



Australian Government

Department of Health

Australian Industrial Chemicals Introduction Scheme

Guidance on validating the chemical dataset in IUCLID6

For assessment certificate applications

Introduction

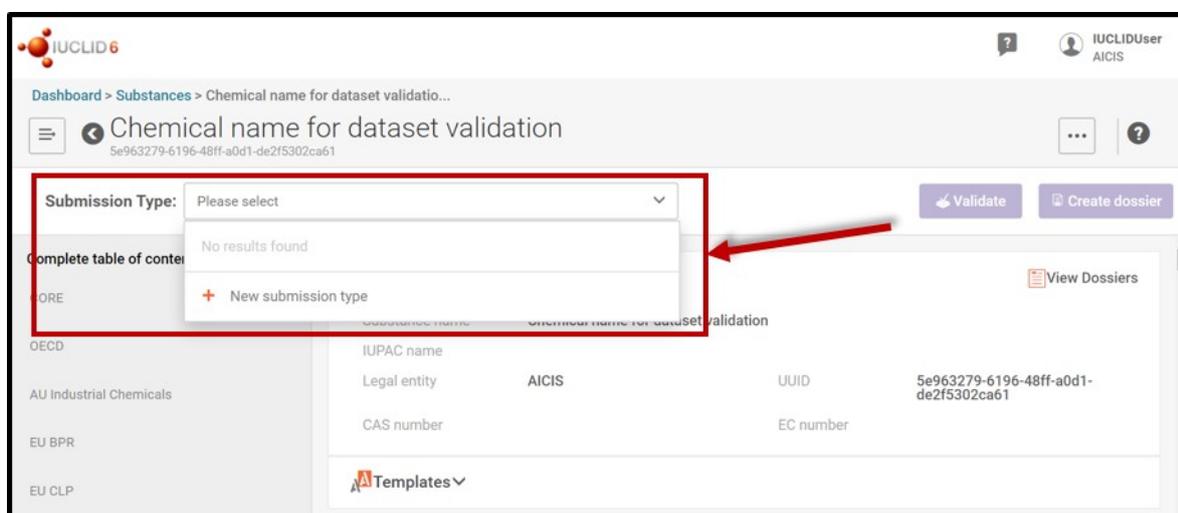
This guidance is for applicants and chemical data providers for an assessment certificate application that includes validation of the IUCLID6 dataset.

Instructions

After entering all chemical-related information in the latest version of IUCLID6 (above Ver. 6.18.0), follow the steps below to validate the prepared chemical dataset.

