

IUCLID 6

Version 4.2.1 release

8th November 2019

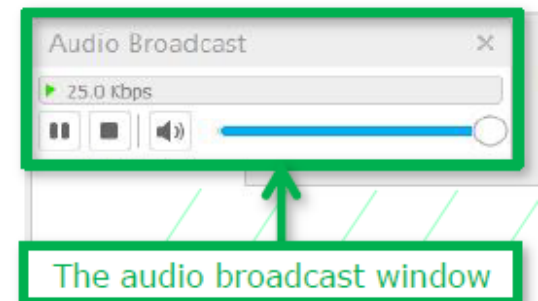
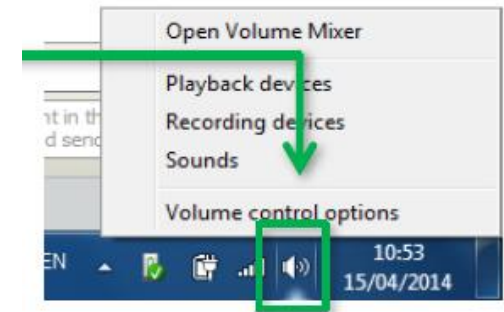


IUCLID 6 is developed by the European Chemicals Agency in association with the OECD



Audio troubleshooting

- If the volume is too low, try to increase the sound volume of your computer.
- If the audio cannot be heard at all, verify that the audio broadcast window shows a green triangle and that the volume slider is not too low.
- If the problem persists, you can use a telephone for receiving audio.
 - Click the button shown above to *Request Audio*
 - Select *Use phone*, enter your phone number
 - Click on the *Call me* button



The audio broadcast window

The *Request audio* button is only needed to connect audio by phone should the audio broadcast not work properly.



WebEx instructions



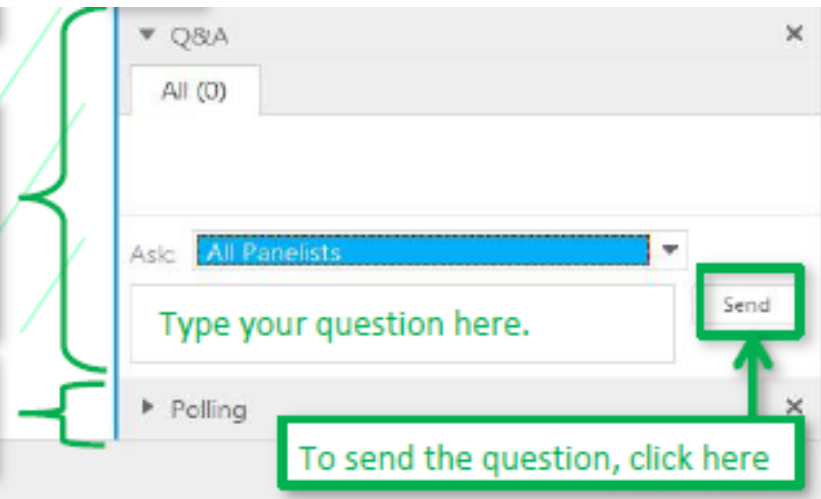
The Q&A panel

- You can post your questions during the entire webinar
- Before the Q&A session, 5 minutes will be left to send additional questions

The Q&A panel

You can send questions during and after the presentations to the panellists, using the Q&A panel
To send a question, select *All panelists* from the drop down menu, write your question in the lower box, and finally click *Send*.

If a poll is opened during the webinar, the polling panel will open automatically



The Q&A panel

- Questions will be answered privately, i.e. you will not see each others questions and answers
- We will answer the most frequently asked questions at the end of the webinar
- Your questions will be kept anonymous



Recordings

- After the meeting, we will publish on the IUCLID 6 website
 - The recording of the webinar (+ presentations)
 - Questions and answers (written document)

IUCLID > Support > Documentation > Webinars

Documentation

- System requirements
- Videotutorials
- Training material
- **Webinars**
- Verification of downloads
- Learn to use the new interface

Webinars

What's new in IUCLID 6.4? (8th November 2019)

Registration to the webinar can be made on [this page](#).

Using the IUCLID web interface for biocides submissions (15th May 2019)



Agenda:

- The webinar introduces you to the latest IUCLID web interface improvements in IUCLID 6 (v3.16.1) for biocides submissions, including the creation and navigation of a BPR dossier, the comparison tool, and the report generator.

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

Agenda for today

What?	Who?
Welcome and introduction	François Le Goff
IUCLID 6.4 release	
IUCLID format update	
The IUCLID web user interface	Mark Roberts
Replacing the classic interface	
Questions and Answers session End of webinar	All participants François Le Goff

IUCLID 6.4 release



Release of IUCLID 6 (v4.2.1)



News alerts

- A news alert was published on 21st October about this version of IUCLID
- Another news alert shared with IUCLID users on the day of the release
- Subscriptions to news alert, by email notifications, can be managed from the IUCLID website (My Account | Subscriptions)

My Account

Subscriptions

- ☒ iuclid-news-general
- ☒ iuclid-news-technical

IUCLID news

30/10/2019

IUCLID 6.4 is available

A new version of IUCLID is available to all users. It includes an extended and more complete web interface, as well as an update to the format.

The web user interface, which is meant to become in the future the only user interface for IUCLID, has been improved. This version includes, for example, direct navigation to referenced documents in dossiers, advanced dossier creation, export and printing options including document selection, and a slightly more compact view for documents.

As in every major update of IUCLID, this version comes with an update of the format to take into account:

- the latest evolutions of the REACH (for example, new nanoforms requirements) and CLP regulations (latest ATPs);
- the future SCIP database notification format for substance of very high concern in articles as mentioned in the waste framework directive; and
- the needs of several regulatory organisations including the European Food Safety Authority (EFSA), and the organisations managing chemicals in Australia and New Zealand.

In relation to the update of the IUCLID format for nanomaterials, this new version of IUCLID will allow users to verify how these substance forms are reported in REACH registration dossiers.

This new version of IUCLID can read all IUCLID 6.2 or older versions.

IUCLID 6.4 will be presented in more detail in the next IUCLID release.

The users of the ECHA Cloud services will have access to the new version of IUCLID.

Note that the IUCLID end-user license agrees with the REACH and CLP, as well as to align with local regulations.

We regularly post additional information on our website.

Additional information

[Download IUCLID 6.4](#) | [Release notes](#) | [Format](#) | [Helpdesk](#)

30/10/2019 - IUCLID 6.4 is available
A new version of IUCLID is available to all users. It includes an extended and more complete web interface, as well as an update to the format.

21/10/2019 - What can you find in the next IUCLID version?
On 30 October, a new version of IUCLID will be made available to all users. It will include an extended and more complete web interface as well as an update to the format.

03/09/2019 - Visit the IUCLID support page and learn to use the IUCLID web interface
IUCLID is moving progressively to a web interface. On the occasion of the next IUCLID release, you can learn more about the new interface on a dedicated webpage.

24/04/2019 - The IUCLID 6.4 final release is available

https://iuclid6.echa.europa.eu/view-article/-/journal_content/title/iuclid-6-4-is-available

License agreement

- The IUCLID 6 license agreement has been updated together with the IUCLID 6.4 release
 - To better take into account IUCLID related tools such as Text Analytics, Data Extractor or the Provider Agent
 - To cover the use of IUCLID 6 under different legislations (not only REACH or CLP for example)

Terms and conditions

Access is provided below to the legal texts that must be agreed to when downloading applications from this website. Each agreement is made separately at the point of download of the application or data.

- **End-user license agreement** for IUCLID 6 Desktop and IUCLID 6 Server.

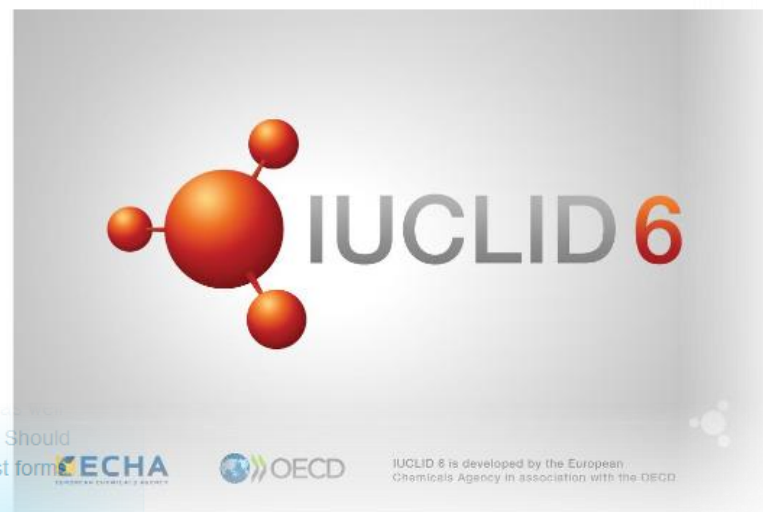
Please note that on 30th October 2019, the IUCLID end-user license agreement has been updated to cover IUCLID-related tools, to explicitly encompass other regulations besides REACH and CLP, and to align with local Finnish law. The change requires no action on the part of users of IUCLID. Should you have any questions about this matter, please contact ECHA through the information request form on ECHA's contact page: <https://echa.europa.eu/contact>

- **End-user licence agreement** for IUCLID 6 Beta
- **Terms and conditions** for REACH Study Results

