

REACH 2018

webinars

Completeness check Validation assistant

15 March 2018

11.00 – 12.00 Helsinki time

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Validation assistant

- Plugin available in IUCLID and IUCLID Cloud
- Assists you in preparing your IUCLID dossier
- Carries out validations on datasets and dossiers to verify that information is given correctly
- Validation report lists all failed automated rules together with failure descriptions for each
- Additional manual verifications done by us are not displayed in the Validation assistant

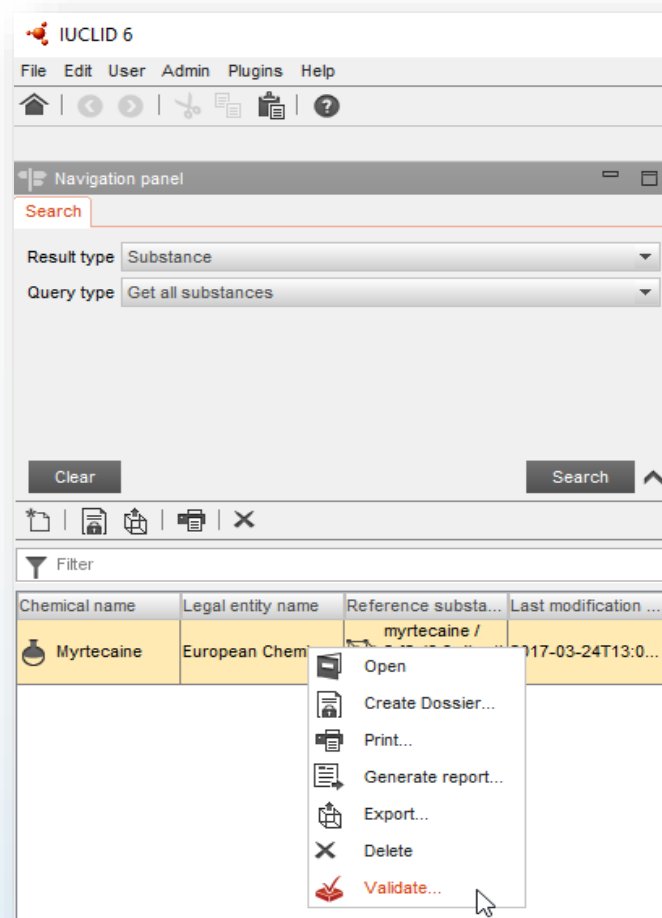
Validation assistant

- Use Validation assistant before you submit to minimise failures
 - Check your substance dataset before your dossier is created to correct any failures
 - Check final dossier before submitting it
- Never submit your dossier if there are failures given by the Validation assistant
 - Your dossier will fail business rules or completeness check



Validation assistant in IUCLID

- Access substance dataset
- Right-click the dataset and select 'validate'
- Fill information requested by the tool in the next steps





Validation assistant results

Number of quality check failures

Number of submission check failures

Number of technical completeness check failures

Validation assistant wizard

Validated entity: Myrtecaine / myrtecaine / 2-[2-(6,6-dimethylbicyclo[3.1.1]hept-2-en-2-yl)ethoxy]-N,N-diethylethanami... / substance X / 9043-30-5
 Time of validation: 2018/03/07 11:20:28
 Validation scenario: SC0144 - Registration, lead >1000, own 10-100/100-1000/>1000, CSR, own GSU

Submission checks (8) ! Quality checks (12) ?

Business rules (0), **completeness check rules (8)**

i 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.

i 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 nu...	Section name	Document name	Message	Rule type	Rule level
TCC_0104_02	1.4	Analytical Information, Analytical determination, (2)	Analytical Information	Section 1.4 is incomplete. At least one row must be created in the table 'Analytical determination'. In each row, the following must be provided: - a selection must be made in the 'Purpose of analysis' picklist - at least one selection must be made in the 'Analysis type' picklist - either an attachment must exist in the 'Attached methods/results' field, or a reason for not providing a method/result must be indicated. To this end, make a selection in the field 'Rationale for no results' and insert an explanation in the 'Justification' field, clearly stating the reasons for not providing the information. Note that the 'Analysis type' field is a multi-select list; if several selections are made, the corresponding results or justifications for all must be provided in the	Completeness check	Failure