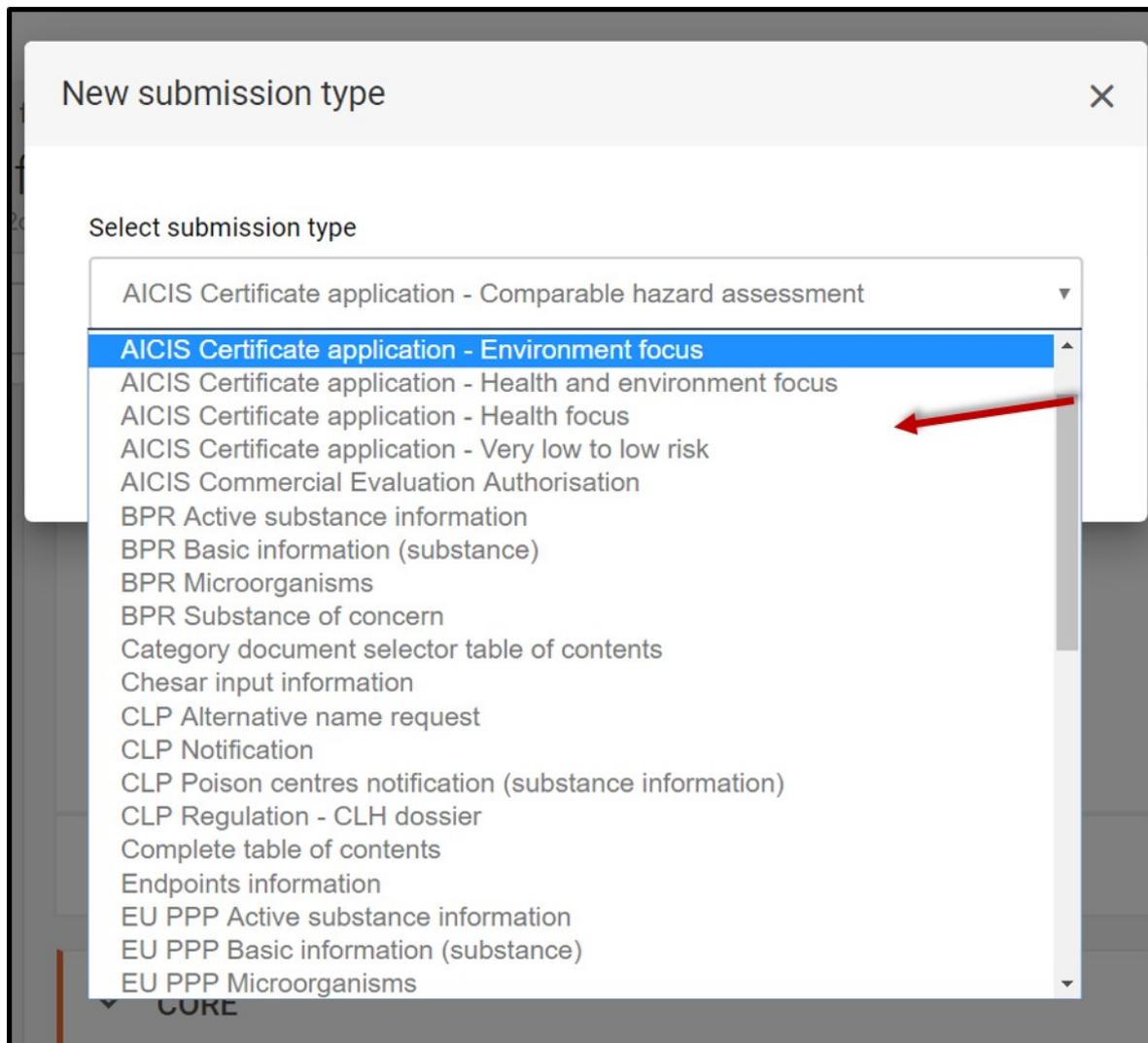
To validate your dataset, select the relevant application type. It will be the one based on your category of introduction.

This will be listed under the 'Submission type' menu.