The European Chemicals Agency

End User License Agreement

30/10/2019

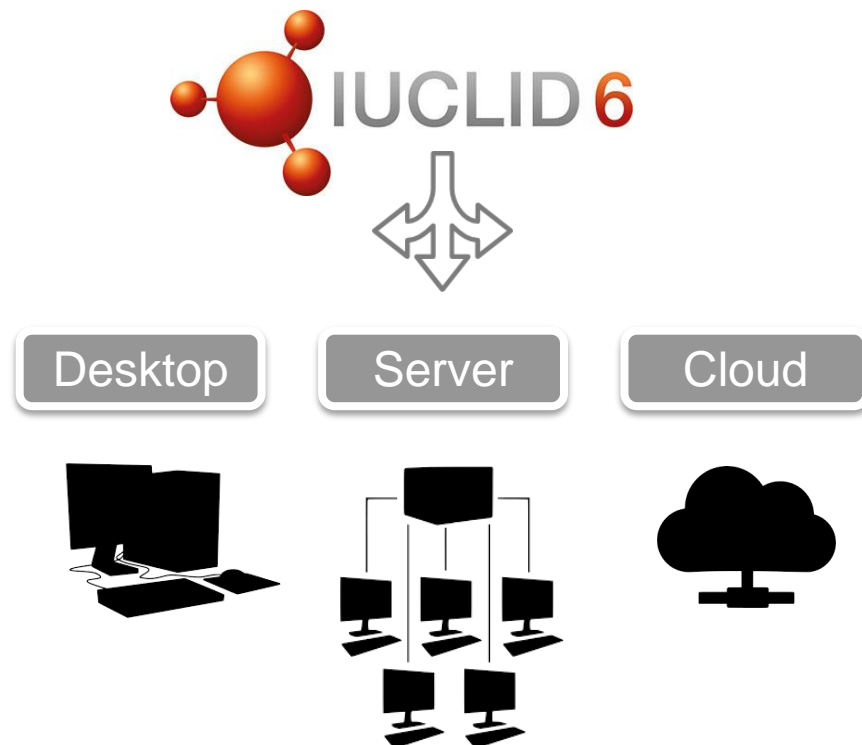


Release of IUCLID 6 (v4.2.1)



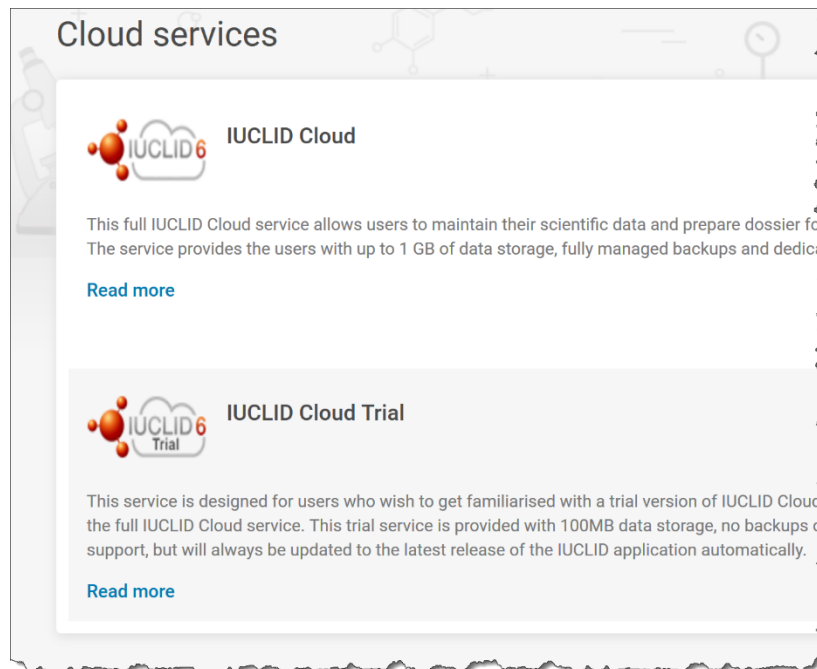
Different distributions of IUCLID

- One IUCLID software, different ways of distributing it
 - Desktop: for single user, on his/her own computer
 - Server: hosted on a server, shared with multiple users
 - Cloud: ECHA Cloud Services, hosted by ECHA, for REACH and CLP users




ECHA Cloud Services

- Cloud instances were updated to version **4.2.0** within two days after the release
- For technical reasons, version **4.2.0** had to be deployed and version **4.2.1** will be available in the Cloud on the 11th of November
- There are only minor changes between these 2 versions: e.g. fixes to dynamic content in web forms
- All REACH and CLP users can subscribe


A screenshot of the IUCLID Cloud services page, presented as a torn piece of paper. The page has a light grey background with faint chemical structures. At the top, the text "Cloud services" is displayed. Below this, there are two main sections. The first section is titled "IUCLID Cloud" and features the IUCLID 6 logo. The text describes the full service, mentioning 1 GB of data storage, fully managed backups, and dedicated support. A "Read more" link is provided. The second section is titled "IUCLID Cloud Trial" and features the IUCLID 6 Trial logo. The text describes the trial service, mentioning 100MB of data storage, no backups, and automatic updates. A "Read more" link is also provided.

Cloud services

 **IUCLID Cloud**

This full IUCLID Cloud service allows users to maintain their scientific data and prepare dossier for... The service provides the users with up to 1 GB of data storage, fully managed backups and dedicated support.

[Read more](#)

 **IUCLID Cloud Trial**

This service is designed for users who wish to get familiarised with a trial version of IUCLID Cloud, the full IUCLID Cloud service. This trial service is provided with 100MB data storage, no backups or support, but will always be updated to the latest release of the IUCLID application automatically.

[Read more](#)

IUCLID 6.4 release



Statistics

- Between 200 and 300 new users are registering on the IUCLID website every month
- ~400 downloads of the latest version of IUCLID in the week following the release
- More than 2,000 IUCLID instances are currently active in ECHA Cloud Services



IUCLID Format

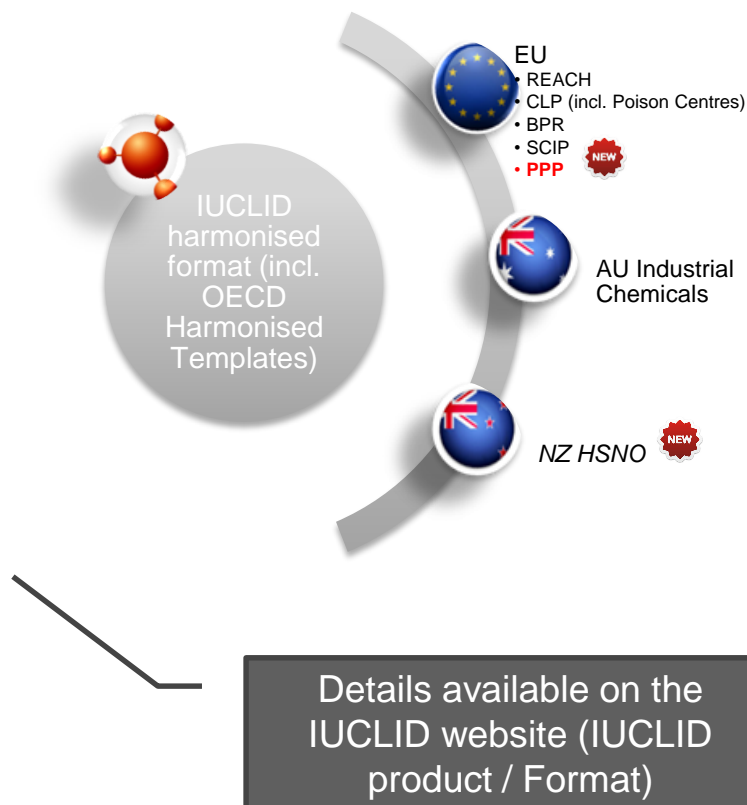


Overview of IUCLID 6.4 format changes



Main reasons for the update of the format

- 50+ different topics in total
- Main changes
 - OECD Harmonised Templates updates
 - UN GHS (rev. 6&7) and EU CLP (ATP 10-14th)
 - Format changes to support members of the OECD IUCLID User group (Australia, New Zealand, ECHA)
 - Nanomaterials REACH Annex update
 - EU Plant Protection Product (EU_PPP) to provide draft EU Pesticides submission types
 - Support for the future ECHA database on substances of concern in articles



OECD Harmonised Templates

One new template and minor updates of existing templates

- Physico-chemical properties and environmental fate
 - **NEW** Dispersion stability of nanomaterials
 - Biodegradation in water screening tests
- Effects on biotic systems
 - Toxicity to microorganisms
 - Short-term toxicity to fish
- Health effects
 - Acute toxicity – inhalation, dermal
 - Repeated dose toxicity – inhalation, oral
 - Genetic toxicity – in vivo
 - Toxicity to reproduction



OECD Harmonised Templates for Reporting Chemical Test Summaries

OECD Harmonised Templates	OECD Harmonised Templates																						
Introduction	The OECD Harmonised Templates (OHTs) are standard data formats for reporting information used for the risk assessment of chemicals, mainly studies done on chemicals to determine their properties or effects on human health and the environment, but also for storing data for use and exposure. They are aimed at developers of database systems, as they prescribe the formats by which information can be entered into and maintained in a database. By using these templates, governments and industry are easily able to electronically exchange test data and summary information.																						
Format and conventions used	The templates can be used to report summary test results for any type of chemical (e.g., pesticides, biocides, industrial chemicals). The OECD Harmonised Templates cover endpoints and reporting elements which are grouped as follows:																						
OECD Harmonised Templates	<table border="0"><tr><td>Physico-chemical properties (incl. nanomaterials)</td><td>- OHTs 1 to 23-5 & 101 to 113</td></tr><tr><td>Environmental fate and behaviour</td><td>- OHTs 24 to 40 & 401</td></tr><tr><td>Effects on biotic systems</td><td>- OHTs 41 to 57</td></tr><tr><td>Health effects</td><td>- OHTs 58 to 84 & 86</td></tr><tr><td>Pesticide residue chemistry</td><td>- OHTs 85-1 to 85-10</td></tr><tr><td>Analytical methods</td><td>- OHT 87</td></tr><tr><td>Efficacy</td><td>- OHTs 88 & 89</td></tr><tr><td>Emissions from treated articles</td><td>- OHT 90</td></tr><tr><td>Intermediate effects</td><td>- OHT 201</td></tr><tr><td>Use and exposure information</td><td>- OHTs 301 to 306</td></tr><tr><td>Generic elements for all OHTs</td><td>- Literature reference - Test material information Reference substance - Chemical inventory</td></tr></table>	Physico-chemical properties (incl. nanomaterials)	- OHTs 1 to 23-5 & 101 to 113	Environmental fate and behaviour	- OHTs 24 to 40 & 401	Effects on biotic systems	- OHTs 41 to 57	Health effects	- OHTs 58 to 84 & 86	Pesticide residue chemistry	- OHTs 85-1 to 85-10	Analytical methods	- OHT 87	Efficacy	- OHTs 88 & 89	Emissions from treated articles	- OHT 90	Intermediate effects	- OHT 201	Use and exposure information	- OHTs 301 to 306	Generic elements for all OHTs	- Literature reference - Test material information Reference substance - Chemical inventory
Physico-chemical properties (incl. nanomaterials)	- OHTs 1 to 23-5 & 101 to 113																						
Environmental fate and behaviour	- OHTs 24 to 40 & 401																						
Effects on biotic systems	- OHTs 41 to 57																						
Health effects	- OHTs 58 to 84 & 86																						
Pesticide residue chemistry	- OHTs 85-1 to 85-10																						
Analytical methods	- OHT 87																						
Efficacy	- OHTs 88 & 89																						
Emissions from treated articles	- OHT 90																						
Intermediate effects	- OHT 201																						
Use and exposure information	- OHTs 301 to 306																						
Generic elements for all OHTs	- Literature reference - Test material information Reference substance - Chemical inventory																						
Downloads																							
Updates and history																							
Contact Us																							

