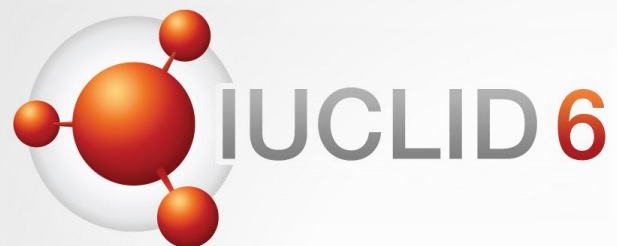


IUCLID 6





IUCLID 6 webinar

Version 1.2 release

2 February 2017 / 12:00-13:00 EET

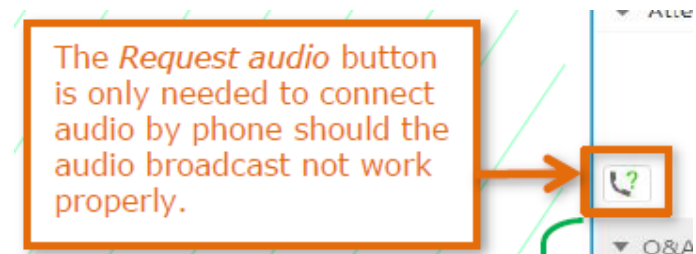
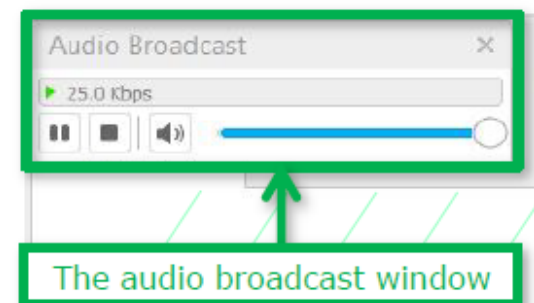


IUCLID 6 is developed by the European
Chemicals Agency in association with the OECD



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



Agenda for today

| What? | Who? | When? |
|--|--------------------------|-------------|
| Welcome and introduction | François Le Goff | 12pm (EEST) |
| Information on IUCLID 6 version 1.2 <ul style="list-style-type: none">Fixes for known issuesImprovements and new features | | |
| DNEL calculator | Jesus Vazquez Rodriguez | |
| Report generator | Mark Roberts | |
| Practical tips for REACH registrants | Tamás Salamon | |
| Sending additional questions | All participants | 5 minutes |
| Questions and Answers session | All participants ECHA | Until 13:00 |

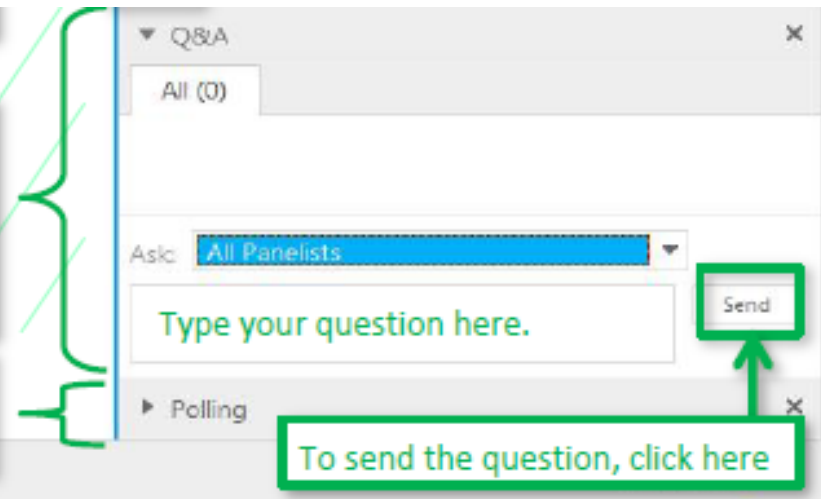
The Q&A panel

- You can post your questions during the entire webinar
- Answers will be given during the webinar and also provided in written form after the event
- Before the Q&A session 5 minutes will be left to send additional questions

The Q&A panel

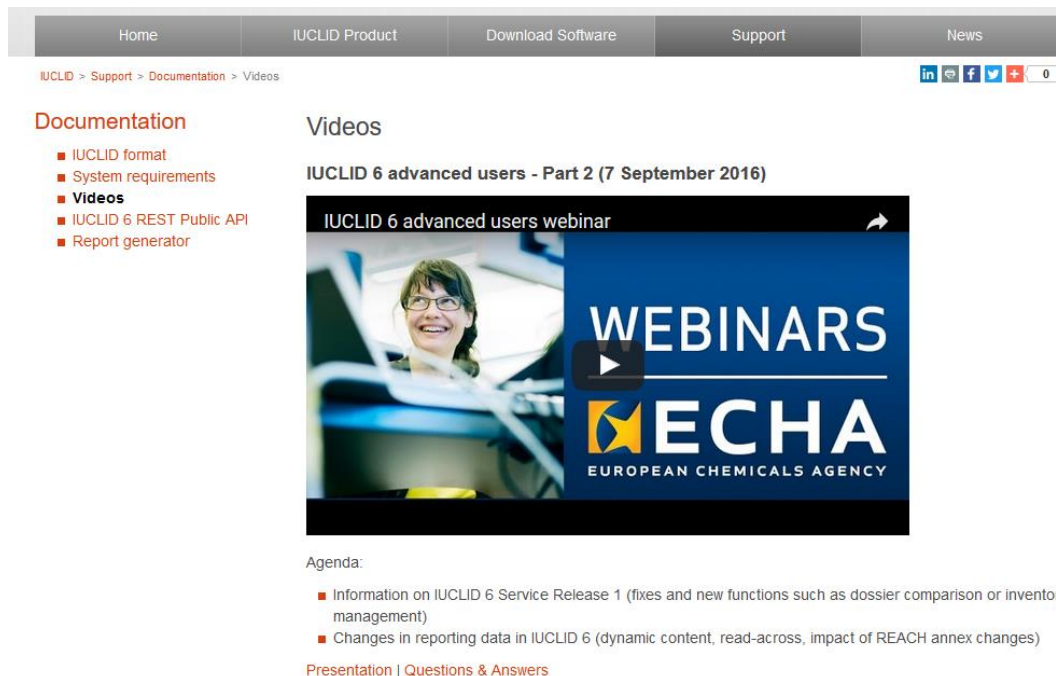
You can send questions during and after the presentations to the panellists, using the Q&A panel
To send a question, select *All panelists* from the drop down menu, write your question in the lower box, and finally click *Send*.

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



Recordings

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



Home IUCLID Product Download Software Support News

IUCLID > Support > Documentation > Videos

Documentation

- IUCLID format
- System requirements
- **Videos**
- IUCLID 6 REST Public API
- Report generator

Videos

IUCLID 6 advanced users - Part 2 (7 September 2016)

IUCLID 6 advanced users webinar

WEBINARS

ECHA
EUROPEAN CHEMICALS AGENCY

Agenda:

- Information on IUCLID 6 Service Release 1 (fixes and new functions such as dossier comparison or inventory management)
- Changes in reporting data in IUCLID 6 (dynamic content, read-across, impact of REACH annex changes)

Presentation | Questions & Answers

IUCLID 6 updates

Service Release 2

- Fixes and improvements
- Hyperlinks
- Public API



Version 1.2.0

IUCLID > News > IUCLID news

IUCLID news

31/01/2017

IUCLID 6 version 1.2.0 is available

A new service release for IUCLID is available. In addition to improvements and features: IUCLID hyperlinks, a DNEL calculator and a public API.

A new service release for IUCLID is available. In addition to improvements and fixes in

1. IUCLID **hyperlinks** are a convenient way for users to refer to IUCLID information
2. A **DNEL calculator** is now available in order to help in the derivation of Workers long-term systemic effects for oral, dermal and inhalation routes based on ECHA C the State Secretariat for Economic Affairs (SECO) from the Swiss Confederation.
3. The first version of the IUCLID 6 **Public API** can be used with the Desktop and Serv applications. More information is available for developers under 'Support \ Docum

This new version is compatible with previous IUCLID 6 versions. For more details about attend the webinar on Thursday 2nd of February 2017. A link to register is available bel

[Download IUCLID 6](#) | [Release notes](#) | [Public API](#) | [Release presentation webinar](#)

- The installation of the new version is recommended (but optional)
- Full compatibility with previous IUCLID 6 versions
- IUCLID 5.6 files can still be imported

Version 1.2.0

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| 1.4. Clipboard manager | 4 |
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| 1.6. DNEL generator (NEW) ← | 5 |
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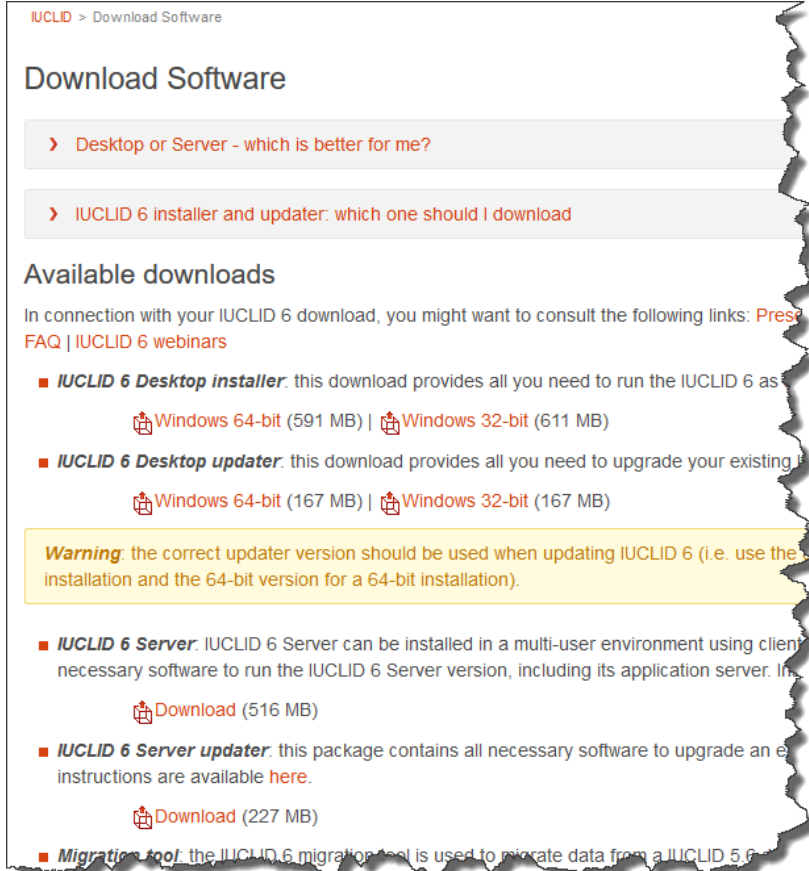
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[Download IUCLID 6](#) | [Release notes](#) | [Public API](#) | [Release presentation webinar](#)

Downloads

- Download page on the IUCLID 6 website updated
- Desktop installer is available for 32-bit and 64-bit (**Warning**: use the correct version to update existing installations)
- Migration tool and Database patch tool are still available although no changes were made compared to previous versions (*to be used only for new IUCLID 6 installations in order to migrate IUCLID 5 data*)



IUCLID > Download Software

Download Software

- › Desktop or Server - which is better for me?
- › IUCLID 6 installer and updater: which one should I download

Available downloads

In connection with your IUCLID 6 download, you might want to consult the following links: [Press? FAQ](#) | [IUCLID 6 webinars](#)

- **IUCLID 6 Desktop installer**: this download provides all you need to run the IUCLID 6 as a desktop application.
[Windows 64-bit \(591 MB\)](#) | [Windows 32-bit \(611 MB\)](#)
- **IUCLID 6 Desktop updater**: this download provides all you need to upgrade your existing IUCLID 6 desktop installation.
[Windows 64-bit \(167 MB\)](#) | [Windows 32-bit \(167 MB\)](#)

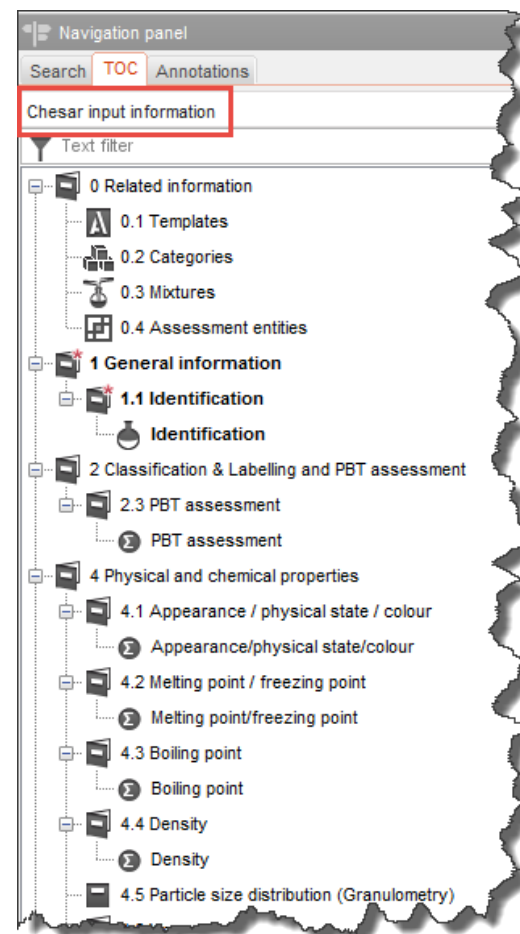
Warning: the correct updater version should be used when updating IUCLID 6 (i.e. use the 32-bit version for a 32-bit installation and the 64-bit version for a 64-bit installation).

- **IUCLID 6 Server**: IUCLID 6 Server can be installed in a multi-user environment using client and server software. This download provides the necessary software to run the IUCLID 6 Server version, including its application server. In order to install IUCLID 6 Server, please refer to the [IUCLID 6 Server installation instructions](#).
[Download \(516 MB\)](#)
- **IUCLID 6 Server updater**: this package contains all necessary software to upgrade an existing IUCLID 6 Server installation. For more information, the instructions are available [here](#).
[Download \(227 MB\)](#)
- **Migration tool**: the IUCLID 6 migration tool is used to migrate data from a IUCLID 5.6 installation to a IUCLID 6 installation. For more information, the instructions are available [here](#).

