Microsoft SQL & Microsoft CRM
- Each product family (biocide, human drug,..) receives its own tables based on data schema of provider
- Search database on top



Product Families

- Human Drugs : APB
 - Fixed length text files via FTP
- Veterinary Drugs : CBIP Vet
 - XML files (Drupal) via email
- Pesticides : Ministry of Health
 - Ministry of Agriculture (Luxembourg)
 - Panama platform (in production in 2020(?))
 - XML files via FTP (?)
- Biocides : Ministry of Health
 - Under development
 - XML files via FTP (?)
- Dangerous mixtures
 - IUCLID format
 - Through FTP, web service, (?)



Product Families

Living Organisms

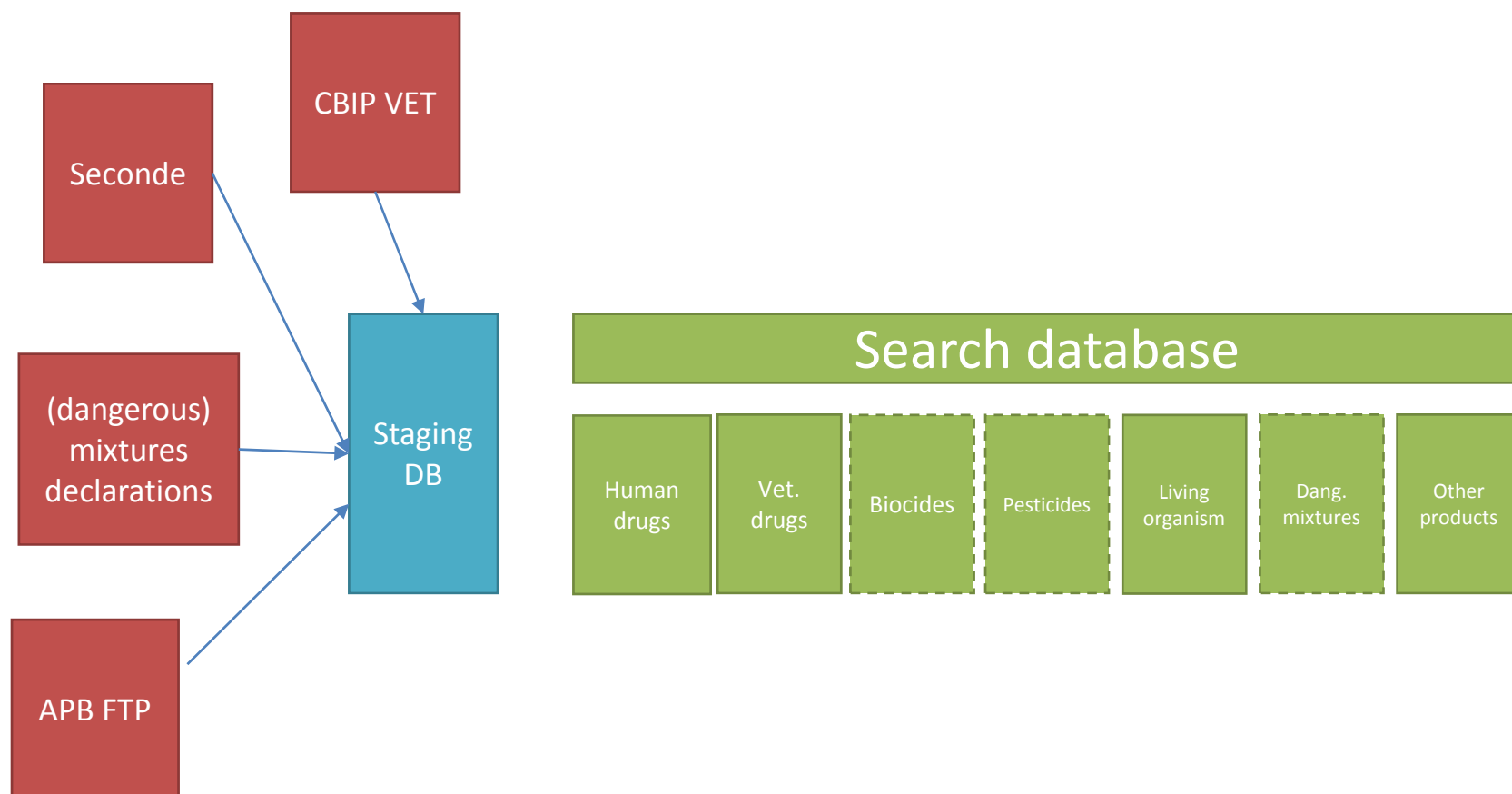
- Data inserted by the Poison Centre itself