Each Template is accessible online in readable format (.doc file), with associated html schema (.xsd file), and with predefined tables or executive summaries (.html files) as available. The links to corresponding OECD Test Guidelines are given where applicable.

IUCLID format changes



OECD Harmonised Templates (OECD)

Ctd...

- Pesticide, residue chemistry
 - Metabolism of residues in crops and rotational crops
 - Nature of residues in processed commodities
 - Residues in crops (field trials) and in rotational crops (limited field studies)
- Efficacy
 - Effectiveness against target organisms and intended uses
 - Efficacy data
- Use and exposure information
 - Consumer uses
 - Uses at industrial sites
 - Widespread uses by professional workers
- Monitoring data



OECD Harmonised Templates for Reporting Chemical Test Summaries

OECD Harmonised Templates

- Introduction
- Format and conventions used
- OECD Harmonised Templates
- Downloads
- Updates and history
- Contact Us

[OECD Harmonised Templates](#)

The OECD Harmonised Templates (OHTs) are standard data formats for reporting information used for the risk assessment of chemicals, mainly studies done on chemicals to determine their properties or effects on human health and the environment, but also for storing data on use and exposure. They are aimed at developers of database systems, as they prescribe the formats by which information can be entered into and maintained in a database. By using these templates, governments and industry are easily able to electronically exchange test study summary information.

The templates can be used to report summary test results for any type of chemical (e.g., pesticides, biocides, industrial chemicals). The OECD Harmonised Templates cover endpoints and reporting elements which are grouped as follows:

Physico-chemical properties (incl. nanomaterials)	- OHTs 1 to 23-5 & 101 to 113
Environmental fate and behaviour	- OHTs 24 to 40 & 401
Effects on biotic systems	- OHTs 41 to 57
Health effects	- OHTs 58 to 84 & 86
Pesticide residue chemistry	- OHTs 85-1 to 85-10
Analytical methods	- OHT 87
Efficacy	- OHTs 88 & 89
Emissions from treated articles	- OHT 90
Intermediate effects	- OHT 201
Use and exposure information	- OHTs 301 to 306
Generic elements for all OHTs	- Literature reference - Test material information Reference substance - Chemical inventory

Each Template is accessible online in readable format (.doc file), with associated html schema (.xsd file), and with predefined tables or executive summaries (.html files) as available. The links to corresponding OECD Test Guidelines are given where applicable.

IUCLID format changes



IUCLID entities (DOMAIN)



- Minor updates in:
 - Test material
 - Contact
 - Mixture
 - Substance
 - Annotation
- New fields in Reference substance to store structure information
- New Article entity to prepare for the future ECHA database on substances of concern in articles

Other IUCLID harmonised documents (CORE)



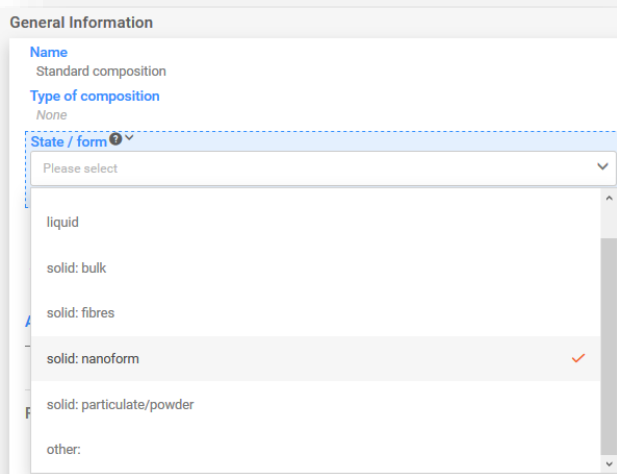
- GHS: updates in accordance with
 - Revisions 6 and 7 of the Globally Harmonised System (GHS)
 - Latest updates of the CLP regulation (ATPs 10, 12 and 14)
 - Main changes
 - Additional text for Precautionary statement increased from 255 to 2,000 characters
 - New reason for no classification
 - New EU hazard statements
 - New flammable gases categories
 - Updated Notes
 - New hazard statement codes: H350i, H360D, H360Df, H360F, H360FD, H30Fd, H361d, H361f, H361fd
- Inclusion of nanomaterial requirements following the update of REACH
 - Composition (substance)
 - Analytical information

New requirements and fields for reporting nanoforms in IUCLID 6.4

- New fields in section 1.2 for reporting REACH Annex VI characterisers of nanoforms
- New completeness check (TCC) rules in Validation assistant
- Dissemination preview adapted to information on nanoforms
- Updated registration manual with specific annex for nanoforms

NEW Section 1.2 Composition. 'State/form' mandatory for all inquiry and registration dossiers (including update dossiers)


Webinar on 12th of November: **Getting ready for revised REACH information requirements for nanoforms**



General Information

Name
Standard composition

Type of composition
None


State / form 

Please select

liquid

solid: bulk

solid: fibres

solid: nanoform 

solid: particulate/powder

other:

Nano-specific advice for sections 4, 5, 6, 7 and 8

All endpoint study records should be filled in as described in chapter 9.6. *Section 8 - Endpoint sections* of this manual, which provides instructions to enter information on scientific studies carried out following Annexes VII to X of the REACH Regulation, adapted according to Annex XI. The present chapter only provides additional reporting information of substances in the nanoform.

The information for each nanoform is expected to be reported in a separate record, clearly detailing the test material used in the study.

Under the *Test material* heading, link the *Test material information*, the test material that was used in the study (or is planned to be used) to the information on the test material as explained in chapter 9.6.

	B	D	E
1	sectionName	field	outcome
0	1.2 Composition	Composition / Characterisation of nanoforms / Type of information reported	Published F
1	1.2 Composition	Composition / Characterisation of nanoforms / Shape / Shape description / 1 / Shape category	Published F
2	1.2 Composition	Composition / Characterisation of nanoforms / Shape / Shape description / 1 / Shape	Published F
3	1.2 Composition	Composition / Characterisation of nanoforms / Shape / Shape description / 1 / Pure shape	Published F
4	1.2 Composition	Composition / Characterisation of nanoforms / Shape / Shape description / 1 / Typical composition	Published F
5	1.2 Composition	Composition / Characterisation of nanoforms / Shape / Shape description / 1 / Range	Published F
6	1.2 Composition	Composition / Characterisation of nanoforms / Particle size distribution and range / Particle size distribution and range flags	Published F
7	1.2 Composition	Composition / Characterisation of nanoforms / Crystallinity / Crystallinity flags	Published F
8	1.2 Composition	Composition / Characterisation of nanoforms / Specific surface area / Specific surface area flags	Published F
9	1.2 Composition	Composition / Characterisation of nanoforms / Surface functionalisation / treatment / Surface functionalisation / treatment flags	Published F
21			

Other IUCLID harmonised documents (CORE)



- Minor updates
 - Cleaning of redundant fields in Assessment entities documents
 - Summary of toxicological information (change of label)
 - Composition (substance, mixture and product summary)
 - Sponsors
 - Identifiers
 - Sites
 - Guidance on safe use
 - Uses at industrial site
 - Manufacture
 - Acute toxicity endpoint summary

REACH specific documents (EU REACH)



- Application for authorisation of uses: new fields created to store information on the scale of use and the number of sites
- Change of the phase-in scheme for registration of substances: update of phrase groups and dynamic form content
 - Inquiry
 - REACH registration dossier headers
- Clarification of labels for dossier headers for intermediate uses

CLP specific documents (EU CLP)



- Poison Centres notifications 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
- Product information
- SDS information (mixtures)

IUCLID format changes



BPR specific documents (EU BPR)



- New document Degree of dissolution and dilution stability
- Update of the following documents
 - Technical characteristics of Biocidal Product
 - Update of the SPC submission type to include links to sites and suppliers (Cf. IUCLID supports the import of Summary of Products Characteristics .xml files to dossier since version 6.3)
 - Intended uses and exposure
 - Directions for use