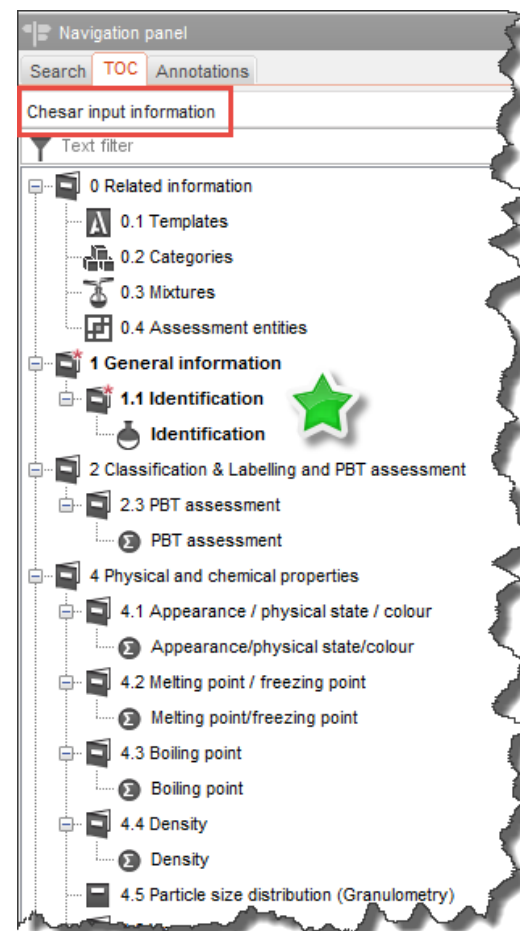
Printing, Report generation, Import

- Most critical issues had been addressed in version 1.1.0 however specific issues were still reported to the Helpdesk
 - All known issues have been corrected in version 1.2.0
 - A system has been put in place in order to fix newly discovered printing issues more efficiently (without waiting for a new IUCLID release)
- Performance issues have been addressed. Although printing is still a memory consuming process in IUCLID, the execution time has been considerably decreased
- (re-)Import performance has also been improved, particularly for 'big' files in 'big' databases

- IUCLID 6 1.2.0 is compatible with the current version of Chesar (3.1)
- You can now filter the content of a dataset based on 'Chesar input information' to help you filling-in the IUCLID information required to perform assessments in Chesar
- This filter can also be applied when exporting the content of a dataset

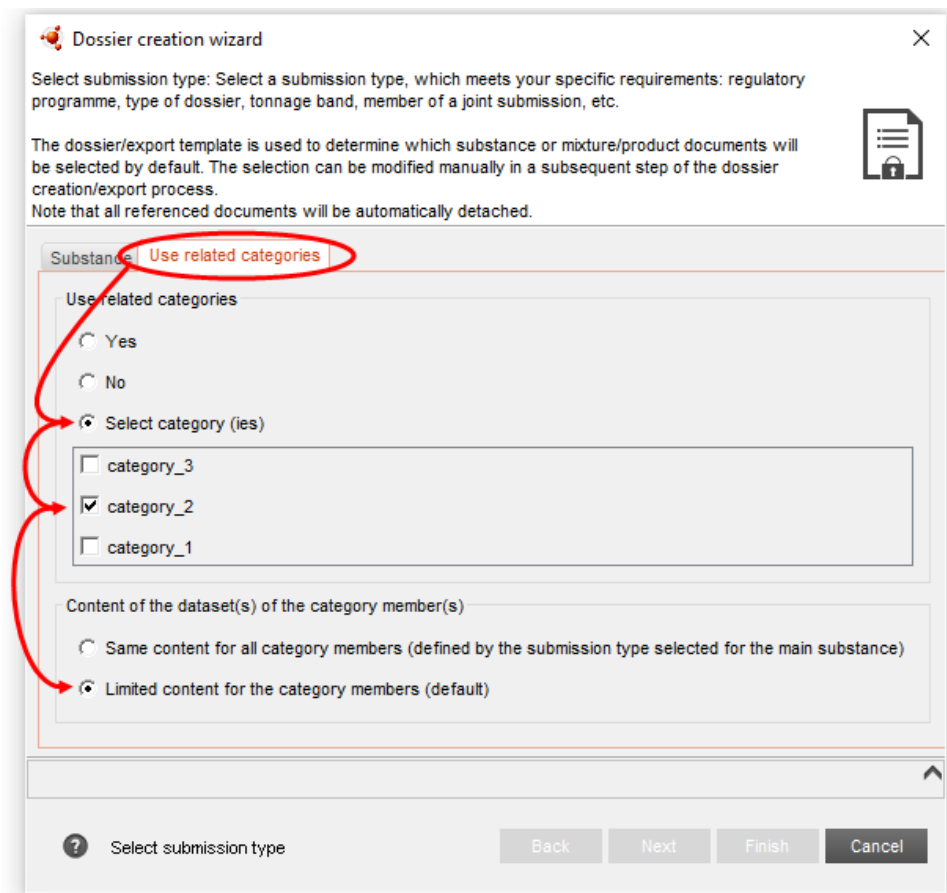


- IUCLID 6 1.2.0 is compatible with the current version of Chesar (3.1)
- You can now filter the content of a dataset based on 'Chesar input information' to help you filling-in the IUCLID information required to perform assessments in Chesar
- This filter can also be applied when exporting the content of a dataset
- The selected record and all parent sections are now highlighted to help navigating more easily to the location of the displayed information



Category-based dossiers

- When creating a dossier or exporting a substance linked to a category, the user can now select the level of information to be included in the category members (others than the main substance of the dossier)
- By default
 - All information is included in export files
 - The limited content is added to the dossiers
- In the second case the content can be limited to only the test summaries in the category members

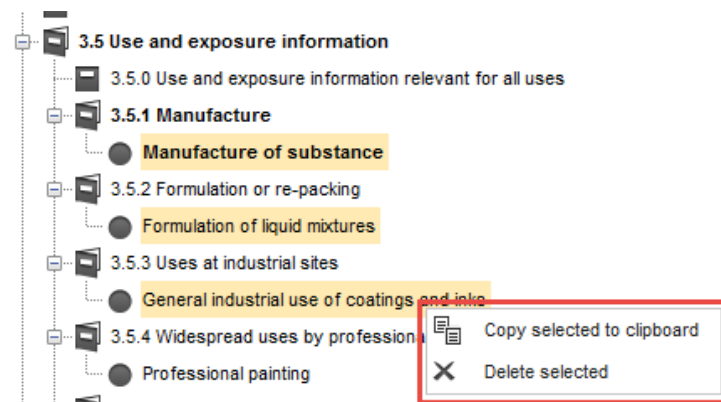
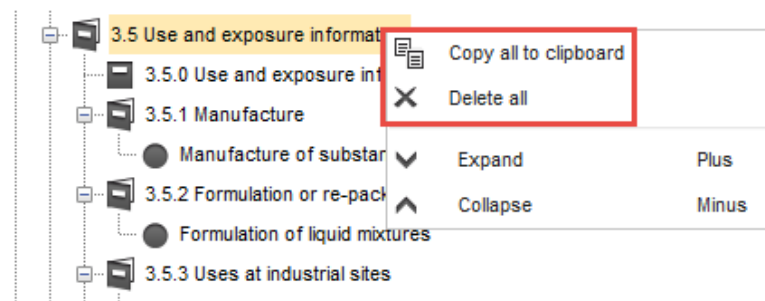


The screenshot shows the 'Dossier creation wizard' window. The 'Substance' field is set to 'Use related categories'. Below this, there are three radio button options: 'Yes', 'No', and 'Select category (ies)'. The 'Select category (ies)' option is selected. Underneath, there are three checkboxes for 'category_3', 'category_2', and 'category_1'. The 'category_2' checkbox is checked. Below this, there are two radio button options for 'Content of the dataset(s) of the category member(s)': 'Same content for all category members (defined by the submission type selected for the main substance)' and 'Limited content for the category members (default)'. The 'Limited content for the category members (default)' option is selected. At the bottom, there is a 'Select submission type' dropdown menu and four buttons: 'Back', 'Next', 'Finish', and 'Cancel'.

Improvements

Bulk actions on records

- Bulk actions on records are now possible:
 - Select several records by maintaining the CTRL key or by a right-click on a section
 - And copy or delete them in bulk



Records sorting

- Records can now be easily sorted / re-ordered by drag and drop:
 - Select a record
 - Maintain the mouse click
 - Move the record to the position needed within the section

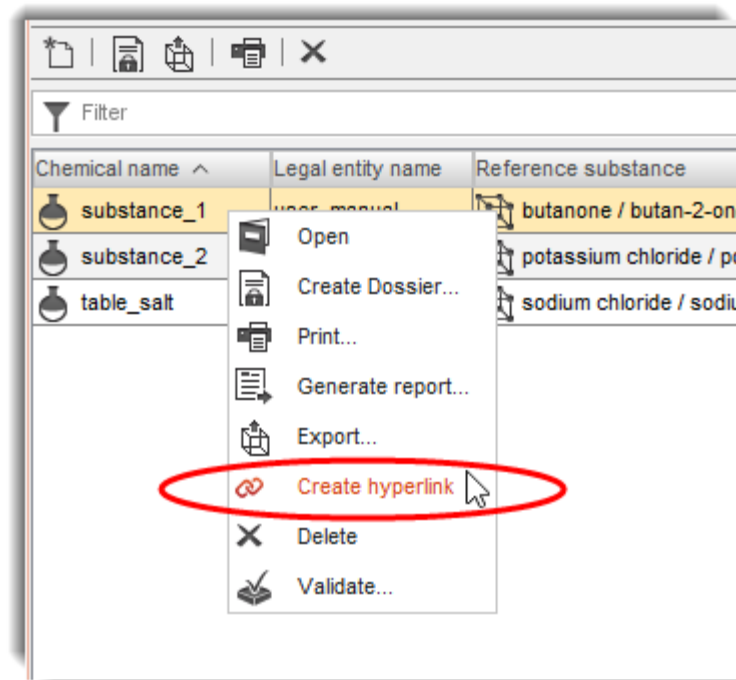


New features



Hyperlinks

- While browsing a IUCLID database (Server version) you can create a hyperlink pointing to a dataset, a dossier or a specific document
- Hyperlinks can be made available to all users sharing the same IUCLID database in order to quickly access a specific information
- The hyperlink will either open a IUCLID client or display the information in an existing one



Hyperlink format:

`http://<IUCLID server>:8080/webstart/launch.jnlp?uuid=<uuid>`

Public API

IUCLID > Support > Documentation > IUCLID 6 REST Public API



Documentation

- IUCLID format
- System requirements
- Videos
- **IUCLID 6 REST Public API**
- Report generator

IUCLID 6 REST Public API

Since version 1.2.0 (January 2017), IUCLID 6 comes with support for web services out of the box (both Desktop and Server versions).

IUCLID 6 offers a public REST Web Services API (IUCLID6 Public REST API) for external systems for integration. This API will be maintained and backward compatibility will be ensured.

› [What are RESTful Web Services?](#)

Download the documentation of the [IUCLID 6 REST Public API](#).

Please report any feedback, for example, bug reports and improvement requests to the [Helpdesk](#).

- The first version of the IUCLID 6 Public API is released with IUCLID 6 1.2.0
- It works with both Desktop and Server versions
- Available web services are documented (e.g. read / update / write / delete, search, import)

In case you are building web services clients for IUCLID, please inform us.

DNEL Calculator

Jesus Vazquez Rodriguez



What is it?

- The DNEL generator offers you the possibility to calculate and report derived non-effect levels (DNELs) in IUCLID according to ECHA Guidance on information requirements and chemical safety assessment, Chapter R.8.
- It has been developed in collaboration with the State Secretariat for Economic Affairs SECO from the Swiss Confederation.



Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

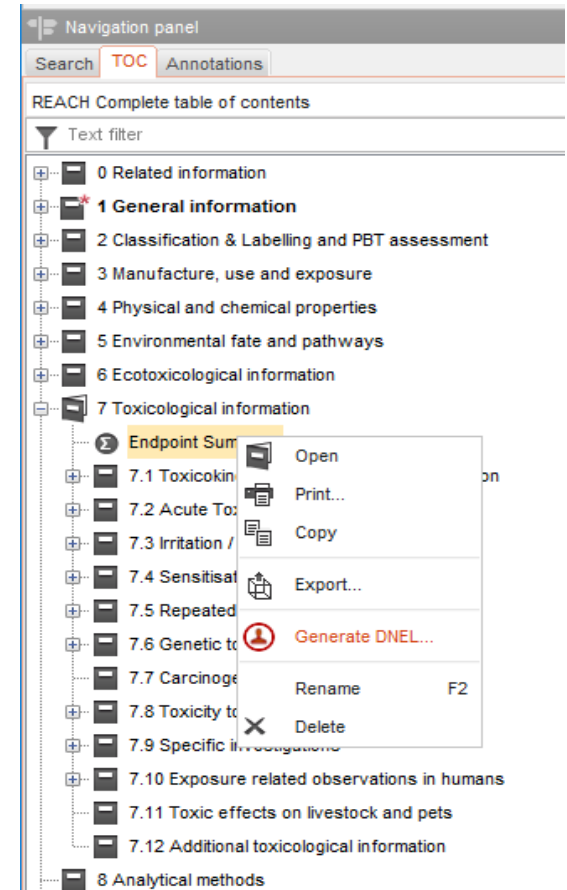
Eidgenössisches Departement für
Wirtschaft, Bildung und Forschung WBF
Staatssekretariat für Wirtschaft SECO

Purpose

- DNEL derivation is a key element for the risk characterisation of a chemical substance.
- The DNEL generator allows you to derive DNELs automatically from the data already available in the **endpoint summaries (sections 7.1, 7.5 and 7.8) of a substance dataset or template** and report them back in the corresponding endpoint summary under section '*7 Toxicological information*'.
- Currently, DNEL calculator only supports the **derivation of workers and general population DNELs for long-term systemic effects for oral, dermal and inhalation routes** according to the ECHA Guidance. Thus, the current version does not support the derivation of DNELs using human data, for acute toxicity, for local effects or for threshold carcinogens.

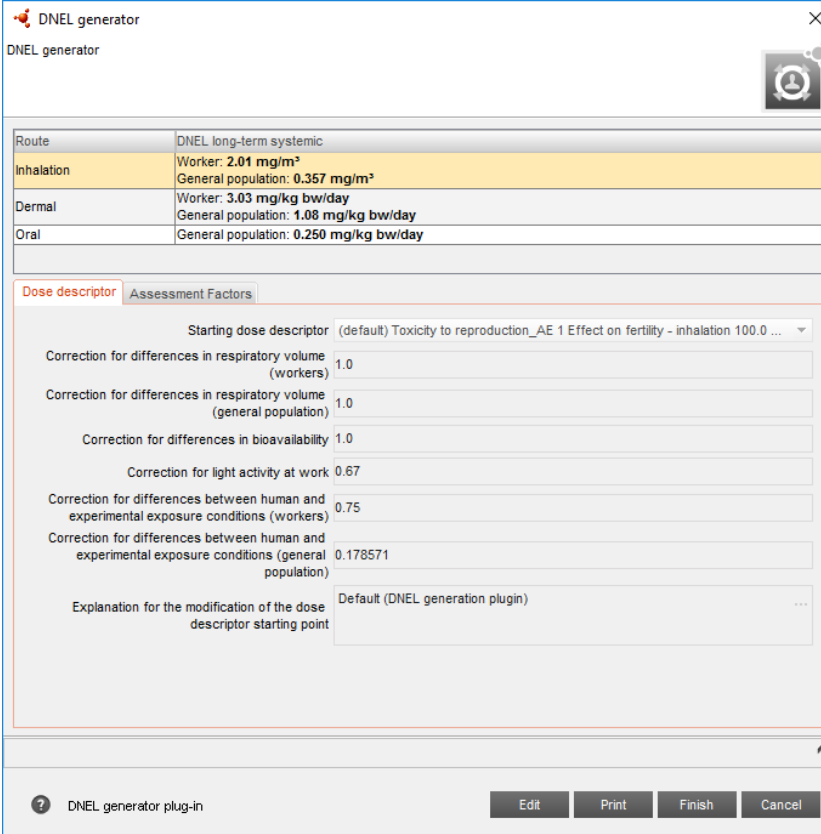
Overview – how it works?