Other Products

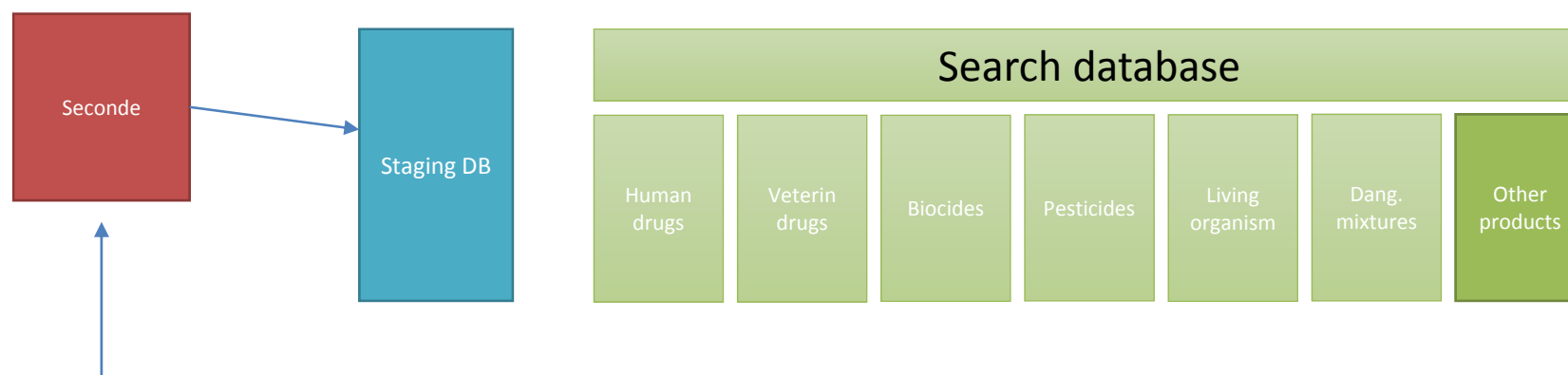
- Contains special agents such as coins, batteries, lamps,..
- Products found in Seconde are created here when involved in a call
- Legacy products



New system



Transition period: 2018-2021



EDF 2.0 DANG: tableau à compléter et à renvoyer avec les fichiers associés à depot@poisoncentre.be									
Identification							Documents fournis (Noms des fichiers associés)		
Dénomination(s) commerciale(s)	Code interne à la firme	Usage exclusif ou non professionnel	Mélange classé comme dangereux sur base du règlement (CE) n° 1272/2008 en raison de ses effets sur le caractère de ses effets physiques	Nouvelle déclaration	Type de mélange: Indiquer P ou F ou M	Fiche de données de sécurité SDS visée à l'article 31 du règlement REACH	Composition chimique complète du mélange	Étiquette	
Obligatoire	Facultatif	(O ou N)	(O ou N)	(O ou N)		Obligatoire	Obligatoire	Obligatoire	
Bubbles in a box,Boîte à bulles; Bubble dosage		N	O	O	H	BUBBLES_IN_A_BOX_SDS.PDF	BUBBLES_IN_A_BOX_COMPO.PDF	BUBBLES_IN_A_BOX_LABEL.PDF	



Transition period

- As long as the Belgian PC is not ready to treat IUCLID data (not before Q3 2020), the data must be notified through the EDF format. The data will be imported in Seconde and when needed, be transferred to the “Other Products DB”. The data has to be send towards depot.lux@poisoncentre.be
- Once the Belgian PC can treat IUCLID data, notifications may be done by using the IUCLID format. Products declared through IUCLID will be stored in the new “dangerous mixtures” database.