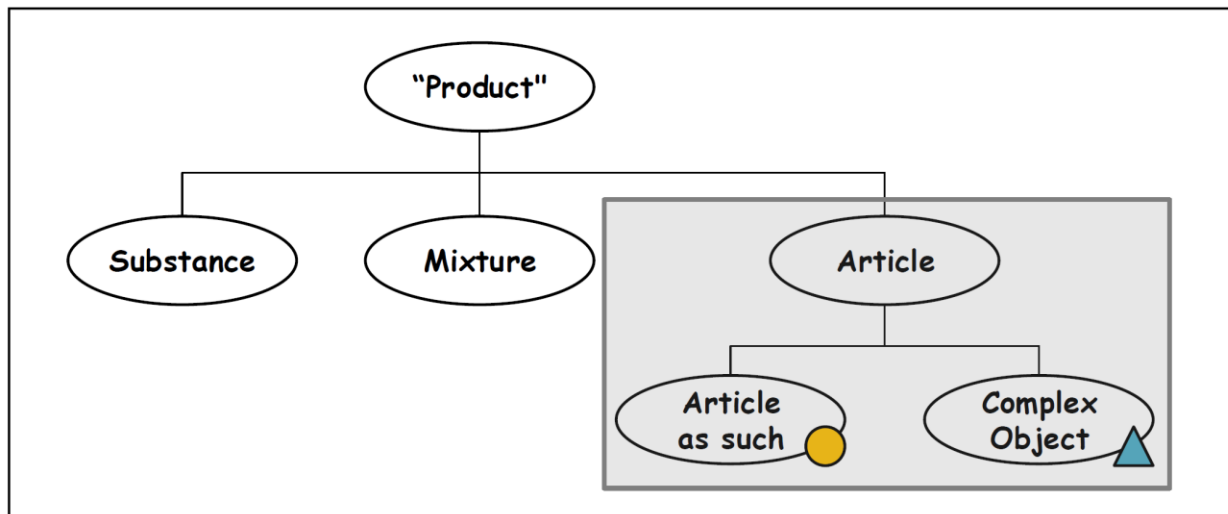
IUCLID format changes



SCIP specific documents (EU SCIP)



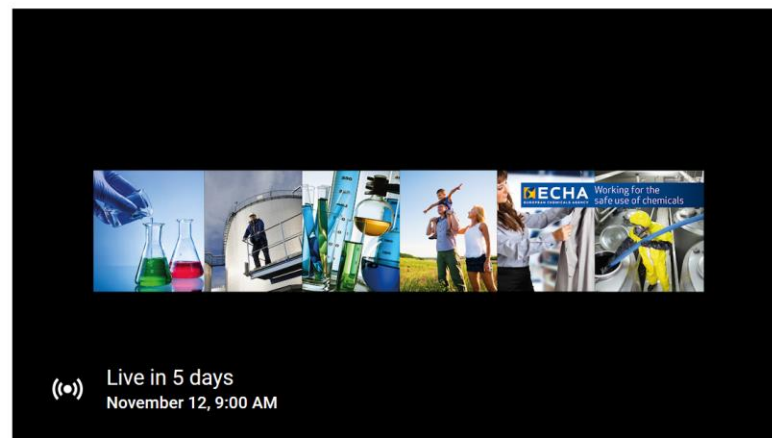
- New definition provider for EU Waste Framework Directive
 - *Article entity (under Domain)*
 - New submission type and dossier header



SCIP database: workshop 12 November

- The workshop consists of plenary presentations and break-out group discussion. The key issues to be covered include:
 - state of play of the project and IT implementation of the SCIP database
 - break-out discussions on efficient notification procedures
 - how to make the data available to waste operators and consumers

Watch live



<https://youtu.be/oU3z1Nc34oI>

Australia specific documents (NICNAS)



- New submission types and associated dossier headers: Chemical certificate applications (several types)

- AICIS Assessment and Evaluation (NAME CHANGE)
- AICIS Certificate Application – Types 1 to 5 (5 NEW)
- Pre-introduction Report (REVISED PROTOTYPE)
- AICIS Commercial Evaluation Authorisation (NEW)

- Pre-introduction report (REVISED PROTOTYPE)
- PBT Assessment – AU (NO CHANGE)
- Information requirements (NEW, for CEA)






- Validation rules for each submission type expanded from 2018 rule set
- New rules identified but not created for v4 to be managed by manual completion checks and included progressively as ECHA priorities allow

New Zealand specific documents (HSNO)



- New definitions provider including the following documents:
 - HSNO Classification
 - Hazardous substance controls
 - Intended pesticide uses
 - Intended exclusive economic zone uses
 - Intended general uses
 - Intended veterinary medicine uses
 - And one submission type 'HSNO Full assessment'

Documentation available

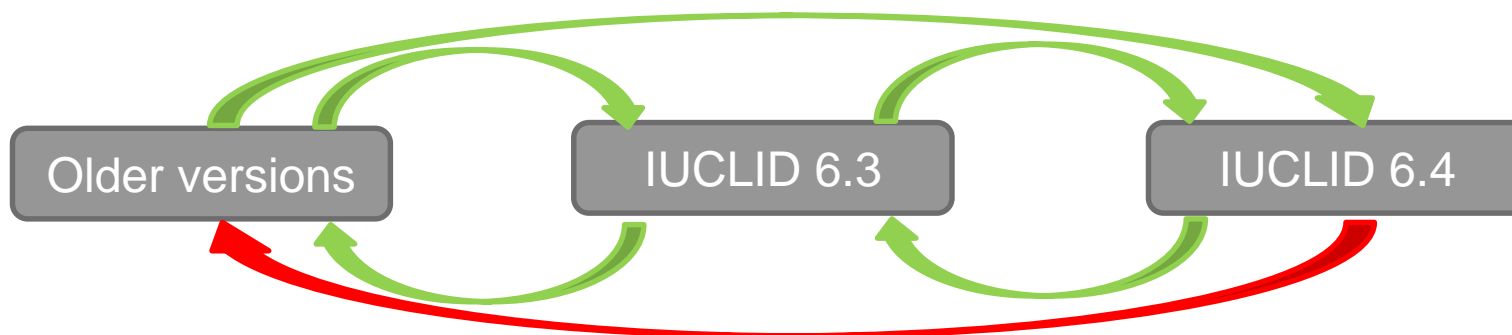
- Format information available @ <https://iuclid6.echa.europa.eu/format>
- Documentation includes
 - .xsd files
 - .doc representation of the format
 - .xls list of all IUCLID fields
 - .xls list of changes compared to previous version
 - Migration rules, in .xml
 - Dynamic content rules, in .xml 
- IUCLID 6.4, published on 30th of October 2019  (.zip | 20.2 MB)
 - More details on the EU Poison Centres Notification format can be found [here](#)
 - The subset of the IUCLID format relevant to **SCIP notifications** can be downloaded from [here](#) (.zip | 689 KB)
 - The **Developpers' guide to the IUCLID format**, created initially for the PCN dossier needs, is a useful source of information to learn more about the structure of IUCLID 'i6z' dossiers.
- IUCLID 6.3, published on 24th of October 2018  (.zip | 16.1 MB)
- IUCLID 6.2, published on 15th of November 2017  (.zip | 15.0 MB)
- IUCLID 6.1, published on 29th of April 2016  (.zip | 14.7 MB)

IUCLID 6 format changes



Compatibility

- **Forward compatibility** provided: all IUCLID 6 files (even IUCLID 5.6) can be imported to the latest version
- **Backward compatibility** offered for the previous major version: export 6.3 files from 6.4
- It is recommended for IUCLID 6.2 users to upgrade to 6.4
- Submission to ECHA can be made with any IUCLID 6 version



Web user interface

What is new in v6.4?



Advanced Settings – Export i6z (dataset, template)



Export Settings
Submission Type: REACH Registration 10 - 100 tonnes

Export to previous major version
☐ [Export to previous major version](#)

Detail level of document fields
☒ Detailed fields (e.g. needed for robust endpoint summaries)
☒ Fields marked "confidential"

Flags for confidentiality
[Select information to be included](#)
☒ Data for which a confidentiality flag may be set, but it is not.
☒ CBI
☒ IP
☒ no PA

Flags for regulatory programme
[Select information to be included](#)
☒ No regulatory purposes
☒ EU: BPD or EU: BPR
☒ EU: CLP
☒ EU: PPP
☒ EU: REACH
☒ CA: CEPA
☒ CA: PCPA
☒ JP: CSCL
☒ OECD: CoCAP
☒ US: EPA HPVC
☒ US: FIFRA
☒ US: TSCA
☒ other:

Included Annotations
☒ [Include annotations](#)

Included Attachments
☒ [Include Attachments](#)

Modification history
☐ [Include modification history](#)

☐ Select documents to be included [Export to i6z](#)

Export to i6z

Create PDF

Export dataset in a format compatible with the previous major version

The main point of the advanced settings is to include or exclude data

- Detail fields, e.g. **details on analytical methods** in *Hydrolysis*
- Fields with 'confidential' in the field label, e.g. **Specific details on test material used for the study (confidential)**
- Confidentiality and Regulatory Programme flags
- Annotations
- Attachments (both inside document and part of the document meta data)
- Modification history

Advanced Settings – Print to PDF (dataset, dossier and templates)



PDF Settings
Submission Type: REACH Registration 10 - 100 tonnes

☒ Include cover page

Included Annotations
☐ Include annotations

Include legal entity
☐ Include legal entity

Detail level of document fields
☒ Detailed fields (e.g. needed for robust endpoint summaries)
☐ Fields marked "confidential"
☐ Include fields with no value

Flags for confidentiality
Select information to be included
☒ Data for which a confidentiality flag may be set, but it is not.
☒ CBI
☒ IP
☒ no PA

Flags for regulatory programme
Select information to be included
☒ No regulatory purposes
☒ EU: BPD or EU: BPR
☒ EU: CLP
☒ EU: PPP
☒ EU: REACH
☒ CA: CEPA
☒ CA: PCPA
☒ JP: CSCL
☒ OECD: CoCAP
☒ US: EPA HPVC
☒ US: FIFRA
☒ US: TSCA
☒ other:

Available when printing from a dataset, dossier, template and their section document

The main point of the advanced settings is to include or exclude data

- Cover page
- Annotations
- Legal entity
- Detail fields, e.g. **details on analytical methods** in *Hydrolysis*
- Fields with 'confidential' in the field label, e.g. **Specific details on test material used for the study (confidential)**
- Confidentiality and Regulatory Programme flags

Advanced Settings – Document selection



Advanced settings

Document selection

Entities

- ☒ REACH Itraining...
- ☒ famprofazone
- ☒ testene
- ☒ myrtecaine
- ☒ formic acid
- ☒ formaldehyde
- ☒ xxxx
- ☒ xxx
- ☒ xxx
- ☒ 2000-580-7
- ☒ guanidinium chlori...
- ☒ REACH training su...
- ☒ 4-isopropyl-1-met...
- ☒ testene
- ☒ 2-[2-(6,6-dimethyl...
- ☒ formic acid / 64-1...