- How to use it?
 - You can use the DNEL calculator by right-clicking the endpoint summary under section '7 Toxicological information' and selecting 'Generate DNEL' from the displayed menu.



Overview – how it works?

- Outcome
 - The results (DNELs calculated according to the Guidance R8) are displayed in a tabular format by route.
 - The dose descriptor used as starting point for the selected route and the parameters used to correct it are set by the tool and displayed in the tab called '*Dose descriptor*' as read-only.
 - The ECHA default assessment factors used to address uncertainties in the extrapolation of experimental animal data to real human exposure situations are displayed in the tab called '*Assessment Factors*' as read-only.



The screenshot shows the 'DNEL generator' application window. It displays a table of results for different routes and a 'Dose descriptor' tab with various assessment factors.

| Route | DNEL long-term systemic |
|------------|---|
| Inhalation | Worker: 2.01 mg/m³ General population: 0.357 mg/m³ |
| Dermal | Worker: 3.03 mg/kg bw/day General population: 1.08 mg/kg bw/day |
| Oral | General population: 0.250 mg/kg bw/day |

Dose descriptor | Assessment Factors

Starting dose descriptor: (default) Toxicity to reproduction_AE 1 Effect on fertility - inhalation 100.0 ...

Correction for differences in respiratory volume (workers): 1.0

Correction for differences in respiratory volume (general population): 1.0

Correction for differences in bioavailability: 1.0

Correction for light activity at work: 0.67

Correction for differences between human and experimental exposure conditions (workers): 0.75

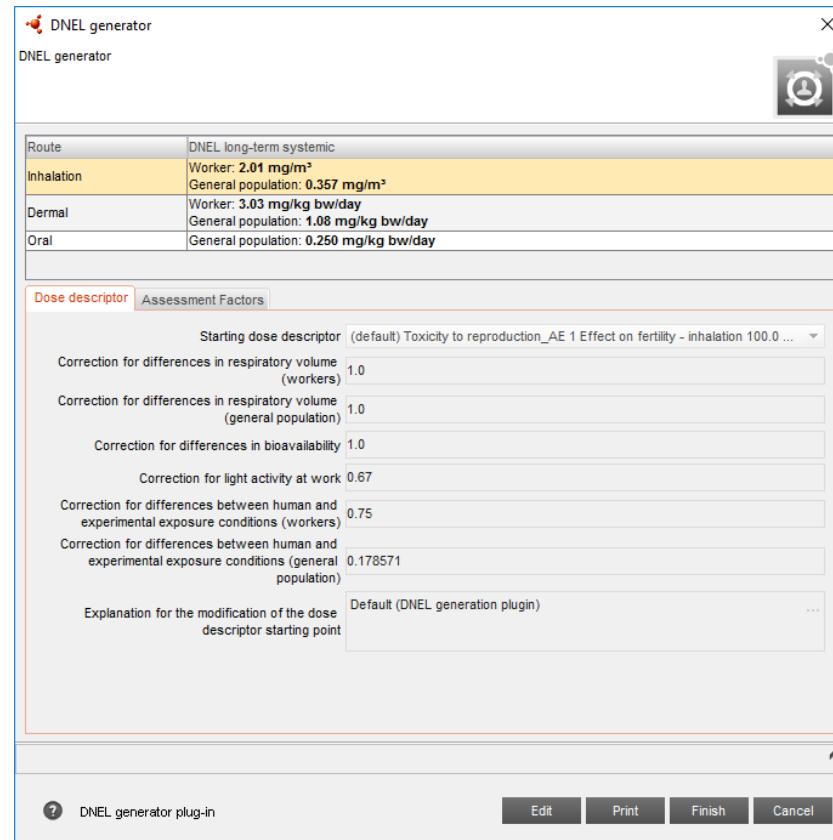
Correction for differences between human and experimental exposure conditions (general population): 0.178571

Explanation for the modification of the dose descriptor starting point: Default (DNEL generation plugin) ...

DNEL generator plug-in | Edit | Print | Finish | Cancel

Overview – how it works?

- Functionalities
 - **Edit button** enables to change the selection of the initial dose descriptor and some parameters used to derive the DNELs in a pop-up window.
 - **Print button** generates a report in a .rtf format containing the derived DNELs information as in section 5.11 of the CSR.
 - **Finish button** closes the calculator after saving the results in the corresponding endpoint summary under section '7 *Toxicological information*'.
 - **Cancel button** closes the calculator without any further action.



The screenshot shows the 'DNEL generator' application window. The title bar reads 'DNEL generator'. Below the title bar, there is a table with the following data:

| Route | DNEL long-term systemic |
|------------|---|
| Inhalation | Worker: 2.01 mg/m ³ General population: 0.357 mg/m ³ |
| Dermal | Worker: 3.03 mg/kg bw/day General population: 1.08 mg/kg bw/day |
| Oral | General population: 0.250 mg/kg bw/day |

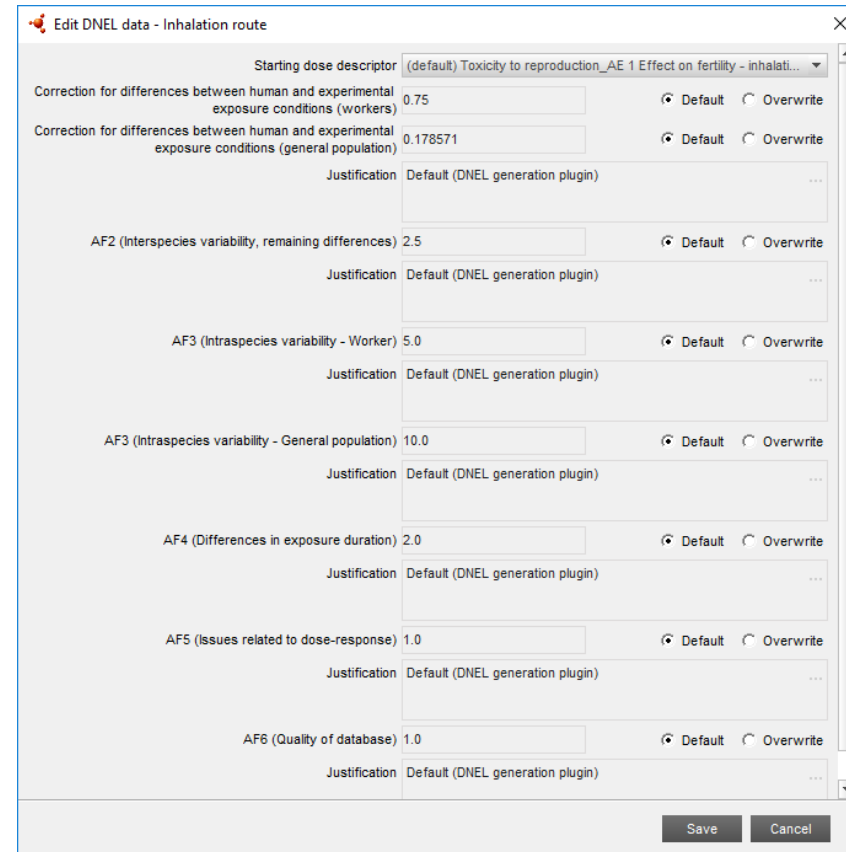
Below the table, there are two tabs: 'Dose descriptor' (selected) and 'Assessment Factors'. The 'Dose descriptor' tab contains the following fields:

- Starting dose descriptor: (default) Toxicity to reproduction_AE 1 Effect on fertility - inhalation 100.0 ...
- Correction for differences in respiratory volume (workers): 1.0
- Correction for differences in respiratory volume (general population): 1.0
- Correction for differences in bioavailability: 1.0
- Correction for light activity at work: 0.67
- Correction for differences between human and experimental exposure conditions (workers): 0.75
- Correction for differences between human and experimental exposure conditions (general population): 0.178571
- Explanation for the modification of the dose descriptor starting point: Default (DNEL generation plugin) ...

At the bottom of the window, there is a status bar with a question mark icon and the text 'DNEL generator plug-in'. To the right of the status bar are four buttons: 'Edit', 'Print', 'Finish', and 'Cancel'.

Overview – how it works?

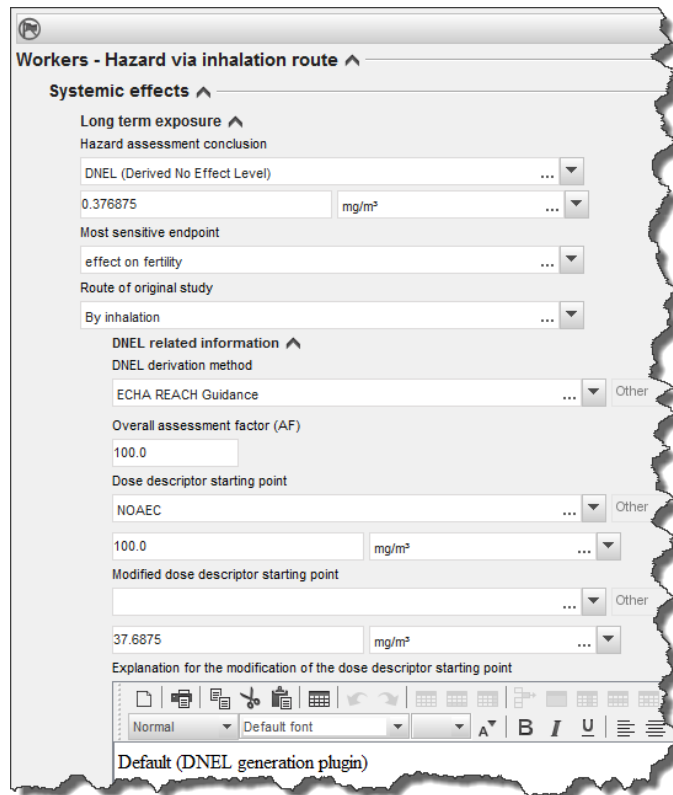
- Edit mode
 - Allows the user to:
 - select a different dose descriptor as starting point,
 - use non-default correction factors for differences between human and experimental exposure conditions,
 - use non-default assessment factors.
 - Any modification from default requires the user to provide a justification.



| Parameter | Value | Default | Overwrite | Justification |
|--|---|----------------------------------|-----------------------|----------------------------------|
| Starting dose descriptor | (default) Toxicity to reproduction_AE 1 Effect on fertility - inhalati... | | | |
| Correction for differences between human and experimental exposure conditions (workers) | 0.75 | <input checked="" type="radio"/> | <input type="radio"/> | |
| Correction for differences between human and experimental exposure conditions (general population) | 0.178571 | <input checked="" type="radio"/> | <input type="radio"/> | |
| AF2 (Interspecies variability, remaining differences) | 2.5 | <input checked="" type="radio"/> | <input type="radio"/> | Default (DNEL generation plugin) |
| AF3 (Intraspecies variability - Worker) | 5.0 | <input checked="" type="radio"/> | <input type="radio"/> | Default (DNEL generation plugin) |
| AF3 (Intraspecies variability - General population) | 10.0 | <input checked="" type="radio"/> | <input type="radio"/> | Default (DNEL generation plugin) |
| AF4 (Differences in exposure duration) | 2.0 | <input checked="" type="radio"/> | <input type="radio"/> | Default (DNEL generation plugin) |
| AF5 (Issues related to dose-response) | 1.0 | <input checked="" type="radio"/> | <input type="radio"/> | Default (DNEL generation plugin) |
| AF6 (Quality of database) | 1.0 | <input checked="" type="radio"/> | <input type="radio"/> | Default (DNEL generation plugin) |

Overview – how it works?

- Reporting in IUCLID
 - It is done in the corresponding endpoint summary under section '7 Toxicological information' from which the DNEL calculator was started.



Workers - Hazard via inhalation route ^

Systemic effects ^

Long term exposure ^

Hazard assessment conclusion

DNEL (Derived No Effect Level) ...

0.376875 mg/m³ ...

Most sensitive endpoint

effect on fertility ...

Route of original study

By inhalation ...

DNEL related information ^

DNEL derivation method

ECHA REACH Guidance ... Other

Overall assessment factor (AF)

100.0

Dose descriptor starting point

NOAEC ... Other

100.0 mg/m³ ...

Modified dose descriptor starting point

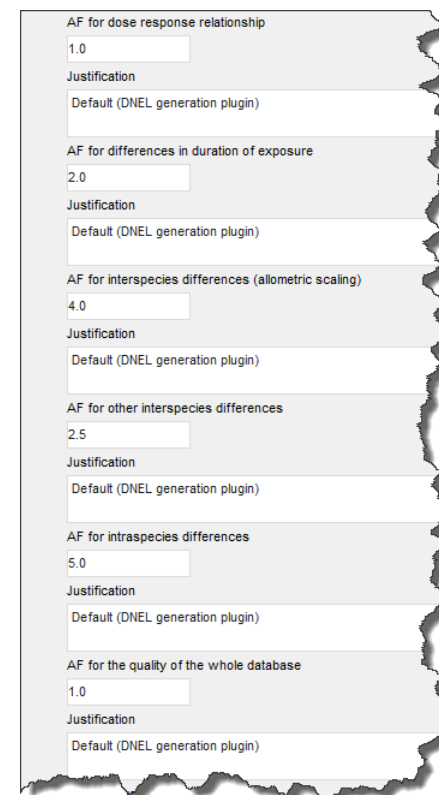
... Other

37.6875 mg/m³ ...

Explanation for the modification of the dose descriptor starting point

Normal Default font A B I U

Default (DNEL generation plugin)



AF for dose response relationship

1.0

Justification

Default (DNEL generation plugin)

AF for differences in duration of exposure

2.0

Justification

Default (DNEL generation plugin)

AF for interspecies differences (allometric scaling)

4.0

Justification

Default (DNEL generation plugin)

AF for other interspecies differences

2.5

Justification

Default (DNEL generation plugin)

AF for intraspecies differences

5.0

Justification

Default (DNEL generation plugin)

AF for the quality of the whole database

1.0

Justification

Default (DNEL generation plugin)

Report Generator

Mark Roberts



Introduction to the Report Generator Plugin

The report generator plugin extracts data from IUCLID's datasets or dossiers to produce a report of this data in one of three formats:

.PDF
.RTF
.XML

CHEMICAL SAFETY REPORT

Active substance 1

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Substance Name: coumarin
EC Number: 202-086-7
CAS Number: 91-64-5
Registrant's Identity: AS Company

Report generator

Report generator



April 2016
Release of IUCLID 6
v1.0.0

The **Report Generator** enables you to create and save a Chemical Safety Report (CSR)

An agency of the European Union

News and Events Press Contact English (en)

ECHA
EUROPEAN CHEMICALS AGENCY

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ECHA > Support > Guidance > Guidance Documents > Guidance on Information Requirements and Chemical Safety Assessment

Guidance on Information Requirements and Chemical Safety Assessment

PATHFINDER

This guidance describes the information requirements under REACH with regard to substance properties, exposure, use and risk management measures, in the context of the chemical safety assessment. It is part of a series of guidance documents that aim to help all stakeholders with their preparation for fulfilling their obligations under the REACH Regulation.

