IUCLID 6

Release notes

Version 1.0.0

29/4/2016
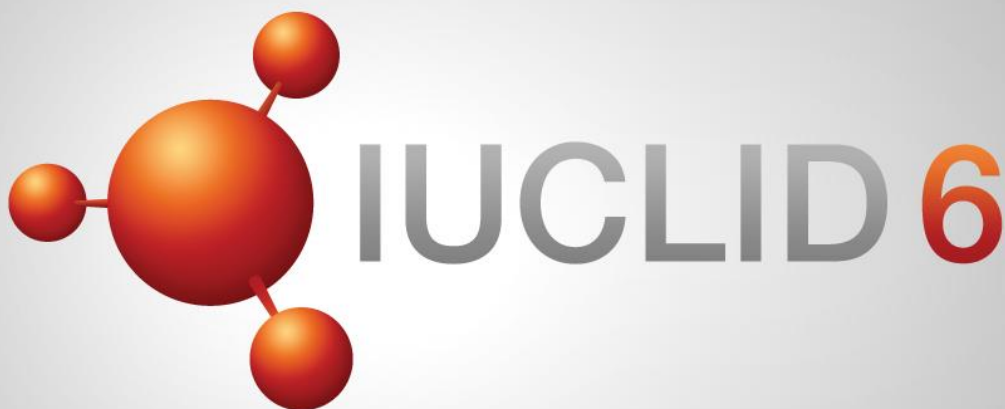
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1.   VERSION 1.0.0 (29 APRIL 2016)

Please also refer to the [Frequently Asked Questions](#) on the IUCLID 6 website.

1.1. IUCLID legislations

IUCLID legislations are a new concept introduced in IUCLID 6. The IUCLID database allows storing data according to different entry forms. The content of these forms is managed differently whether they are used by all IUCLID users (CORE legislation) or within the context of a regulation (e.g., REACH Regulation data entry forms are managed in the REACH legislation).

The list of entry forms belonging to each IUCLID legislation is published on the IUCLID 6 website:

http://iuclid6.echa.europa.eu/web/iuclid/documentation

1.1.1. CORE (version 2.25)

IUCLID CORE contains the main documents of IUCLID such as the substance identification, the classification and labelling information or the endpoint summaries.

1.1.2. OECD (version 2.20)

OECD contains the set of [documents harmonised at the OECD](#) level to report studies done on chemicals to determine their properties or effects on human health and the environment.

1.1.3. REACH (version 2.5)

REACH contains the specific documents used for the REACH Regulation, such as the inquiry or the opt-out information.

1.1.4. CLP (version 2.5)

CLP contains the specific documents used for the CLP Regulation.

1.1.5. BPR (version 2.6)

BPR contains the specific documents used for the Biocidal Products Regulation.

1.2. IUCLID functionalities

1.2.1. Annotations

- (IUCVI-8905) Import of IUCLID 5 files containing only annotations is not possible in IUCLID 6. The annotations should be exported with their parent documents from IUCLID 5 in order to be migrated during the import to IUCLID 6.

1.2.2. Assessment entities

- (IUCVI-9005) Assessment Entity for "(group) of constituent" should retrieve only the list of reference substances available in the substance current substance dataset. Currently all available reference substances are listed and IUCLID displays an error message if an incorrect reference substance is selected.

1.2.3. Clipboard manager

- (IUCVI-8989 & IUCVI-6957) The clipboard manager content should be updated in case a document is deleted.

1.2.4. Documents management

- (IUCVI-8994) In IUCLID 5, the data entry forms were differentiating between 'Basic' and 'Details' fields. This was used to filter the content of the documents in the User Interface and to filter the content of the datasets during export and dossier creation. This option is not yet available.
- (IUCVI-8747) Changes without saving can cause an error if the user wants to delete a record.
- (IUCVI-8409) The content of rich-text area cannot be copied using Ctrl+C.

1.2.5. Dossier

- (IUCVI-8946) "Go to link target" in Inventory number field of a reference substance is not available when the reference substance is included in a dossier.
- (IUCVI-8923) The export option should not be activated for single documents in a dossier.
- (IUCVI-9028) When creating a dossier from a mixture / product linking to itself via a composition document, it is not possible to create a dossier of type 'BPR active substance application).