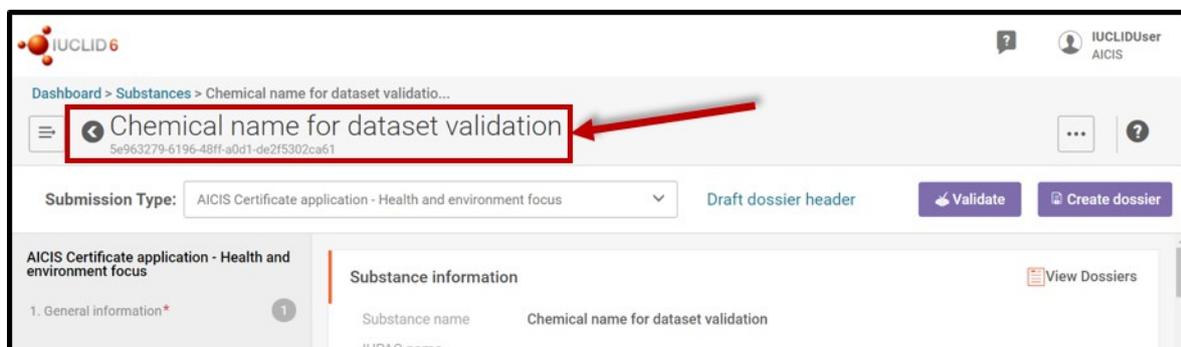


The screenshot displays the IUCLID6 web interface. At the top, the IUCLID6 logo is on the left, and a user profile for 'IUCLIDUser AICIS' is on the right. The breadcrumb trail reads 'Dashboard > Substances > Chemical name for dataset validation...'. The main heading is 'Chemical name for dataset validation' with a sub-heading '5e963279-6196-48ff-a0d1-de2f5302ca61'. A red box highlights the 'Submission Type' dropdown menu, which is currently set to 'Please select'. The dropdown list shows 'No results found' and a '+ New submission type' option. A red arrow points from the dropdown to the 'Validate' button. Below the dropdown, there are buttons for 'Validate' and 'Create dossier'. The main content area shows a table with columns for 'IUPAC name', 'Legal entity', 'CAS number', 'UUID', and 'EC number'. The 'Legal entity' is 'AICIS' and the 'UUID' is '5e963279-6196-48ff-a0d1-de2f5302ca61'. There is also a 'View Dossiers' button and a 'Templates' dropdown menu.

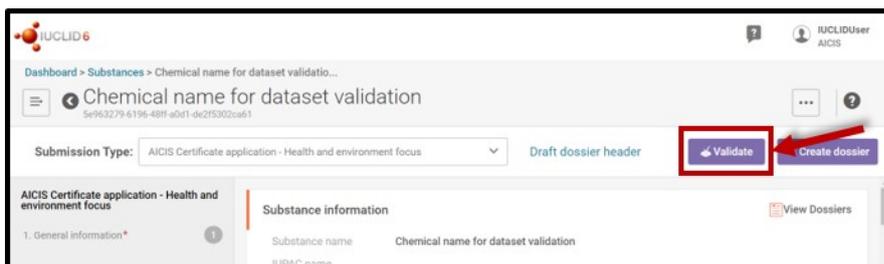
Select the relevant application type from the 'Pick list' and then click 'Apply'.



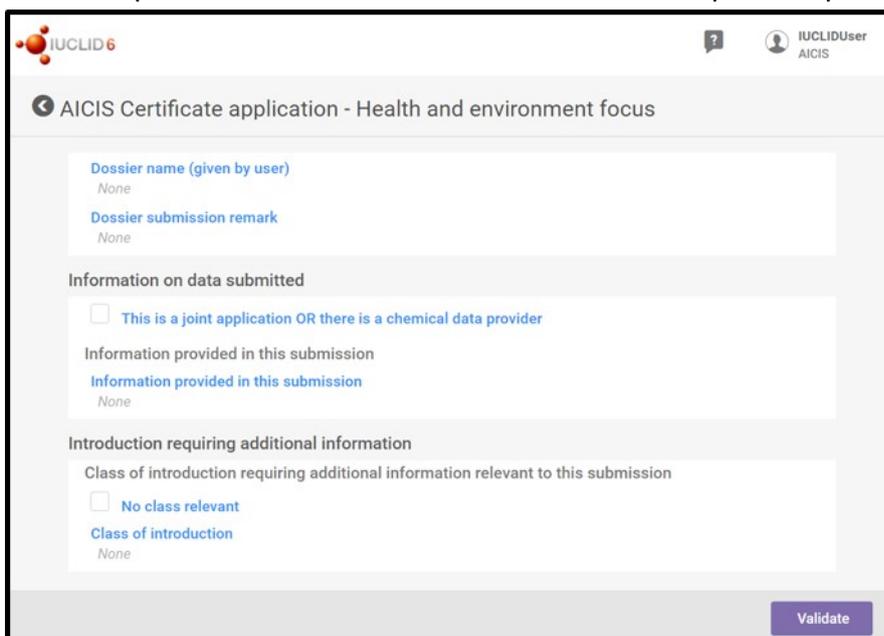
You will then need to confirm that the chemical dataset you wish to validate is open. Check for the correct chemical name.