The Guidance covers:

- the collection of available information regarding the intrinsic properties of substances to be registered
- the assessment of this information against the requirements specified by REACH,
- the identification of data gaps and
- the generation of the additional information required to fill the data gaps.

The Guidance also aims to assist industry in conducting Chemical Safety Assessments and preparing Chemical Safety Reports, when required. A CSR may be required as part of a registration dossier (for non intermediates > 10 t/a), as part of an authorisation application, or as part of downstream user obligations. It also sets out the basic principles for authorities preparing a risk assessment. This may be needed in support of a restriction proposal, of a proposal to include substances into the authorisation regime, or as part of a Substance Evaluation.

The Guidance consists of two major parts: **Concise** guidance (Part A to F) and supporting **reference** guidance (Chapters R.2 to R.20).

Identify your obligations

Consultation Procedure

Guidance Documents

Guidance in a Nutshell

Guidance Factsheets

Practical Guides

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In succeeding releases of IUCLID, the CSR has been streamlined to improve its readability

Find guidance about the CSA/CSR on ECHA's support page

Report generator



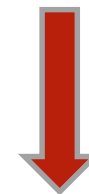
ECHA publishes an SPC Report Template on the IUCLID 6 webpage to use with the Report Generator

Advanced features of the Report Generator plugin are ready to be used with v1.1.0 of IUCLID 6

October 2016

Enables all users to customize their own report templates for their own purposes and needs

The screenshot shows the IUCLID 6 website interface. At the top left is the IUCLID 6 logo. To its right is a search bar with the text "Search the IUCLID 6 website" and a "Sign In" link. Below the search bar is a navigation menu with items: Home, IUCLID Product, Download Software, Support, and News. The main content area is titled "IUCLID news" and contains a news item dated "27/10/2016". The text of the news item reads: "The advanced features of the IUCLID 6 Report generator are now described on this website. You can generate your own reports based on IUCLID data. The extraction of the SPC data in XML format is indicated as an example. IUCLID 6 includes a Report Generator. This feature of IUCLID 6 allows you to create a Chemical Safety Report (CSR) in a printable format (RTF or PDF) or, in XML format. The Report Generator can be used to create custom reports, in which data is extracted from datasets and dossiers stored in a IUCLID 6 database. The fields included in the report, and its format, are determined by a report template that can be customised. This advanced feature of the Report Generator is now described on a new web page on the IUCLID 6 website. As an example, the report template used to generate the CSR under REACH is made available. This is the same report template that is already included by default in your IUCLID 6 installation. At the same time, a new report template is also published on the website. It allows the extraction of the IUCLID data that are relevant for the Submission of Product Characteristics (SPC), under the EU Biocidal Products Regulation. The output data format (XML) is compatible with the SPC Editor host, ECHA. Instructions on how to use this new report template are available on the IUCLID 6 website. This report will also be included in future IUCLID releases." At the bottom of the news item, there is a link: "IUCLID 6 manual | Report Generator page | Instructions on how to generate an SPC XML file".



Customize a template using Freemaker and Docbook programming languages

Report generator



Latest release of IUCLID

31 January
2017

Release of
IUCLID 6
v1.2.0

The SPC report template is now in-built inside the Report Generator and can be generated using the Report Generator wizard (see Practical example 1)

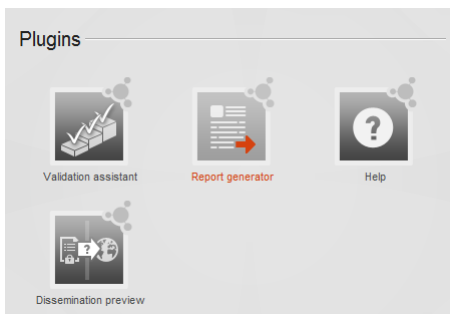
The advanced features of the Report Generator are improved to enable a report to be generated from a Mixture/Product in **.PDF** or **.RTF** formats

Report generator

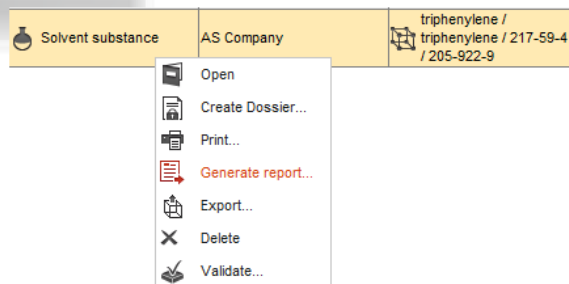


Launch the Report Generator wizard

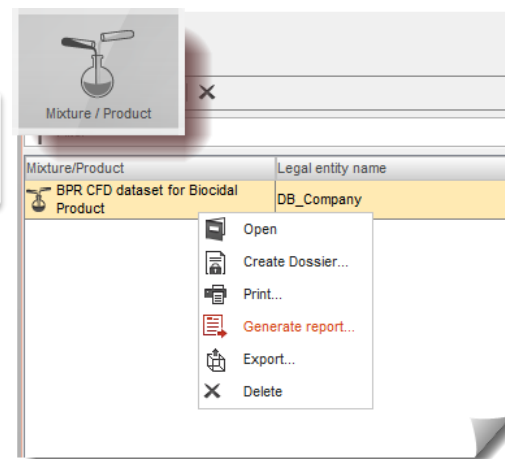
Select the Report Generator icon from the IUCLID homepage



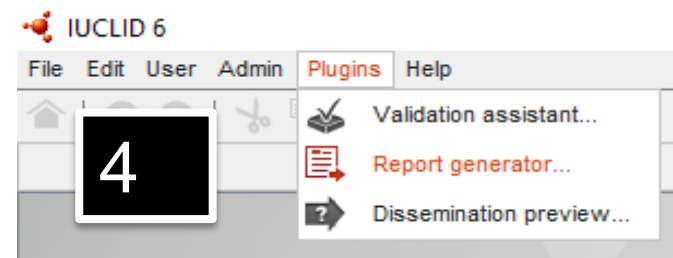
Right-click on a substance



Right-click on a mixture



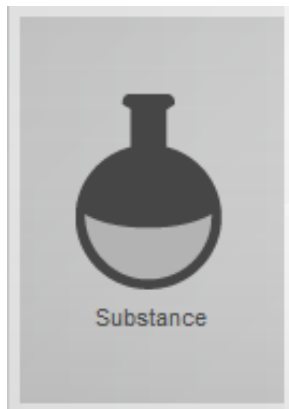
Select the report generator from 'Plugins' in the address bar



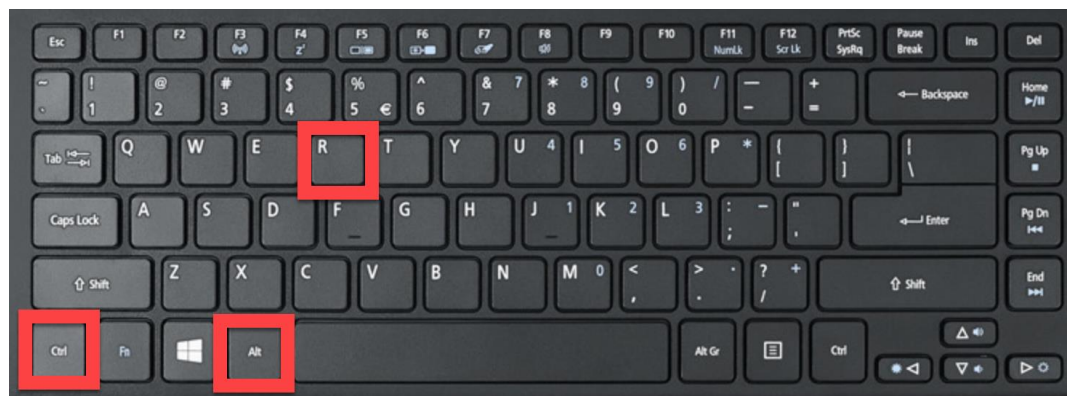
Report generator



Launch the Report Generator plugin: for use with customized reports



Launch the Report Generator manually by selecting a Substance or Mixture/Product dataset or dossier, and pressing 'Ctrl + Alt + R' on your keyboard

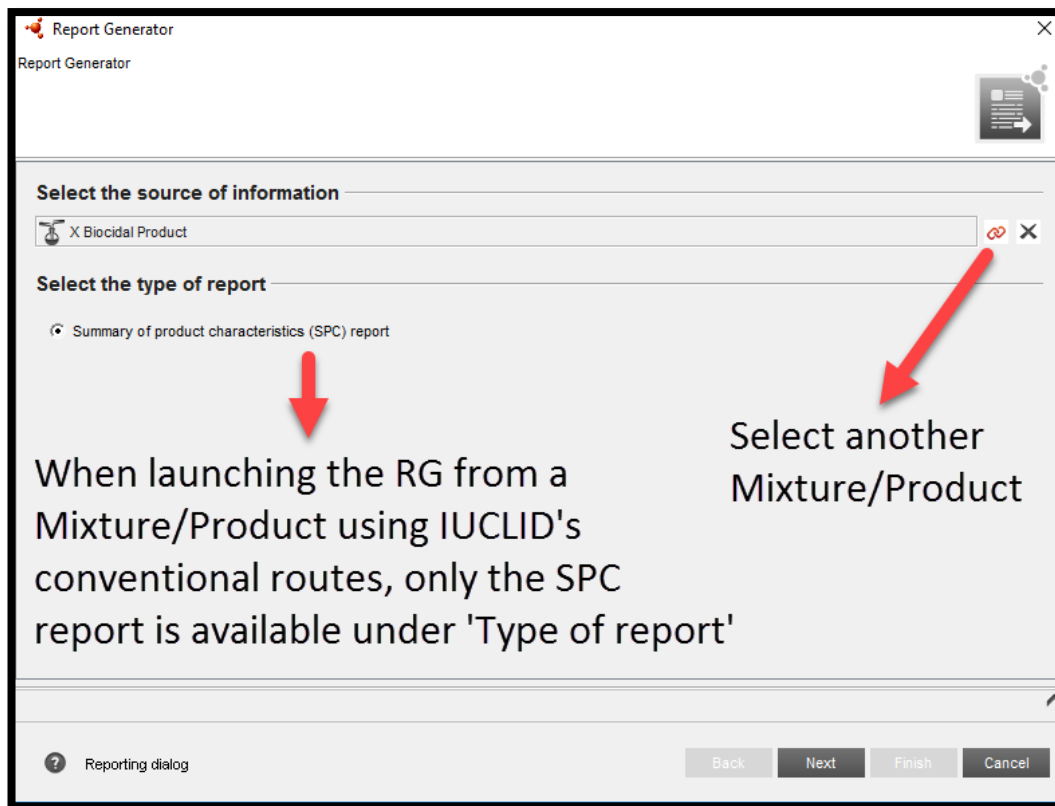
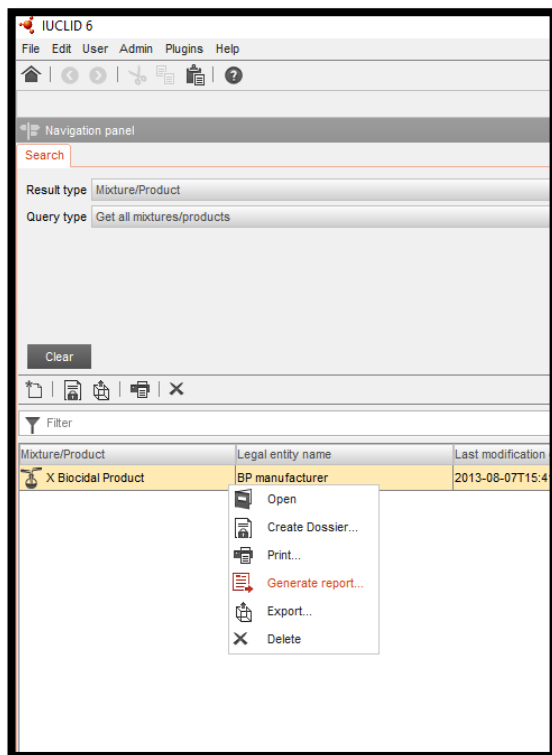


Report generator



Practical Example 1: Generating an SPC report from a Mixture/Product

Go to your Mixture/Product dataset or dossier



Report generator



Search for a Mixture,
Substance, or Dossier

Filter your search using 'Query type'

Query for substances

Result type: Substance

Query type: Substance

Clear Search

Query for substances

Result type: Substance

Query type: Get all substances

Clear Search

Query for substances

Result type: Substance

Query type: Find substances

Chemical name: Test*

Legal entity owner

Other name

IT system identifier

Reference substance name

Clear Search

Report Generator

Select the source of information

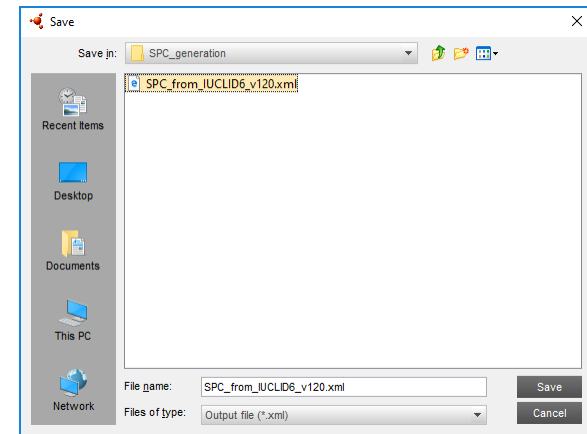
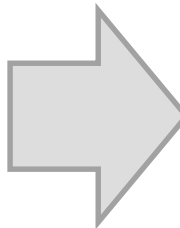
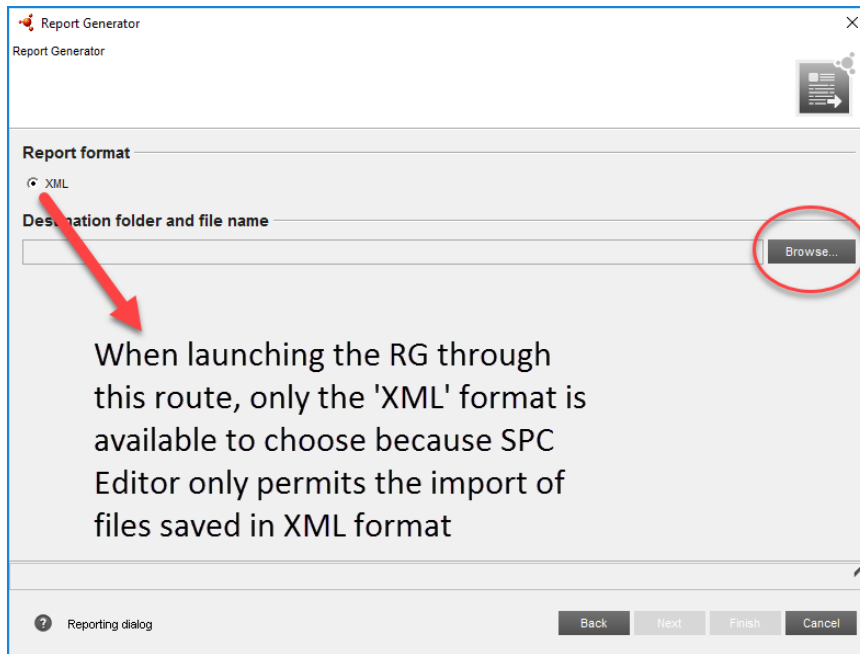
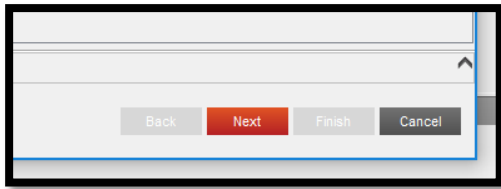
Test Report Subst