Documents

REACH Itraining substance X

- ☒ 1 General information
 - ☒ 1.2 Composition
 - ☒ LE composition
 - ☒ Composition
 - ☒ 1.3 Identifiers
 - ☒ Identifiers-copy
 - ☒ 1.4 Analytical Information
 - ☒ Analytical Information
 - ☒ 1.7 Suppliers
 - ☒ Suppliers.001-copy
 - ☒ 1.8 Recipients
 - ☒ European Chemicals Agency / Helsinki / Finland-copy
 - ☒ 1.10 Assessment approach (assessment entities)
 - ☒ Assessment approach
- ☒ 2 Classification & Labelling and PBT assessment
 - ☒ 2.1 GHS
 - ☒ GHS.001
 - ☒ 2.2 DSD - DPD
 - ☒ Standard classification-copy
 - ☒ Test composition-copy
 - ☒ 2.3 PBT assessment
 - ☒ PBT assessment-copy
 - ☒ PBT assessment.001-copy

☒ Select documents to be included **Next**

☒ amino(imino)meth... ☒ 2013

Available for

- Dossier creation

Create dossier

- Print to PDF (dataset, template)

Export to i6z

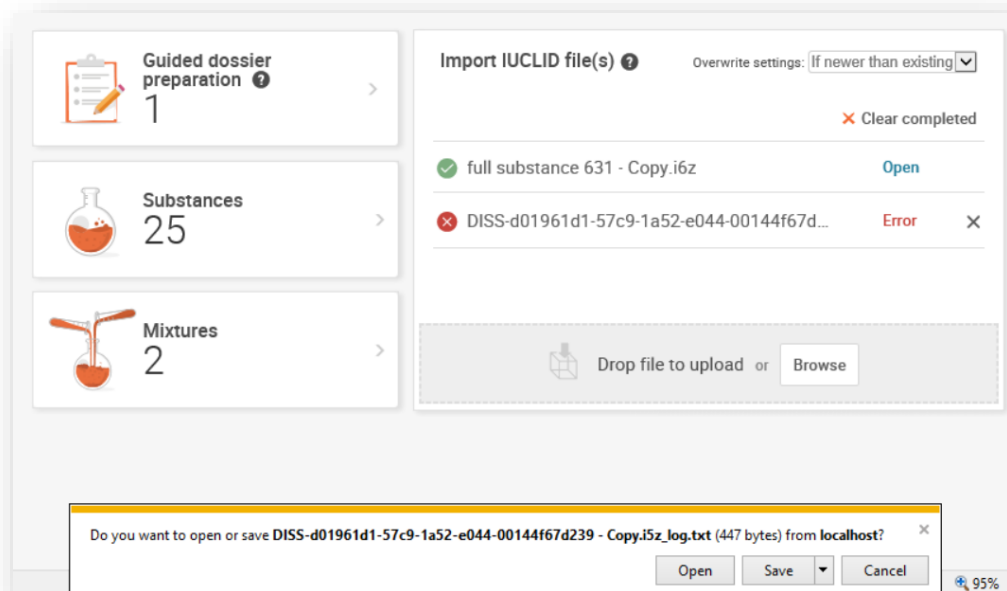
Create PDF

- Export i6z (dataset, template)

Export to i6z

Create PDF

Logs (import/export)



Access the logs to receive an initial indication why there was an error during export or import

The log is a text file (.txt) stating the reason for the error, e.g. the dossier is already existing in the database

```
ddf095a7-a4f0-4a86-851f-35a2f7dd49f9.i6z_log.txt - Notepad
File Edit Format View Help
2019-11-04 11:36:23 - The dossier is already present in the database

2019-11-04 11:36:23 - Started import of file: 319062e2-cc67-488e-b069-02115ff5a5cc_ddf095a7-a4f0-4a86-851f-35a2f7dd49f9.i6z
2019-11-04 11:36:23 - Overwrite mode: IF_NEWER_THAN_EXISTING
2019-11-04 11:36:23 - Dossier already exists in the database (uuid: ddf095a7-a4f0-4a86-851f-35a2f7dd49f9).
2019-11-04 11:36:23 - The dossier is already present in the database
```

Template management



Template view

Create
Edit
Delete
Export (as an i6z file)
Search (by template name)
Print

A Template supports the re-use of IUCLID data between substances and mixtures

Templates can be used:

1) as a read-only Source of data which is referenced by other substances or mixtures

Inherit

2) as a set of data to copy into other substances or mixtures

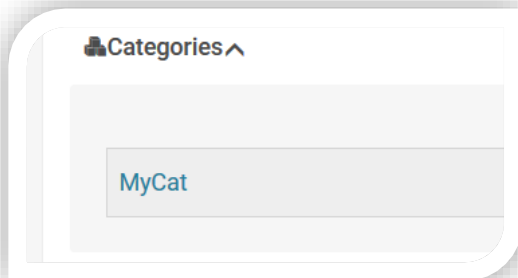
Copy

Substance/Mixture table of contents view

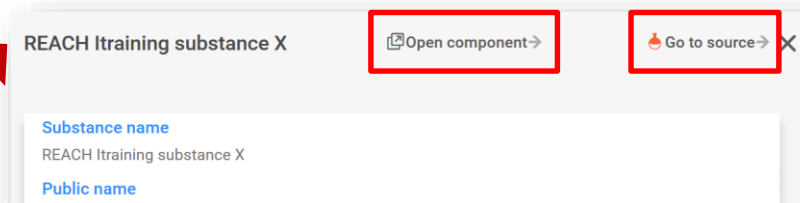
Review Categories in a substance dossier



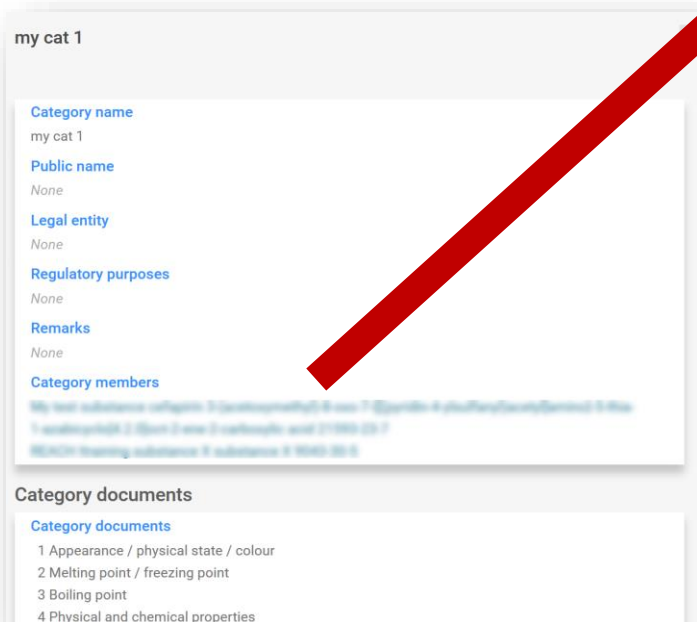
Category view in a substance dossier as currently seen in the TOC



From the category member, open the component (substance section 1.1) or source (substance table of contents)



Open category object



During dossier creation in the web interface, If your substance is a Category member the Category object and other Category substances will be part of the created dossier with the default options automatically applied.


For the default settings, see **section 7.1.2** of the IUCLID functionalities manual (classic version).

Modification history

Full substance dataset modification

1 General information *

1.1 Identification

 **REACH Itraining substance X**
Last Modified:04/11/2019 14:13


Full modification history of a substance dataset is found from the root document, e.g. section 1.1 under a REACH submission type.

- Import (e.g. of dataset)
- Modifications on the dataset
- Creation of a document
- Deletion

Document modification history

7.2 Acute Toxicity *

7.2.1 Acute toxicity: oral *

 **Acute toxicity: oral.001-copy**
Last Modified:04/11/2019 11:09

7.2.2 Acute toxicity: inhalation *

 **Acute toxicity: inhalation.001-copy**
Last Modified:04/11/2019 11:09

Modification history available per document

Identify the change by the modification **date** and the **user** who made the modification

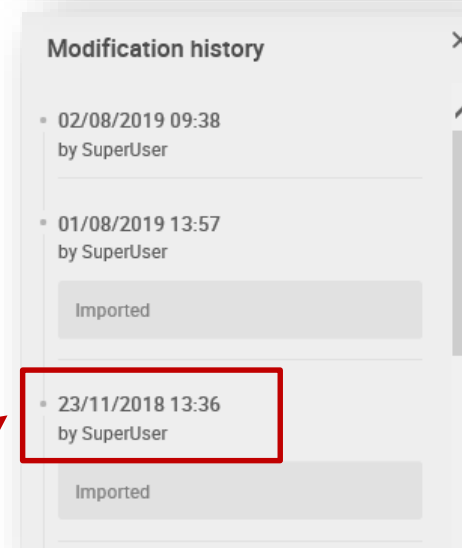
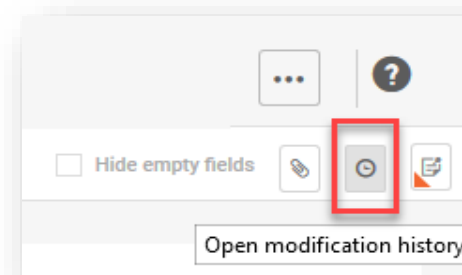


Table view



Tabular layout for easier comparison of information

From Characterisation of nanoforms (Substance composition / 1.2)

Cross-reference + New item		
#	Reason / purpose	Related information
1	other: Other reason goes here Remark on other reason	other toxicological threshold 7 mg/m³ no hazard identified low hazard (no threshold derived) medium hazard (no threshold derived)
2	justification for reporting set of similar nanoforms	NOAEC > 20 mg/L air (nominal)

Add 'New item' to add a row to the table

Hover over the row and it will be highlighted

From Effect levels (P0) (Toxicity to reproduction / 7.8.1)

Effect levels (P0) + New item				
#	Key result	Dose descriptor	Effect level	Based on
1	<input checked="" type="checkbox"/> Key result	NOAEC	78 mg/kg bw/day (actual dose received)	None

Set values ×

☒ **Key result**

Dose descriptor
NOAEC × ▼

Add remark press Esc to close

Effect level
78 mg/kg bw/day (actual dose received)

Based on
None

Sex
male/female

Basis for effect level
☒ other:xxxx

Remarks on result
None

Click on the row you want to edit to change the information in a sliding window.

