



IUCLID FOR THE SUBMISSION AND ASSESSMENT OF APPLICATIONS

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WHAT IS IUCLID



International Uniform Chemical Information Database

- IUCLID is a software to record, store, maintain and exchange data on chemical substances
- Standard exchange format based on predefined fields for:
 - organising data
 - accessing information
 - comparing
 - reporting
 - evaluating
 - publishing data

- Co-developed by ECHA and OECD based on OECD harmonized templates (OHT)

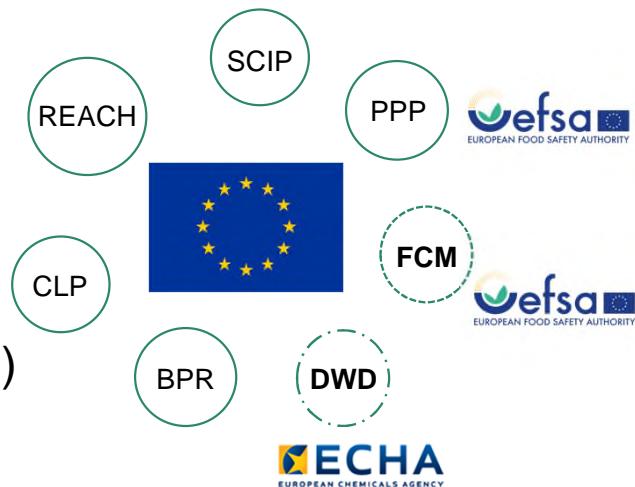


WHAT IS IUCLID



International Uniform Chemical Information Database

- Central role in the IT environments of organizations managing scientific data on chemicals in a regulatory context
- EU institutions (ECHA, EFSA) are using IUCLID for submission of dossiers on regulated products
- ECHA is currently developing IUCLID for the submission/assessment of applications on drinking water materials (DWCM) based on the drinking water directive (DWD)
- IUCLID will be also used for applications of FCM substances (Reg. (EU) 10/2011)



IUCLID FOR DRINKING WATER CONTACT MATERIALS - PROGRESS



IUCLID FOR DWCM - SECTIONS

1 General information	4
> 1.1 Identification	1
> 1.2 Composition	1
> 1.3 Identifiers	1
> 1.4 Analytical information	1
1.5 Relevant chemical species other than the applied-for entry (linked datasets)	
> 2 Classification and labelling	1
> 3 Physical and chemical properties	2
> 4 Intended use of the applied-for entry	1
> 5 Data on migration of the substance, electrochemical tests	3
6 Analytical methods	
7 Toxicological data	3
8 Risk acceptance	
9 Assessment by other authorities	
10 Reports	
Inherited templates	
<input type="checkbox"/> specific documents developed by ECHA for DWM applications	

- Type of information **similar to the one currently submitted for FCM substances (Reg. (EU) 10/2011)**

> 5 Data on migration of the substance, electrochemical tests	3
> 5.1 Data on migration of the substance	+
● Data on migration of the substance.001	
● Data on migration of the substance.002	
> 5.2 Data on electrochemical test and passivation tendency of a metallic material	1

Experimental study migration test results

Migration into water + New item Import file

Diffusion-based modelling

Model details and parameters

The modelling software used

Temperature of the system (°C)

Material under test

Geometry of the material

S/V ratio (dm-1)

Thickness of the material (Dp)

- Approach to data reporting different than other infrastructure (e.g. ESFC): every relevant single piece of information is reported separately



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IUCLID FOR DWCM- SECTIONS

- Report information via picklists, free text or attachments

Material type

- Please select
- organic materials
- cementitious materials
- metallic materials
- enamels, ceramic and other inorganic materials

Migration into water

Time period

Duration (h)

Sample no.

Test conditions

- Repeatable block of fields

Experimental study migration test results

Migration into water

Test temperature (°C)

S/V-ratio (dm⁻¹)

Migration period length

Test water type

Total number of migration periods

Migration int

Migration into wa

Migration into water

Test temperature (°C)	S/V-ratio (dm ⁻¹)	Migration period length	Test water type	Total number of migration periods
20	20	24 h	test water	8
20	20	24 h	test water	8
20	20	24 h	test water	8
20	20	24 h	test water	8
20	20	24 h	test water	8
20	20	24 h	test water	8
20	20	24 h	test water	8
20	20	24 h	test water	8

Relevant chemical species

+ New item

Import file

1 Relevant chemical species

Relevant chemical species type (organic and cementitious materials)

MTCTap (µg/L)

Basis for selecting an MTCTap value

Justification for the derivation of the MTCTap value

Residual concentration of the relevant chemical species in the material (% w/w)

- Generate a report

View Dossiers

Validate

Create dossier

Export to i6z

Create document PDF/RTF

Create component PDF/RTF

Generate report

Compare

Clone

Copy data from ...

Bulk operations

Slide 6

ZP4 New slide, previous version is hidden above
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IUCLID FOR FOOD CONTACT MATERIALS



International Uniform Chemical Information Database

- IUCLID format will be used to submit applications used for risk assessment of FCM instead of ESFC (likely in 2026-2028).
- IUCLID is intended to be used not only for submission, but also to evaluate data (contrary to the presently used system) → substantial change in the working of EFSA and MS
- EFSC will be kept as tool linked to IUCLID to interact with applicants (i.e. only administrative aspects, not for submitting data)



IUCLID FOR FOOD CONTACT MATERIALS - PROGRESS

ECHA-EFSA collaborations (FIP unit)

- FCM WG kept informed on ongoing work on DWD IUCLID format
- EFSA participating in ECHA's DWD Guidance and IT Tools User Group

Building of the FCM IUCLID format (FDP unit):

- Definition of the “table of content” (i.e. high-level categories) to be applied to the IUCLID format → currently under finalisation
- Adaptation of already available templates (e.g. as OHT, from DWD) and building of ad-hoc templates (i.e. those not available as OHT/ not adaptable) → ongoing



FINAL CONSIDERATIONS ON THE USE OF IUCLID FOR FCM

IUCLID is widely used in EU to handle information on chemicals and will be soon used for submission and evaluation of applications in the field of FCM.

- Access to EFSA applications by MS representatives will be done via IUCLID.
- MS may wish to also use IUCLID for their applications within national legislation
- Useful/key for interoperability, access, sharing data/information between EU and MSs as well as amongst MSs

The IUCLID format for applications of FCM substances:

- Is already being built considering the DWD IUCLID format
- EFSA is kept informed on IUCLID DWD format, identifying key elements to be considered when building the FCM IUCLID format.
- Update to FCM Network next year



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