Select the type of report

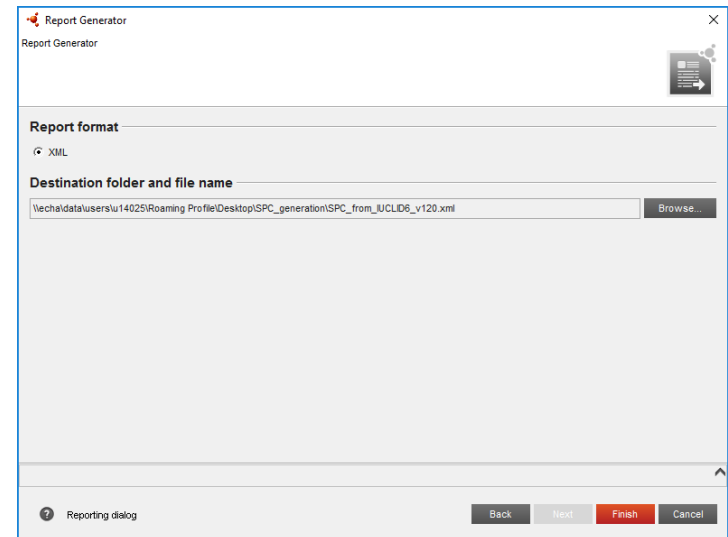
Chemical safety report (CSR)

Assign Close

Report generator



Save the file on your machine

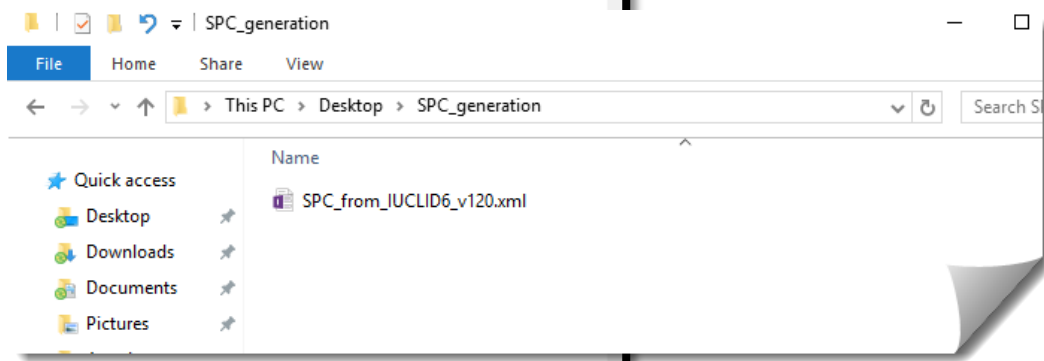


Report generator



The SPC report will now be saved as an xml file on your machine and will also appear in your default web browser

```
<?xml version="1.0" encoding="UTF-8" standalone="true"?>
<!-- SPC main template file -->
- <ns4:SPC xml:lang="en" xmlns:ns4="http://echa.europa.eu/schema/spc/1.0/" xmlns:ns3="http://www.w3.org/1999/xhtml"
xmlns:ns2="http://www.w3.org/2000/09/xmlsig#">
<!-- Macros -->
<!-- Functions -->
- <ns4:lang>
  <representation>en</representation>
</ns4:lang>
<!-- ProductInfo -->
- <ns4:ProductInfo>
  <ns4:FormulationType code="58478"> RB Bait (ready for use) </ns4:FormulationType>
  - <ns4:Composition xsi:type="ns4:ProductCompositionType" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">
    - <ns4:ActiveSubstance>
      <ns4:CommonName>coumarin</ns4:CommonName>
      <ns4:CAS>91-64-5</ns4:CAS>
      <ns4:IUPACName>2H-chromen-2-one</ns4:IUPACName>
      <ns4:EC>202-086-7</ns4:EC>
    - <ns4:Concentration>
      <ns4:Value>0.005</ns4:Value>
    </ns4:Concentration>
  </ns4:ActiveSubstance>
  - <ns4:SubstanceOfConcern>
    <ns4:CommonName>triphenylene</ns4:CommonName>
    <ns4:CAS>217-59-4</ns4:CAS>
    <ns4:IUPACName>triphenylene</ns4:IUPACName>
    <ns4:EC>205-922-9</ns4:EC>
  - <ns4:Concentration>
    <ns4:Value>90</ns4:Value>
  </ns4:Concentration>
    <ns4:Function code="SOLVENT">SOLVENT</ns4:Function>
  </ns4:SubstanceOfConcern>
  - <ns4:OtherSubstance>
    <ns4:CommonName>oryzalin</ns4:CommonName>
    <ns4:CAS>19044-88-3</ns4:CAS>
```



Report generator

Import the XML file into SPC Editor



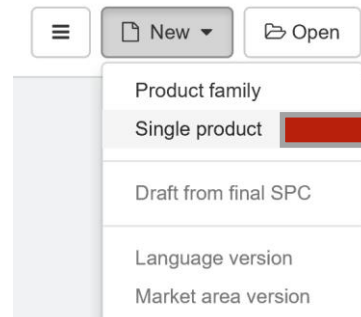
Open the SPC Editor tool:

1



SPC Editor

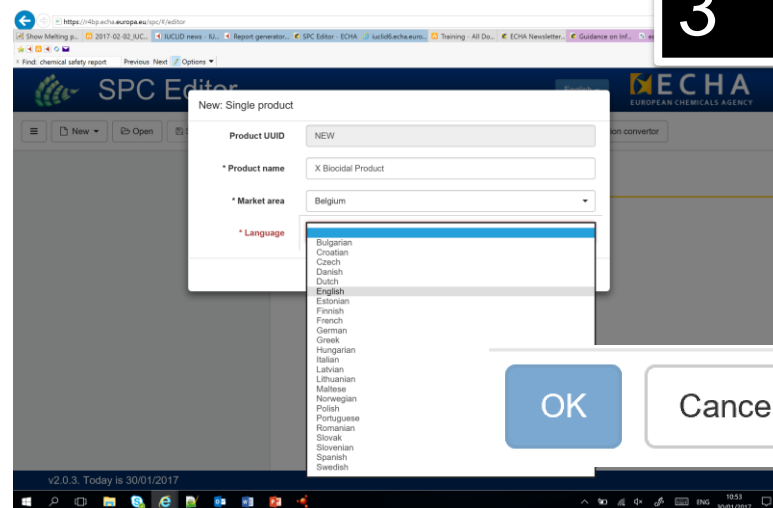
2



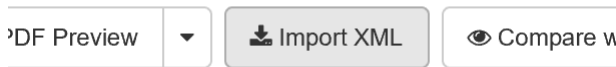
Select a Single Product, the XML does not support Product families

Enter some basic information about the product

3



4



Click on 'Import XML' from the navigation bar of SPC Editor

Report generator



Navigation panel

search TOC Annotations

PR Active substance application (representative product)

Text filter

- 0 Related information
- 1 Applicant
- 2 Identity of the representative biocidal product
 - 2.1 Trade name or proposed trade name
 - 2.2 Manufacturer's development code and number of the representative biocidal product
 - 2.3 Representative biocidal product composition
 - Product composition.001
 - 2.4 (Cf. 2.3) Formulation and nature of the representative biocidal product
- 3 Physical, chemical and technical properties
- 4 Physical hazards and relevant characteristics
- 5 Methods of detection and identification
- 6 Effectiveness against target organisms
- 7 Intended uses and exposure
- 8 Toxicological profile for humans and animals
- 9 Ecotoxicological studies
- 10 Environmental fate and behaviour
- 11 Measures to protect humans, animals and the environment
- 12 Classification & Labelling
- 13 Summary and evaluation

CORE / Composition / Product composition.001 / X Biocidal Product IUCLID

Administrative data

General information

Mixture/product name
X Biocidal Product

Brief description

Formulation type
RB Bait (ready for use)

Components

Active substance 1 / coumarin / 2H-chromen-2-one / 91-64-5, 0.005 % (w/w)

Component flag

Name
Active substance 1 / coumarin / 2H-chromen-2-one / 91-64-5

Function
active substance ... Other










Typical concentration
0.005 % (w/w) ...

Concentration range

Example; Section 2.3 of a Mixture => Submission type: 'BPR Biocidal product authorisation'

Function = 'Active substance', resulting in the information from this Component block appearing in 'Active substance' in SPC Editor

Expand all Collapse all

- X Biocidal Product  
- Product information 
- H & P statements 
- Authorised uses  
- Directions for use 
- Administrative information 
- Other information 

X Biocidal Product Belgium English

Active substances

Move up Move down

Active substance 1 / coumarin / 2H-chromen-2-one / 91-64-5
Function
active substance

Delete

* BAS number

* Common name coumarin Reference substance name*
coumarin

IUPAC name 2H-chromen-2-one IUPAC name
2H-chromen-2-one

CAS information
CAS number
91-64-5

CAS number 91-64-5 EC number 202-086-7

Inventory
Inventory number
EC / 202-086-7 / coumarin / 91-64-5 / C9HE02

* Content (%) 0.005 Typical concentration
0.005 % (w/w)

Remember! Not all SPC Editor fields are populated

Report Generator



Practical Example 2: Uploading a customized report template

Report Generator

Select the source of information

BPR CFD dataset for Biocidal Product

Select template and/or stylesheet files

Template file

Stylesheet file

Template is required for report generation

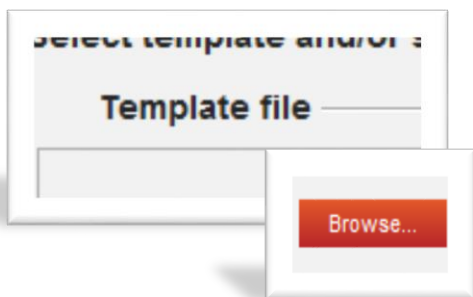
Reporting dialog

Back Next Finish Cancel

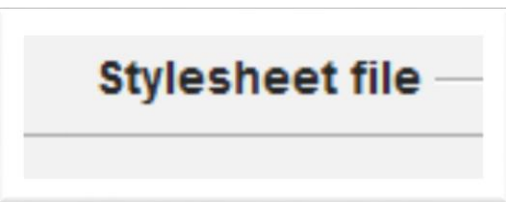
Press 'Ctrl+Alt+R' on a dataset or dossier to launch the advanced features of the report generator

No 'Report type' is given in the Report generator when launched via 'Ctrl + Alt + R'

Report Generator



A Template file **must** be selected



A Stylesheet file is optional, it conditions the formatting of the reports such as table colours'

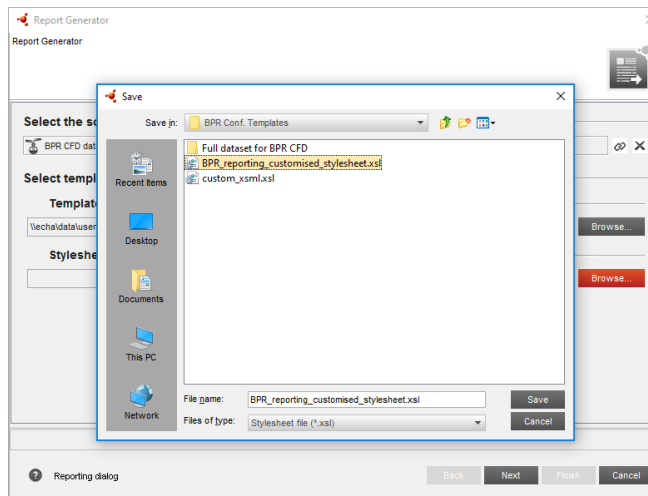


Table 1.1. Confidentiality requests

| Section in IUCLID | Type | Item | Name | Section UUID | Justification |
|-------------------|---------|------------------------------------|--|--------------------------------------|--------------------------------------|
| 3.1 | Product | Appearance (at 20°C and 101.3 kPa) | Appearance (at 20°C and 101.3 kPa).001 | a171a961-8af8-4658-aab9-5fc75c10677c | Justification FOR product appearance |

Report Generator



The screenshot shows a "Report Generator" dialog box with the following sections:

- Select the source of information**: A text field containing "BPR CFD dataset for Biocidal Product" with a refresh icon and a close icon.
- Select template and/or stylesheet files**:
 - Template file**: A text field containing the path "\\echa\data\users\lu14025\Roaming Profile\Desktop\BPR Conf. Templates\00_bpr_conf_requests_main.ftl" and a "Browse..." button.
 - Stylesheet file**: A text field containing the path "\\echa\data\users\lu14025\Roaming Profile\Desktop\BPR Conf. Templates\BPR_reporting_customised_stylesheet.xsl" and a "Browse..." button.

At the bottom of the dialog, there is a "Reporting dialog" label with a question mark icon and four buttons: "Back", "Next" (highlighted in red), "Finish", and "Cancel".

Example of the uploaded template and stylesheet

Report Generator



The screenshot shows a 'Report Generator' dialog box with the following elements:

- Report format:** Three radio button options: 'RTF (Office)', 'PDF' (which is selected), and 'XML'.
- Destination folder and file name:** A text input field containing the path '\\echa\data\users\u14025\Roaming Profile\Desktop\BPR Conf. Templates\BPR_CFD_Report.pdf' and a 'Browse...' button to its right.
- Buttons:** At the bottom, there are four buttons: 'Back', 'Next', 'Finish' (highlighted in red), and 'Cancel'.
- Footer:** A small help icon and the text 'Reporting dialog' are located in the bottom left corner.