Flag view (in datasets and templates)



See directly from the IUCLID document what has been flagged as confidential or what is used in a particular regulatory programme

Endpoint study record (OHT) document-level flag

Administrative data



EU: REACH, EU: CLP, CA: CEPA

Endpoint

bulk density

Substance composition degree of purity flag

Degree of purity



EU: REACH

> 95 < 100 % (w/w)

Set Flags

Confidentiality

CBI

Justification

Declaration:
We, [NAME], claim [SHORT SUMMARY OF INFORMATION] confidential in accordance with [RELEVANT REFERENCE TO THE LEGISLATION]).
We, [NAME], hereby declare that, to the best of our knowledge as of today ([DATE]), and in accordance with the due measures of protection that we have implemented, a member of the public should not be able to obtain access to the

2136/32768

Use restricted to selected regulatory programmes

Select/Deselect all

☐ EU: BPD or EU: BPR -[Biocidal Products Directive 98/8/EC or EU: BPR - Biocidal Products Reg...]

☐ EU: CLP-[Classification, Labelling and Packaging]

☐ EU: PPP-[Plant Protection Products Directive 91/414/EEC]

☒ EU: REACH-[Registration, Evaluation and Authorisation of Chemicals]

☐ CA: CEPA-[Existing Substances Program under the Canadian Environmental Protectio...]

☐ CA: PCPA-[Pest Control Products Act]

Dataset / Dossier distinction



Dashboard > Substances

Substances + New substance ?

13 results found

Datasets **Dossiers**

Sort by New

REACH Itraining substance X 07/11/2019 10:46

Inventory number	944-347-4	CAS number	9043-30-5	IUPAC name	substance X
Legal Entity	European Chemicals Agency				

Datasets **Dossiers**

Dataset view (orange/red)

REACH Itraining substance X 07/11/2019 10:46

Inventory number	944-347-4	CAS number	9043-30-5	IUPAC name	substance X
Legal Entity	European Chemicals Agency				

Dossier view (purple)

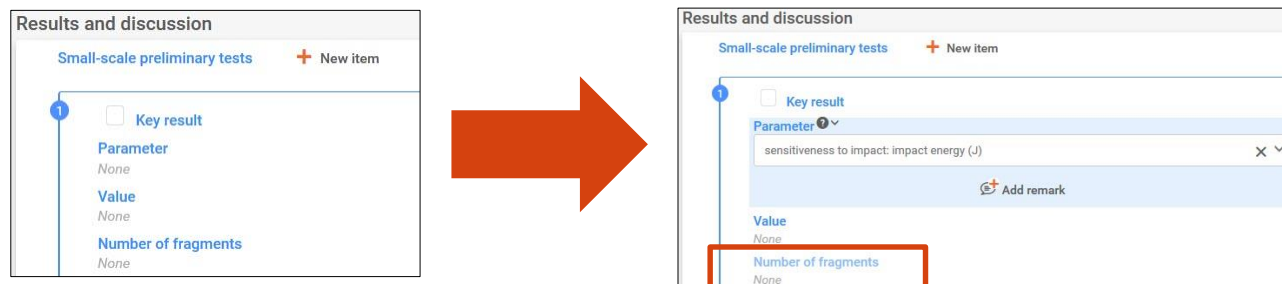
my dossier2 07/11/2019 10:46

Subject name	REACH Itraining substance X / 944-347-4 / substance X / 9043-30-5	Submission type	REACH Registration 10 - 100 tonnes
--------------	---	-----------------	------------------------------------

Dynamic content rules disable or hide certain fields, blocks of fields or picklist values within IUCLID documents based on selection(s) made in other fields within the same document.

Disabled field

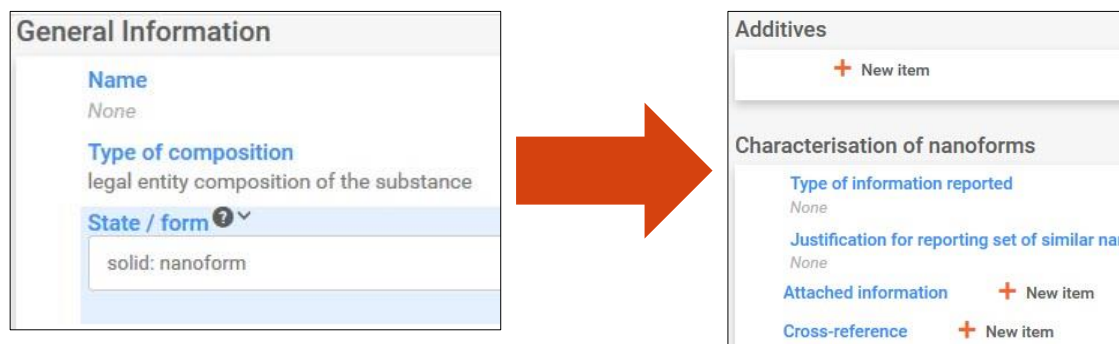
Field 'Number of fragments' is disabled (greyed out) due to the selection in the field 'Parameter':



The diagram illustrates a dynamic content rule. On the left, a screenshot of the 'Results and discussion' section shows a list of fields: 'Key result', 'Parameter' (with value 'None'), 'Value' (with value 'None'), and 'Number of fragments' (with value 'None'). An orange arrow points to the right, where the same section is shown after a selection. The 'Parameter' field now has a value 'sensitiveness to impact: impact energy (J)'. The 'Number of fragments' field is now greyed out and its value is 'None', indicating it is disabled.

Show/hide block of fields

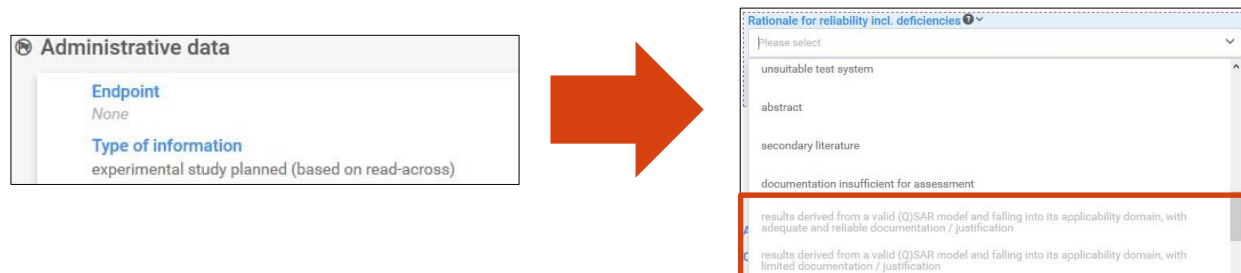
Block of fields 'Characterisation of nanoforms' is shown only if the 'solid: nanoform' value is selected in the field "State / form":



The diagram illustrates a dynamic content rule. On the left, a screenshot of the 'General Information' section shows the 'State / form' field with the value 'solid: nanoform'. An orange arrow points to the right, where the same section is shown after the selection. The 'Characterisation of nanoforms' block is now visible, containing fields like 'Type of information reported', 'Justification for reporting set of similar nan', 'Attached information', and 'Cross-reference'.

Disabled picklist value

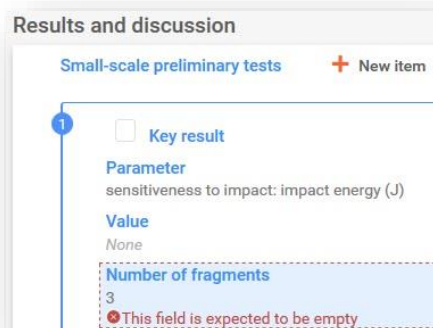
Based on the selection made in the field 'Type of information', some of the picklist values in the field 'Rationale for reliability incl. deficiencies' cannot be selected (greyed out):



The image shows two screenshots connected by a large orange arrow. The left screenshot shows the 'Administrative data' section with 'Endpoint' set to 'None' and 'Type of information' set to 'experimental study planned (based on read-across)'. The right screenshot shows the 'Rationale for reliability incl. deficiencies' picklist. It contains several options: 'unsuitable test system', 'abstract', 'secondary literature', 'documentation insufficient for assessment', and two options related to Q/SAR models. The two Q/SAR model options are greyed out, indicating they are disabled based on the selection in the 'Type of information' field.

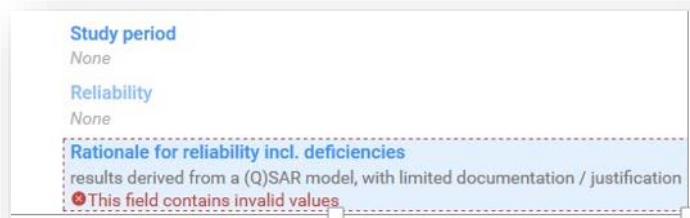
Warning messages (empty and invalid)

Field 'Number of fragments' has to be empty due to selection in the field 'Parameter'. User is not allowed to save the document until **the text field** is empty:



The image shows the 'Results and discussion' section. Under 'Small-scale preliminary tests', there is a 'Key result' entry. The 'Parameter' is 'sensitiveness to impact: impact energy (J)' and the 'Value' is 'None'. The 'Number of fragments' field is highlighted with a dashed border and contains the value '3'. A red warning message is displayed below the field: 'This field is expected to be empty'.

Picklist value that should be disabled is selected. User is not allowed to save the document until a valid value is selected:



The image shows the 'Study period' and 'Reliability' sections. 'Study period' is set to 'None' and 'Reliability' is set to 'None'. The 'Rationale for reliability incl. deficiencies' picklist is highlighted with a dashed border and contains the value 'results derived from a (Q)SAR model, with limited documentation / justification'. A red warning message is displayed below the picklist: 'This field contains invalid values'.