1.2.6. Export

- (IUCVI-8983) Steps to reproduce: login as IUCLID 6 user; find a substance; export the substance; open "Background Jobs"; find the background job related to the export of the substance; click on "Report"; click on "Details" tab; try to edit a UUID or Last modified date by double clicking. An error is reported.

1.2.7. Migration

- (IUCVI-8642) Error in migration tool when the user selects "Previous" when the migration process has already started.

1.2.8. Printing

- (IUCVI-8981) An error appear if the user deletes a substance that is being printed.

1.2.9. User interface

- (IUCVI-2421) User interface issues appear when the IUCLID client is used under a Linux environment (e.g., icons are not available).
- (IUCVI-8974) Sections in tabs, like in section 3.5, are not collapsed automatically if the user has chosen this option in his preferences.

1.2.10.   User management

- (IUCVI-8802) Login fails when the user has a password containing only spaces.

1.2.11.   Search

- (IUCVI-8965) Search by dossier template: BPR mixture dossier types are missing.
- (IUCVI-8823) Search for substance by reference substance using the criterion 'Synonyms' is not working.
- (IUCVI-8424) Search mixture/product by synonyms does not work.
- The advanced search module is not available.

1.3. IUCLID modules

1.3.1. Validation assistant

The Validation assistant contains:

- All automated completeness check (TCC) rules; please note that the Validation assistant does not predict the manual verification checks performed by ECHA during completeness check.
- Those business rules (BR) that rely on IUCLID data only. Business rules that depend on information from the ECHA database (e.g. submission history) are not included in the Validation assistant.

Validation is supported on both dossiers and substance datasets.

Future versions of the Validation assistant will include quality checks to support users in improving consistent reporting of information.

Disclaimer: The Validation assistant simulates the submission checks carried out by ECHA as far as possible. The responsibility remains with the submitter to ensure that their dossier fulfils all the relevant legal requirements.

1.3.2. Report generator

The Report generator in IUCLID 6 allows the user to generate reports based on data stored in a IUCLID 6 dataset or dossier.

1.3.2.1. *Chemical Safety Report*

This section of the Release notes relates to the generation of the Chemical Safety Report (CSR) using the Report generator.

1.3.2.1.1. Changes compared to previous version

In these release notes, we highlight the changes compared to the previous version of the CSR generated by IUCLID 5:

1.3.2.1.1.1. *General*

- The information in Part A should be provided in section 13 of IUCLID before proceeding with the generation of the CSR
- The creation of a Joint or Own CSR is now defined in section 13 of IUCLID. This section includes the picklist options "all uses" "own CSR" or "joint CSR" which trigger the corresponding CSR generation type

- Information triggered from the CSR report generator has been updated according to the new IUCLID format
- Table numbers are numbered according to the related chapter and not consecutively as in the previous versions of the CSR generator

1.3.2.1.1.2.   Chapter 1

- Nanomaterial information has been added to the CSR

1.3.2.1.1.3.   Chapter 2

- Changes have been made to the layout of the tables related to all uses so as to better accommodate the new information captured from IUCLID

1.3.2.1.1.4.   Chapter 3

- Classification and labelling according to DSD/DPD has been removed from the generated CSR

1.3.2.1.1.5.   Chapter 9 and 10

- No information is available in these sections besides the Chapter headers

1.3.2.1.2.   Known issues and areas for improvement

During our testing we have collected a list of known issues and improvements requested by users that will be taken into account in the next version(s) of the CSR generator. They are identified below.

1.3.2.1.2.1.   General

- Labels are always printed in the CSR even if no information is available in the corresponding IUCLID fields. This leads to an increased number of pages in the CSR.
- Remarks are generally indicated in parenthesis. However in cases where no "remarks" have been provided in IUCLID the opening and closing parentheses are always printed as (). For example in the result tables the following may be printed "LD50: >5000 mg/kg bw (male/female) based on: () ()"
- Assessment entities are not currently taken into consideration for the generation of the CSR.
- Rich-text field issues:
    - Currently, when a table is created or pasted into a rich-text field in IUCLID, it may not be correctly displayed in the CSR
    - When text is numbered using the [1,2] button, the numbering is not sequential, with each number remaining as "1."
    - Not all changes to the font in a rich-text field are reflected in the generated CSR, affecting for example the display of the font size and style

1.3.2.1.2.2.   Table of Content (TOC)

- Page numbers are not available in the TOC. To get the page numbers, please press the

following "CTRL+ a and F9"