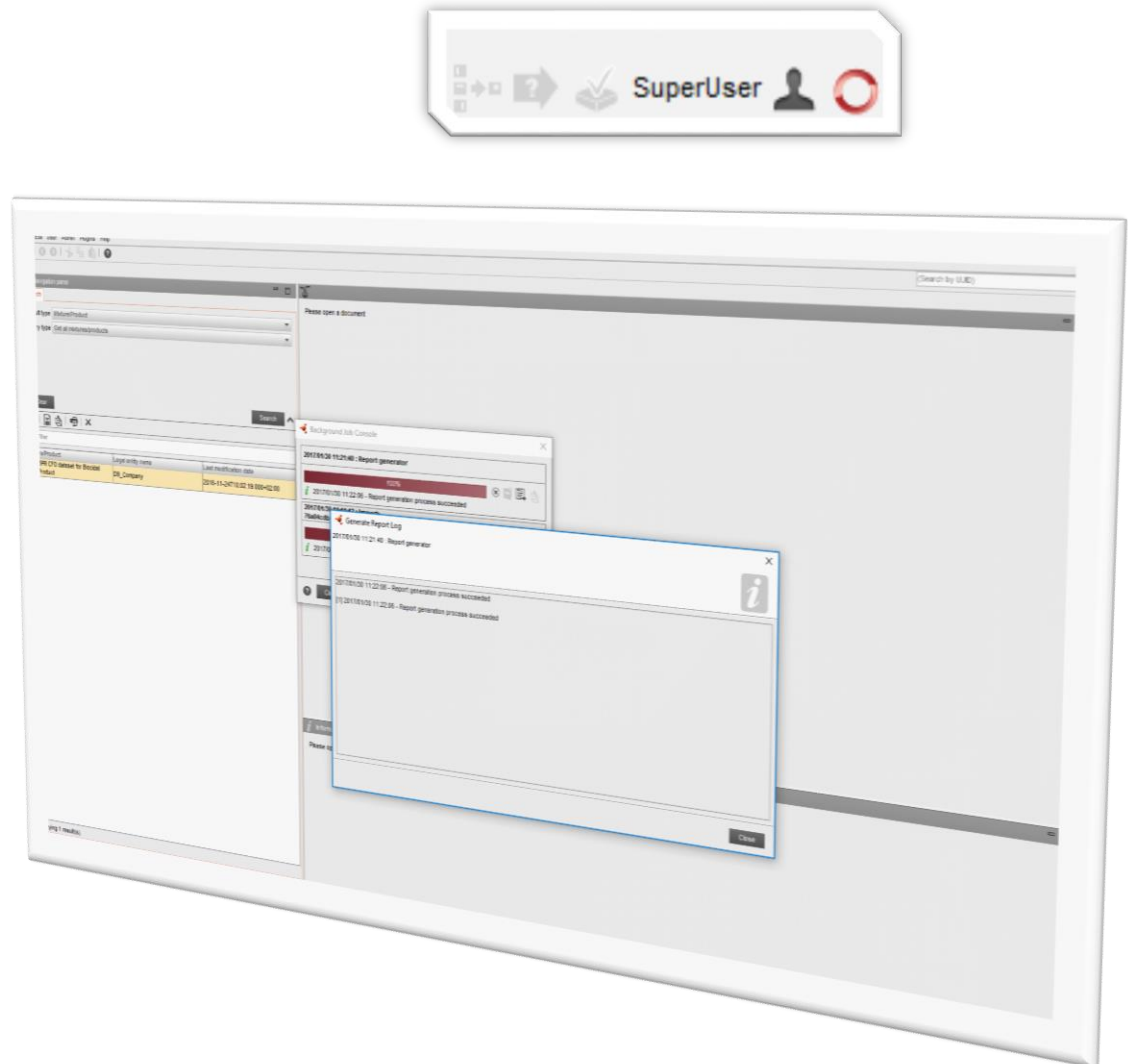
Choose to output your report in one of these formats

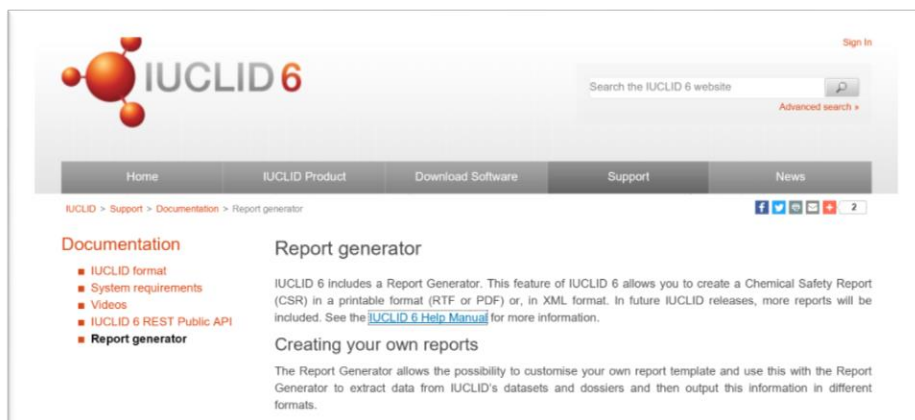
Select 'Browse' to choose where you want to save your report

Report Generator

If your report fails to open, check the background jobs in the bottom-right of the IUCLID 6 homepage, this will give you more details as to why the report failed to generate

If an in-built report fails to generate, such as the CSR or SPC, you can contact the ECHA helpdesk for technical support





Example templates on the IUCLID 6 webpage

- DocBook report template example (.ftl)
- XML report template example (.ftl)
- Test IUCLID 6 dataset (.i6z)

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

```
6 <!-- Example template file -->
7 <#assign locale = "en" />
8 <#book version="5.0" xmlns="http://docbook.org/ns/docbook" xmlns:xi="http://www.w3.org/2001/XInclude">
9
10 <#assign substance = rootDocument />
11
12 <info>
13 <title>This is my example title</title>
14 <cover>
15 <para>
16 This is some info on the cover page
17 </para>
18 </cover>
19 </info>
20
21 <!-- Part A -->
22 <part>
23 <title>First part of the document (if needed)</title>
24
25 <chapter label="1">
26 <title role="HEAD-1">First Chapter</title>
27 <para>
28 Some content
29 </para>
30
31 <para>
32 Substance name: <@com.text substance.ChemicalName/>
33 </para>
34
35 <#assign compositionList = iuclid.getSectionDocumentsForParentKey(substance.documentKey, "FLEXIBLE_RECORD", "SubstanceComposi
36
```

ECHA can potentially publish your customized templates on the IUCLID 6 webpage, contact: iuclid6@echa.europa.eu

Useful sources of information and support

- IUCLID 6 Webpage => Report generator

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

- ECHA Website => Guidance for CSR/CSA

<https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment>

- IUCLID Help manual

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

- ECHA Helpdesk

<https://echa.europa.eu/contact>

Practical tips for REACH registrants

Tamás Salamon

- Tips for REACH registrants in general
- Validation Assistant plug-in
- Tips for registrants – TCC procedure
- IUCLID and registration support



Please note:

The screenshots used during the presentation are illustrations only!

The advices are valid both for initial submissions as well as updates.

The tips focus on the Technical Completeness Check performed by ECHA.



Tips for REACH registrants - general



Use IUCLID 1.2.0

- New features
- Plug-ins
- Up to date

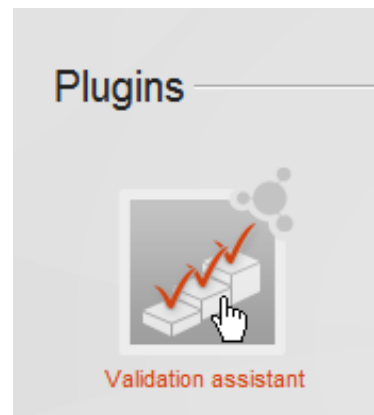
Use the Validation Assistant plug-in

- Supports REACH dossier creation
- Helps to create a complete dossier
- Easy to use

Tips for REACH registrants - general

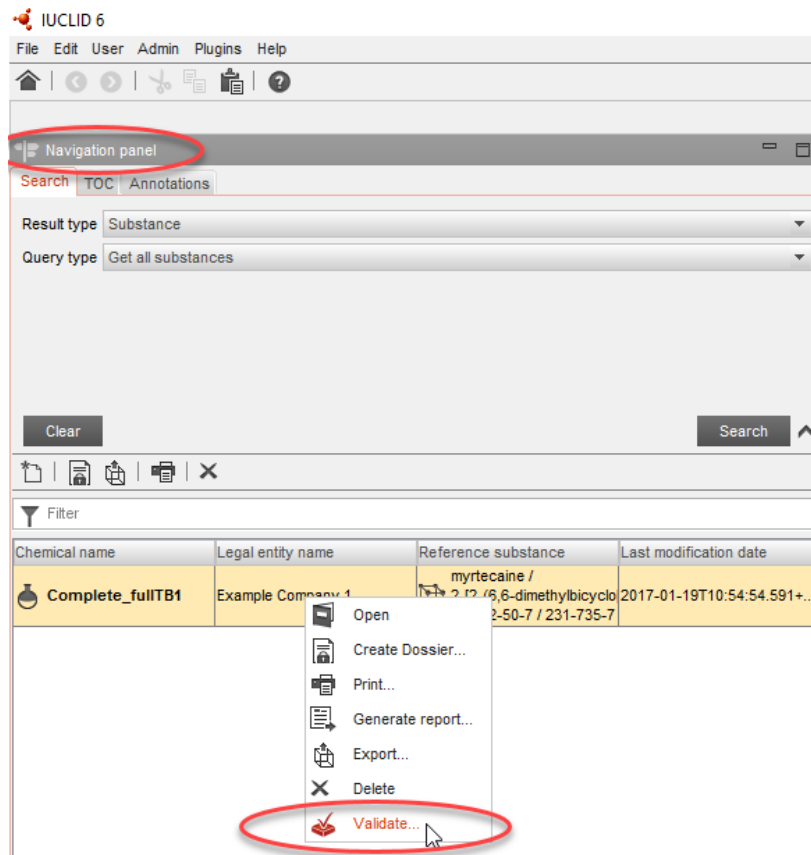


- Validation Assistant plug-in



Using the Validation Assistant

- Use the Validation Assistant on your substance dataset



The screenshot displays the IUCLID 6 software interface. At the top, the menu bar includes 'File', 'Edit', 'User', 'Admin', 'Plugins', and 'Help'. Below the menu bar is a navigation panel, which is circled in red. The main area contains search filters for 'Result type' (set to 'Substance') and 'Query type' (set to 'Get all substances'). A 'Clear' button and a 'Search' button are visible. Below the search area is a table with columns: 'Chemical name', 'Legal entity name', 'Reference substance', and 'Last modification date'. The first row of the table is highlighted in yellow and contains the following data: 'Complete_fullTB1', 'Example Company 1', 'myrtecaine / 2,2,6,6-tetramethylbicyclo[2.2.1]heptane-2,5,7,7-tetramine', and '2017-01-19T10:54:54.591+...'. A context menu is open over the first row, listing actions: 'Open', 'Create Dossier...', 'Print...', 'Generate report...', 'Export...', 'Delete', and 'Validate...'. The 'Validate...' option is circled in red.

| Chemical name | Legal entity name | Reference substance | Last modification date |
|------------------|-------------------|---|-----------------------------|
| Complete_fullTB1 | Example Company 1 | myrtecaine / 2,2,6,6-tetramethylbicyclo[2.2.1]heptane-2,5,7,7-tetramine | 2017-01-19T10:54:54.591+... |

Using the Validation Assistant

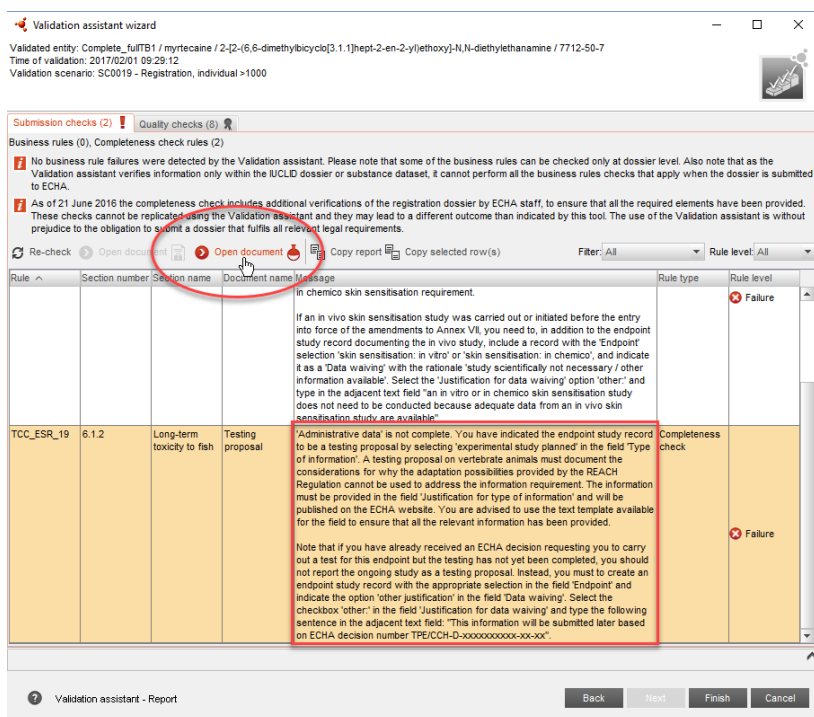


- Select the scenario that applies to your substance

The screenshot shows a window titled "Validation assistant wizard" with the subtitle "Validation assistant - Submission type specification". The main area is titled "Dossier type" and contains a "Select submission type" dropdown menu. A list of options is displayed, with "REACH Registration 1 - 10 tonnes, standard requirements" selected and highlighted in yellow. To the left of the list is a checkbox labeled "Use advanced settings" which is currently unchecked. At the bottom of the window, there is a red error message: "Please select a submission type". Below the error message is a help icon and the text: "Provide the submission type information in order to determine the scenario of the validation." At the bottom right, there are four buttons: "Back", "Next", "Finish", and "Cancel".

Click on the failure

- Open document in substance dataset



Validation assistant wizard

Validated entity: Complete_fuitB1 / myrtecaine / 2-[2-(6,6-dimethylbicyclo[3.1.1]hept-2-en-2-yl)ethoxy]-N,N-diethylethanamine / 7712-50-7
Time of validation: 2017/02/01 09:29:12
Validation scenario: SC0019 - Registration, individual >1000

Submission checks (2) Quality checks (6)

Business rules (0), Completeness check rules (2)

No business rule failures were detected by the Validation assistant. Please note that some of the business rules can be checked only at dossier level. Also note that as the Validation assistant verifies information only within the IUCLD dossier or substance dataset, it cannot perform all the business rules checks that apply when the dossier is submitted to ECHA.

As of 21 June 2016 the completeness check includes additional verifications of the registration dossier by ECHA staff, to ensure that all the required elements have been provided. These checks cannot be replicated using the Validation assistant and they may lead to a different outcome than indicated by this tool. The use of the Validation assistant is without prejudice to the obligation to submit a dossier that fulfils all relevant legal requirements.