Validation assistant - Report Back Next Finish Cancel



Validation assistant results

Validation assistant wizard

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

Rule	Section nu...	Section name	Document name	Message	Rule type	Rule level
TCC_0104_02	1.4	Analytical Information, Analytical determination, (2)	Analytical Information	Section 1.4 is incomplete. At least one row must be created in the table 'Analytical determination'. In each row, the following must be provided: - a selection must be made in the 'Purpose of analysis' picklist - at least one selection must be made in the 'Analysis type' picklist - either an attachment must exist in the 'Attached methods/results' field, or a reason for not providing a method/result must be indicated. To this end, make a selection in the field 'Rationale for no results' and insert an explanation in the 'Justification' field, clearly stating the reasons for not providing the information. Note that the 'Analysis type' field is a multi-select list; if several selections are made, the corresponding results or justifications for all must be provided in the	Completeness check	Failure

Validation assistant - Report Back Next Finish Cancel

Failing IUCLID section number and name

Rule ID

Name of failing document

Failure description



Finding the failing document

Validation assistant wizard

Validated entity: Myrtecaine / myrtecaine / 2-[2-(6,6-dimethylbicyclo[3.1.1]hept-2-en-2-yl)ethoxy]-N,N-diethylethanami... / substance X / 9043-30-5
 Time of validation: 2018/03/07 11:20:28
 Validation scenario: SC0144 - Registration, lead >1000, own 10-100/100-1000/>1000, CSR, own GSU

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i 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.

i 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 nu...	Section name	Document name	Message	Rule type	Rule level
TCC_0104_02	1.4	Analytical Information, Analytical determination, (2)	Analytical Information	Section 1.4 is incomplete. At least one row must be created in the table 'Analytical determination'. In each row, the following must be provided: - a selection must be made in the 'Purpose of test/analysis' field - at least one selection must be made in the 'Justification' field - either an attachment must be provided for not providing a method, or the field 'Rationale for no results' must be filled in, clearly stating the reasons Note that the 'Analysis type' field is a multi-selection list, if several selections are made, the corresponding results or justifications for all must be provided in the 'Justification' field.	Completeness check	Failure

Validation assistant - Report

Back Next Finish Cancel



Locating the failure

Name of failing table

Failing row number

The screenshot shows the ECHA REACH 2018 interface. At the top, there is a table listing failing rules. Below it, the 'Analytical determination' table is expanded, showing a table with columns for Purpose of analysis, Analysis type, Type of information..., Attached methods/r..., and Rationale for no... The table contains two rows, with the second row highlighted in yellow.

Rule	Section number	Section name	Document name	Message
TCC_0104_02	1.4	Analytical Information, Analytical determination (2)	Analytical determination	Section 1.4 is incomplete. A 'determination'. In each row of the table - a selection must be made - at least one selection must be made - either an attachment must be provided - a selection in the field 'Ration...

Purpose of analysis	Analysis type	Type of information...	Attached methods/r...	Rationale for no...
identification and/or quantification	other: migrated information	methods	UV_IR_NMR_MS.doc / 23.5 KB / application/msword	
identification and/or quantification	other: xxx	results		



Correct, save and re-check

CORE / Analytical information / Analytical determination / Myrtecaine / myrtecaine / 2-[2-(6,6

Analytical information

Methods and results of analysis

Analytical determination

Purpose of analysis	Analysis type	Type of informatio...	Attached methods/...
identification and/or quantification	other: migrated information	methods	UV_IR_NMR_MS.doc / 23.5 KB / application/msword
identification and/or quantification	other: xxx	results	Attachment for online dossier.pdf

← Save your changes

↓ Unhide validation assistant if not visible

Validation assistant wizard

Validated entity: Myrtecaine / myrtecaine / 2-[2-(6,6-dimethylbicyclo[3.1.1]hept-2-en-2-yl)ethoxy
Time of validation: 2017/04/11 14:30:52
Validation scenario: SC0019 - Registration, individual >1000

Information panel

Type: Flexible Record

UUID: 6a414660-c852-3fed-b3a7-90813e1c242

Dossier UUID:

SuperUser

Submission checks (1) ! Quality checks (1)

Business rules (0), Completeness check rules (1)

! No business rule failures were detected by the Validation assistant. Please note that some of the Validation assistant verifies information only within the IUCLID dossier or substance dataset, it does not verify information to ECHA.