Web interface

Plans for 2020



Managing data

- Inventory management (create, update, delete, **export**, print)
- Managing category objects

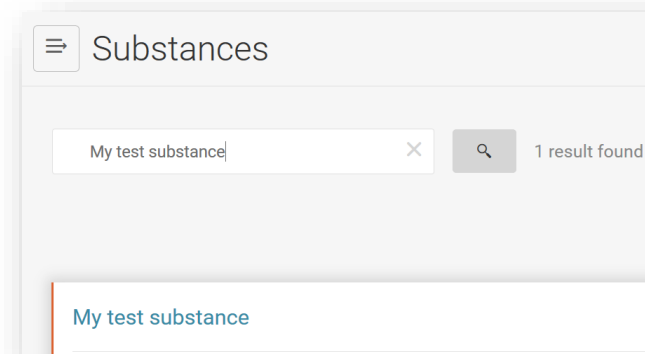


IUCLID search

- Extend search capabilities

Navigation

- Improve the IUCLID table of contents to accommodate complex and hierarchical datasets (SCIP / PCN / BPR)
- Section navigation within a document



Navigation continued ...

- Inbound/outbound references (navigate through referenced IUCLID documents and entities)

Example reference links from a reference substance

User management

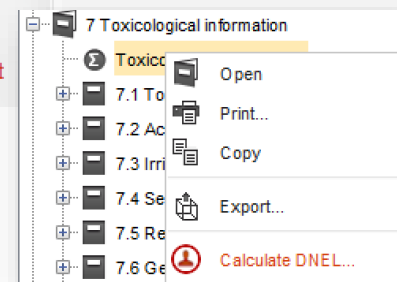
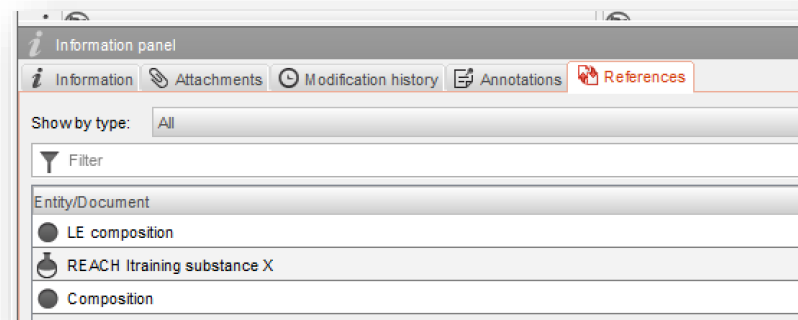
- Full User/Role/Group management and profile settings

Advanced calculation tools

- DNEL and PNEC calculator

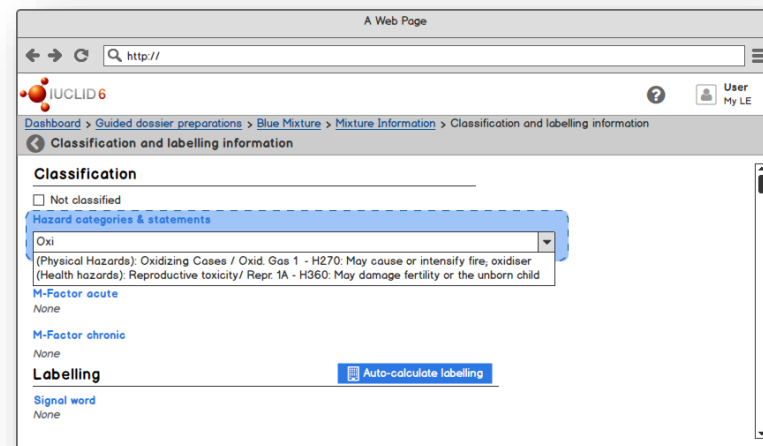
Performance

- Continue to analyse and where possible, improve the performance of the web interface



Data entry (new GHS document view)

- Simplified and more user-friendly view of C&L information
- C&L selector to assist you in building your classification categories and associated hazard statements
- Labelling calculator based on C&L selection



A Web Page

← → ↻ http://

IUCLID 6 ? User My LE

Dashboard > Guided dossier preparations > Blue Mixture > Mixture Information > Classification and labelling information

Classification and labelling information

Classification

☐ Not classified

Hazard categories & statements

Oxi

(Physical Hazards): Oxidizing Cases / Oxid. Gas 1 - H270: May cause or intensify fire, oxidiser
(Health hazards): Reproductive toxicity/ Repr. 1A - H360: May damage fertility or the unborn child

M-Factor acute

None

M-Factor chronic

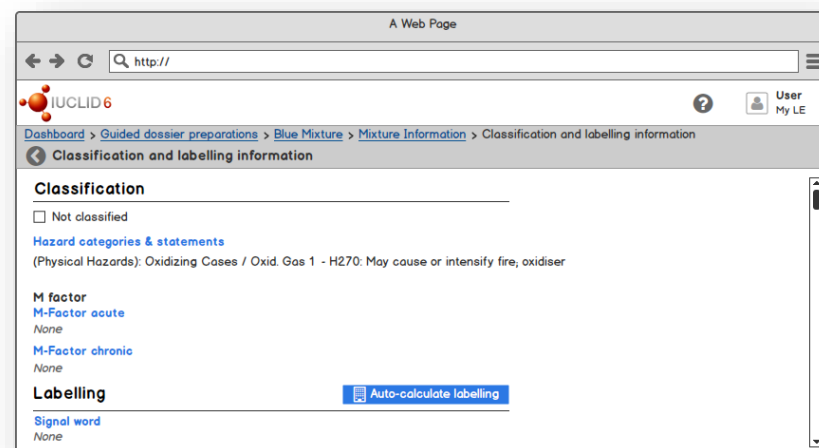
None

Labelling [Auto-calculate labelling](#)

Signal word

None

! Mock-ups of the C&L selector – implementation and interface may differ slightly !



A Web Page

← → ↻ http://

IUCLID 6 ? User My LE

Dashboard > Guided dossier preparations > Blue Mixture > Mixture Information > Classification and labelling information

Classification and labelling information

Classification

☐ Not classified

Hazard categories & statements

(Physical Hazards): Oxidizing Cases / Oxid. Gas 1 - H270: May cause or intensify fire, oxidiser

M factor

M-Factor acute

None

M-Factor chronic

None

Labelling [Auto-calculate labelling](#)

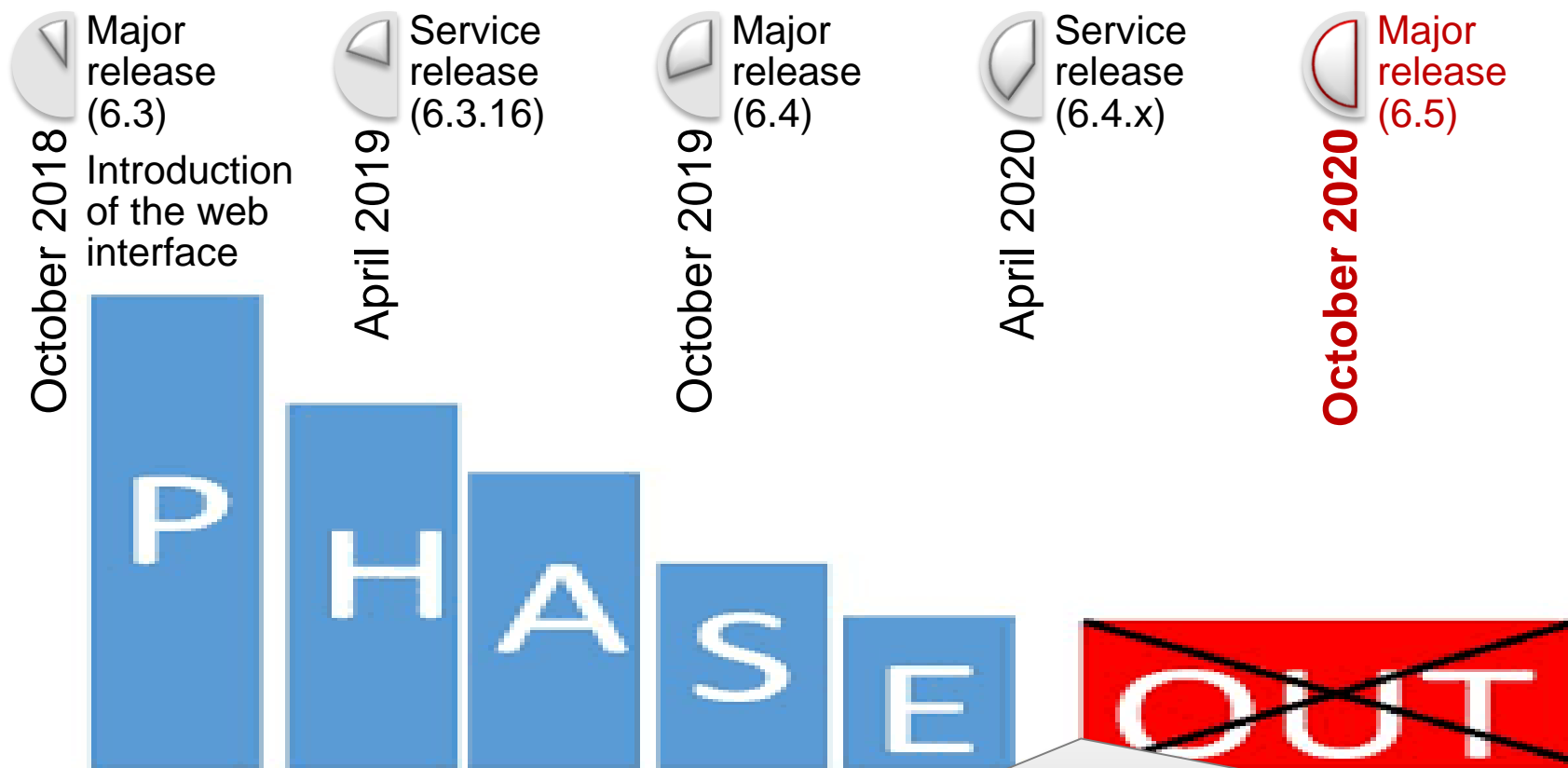
Signal word

None

Replacing the classic interface



Transition to one user interface (public releases)