Re-check Open document Open document Copy report Copy selected row(s) Filter: All Rule level: All

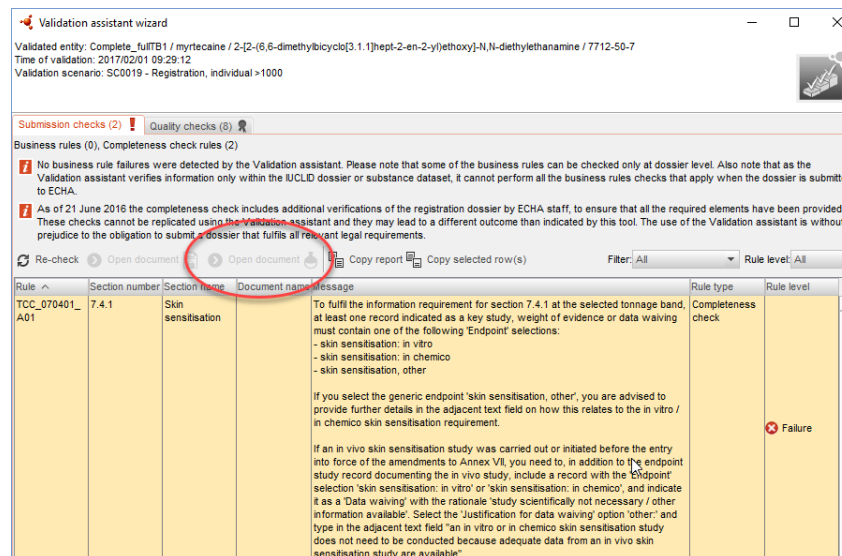
| Rule | Section number | Section name | Document name | Message | Rule type | Rule level |
|------------|----------------|----------------------------|------------------|---|--------------------|------------|
| | | | | In chemico skin sensitisation requirement. If an in vivo skin sensitisation study was carried out or initiated before the entry into force of the amendments to Annex VII, you need to, in addition to the endpoint study record documenting the in vivo study, include a record with the 'Endpoint selection' 'skin sensitisation: in vitro' or 'skin sensitisation: in chemico', and indicate it as a 'Data waiving' with the rationale 'study scientifically not necessary / other information available'. Select the 'Justification for data waiving' option 'other' and type in the adjacent text field 'an in vitro or in chemico skin sensitisation study does not need to be conducted because adequate data from an in vivo skin sensitisation study are available'. | Completeness check | Failure |
| TCC_ESR_19 | 6.1.2 | Long-term toxicity to fish | Testing proposal | 'Administrative data' is not complete. You have indicated the endpoint study record to be a testing proposal by selecting 'experimental study planned' in the field 'Type of information'. A testing proposal on vertebrate animals must document the considerations for why the adaptation possibilities provided by the REACH Regulation cannot be used to address the information requirement. The information must be provided in the field 'Justification for type of information' and will be published on the ECHA website. You are advised to use the text template available for the field to ensure that all the relevant information has been provided. Note that if you have already received an ECHA decision requesting you to carry out a test for this endpoint but the testing has not yet been completed, you should not report the ongoing study as a testing proposal. Instead, you must to create an endpoint study record with the appropriate selection in the field 'Endpoint' and indicate the option 'other justification' in the field 'Data waiving'. Select the checkbox 'other' in the field 'Justification for data waiving' and type the following sentence in the adjacent text field: 'This information will be submitted later based on ECHA decision number TPE/CCH-D-xxxxxx-xx-xx'. | Completeness check | Failure |

Validation assistant - Report

Back Next Finish Cancel

Click on the failure

- Open document in substance dataset is unavailable



Validation assistant wizard

Validated entity: Complete_fuitB1 / myrtecaine / 2-[2-(6,6-dimethylbicyclo[3.1.1]hept-2-en-2-yl)ethoxy]-N,N-diethylethanamine / 7712-50-7
Time of validation: 2017/02/01 09:29:12
Validation scenario: SC0019 - Registration, individual >1000

Submission checks (2) Quality checks (6)

Business rules (0), Completeness check rules (2)

No business rule failures were detected by the Validation assistant. Please note that some of the business rules can be checked only at dossier level. Also note that as the Validation assistant verifies information only within the IUCLD dossier or substance dataset, it cannot perform all the business rules checks that apply when the dossier is submitted to ECHA.

As of 21 June 2016 the completeness check includes additional verifications of the registration dossier by ECHA staff, to ensure that all the required elements have been provided. These checks cannot be replicated using the Validation assistant and they may lead to a different outcome than indicated by this tool. The use of the Validation assistant is without prejudice to the obligation to submit a dossier that fulfils all relevant legal requirements.

Re-check Open document Open document Copy report Copy selected row(s) Filter: All Rule level: All

| Rule | Section number | Section name | Document name | Message | Rule type | Rule level |
|----------------|----------------|--------------------|---------------|--|--------------------|------------|
| TCC_070401_A01 | 7.4.1 | Skin sensitisation | | To fulfil the information requirement for section 7.4.1 at the selected tonnage band, at least one record indicated as a key study, weight of evidence or data waiving must contain one of the following 'Endpoint' selections: - skin sensitisation: in vitro - skin sensitisation: in chemico - skin sensitisation: other If you select the generic endpoint 'skin sensitisation, other', you are advised to provide further details in the adjacent text field on how this relates to the in vitro / in chemico skin sensitisation requirement. If an in vivo skin sensitisation study was carried out or initiated before the entry into force of the amendments to Annex VII, you need to, in addition to the endpoint study record documenting the in vivo study, include a record with the 'Endpoint' selection 'skin sensitisation: in vitro' or 'skin sensitisation: in chemico', and indicate it as a 'Data waiving' with the rationale 'study scientifically not necessary / other information available'. Select the 'Justification for data waiving' option 'other' and type in the adjacent text field 'an in vitro or in chemico skin sensitisation study does not need to be conducted because adequate data from an in vivo skin sensitisation study are available'. | Completeness check | Failure |

Using the Validation Assistant



- Correct the failure in the substance dataset and unhide the VA report

Substance name*
Complete_fuITB1

Public name
Test

Legal entity flags

Legal entity*
Example Company 1 / Example city / Finland

Third party flags

Third party

Role in the supply chain ^

Role flags

Manufacturer
 Importer
 Only representative
 Downstream user

Identification of substance ^

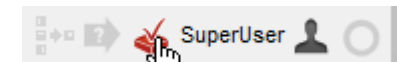
Reference substance flags

Reference substance
myrtecaine / 2-[2-(6,6-dimethylbicyclo[3.1.1]hept-2-en-2-yl)ethoxy]-N,N-diethylethanamine / 7712-50-7 / 231-735-7

Information panel

Type Substance
UUID IU/CS-167863c3-902e-49b8-aa95-827e560a380a
Dossier UUID

SuperUser



Using the Validation Assistant



- Re-check the substance dataset

Submission checks (20) ! Quality checks (11) 👤

Business rules (0), Completeness check rules (20)

f No business rule failures were detected by the Validation assistant. Please note that some of the business rules can

f As of 21 June 2016 the completeness check includes additional verifications of the registration dossier by ECHA staff submit a dossier that fulfils all relevant legal requirements.

Re-check Open document Open document Copy report Copy selected row(s)

- Create the registration dossier and run the Validation Assistant on it too!

IUCLID 6

File Edit User Admin Plugins Help

Navigation panel

Search

Result type Dossier

Query type Get all dossiers

Clear Search

Filter

| Dossier Name | Subject Name | Creation date |
|---|-------------------|-------------------------------|
| R_ABOVE_1000 / SUBSTANCE: C bryrtcaine / 2-[2-(6,6-dimethylbicyclo[3.1.1]hept-3-ylidene)ethyl]pyrrolidine 2017-01-19 / 1.2.0_n | Complete: fullTB1 | 2017-01-19T11:37:32.123+02:00 |

Open
Print...
Generate report...
Export...
Delete
Validate
Dissemination preview...
Compare...

Using the Validation Assistant



- Note the disclaimers!
They tell what the results mean
- Business rules
- Completeness checks

Validation assistant wizard

Validated entity: Complete_fullTB1 / myrtecaine / 2-[2-(6,6-dimethylbicyclo[3.1.1]hept-2-en-2-yl)ethoxy]-N,N-diethylethanamine / 7712-50-7
Time of validation: 2017/02/01 09:37:41
Validation scenario: SC0019 - Registration, individual >1000

Submission checks (0) ! Quality checks (8)

Business rules (0), Completeness check rules (0)

f No business rule failures were detected by the Validation assistant. Please note that some of the business rules can be checked only at dossier level. Also note that as the Validation assistant verifies information only within the IUCLID dossier or substance dataset, it cannot perform all the business rules checks that apply when the dossier is submitted to ECHA.

f No completeness check failures were detected by the Validation assistant. However, as of 21 June 2016 the completeness check includes additional verifications of the registration dossier by ECHA staff, to ensure that all the required elements have been provided. These checks cannot be replicated using the Validation assistant and they may lead to a different outcome than indicated by this tool. The use of the Validation assistant is without prejudice to the obligation to submit a dossier that fulfils all relevant legal requirements.

Re-check Open document Open document Copy report Copy selected row(s) Filter: All Rule level: All

| Rule | Section number | Section name | Document name | Message | Rule type | Rule level |
|------|----------------|--------------|---------------|---------|-----------|------------|
|------|----------------|--------------|---------------|---------|-----------|------------|

Validation assistant - Report

Back Next Finish Cancel

- Completeness check
 - Checks if required elements provided
 - In case automatic rules cannot be used (i.e. deviations)
 - Does not check quality of the provided requirements
- Validation Assistant cannot predict manual checks performed by ECHA staff
- Certain areas of focus
 - Substance ID
 - Data waivers
 - CSR
 - Testing proposals

Tips based on experience

Substance Identity



Tips based on experience – Substance ID



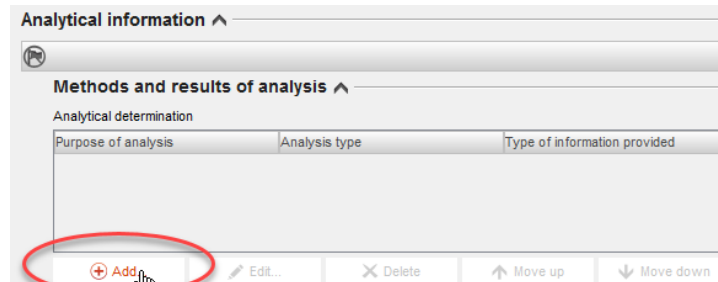
- IUCLID section 1.4 ‘Analytical Information’
 - ‘Identification’ and ‘Quantification’ should be provided with attachment in ‘Analytical determination’ table

The screenshot displays the IUCLID software interface. On the left is a navigation panel with a tree view of sections. The 'Analytical information' section is highlighted with a red box. The main window shows the 'Analytical information' section expanded. A table titled 'Methods and results of analysis' is highlighted with a red border. The table has the following columns: Purpose of analysis, Analysis type, Type of information provided, Attached methods/results, Rationale for no results, Justification, and Remarks. Below the table are sections for 'Optical activity', 'Remarks', and 'Related composition(s)'. At the bottom, there is an 'Information pane' showing details like Type (Public Record), GUID (93f67395-9c7e-3e64-851e-32e2c4932199), and Dossier GUID.

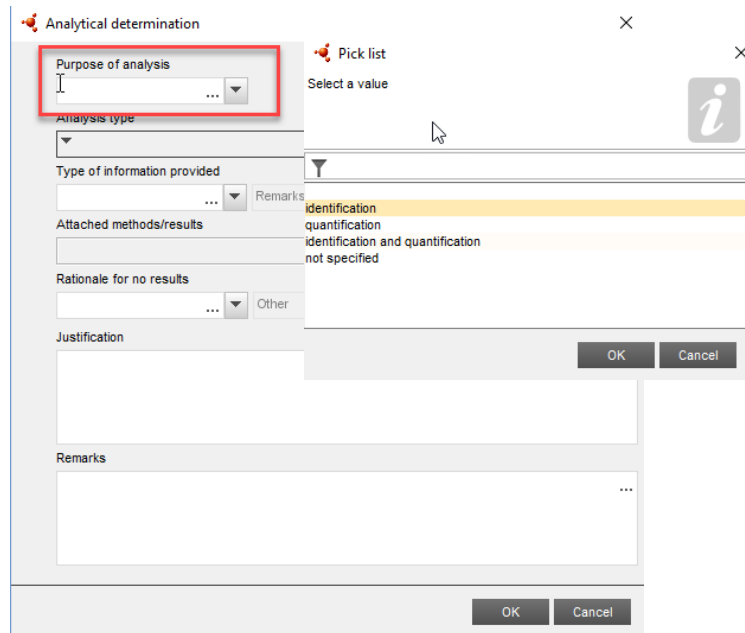
Tips based on experience – Substance ID



- Add row



- 'Purpose of the analysis' picklist



Tips based on experience – Substance ID



'Identification' and 'Quantification'

Analytical information ^

Methods and results of analysis ^

Analytical determination

| Purpose of analysis | Analysis type | Type of information provided | Attached methods/results | Rationale for no results |
|---------------------|---|------------------------------|--|--------------------------|
| identification | chromatography – other, chromatography – HPLC | methods and results | Report_gen_01.pdf / 285.451 KB / application/pdf | |
| quantification | titration | methods and results | Report_gen_01.pdf / 285.451 KB / application/pdf | |

+ Add... Edit... X Delete ↑ Move up ↓ Move down

'Identification and Quantification'

Analytical information ^

Methods and results of analysis ^

Analytical determination

| Purpose of analysis | Analysis type | Type of information provided | Attached methods/results | Rationale for no results |
|-----------------------------------|-------------------------|------------------------------|--|--------------------------|
| identification and quantification | IR, chromatography – IC | methods and results | Report_gen_01.pdf / 285.451 KB / application/pdf | |

+ Add... Edit... X Delete ↑ Move up ↓ Move down

Tips based on experience – Substance ID



- IUPAC name should be provided
 - Section 1.1 reference substance
 - If unavailable then chemical name in same field

Identification of substance ^

Reference substance flags

Reference substance

water / water / 7732-18-5 / 231-791-2

| Inventory | Inventory number | Inventory name |
|--------------|------------------|----------------|
| EC Inventory | 231-791-2 | water |
| CAS number | CAS name | |
| 7732-18-5 | | |
| IUPAC name | | |
| water | | |

