

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.

					IUCLIDUser AICIS
Dashboard > Substances ⇒ Chemi 5e963279-619	Chemical name for cal name for cal name for 6-48ff-a0d1-de2f5302ca	r dataset validatio or dataset valid 61	lation		
Submission Type:	Please select		~		
Complete table of conter	No results found				
ORE	+ New submissi	on type	View Dossiers		
OECD		IUPAC name			
AU Industrial Chemicals		Legal entity	AICIS	UUD	5e963279-6196-48ff-a0d1- de2f5302ca61
EU BPR		CAS number		EC number	
EU CLP		A Templates ∨			

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

New submission type	×
Select submission type AICIS Certificate application - Comparable hazard assessment	•
AICIS Certificate application - Environment focus AICIS Certificate application - Health and environment focus AICIS Certificate application - Very low to low risk AICIS Certificate application - Very low to low risk AICIS Commercial Evaluation Authorisation BPR Active substance information BPR Basic information (substance) BPR Microorganisms BPR Substance of concern Category document selector table of contents Chesar input information CLP Alternative name request CLP Notification CLP Poison centres notification (substance information) CLP Regulation - CLH dossier Complete table of contents Endpoints information EU PPP Active substance information EU PPP Basic information (substance) EU PPP Microorganisms	

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

				2	IUCLIDUser AICIS
Dashboard > Substances	> Chemical name fo	r dataset validatio			
➡ Chemic 5e963279-6196	cal name fo	or dataset valida	ation		0
Submission Type:	AICIS Certificate app	lication - Health and environm	ent focus Va	lidate	Create dossier
AICIS Certificate application	on - Health and	Substance information	n	0	View Dossiers
1. General information*	0	Substance name	Chemical name for dataset validation		

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

			IUCLIDUser AICIS
Dashboard > Substance	s > Chemical name fo ical name fo 26-4811-a0d1-de215302co	r dataset validatio or dataset validation 61	0
Submission Type:	AICIS Certificate ap	Dication - Health and environment focus	🖌 Validate 🔷 Create dossier
AICIS Certificate applicate environment focus	tion - Health and	Substance information Substance name Chemical name for dataset validation	View Dossiers

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

	?	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 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 No class relevant Class of introduction None		
		Validate

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'.

	2	AICIS
• AICIS Certificate application - Health and environment focus		
Dossier name (given by user) None Dossier submission remark		Î
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.

110		~ 4
	Select/Deselect all	A
	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.

										,	-	AICIS
V	Validated entity: Validation time: Validation scenario:	Chem 23/06 SCAU	ical name f /2020 14:0 0129 - T1; ju	or dataset valida 2 vint application;	ition SID, C&L, use & expo,	phys-che	∅ Re-validate	Edit do:	ssier settings	ΣEx	po <mark>rt to l</mark>	Excel
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Make sure the validation assistant report has no failures in the 'Quality checks' tab.

					UCLIDUser AICIS
Validated entity: Cher Validation time: 23/0 Validation scenario: SCA	nical name for dataset validation 16/2020 14:02 U0129 - T1; joint application; SID, C&L, use & expo, phys-che	C Re-validate	Edit dossier settings	Export to Ex	cel X
I Submission checks 17	Quality checks 0				
No completeness check failur	es were detected by the Validation assistant. However, as of 1	July 2020, the comple	teness check includes additiona	el verifications of the	
submitted dossier performed by A Validation assistant and they may dossier that fulfils all relevant info	AICIS staff, to ensure that all the required elements have been p (lead to a different outcome than indicated by this tool. The us ormation requirements.	provided. These checks e of the Validation ass	s performed by AICIS staff cann istant is without prejudice to the	ot be replicated usin e obligation to subm	ig the it a

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.