To run the validation assistant, click on the 'Validate' button.



This will open the 'Validation assistant'. You will be required to provide further details.



If you are a joint applicant or a chemical data provider:

- tick the 'This is a joint application OR there is a chemical data provider' checkbox
- select the role that applies to you, either 'Certificate applicant' or 'Chemical data provider'.

IUCLID6

IUCLIDUser
AICIS

← AICIS Certificate application - Health and environment focus

Dossier name (given by user)
None

Dossier submission remark
None

Information on data submitted

This is a joint application OR there is a chemical data provider

Role of information provider in this submission

Certificate applicant

Chemical data provider

Information provided in this submission
Information provided in this submission
None

Introduction requiring additional information
Class of introduction requiring additional information relevant to this submission

Validate

You will then need to select the information you are providing in the submission.

Click on the arrow in the 'Information provided in this submission' field. Click on the check box for all applicable sections.

Information provided in this submission

Information provided in this submission ?

- Select/Deselect all
- Identity, composition and analytical information
- Classification & labelling
- Manufacture, use and exposure
- Physical and chemical properties
- Environmental fate and pathways
- Ecotoxicological and toxicological information

If your chemical has not been categorised as a specified class of introduction, then check the 'No class relevant' checkbox.

Introduction requiring additional information

Class of introduction requiring additional information relevant to this submission