1.3.2.1.2.3.   Chapter 1:

- EC name information is missing in Table 1. Substance identity
- CAS number (EC inventory) information is missing in Table 1. Substance identity
- Structural formula image is missing from chapter 1.1. "Name and other identifiers of the substance"
- The Characterisation of a nanomaterial in all compositions is wrongly appearing when no information is available in the fields

1.3.2.1.2.4.   Chapter 2

- ERC description in all Contributing activity/technique for the environment is not displayed in the text
- PROC description in all Contributing activity/technique for the environment is not displayed in the text
- SU 0, AC02 and AC0 are not printed if the corresponding free text field is not populated. However, when the text field beside them is populated, this free text is correctly transferred to the CSR

1.3.2.1.2.5.   Chapter 3

- The CSR currently prints all classification tables' headers when no corresponding classification is available in IUCLID
- Currently, no pictogram images are available in the CSR

1.3.2.1.2.6.   Chapter 4

- The "Justification for classification or non-classification" in section 4.14 "Explosiveness", 4.15 "Flammability" and 4.16 "Oxidising properties" are not transferred to the corresponding section in the CSR (6.1 Explosivity, 6.2 Flammability, 6.3 Oxidising potential)

1.3.2.1.2.7.   Chapter 5

- The studies in the results table are not sorted according to the "Species", "Type of study", "Endpoint", "Type of genotoxicity" or "Route of administration"
- Skin irritation /corrosion: only the studies having "Category 1 (corrosive) based on GHS criteria", " Category 1A (corrosive) based on GHS criteria", "Category 1B (corrosive) based on GHS criteria", " Category 1C (corrosive) based on GHS criteria" selected in the "interpretation of results" field, are reported in the CSR
- Eye irritation: only the studies having "Category 1 (irreversible effects on the eye) based on GHS criteria", "Category 2 (irritating to eyes) based on GHS criteria", "Category 2A (irritating to eyes) based on GHS criteria", "Category 2B (mildly irritating to eyes) based on GHS criteria" selected in the "interpretation of results" field, are reported in the CSR

1.3.2.1.2.8.   Annexes

- References: All references mentioned in the CSR are reported in the first Annex named

"References" and ordered according to how they appear in the CSR. The references are not ordered alphabetically

- Test material information: currently the indication of which endpoint study the test material is linked to, is missing

1.3.3. Dissemination preview

Known issues:

- Filtering of dossiers containing categories: inherited templates linked to category member substances other than the registered substance are not filtered correctly. Documents in such templates should be removed by the Dissemination preview, and will not be published on the website.

IUCLID sections for which filtering is not supported in this version (i.e. the dissemination preview will not remove any data in the following sections):

- Section 3.5: Use and exposure information
- Section 3.6: Uses advised against
- Section 4.28: OECD harmonised templates on 'Additional physico-chemical properties of nanomaterials'

1.3.4. Fee calculation

The Fee calculation plug-in is not available in IUCLID 6 yet.

1.3.5. Help system

The IUCLID 6 Help System is intended to enable any user to learn how to use IUCLID 6 without having to refer to the IUCLID Helpdesk, or to seek additional training. It serves as a complete reference manual for all IUCLID 6 features, functions, and options. It is integrated in to the application itself, with access being provided via links in the user interface, and by pressing the function key F1.

The reference manual for all IUCLID 6 features, functions, and options can also be downloaded in .pdf format and is available in different languages from the IUCLID 6 website.

In addition, the Help System integrated in IUCLID 6 also includes manuals on how to use the application for regulatory purposes, including help on entering data into Substance datasets.

1.3.5.1.   Known issues

- (IUCVI-8962) When the user selects the option to print, the Print dialog should appear allowing the user to proceed with the printing process. Instead, it has been reported in some cases that no Print dialog appears, and no print activity is indicated to the user. Furthermore, an error appears in IUCLID.

- (IUCVI-8028) Steps to reproduce the issue: open the Help System: Press F1 or from menu select Help -> Help; expand section "Functionalities of IUCLID 6" in the tree view pane; double-click on "Changes to this document"; double-click on "9.... Legal entity site". The highlighted selection changes from "9.... Legal entity site" back to "Changes to this document", instead of remaining on the currently selected topic. This erratic behaviour occurs to all topics/sub-topics within the "Functionalities of IUCLID6" section.

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