New EDF format contains

- Both fields are NOT mandatory

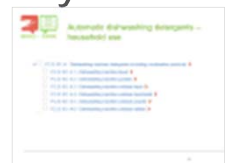
Final situation from 2021





Dangerous mixtures when everything in place (from 2021)

- A new database for the dangerous products will be created based on the IUCLID schema
- Data will be imported through eDelivery (S2S integration with ECHA)
- Belgian Poison Centre will NOT use the portal itself
 - Communication with the industry will be done through email as before
- Data will be stored in a dedicated application/database for dangerous products (to avoid performance issues on the searchable database)
- Data will be transferred to CRM when used in a case
- An additional categorisation field will be foreseen by the Poison Centre that contains a copy of the categorisation field filled in by the industry and that can be adapted by the Poison Centre
- Local submission using IUCLID European format will be possible





Voluntary submissions

- 🗨 Voluntary submissions (unclassified, dangerous environment, ..)
- 🗨 Local submission preferably in IUCLID format



Implementation deadline CLP Annex VIII

🗉 January 1st, 2020 is unrealistic

- ECHA is still developing / changing PCN Format. As a result, AB's /PC's have to wait to start final development. A premature start would result in unnecessary additional costs.
- Given examples of ECHA are poor
 - IUCLID PCN v1.1 examples are too simple
 - ECHA follows a script when giving courses about the portal.
- Pending questions : Still too much unknown facts
 - What are the technical requirements for eDelivery?
Current documentation only explains the architecture.
 - How many data will we receive when the system is coming online?
 - What will be the impact if the IUCLID format changes?
- The version that would be used on January 1st, 2020 will not take the workability issues in account. This could later have a great impact on our systems when implementing them.



Implementation deadline CLP Annex VIII

- The AB's/PC's need more time to be ready:
- Investments need to be done in hardware such as servers and storage. How much storage do we need?
 - Specifications need to be made for developing new software
 - AB's/PC's are afraid to start developing as long as ECHA is still making changes, because most of the development will be done by external companies.
 - Money need to be found for all of the above.



Implementation deadline CLP Annex VIII

- ❏ Deadline will be postponed to January 1st, 2021 according to first revision to CLP Annex VIII
- ❏ The risk exists that the first revision to CLP Annex VIII will not be published in the Official Journal until the end of December 2019
- ❏ Therefore, Industry will be faced with the situation where CLP Annex VIII (in its current form) will apply for a number of weeks during early 2020 before the revised applicability deadline comes in to force.
- ❏ Belgian Poison Center will **NOT** be able to treat IUCLID dossiers during that period. The EDF Format will have to be used.

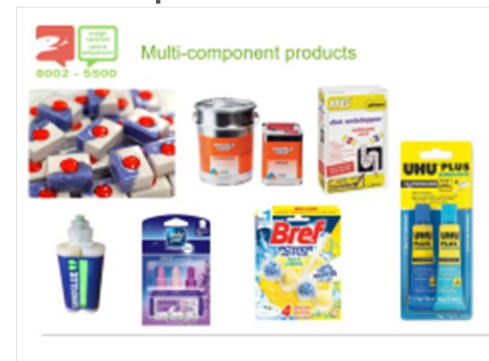


Current situation at the Poison Center

- The Belgian Poison Center is able to read a IUCLID dossier and to store the information in a SQL database.
- Making the information visible has yet to be developed
- Treating updates is under investigation.
- The S2S integration through eDelivery is not yet implemented. The Belgian Poison Center is currently not capable of receiving IUCLID dossiers which are submitted on the ECHA portal.