! As of 21 June 2016 the completeness check includes additional verifications of the registration information. These checks cannot be replicated using the Validation assistant and they may lead to a different interpretation of the obligation to submit a dossier that fulfils all relevant legal requirements.

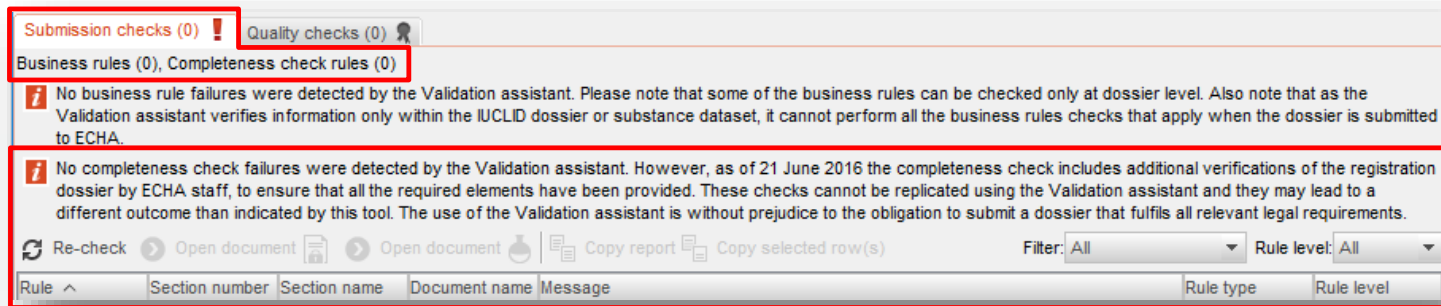
Re-check Open document Open document Copy report Copy se

Rule	Section number	Section name	Document name	Message
TCC_0104_02	1.4	Analytical Information, Analytical	Analytical determination	Section 1.4 is incomplete. At least one 'Analytical determination'. In each row, there must be a selection made in the

← Re-check to see if you correctly amended the failure

Correct, save and re-check

- Do not submit the dossier before all '**Submission check**' failures are fixed



The screenshot shows the 'Submission checks (0)' and 'Quality checks (0)' tabs. Below the tabs, there are two informational messages:

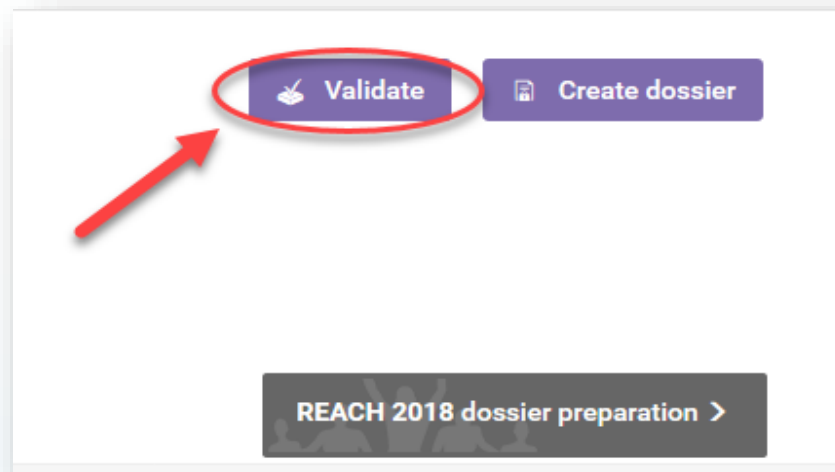
- Business rules (0), Completeness check rules (0)**
No business rule failures were detected by the Validation assistant. Please note that some of the business rules can be checked only at dossier level. Also note that as the Validation assistant verifies information only within the IUCLID dossier or substance dataset, it cannot perform all the business rules checks that apply when the dossier is submitted to ECHA.
- 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.