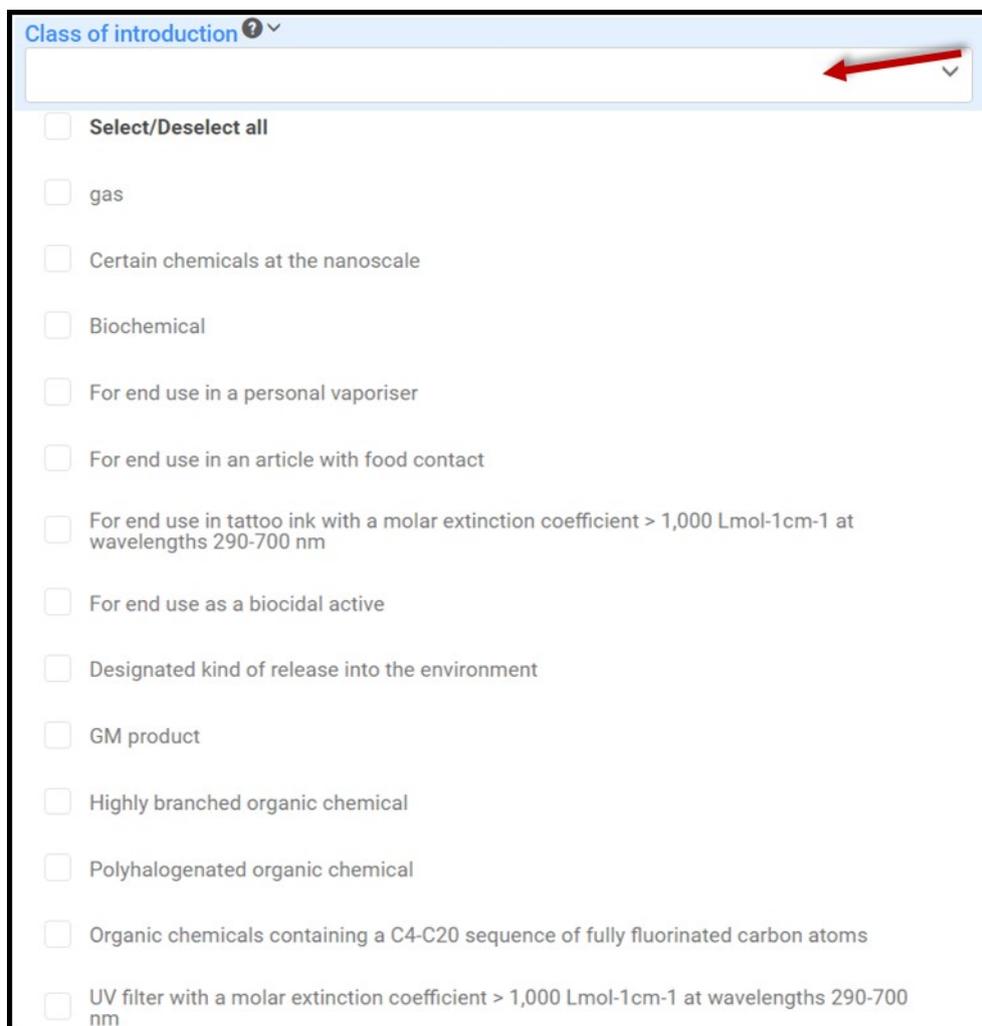
No class relevant

Class of introduction

None

If your chemical has been categorised as a specified class of introduction, you will have had additional information requirements to fulfil. Click on the arrow in the 'Class of introduction' field.

This will open a drop-down list menu allowing you to select the relevant class of introduction. Click on the check box that applies.



Class of introduction ? ▾

- Select/Deselect all
- gas
- Certain chemicals at the nanoscale
- Biochemical
- For end use in a personal vaporiser
- For end use in an article with food contact
- For end use in tattoo ink with a molar extinction coefficient > 1,000 Lmol⁻¹cm⁻¹ at wavelengths 290-700 nm
- For end use as a biocidal active
- Designated kind of release into the environment
- GM product
- Highly branched organic chemical
- Polyhalogenated organic chemical
- Organic chemicals containing a C4-C20 sequence of fully fluorinated carbon atoms
- UV filter with a molar extinction coefficient > 1,000 Lmol⁻¹cm⁻¹ at wavelengths 290-700 nm

Once you have completed the information on data submitted, and identified if the introduction required additional information, click the 'Validate' button. This will then run the validation assistant.

When the validation is complete, the program will display the following validation assistant report. Make sure the report has no failures in the 'Submission checks' tab.

The screenshot shows the IUCLID 6 validation assistant interface. At the top, the validated entity is 'Chemical name for dataset validation', with a validation time of 23/06/2020 14:02 and a validation scenario of 'SCAU0129 - T1; joint application; SID, C&L, use & expo, phys-che...'. The interface includes buttons for 'Re-validate', 'Edit dossier settings', and 'Export to Excel'. Below the header, there are two tabs: 'Submission checks' (17) and 'Quality checks' (0). The 'Submission checks' tab is active and highlighted with a red box and a red arrow. Underneath, there are two checked categories: 'Business rules' (4) and 'Completeness check rules' (13). A blue information box explains that as of 1 July 2020, the completeness check includes additional verifications performed by AICIS staff. Below this, two failure items are listed with red 'x' icons: 1. 'Completeness check rule (TCC_AU_0004)' with details about use descriptions in sections 3.5.2-3.5.5. 2. 'Chemical name for dataset validation' (1.1 Identification) with the rule TCC_0101_03, stating the substance must be identified by linking a reference substance in section 1.1.

Make sure the validation assistant report has no failures in the 'Quality checks' tab.

This screenshot shows the same IUCLID 6 validation assistant interface, but with the 'Quality checks' tab (0) selected and highlighted with a red box and a red arrow. The 'Submission checks' tab (17) is still visible. A blue information box at the top of the main content area states: 'No completeness check failures were detected by the Validation assistant. However, as of 1 July 2020, the completeness check includes additional verifications of the submitted dossier performed by AICIS staff, to ensure that all the required elements have been provided. These checks performed by AICIS staff 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 information requirements.'

Most of the errors will have hyperlinks that take you to the correct document to rectify the errors.

Repeat this step until there are no submission or quality checks.

Once all checks have been passed, you can then create a dossier and download it as an .i6z file to upload it in the portal. You can then declare your application. You must do this step in the business portal.