IUCLID Dossier

- The current IUCLID format is version 6.4
- Doesn't take into account
 - Workability issues of the industry
 - Proposal for ICG (interchangeable component group)
 - multiple suppliers for the 'same' component
 - use of different, but technically equivalent raw materials with same hazard classification and no impact on emergency health response
 - No proposals yet for cement, petroleum and bespoke mixtures
 - Multicomponent products
- Group submission is not yet supported





IUCLID Dossier

- October 30th, 2019 release of Version 6.4
 - Update of the language phrases to reflect ISO 639 codes
 - Dossier contact added to the contact type in the *Contact document*
 - PCN dossier header
 - New update reason 'correction of error'
 - Reorganisation of notification types and submission types
 - 'Submission of non-hazardous mixture' replaced by 'Voluntary submission'
 - 'PCN number', 'Market placement' and 'Language' made mandatory



IUCLID Dossier

- October 30th, 2019 release of version 6.4
 - Fields changed from 'multilingual' to 'not multilingual'
 - Other name
 - Trade name
 - ID under the *Identifiers document*
 - PCN number
 - External system identifier
 - 'Generic Product Identifier' checkboxes included in the *Composition* and *Composition summary* documents



IUCLID Dossier

- October 30th, 2019 release of version 6.4
 - Classification and labelling information (*GHS document*) updated to take into account ATPs 10th to 14th(and GHS rev. 6 & 7)
 - Additional text for Precautionary statement increased from 255 to 2,000 characters
 - New EU Hazard statements
 - New flammable gases categories
 - Updated Notes
 - New phrases: H350i, H360D, H360Df, H360F, H360FD, H30Fd, H361d, H361f, H361fd



Creating a IUCLID dossier

- Can be done through one of the tools of ECHA
 - IUCLID Cloud (ECHA Submission Portal)
 - IUCLID Desktop
 - IUCLID Server
- Using third party software or internal developed software. For example the SAP add-on of Opesus



ECHA Submission Portal

- ❏ Currently too many clicks to create a dossier. This has been noticed by the members of the ICT user group during the workshop in Helsinki in November 2018.
- ❏ Too many different screens to define an object. For example, five different screens must be opened to define a substance
 - Specify substance
 - Function and Concentration
 - Substance identification
 - Classification
 - Labelling
- ❏ DETIC tested the system and needed on average 2 hours to submit a mixture with 4 components



ECHA Submission Portal

ECHA Submission portal

The ECHA Submission portal is an online tool that supports both industry and authority users in fulfilling their obligations related to the notification of hazardous mixtures as required under Article 45 of the CLP Regulation.

The portal allows industry to prepare and submit poison centre notification (PCN) dossiers containing information on hazardous mixtures to appointed bodies. It is also a secure dispatch system by making the information available to appointed bodies for use by poison centres.

Currently, only Germany and Estonia are accepting submissions made through the ECHA Submission portal.





+ New item

No items added
+ New item

nl

en

Dit product is acuut niet toxisch. Na inslikken kan braken optreden. Een zeer omvangrijke inname kan symptomen van alcoholvergiftiging teweegbrengen; symptomatisch behandelen. Wek geen braken op. Indien er irritatieverschijnselen optreden zullen deze licht tot matig zijn, afhankelijk van de blootstelling. Bij aanraking



ECHA Submission Portal



Dashboard > Guided dossier preparations > test dreft citroen > Mixture Information > Mixture composition

Mixture composition

Mixture components

+ Mixture component

Orange Oil Sweet test (< 1 % (w/w))

07/08/2019 13:34

×

test

07/08/2019 13:34

×

Substance components

+ Substance component

water (ca. 90 % (w/w))

07/08/2019 13:34

×

amine oxide (>= 2 <= 3 % (w/w))

07/08/2019 13:34

×

lauryl deceth (> 3 <= 4 % (w/w))

07/08/2019 13:34

×

Generic Product Identifier components


+ Generic Product Identifier component

Perfume (< 1 % (w/w))

