

Australian Government

**Department of Health** Australian Industrial Chemicals Introduction Scheme

# Guidance on validating the chemical dataset when submitting it in the business portal

For assessment certificate applications

# Introduction

This guidance is for applicants and chemical data providers for a certificate assessment application that includes validation of the chemicalrelated information entered in the chemical dossier tab.

# Instructions

When you have completed the chemical dossier, you will need to click 'Validate chemical dataset'. This step allows you to check that you have completed the relevant sections and summarises the information you have provided to support your certificate application.

Chemicals

Name	Dataset status	Actions
Nanostick	NA	Edit Validate chemical dataset

als Drints and Capita as	superior sectors sectors		44.902		
ck Prints and Coatings					
Overview	Participants	Application type	Invoice	CBI	Chemical dossier
Declaration					
Information on data submitted					
Information provided in this su	Ibmission				
Information provided in this submission					
					¢
Edit					
1					
Introduction requiring additional	information				
Class of introduction requiring	additional information relevant to this	submission			
No class relevant					
Class of introduction					^
Edit					*
USI-VACEN					
ine					

### To edit the information on data submitted field, click on 'Edit'.

1	nformation on data submitted	
	Information provided in this submission	
	Edit	0

## This will open a pop-up window containing a checklist for you to complete.

Edit Information provided in this submission	>
Information provided in this submission	
Identity, composition and analytical information	
Classification & labelling	
Manufacture, use and exposure	
Physical and chemical properties	
Environmental fate and pathways	
Ecotoxicological and toxicological information	
Guidance on safe use	

Check on each of the relevant information points and then click on 'Save' to save your selections in the field.

nformation provided in this submission	
formation provided in this submission	
Identity, composition and analytical information	
Classification & labelling	
Manufacture, use and exposure	
Physical and chemical properties	
Environmental tate and pathways	
Ecotoxicological and toxicological information	

If your chemical was not categorised as a specific class of introduction, then you can check the 'No class relevant' check box and then 'Save the information' to go back to the main window.

### No class relevant

If your chemical has been categorised as a specified class of introduction, you will have had additional information requirements to fulfil. To edit the information on the class of introduction, click on 'Edit'.

Introduction requiring addit	litional information	
Class of introduction req	quiring additional information relevant to this submission	
Class of introduction		\$
Ede		

## This will open a pop-up window containing a checklist for you to complete.

Edit Class of introduction

### Class of introduction

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



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Check on the relevant class of introduction and then click on 'Save' to save your selection in the field.

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0

Click on 'Save' to save the information entered and go back to the certificate application page.

A validation report will then be generated.

If the program finds no failures, you can move on to the 'Declaration' step. If the validation report finds failures, these will be listed in the 'Validation report'. This report will indicate any discrepancies or absences in the dataset you have submitted, allowing you to fix them before submitting the dataset to AICIS.

### Validation report

Section						
number	Section name	Document name	Message	Rule type	Rule level	Actions
1.1	Identification	aldehyde kolla	The molecular formula, molecular weight and structural formula of each reference substance must be indicated in the designated fields or a justification for not providing this information must be given in the 'Remarks' field of the reference substance.	Business rule	FAILURE	View document
1.2	Composition	Composition.001	For each composition in section 1.2, at least one constituent must be defined. All constituents must be identified by linking a reference substance.	Business rule	FAILURE	View document
1.2	Composition	Composition.001	For each constituent, impurity and additive of a composition, the full 'Concentration range' must be provided (lower and upper value), together with a unit. If you are reporting a constituent, impurity or additive at exactly 0% or 100%, provide this value, together with the unit, in the field 'Typical concentration' and leave the 'Concentration range' fields empty.	Business rule	FAILURE	View documen
1.2	Composition	Composition.001	For each legal entity composition, at least one value and a unit must be provided for the 'Degree of purity'.	Completeness check	FAILURE	View documer
1.2	Composition	Composition 001	Section 1.2 is incomplete. For each legal entity composition, the 'State/form' must be indicated. If none of the available picklist values apply, select 'other' and provide the appropriate value in the below field. If the substance covers different physical states or forms, a separate composition should be created for each of them.	Completeness check	FAILURE	View docume
1.4	Analytical Information	Analytical information.001	An indication of the optical activity of the substance should be provided in section 1.4 in the field 'Optical activity'.	Quality check	FAILURE	View docume
1.4	Analytical Information	Analytical information 001	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 - 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 kettlications for all must be provided in	Completeness check	FAILURE	View document
	1.1 1.2 1.2 1.2 1.2 1.2 1.4	1.1     Identification       1.2     Composition       1.2     Composition       1.2     Composition       1.2     Composition       1.2     Composition       1.4     Analytical Information       1.4     Analytical Information	InterferenceGenerationGeneration1.1Identificationaldehyde kolia1.2CompositionComposition 0011.2CompositionComposition 0011.2CompositionComposition 0011.2CompositionComposition 0011.4Analytical InformationAnalytical information 0011.4Analytical InformationAnalytical information 001	InteractionDescriptionDescription1.1Identificationaidehyde kollaThe molecular formula, molecular weight and structural formula of each reference substance.1.2CompositionComposition 001For each composition in section 1.2, at least one constituent must be defined AI constituents must be identified by linking a reference substance.1.2CompositionComposition 001For each composition in section 1.2, at least one constituent must be defined AI constituents must be identified by linking a reference substance.1.2CompositionComposition 001For each composition in section 1.2, at least one constituent must be defined AI constituents must be identified by linking a reference substance.1.2CompositionComposition 001For each composition, at least one constituent must be provided for the Degree of purity.1.2CompositionComposition 001Section 1.2 is incomplete. For each legal entity composition, the Stateformy must be indicated if none of the available pickint values apply, select "other" and provided in seguration covers different physical states or forms, a segarate composition should be created for each of them.1.4Analytical InformationAnalytical information001No indication of the optical activity of the substance should be provided in the table "Availytical determination". In each row, the following must be provided. 	Name ControlOperationDescriptionDescriptionDescriptionDescription1.1Identificationaldehyde koliaIn the molecular longuity in the Youding this information must be given in the Youding this information.Business rule1.2CompositionComposition 001For each composition 12, at last one constituent must be defined All contentituents must be lidentified by linking a reference substance.Business rule1.2CompositionComposition 001For each constituent, impuity or additive of a composition, the full 'Concentration range' must be indicated if mone of the available picking trained to the You and the You and You are reporting a constituent, impuity or additive of a composition, the Stateform must be provided for the Degree of parity.Completeness1.2CompositionComposition 001Section 12 is incomplete. For each legal entity composition, the Stateform must be indicated if nene of the available picking values apply, select "thm", and provided in section 14 in the field 'Optical activity.Completeness1.4Analytical InformationAnalytical information 001Section 12 is incomplete. For each legal entity composition, the Stateform must be indicated if nene of the available picking values apply, select "thm", and provided in section 14 in the field 'Optical activity.Completeness1.4An	Name of exercising exercisingDescriptionReference interpresent 

### To action a failure, click on view document under 'Actions'.

Actions

### View document

This will take you to the relevant document in the dataset.

Overview					
	Participants	Application type	Invoice	СВІ	Chemical dossier
Declaration					

The error message will describe what you need to do to rectify the validation failure.

Once all validation failures have been rectified, re-validate the chemical dataset to confirm there is nothing outstanding.

 Chemicals
 Dataset status
 Actions

 Nanostick
 Draft
 Central Constraints

 Draft
 Central Constraints
 Central Constraints

When all issues have been resolved you can move on to the 'Declaration' step.