We will continue to monitor the use of the web interface in order to plan the phasing-out of the classic interface together with different IUCLID users



You can continue to send your questions during the next 5 minutes



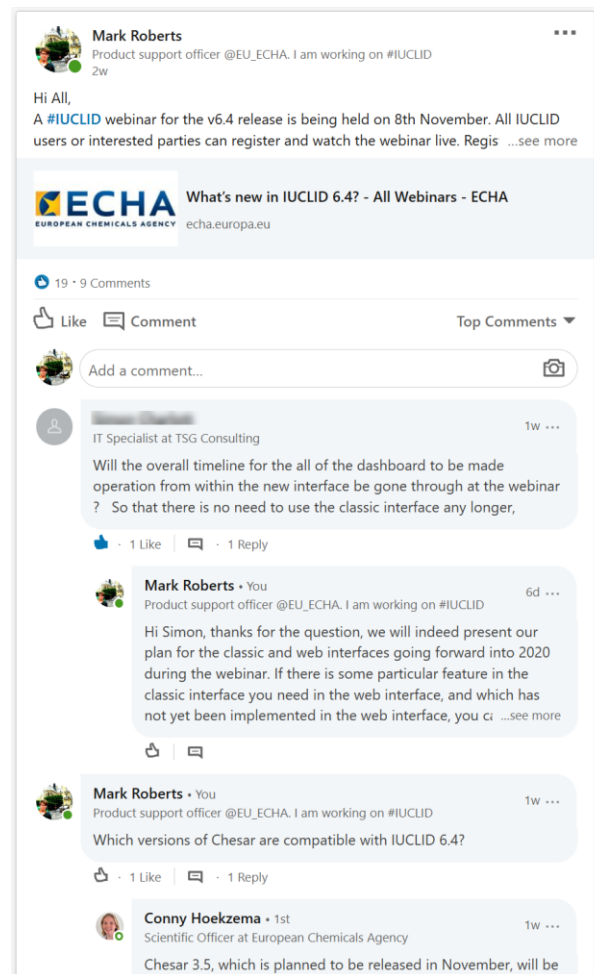
Release of IUCLID 6.3



LinkedIn group

<https://www.linkedin.com/groups/12043483/>

- Information channel on IUCLID-related news
- You can request to join if you have a LinkedIn account
- We asked you to provide some pre-webinar questions:
 - Chesar 3.5/3.4 compatibility
 - Backwards migration to v6.3
 - Future of classic interface

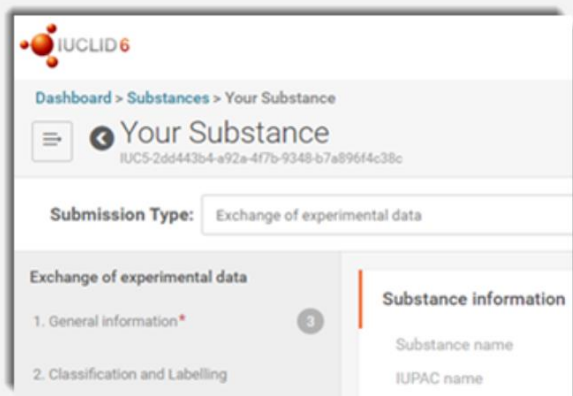


Before ending the webinar



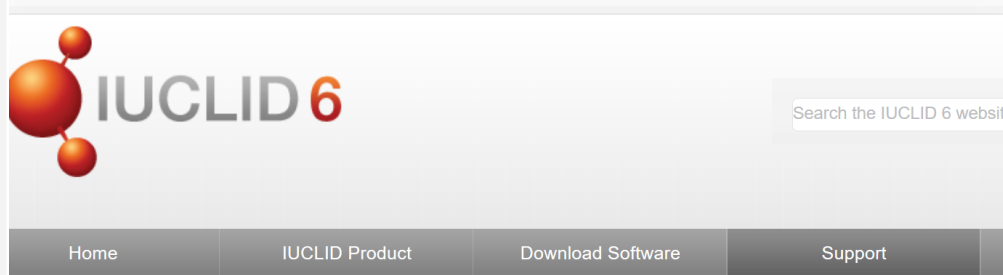
New IUCLID webpage

To learn about the new interface, click on the image.



► Download IUCLID

<https://iuclid6.echa.europa.eu/web/iuclid/learn-to-use-the-new-interface>



Home > Support > Documentation > Learn to use the new interface

Navigation

Documentation

- System requirements
- Videotutorials
- Training material
- Webinars
- Verification of downloads
- Learn to use the new interface

Learn to use the new interface

A new web user interface is being phased in for all distributions of the IUCLID software Cloud. We recommend that IUCLID users become familiar with the new interface as soon as possible.

To support the IUCLID user community during the transition, this webpage provides training material specifically to help you get familiar with using the web user interface. Whether you are a new user or a user of the 'classic' user interface, this webpage will help you understand what features the new web interface has, how to use them, and how to navigate and search in the new interface.

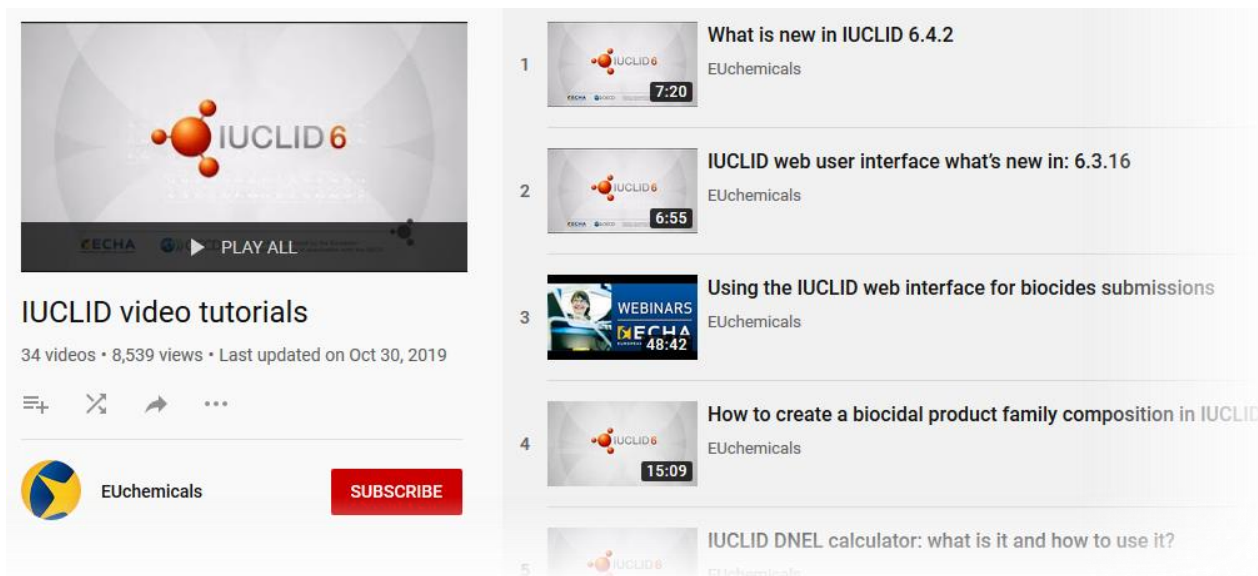
Install the latest version of IUCLID which includes the web interface from [here](#). Alternatively, you can use the [IUCLID Cloud](#) to use the web interface if you are submitting dossiers under the REACH regulation.

Video tutorials

- Please check our video tutorials on the YouTube playlist
 - **What is new in IUCLID 6.4.2**
 - Install IUCLID 6
 - Update IUCLID 6
 - Run the Validation Assistant
 - IUCLID Cloud videos ...



<https://www.youtube.com/playlist?list=PLOGDACSd6qyDkdXwPua1Fjb5bJksY75k>



IUCLID video tutorials
34 videos • 8,539 views • Last updated on Oct 30, 2019

EuChemicals **SUBSCRIBE**

- 1 What is new in IUCLID 6.4.2
EuChemicals 7:20
- 2 IUCLID web user interface what's new in: 6.3.16
EuChemicals 6:55
- 3 Using the IUCLID web interface for biocides submissions
EuChemicals 48:42
- 4 How to create a biocidal product family composition in IUCLID
EuChemicals 15:09
- 5 IUCLID DNEL calculator: what is it and how to use it?
EuChemicals

Getting ready for revised REACH information requirements for nanoforms

- 12 November 2019 / 11:00 - 13:30 EET, GMT +2

Updated REACH Annexes for the nanoforms of substances begin to apply as of 1 January 2020. The updated Annexes introduce new concepts: nanoform and a set of similar nanoforms. The updated REACH Annex VI also defines specific characterisation parameters for the nanoforms of substances.

The first part of this webinar explains what a nanoform is and how to build a set of similar nanoforms. It also explains how to fulfil data requirements for the characterisation of nanoforms. The second part introduces new IUCLID fields for reporting the characterisation parameters of nanoforms and gives some practical examples on how to use the different fields. You will also have the chance to ask questions from our experts.

- <https://echa.webex.com/echa/onstage/g.php?MTID=e8fdc774cd838c4fed187236f63507ae5>

SCIP workshop

- 12 November 2019

The workshop consists of plenary presentations and break-out group discussions; more details can be found in the draft programme. The key issues to be covered include:

- state of play of the project and IT implementation of the SCIP database;
- break-out discussions on efficient notification procedures; and
- how to make the data available to waste operators and consumers.

- Watch live: <https://youtu.be/oU3z1Nc34oI>



Thank you for your participation

echa.eu

iuclid6.echa.europa.eu

oecd.org/ehs/templates



IUCLID 6 is developed by the European Chemicals Agency in association with the OECD