07/08/2019 13:34

×

ECHA Submission Portal

 IUCLID 6

Dashboard > Guided dossier preparations > test dreft citroen > Product information > Product details > Product details

Product details

1 Product identifiers

2 Market placement

3 Additional information

Colour and physical state

Link to the information about colour and physical state

GeneralInformation X

+ Select

Packaging

☐ Product not packaged

Link to the packaging information

Packaging X

+ Select

Product use category

Use type

Consumer X

Main intended use

PC-CLN-10.OTH Other kitchen and related cleaning products X



ECHA Submission Portal



Dashboard > Guided dossier preparations > test dreft citroen > Mixture Information > Unique formula identifiers (UFI) an... > Unique formula identifiers (UFI) an...

Unique formula identifiers (UFI) and other identifiers

1 Regulatory Programme Identifiers

Regulatory Programme Identifiers

Regulatory Programme Identifiers

[+ New item](#)

CLP unique formula identifier (UFI)

[/](#) [X](#)

Other IT system identifiers

Other IT system identifiers

[+ New item](#)

No items added

[+ New item](#)



ECHA Submission Portal

📅 October 2019 release

- Updated PCN format
- Implementation of the IT solution to support dispatching of multiple IUCLID dossier versions
- Submitted IUCLID dossier version added to Submission report
- Validated IUCLID version added to Validation report
- Mandatory fields highlighted in guided dossier tool



ECHA Submission Portal

📅 October 2019 release

- New icons for the submission status (consistency among ECHA Submission systems)
- Integration between Submission portal and Interact for the PCN database (ongoing)
- Integration between Submission portal and ECHA Data Integration Platform for reporting needs (ongoing)
- Bugs fixed
- UFI generator: possible to generate UFI without providing VAT (tool and docs)



ECHA Submission Portal

January 2020 release

- Improvement of validation report
- Multilingual fields available in dataset view
- Continuation of navigation improvements
- Re-organisation of Classification and Labelling section
- Facilitate the way to update dossiers



Mixtures in Mixtures

- A **mixture in mixture (MiM)** – i.e. a mixture (as defined in Article 2(8) of CLP; see section 2) used in the composition of a second mixture that is placed on the market and the subject of the current submission.
- A MiM must contain one of the following information
 - SDS and contact details supplier of MiM
 - UFI of the MiM
- The Belgian Poison Center has no access to info of a MiM if it's not in their national database. Therefore, if using a UFI for a MiM, the MiM has to be declared prior to the declaration of the mixture containing the MiM.



Submission languages

- The Belgian Poison Center will accept submissions as agreed with the industry
- Submissions may be performed in one language
 - Preferably English
 - French or German submissions will also be accepted
- Trade Names needed for identification of a product need to be submitted in all national languages



Hope and worries



Expectations from harmonization

- UFI: ideal tool for product identification
Need for an information campaign
- Categorisation system:
 - better reporting, comparable data between Poison Centre
 - allow search for comparable formulations when product not found in data base
- Structure of the data: search by ingredient.....



Worries about new declaration system

- What will be the impact of adaptations to the IUCLID format?
- In which degree will the amount of notifications grow?
- Answering the phone will be a challenge if mixtures are notified using many MiM's and using ICG's



**antigif
centrum
centre
antipoisons**

Multi-component products





Automatic dishwashing detergents – household use

- ▲ ☐ P.2.5.10.1.4 - Dishwashing machine detergents (including combination products) ➤
 - ☐ P.2.5.10.1.4.1 - Dishwashing machine liquid ➤
 - ☐ P.2.5.10.1.4.2 - Dishwashing machine powder ➤
 - ☐ P.2.5.10.1.4.3 - Dishwashing machine unidose liquid ➤
 - ☐ P.2.5.10.1.4.4 - Dishwashing machine unidose liquid/solid ➤
 - ☐ P.2.5.10.1.4.5 - Dishwashing machine unidose powder ➤
 - ☐ P.2.5.10.1.4.6 - Dishwashing machine unidose tablets ➤