Below the messages, there are buttons for 'Re-check', 'Open document', 'Copy report', and 'Copy selected row(s)'. There are also dropdown menus for 'Filter: All' and 'Rule level: All'. At the bottom, there is a table header with columns: Rule, Section number, Section name, Document name, Message, Rule type, and Rule level.

- We perform additional checks that the Validation assistant cannot predict

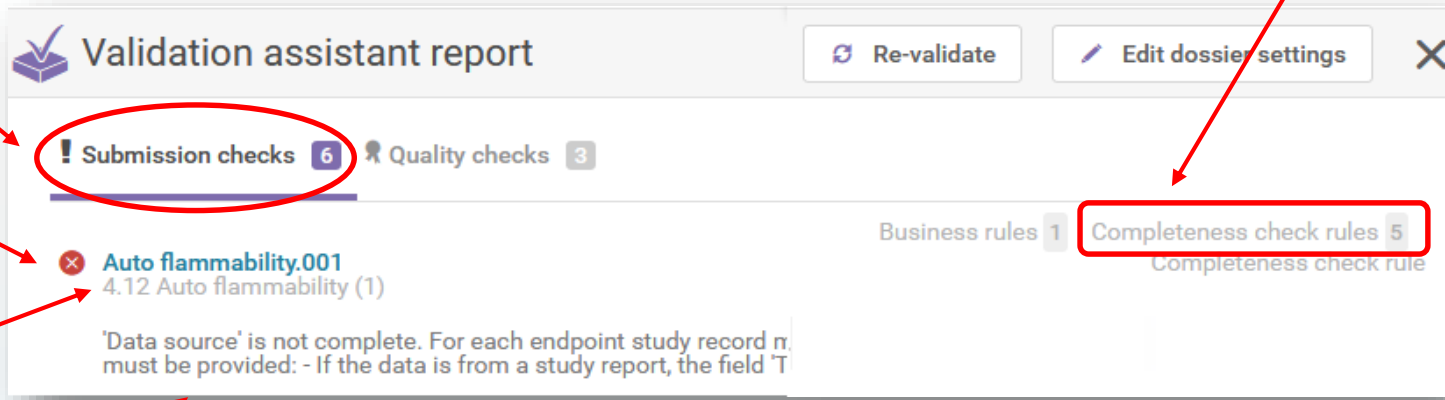
Validation assistant in IUCLID Cloud

- Switch to dataset view
- Click “validate”



Validation assistant in IUCLID Cloud

Correct failures detected in the Validation assistant report



The screenshot shows the 'Validation assistant report' interface. At the top, there are buttons for 'Re-validate' and 'Edit dossier settings'. Below the title, there are two summary items: 'Submission checks 6' (circled in red) and 'Quality checks 3'. On the right side, there are two more summary items: 'Business rules 1' and 'Completeness check rules 5' (circled in red). The main content area shows a failure for 'Auto flammability.001' under the '4.12 Auto flammability (1)' section. The failure description states: ''Data source' is not complete. For each endpoint study record n, must be provided: - If the data is from a study report, the field 'T'. Red arrows point from text labels to these specific elements in the interface.

Number of submission check failures

Number of completeness check failures

Name of failing IUCLID section

Name of failing document

Failure description



REACH 2018

Correct, save and re-check

Validation assistant report


 Submission checks **10**  Quality checks **4**

 [Composition.001](#)
Composition Impurities, (1)

← Click the name of the failing section to be taken to the error

↓ Save your changes

→ Go back to the validation report

 **Composition Impurities, (1)** [Validation report](#)

Each impurity of a legal entity composition must be identified by providing as a minimum one of the following: -EC number; -CAS number and CAS name; -IUPAC name. For impurities that cannot be identified with any of the above types of identifiers, the phrase 'unknown impurities' should be inserted in the 'IUPAC name' field, and the nature, number and relative amounts of the impurities should be sp...
[Read more](#)


General Information

Name
Legal Entity Composition 24/255

Type of composition
legal entity composition of the substance x v

State / form
liquid x v

Description A. Insert existing templates v





Take home messages

- Use the Validation assistant to check if you give all expected information in your dossier
- Correct all failures that appear in the Validation assistant report
- Do not submit your dossier before all the failures are corrected
- We perform additional checks that the Validation assistant cannot predict