Tips based on experience – Substance ID



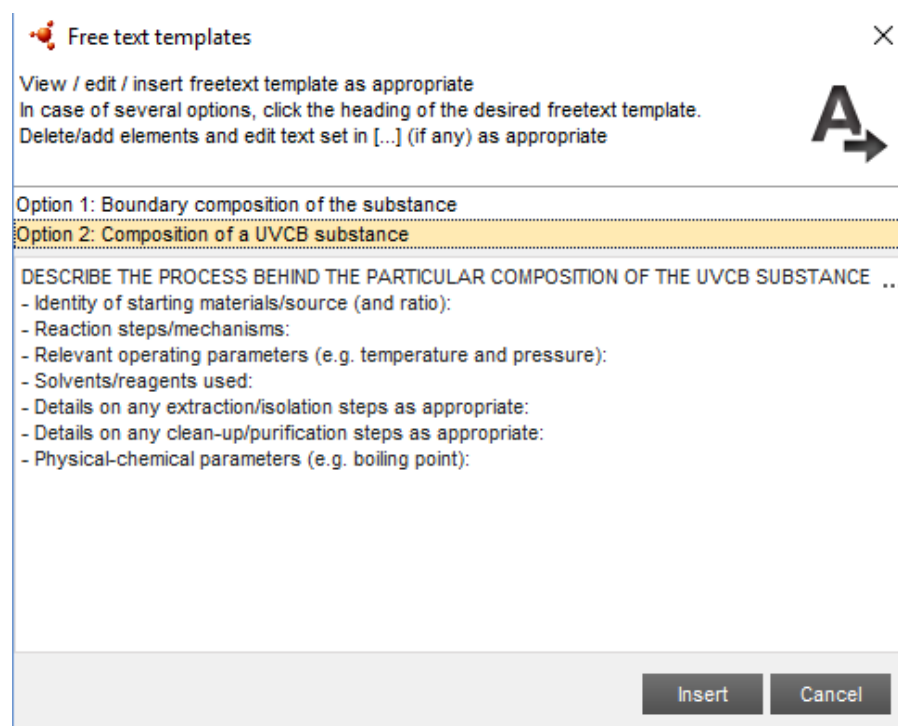
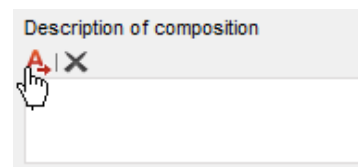
- UVCB substances:
 - Manufacturing process description should be provided for the **registered substance**
 - IUCLID section 1.2

The screenshot displays the IUCLID 6 software interface. On the left, a navigation panel shows a tree structure of sections. Section 1.2, 'Composition', is highlighted, and its sub-section 'Standard composition' is selected. The main area on the right shows the 'General Information' form for a substance. The 'Type of composition' dropdown is set to 'legal entity composition of the substance'. The 'Description of composition' field contains the text '[Manufacturing process description]'. The 'Attached description' section is empty. The 'Justification for deviations' section is also empty. The 'Related composition(s)' section is empty.

Tips based on experience – Substance ID



- UVCB substances:
 - Use the Text template
 - Address all the points



Tips based on experience – Substance ID



- UVCB substances
 - Breakdown of the composition should be provided for the **registered substance** in IUCLID section 1.2 ‘Composition’
 - If it cannot be provided constituent by constituent, the group of constituents should be provided at least

Constituents ^

labeltalol / 2-hydroxy-5-{1-hydroxy-2-[(1-methyl-3-phenylpropyl)amino]ethyl}benzamide / 36894-69-6 / 253-258-3, ca. 99.9 % (w/w), >= 99.7 - <= 100.0 % (w/w)

Reference substance

labeltalol / 2-hydroxy-5-{1-hydroxy-2-[(1-methyl-3-phenylpropyl)amino]ethyl}benzamide / 36894-69-6 / 253-258-3

| Inventory | Inventory number | Inventory name |
|--|------------------|----------------|
| EC Inventory | 253-258-3 | labeltalol |
| CAS number | CAS name | |
| 36894-69-6 | | |
| IUPAC name | | |
| 2-hydroxy-5-{1-hydroxy-2-[(1-methyl-3-phenylpropyl)amino]ethyl}benzamide | | |

Typical concentration

ca. 99.9 % (w/w)

Concentration range

>= 99.7 <= 100.0 % (w/w)

Remarks

Tips based on experience – Substance ID



- UVCB substances:
 - In exceptional cases where the nature of substance does not allow identification of any separate constituents, a justification should exist under the highlighted field

A screenshot of the IUCLID 6 web interface. The browser address bar shows the path: CORE / Composition / Standard composition / Complete_fullTB1 / myrtecaine / 2-[2-(6,6-dimethylbicyclo[3.1.1]hept-2-en-2-yl)ethoxy]-N,N-diethylet... IUCLID. The main content area is titled 'General Information ^'. It contains several fields: 'Name' (Standard composition), 'Type of composition' (legal entity composition of the substance), and 'State / form'. Below these is a 'Description of composition' field with a text area and a 'Description of composition' label. Underneath is an 'Attached description' table with columns for 'Attached document' and 'Remarks'. A table entry is visible with the text 'Tips based on experience - Sub...'. At the bottom of the form is a 'Justification for deviations' field, which is highlighted with a red rectangular border. Above this field are buttons for '+ Add...', 'Edit...', 'Delete', 'Move up', and 'Move down'.

Tips based on experience

Data waivers



Tips based on experience – Data waivers



- Do not report study results as data waivers

OECD / Flammability / FlammabilityDW.001 / Complete_fullITB1 / myrtecaine / 2-[2-(6,6-dimethylbicyclo[3.1.1]hept-2-en-2-yl)ethoxy]-N,N-diethylet... OECD

Administrative data ^

Endpoint
flammable solids ... Remarks

Type of information
... Other ... Remarks

Adequacy of study
...

Robust study summary
 Used for classification
 Used for SDS


Study period
...

Reliability
... Other

Rationale for reliability incl. deficiencies
... Other ... Remarks

Data waiving
study technically not feasible ...

Justification for data waiving
other: The study does not need to be conducted... Further information under 'Justification for type of information' field

Justification for type of information
According to the study... 

Tips based on experience – Data waivers



- In case an information requirement has **not** been provided a justification must exist

A screenshot of the IUCLID 6 administrative data form. The form is titled 'Administrative data' and contains several sections: 'Endpoint', 'Type of information', 'Adequacy of study', 'Study period', 'Reliability', and 'Rationale for reliability incl. deficiencies'. Each section has a dropdown menu and a 'Remarks' field. The 'Data waiving' section is highlighted with a red box. It contains a dropdown menu for 'Data waiving', a 'Justification for data waiving' field, and a 'Justification for type of information' field with a text input area and a close button (X).

Tips based on experience – Data waivers



- 'Data waiving' picklist

A screenshot of the IUCLID 6 software interface. The background shows a form with several fields: 'Study period', 'Reliability', 'Rationale for reliability incl. deficiencies', 'Data waiving', 'Justification for data waiving', and 'Justification for type of information'. The 'Data waiving' field is highlighted with a red rectangle. A 'Pick list' dialog box is open over this field, displaying a list of five options: 'study technically not feasible', 'study scientifically not necessary / other information available', 'exposure considerations', 'study waived due to provisions of other regulation', and 'other justification'. The dialog box has a title bar with a close button, a search filter, and 'OK' and 'Cancel' buttons at the bottom.

Tips based on experience – Data waivers



- Use the existing justifications if applicable

Administrative data ^

Endpoint
flammable solids ...

Type of information
...

Adequacy of study
...

Robust study summary
 Used for classification
 Used for SDS

Study period
...

Reliability
...

Rationale for reliability incl. deficiencies
...

Data waiving
...

Justification for data waiving
▼ the study does not need to be conducted for explosives

Justification for type of information
A | X

Attached justification

Remarks

Select picklist values

the study does not need to be conducted because the substance is a gas and the concentration of the flammable gas in a mixture with inert gases is so low that, when mixed with air, the concentration is all time below the lower limit. - [study scientifically not necessary / other information available]

Remarks ...

the study does not need to be conducted for explosives - [study technically not feasible]

Remarks ...

the study does not need to be conducted because the substance is pyrophoric - [study technically not feasible]

Remarks ...

the study does not need to be conducted for organic peroxides - [study technically not feasible]

Remarks ...

the study does not need to be conducted for self-reactive substances - [study technically not feasible]

Remarks ...

Deselect all Select all OK Cancel

Tips based on experience – Data waivers



- If not applicable select 'other:' and provide a short description of the justification in the field next to

Administrative data ^

Endpoint
flammable solids

Type of information

Adequacy of study

Robust study summary

Used for classification

Used for SDS

Study period

Reliability

Rationale for reliability incl. deficiencies

Data waiving

Justification for data waiving
▼ other: The study does not need to be conducted because...

Justification for type of information

Select picklist values

Remarks

the study does not need to be conducted because the organic substance does not contain metals or metalloids and hence, the classification procedure does not need to be applied - [study scientifically not necessary / other information available]

Remarks

the study does not need to be conducted because the experience in production or handling shows that the substance does not react with water, e.g. the substance is manufactured with water or washed with water - [study scientifically not necessary / other information available]

Remarks

the study does not need to be conducted because the substance is known to be soluble in water to form a stable mixture - [study scientifically not necessary / other information available]

Remarks

other: The study does not need to be conducted because...]

Remarks

Deselect all Select all OK Cancel

Tips based on experience – Data waivers



- If needed a detailed justification in the highlighted textbox

Data waiving

study technically not feasible ... ▼

Justification for data waiving

▼ other: The study does not need to be conducted because...

Justification for type of information

A₂ | X

Detailed justification...|

Tips based on experience – Data waivers



- Avoid **only** referring to other Endpoint study records or different places in the dossier

A screenshot of a web form titled 'Justification for data waiving'. It contains a dropdown menu with the selected option 'other: See later'. Below this is a section titled 'Justification for type of information' with a search icon and a close icon. The text 'See in CSR' is entered in the field, and a large red 'X' is overlaid on it, indicating that this justification is incorrect.

Justification for data waiving

▼ other: See later

Justification for type of information

A X

See in CSR

- The justification should be in the right place!

Tips based on experience

Chemical Safety Report



Tips based on experience – CSR



- If the registered tonnage is 10 tpa or above a CSR must be provided in IUCLID section 13*
* *Unless it is a joint CSR provided by the lead registrant*

The screenshot displays the IUCLID 6 web interface. On the left is a navigation panel with a search bar and a table of contents. The '13 Assessment reports' section is highlighted with a red box, and its sub-item '13.1 Chemical Safety Report (Part A)' is also highlighted. The main content area shows the 'Administrative data' section, which includes an 'Assessment report' section. This section contains a document titled 'CSR.pdf / 2.678 KB / application/pdf' and a dropdown menu for 'Type of report' set to 'REACH Chemical safety report (CSR)'. Below this, there are sections for 'SUS contains', 'CSR contains', and 'Type of CSR', each with a dropdown menu. The 'Chemical safety assessment/report tool used' section also has a dropdown menu. The 'Further information on the attached file' section is currently empty. The 'Discussion' section is visible at the bottom of the main content area.

Tip based on experience

Testing proposals



Tips based on experience – Testing proposals



- Each testing proposal on the registered substance on vertebrate animals must include considerations for alternative methods
- The information will always be published for 3rd party consultations
- The considerations should be provided in the ‘Justification for type of information’ field

Administrative data ^

Endpoint
developmental toxicity ... Remarks

Type of information
experimental study planned ... Other ... Remarks

Adequacy of study
...
 Robust study summary
 Used for classification
 Used for SDS

Study period

Reliability
... Other

Rationale for reliability incl. deficiencies
... Other ... Remarks

Data waiving
...
Justification for data waiving

Justification for type of information
A | X

Tips based on experience – Testing proposals



- Use the Text templates available and address all the points

Administrative data ^

Endpoint
developmental toxicity ... Remarks

Type of information
experimental study planned ... Other ... Remarks

Adequacy of study
...

Robust study summary
 Used for classification
 Used for SDS

Study period
...

Reliability
...

Rationale for reliability incl. deficiencies
...

Data waiving
...

Justification for data waiving
...

Justification for type of information
...

Free text templates X

View / edit / insert freetext template as appropriate
In case of several options, click the heading of the desired freetext template.
Delete/add elements and edit text set in [...] (if any) as appropriate

Type 'Waiving of standard information'
Type 'Experimental study planned / Testing proposal on vertebrate animals'
Type 'QSAR prediction'
Type 'Read-across (analogue)'

TESTING PROPOSAL ON VERTEBRATE ANIMALS
[Please provide information for all of the points below. The information should be specific to the endpoint for which testing is proposed. Note that for testing proposals addressing testing on vertebrate animals under the REACH Regulation this document will be published on the ECHA website along with the third party consultation on the testing proposal(s).]

NON-CONFIDENTIAL NAME OF SUBSTANCE:
- Name of the substance on which testing is proposed to be carried out
- Name of the substance for which the testing proposal will be used [if different from tested substance]

CONSIDERATIONS THAT THE GENERAL ADAPTATION POSSIBILITIES OF ANNEX XI OF THE REACH REGULATION ARE NOT APPROPRIATE TO GENERATE THE NECESSARY

Insert Cancel

Useful links

Please note: We are not able to answer questions regarding the completeness of your dossier via HelpDesk or personal e-mails. Only able to perform the TCC in REACH-IT!

- Where can I know more about the manual checks at TCC?

https://echa.europa.eu/documents/10162/13652/manual_completeness_check_en.pdf

- ECHA HelpDesk

<http://echa.europa.eu/web/guest/contact>



Questions and answers

Please continue to send your questions for the next 5 minutes, using the Q&A panel



Questions and answers



Future updates



Planned releases

- More information on the planned IUCLID 6 releases can be found on the IUCLID 6 website
- <https://iuclid6.echa.europa.eu/project-iuclid-6#ServiceRelease>

The screenshot shows the IUCLID 6 website interface. At the top left is the IUCLID 6 logo. To the right is a search bar with the text "Search the IUCLID 6 website" and a magnifying glass icon. Below the search bar is a navigation menu with links for "Home", "IUCLID Product", "Download Software", "Support", and "News". In the top right corner, there is a "Sign In" link and a social media sharing bar with icons for Facebook, Twitter, LinkedIn, and a share icon, along with a "5" notification badge.

The main content area is titled "IUCLID Product" and contains a sub-section "IUCLID 6 maintenance and service releases". The text below this section states: "After the release of IUCLID 6 to the public, service and maintenance releases are prepared in order to fix reported issues and to provide improvements and new features requested by the users. Under this section the current planning and scope for the future releases are made available for information only and are subject to change (updated on 5 September 2016)."

The planned releases are listed as follows:

- 21st June 2016 (maintenance release)
 - Compatibility with Chesar 3
 - Performance improvements for performance issues detected in dossier creation
- October 2016 (service release 4), can include for example:
 - Other user requirements currently not prioritised
 - LDAP connectivity
 - Spell checker
 - Attachments versioning
 - Announcements for IUCLID system administrators
 - Link to email server (e.g. for resetting passwords)

At the bottom of the page, there are logos for ECHA (European Chemicals Agency) and OECD. To the right of these logos, it says "IUCLID 6 is developed by the European Chemicals Agency in association with the OECD". In the bottom right corner, there is a "Legal notice" link and a small circular icon.



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

