Australian Government
Department of Health
Australian Industrial Chemicals Introduction Scheme

Guide to applying online for an assessment certificate

January 2023

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Contents

Introduction

Objective

This document aims to help introducers with preparing and submitting information to the Australian Industrial Chemicals Introduction Scheme (AICIS) to get a certificate before introducing a new industrial chemical.

You will need to provide and summarise the work health, safety, public health and environmental effects of the chemical. You must also discuss the effects and hazards of the chemical in the context of its proposed use.

In your summary, you need to detail the results of the tests used to determine the toxic effects of the chemical. In tests where no adverse effects are observed, you must comment on the dosages in the tests used. You must also highlight the physical and chemical hazards of the chemical (for example, flammability and reactivity).

When entering information into the chemical dataset, there will be opportunities to flag if you would like the information to be considered as confidential business information (CBI) **or** to provide justification if any information is missing from your notification.

We recommend that applicants follow the guidance as closely as practicable. If you don't complete steps in accordance with the guidance's recommendations, the application process could fail and you may need to start again.

It is also important to note that AICIS regulatory scientists will only be able to provide assistance in relation to the data validation step. Our staff doesn't have access to your certificate application during the submission process. This means we will not have the capacity to assist you with any issues regarding the electronic certificate application process.

If you experience any technical problems when completing the information required using the business portal or when directly submitting chemical information in a IUCLID6 file, please contact us.

Note: The certificate application software will be updated from time-to-time. Where available, this document will describe and accommodate known limitations in the certificate application process.

Outline of content

- Register your business with AICIS
- Categorise your chemical introduction
- Create a substance dataset in the AICIS Business Services Portal

Important note – prior to starting you must have:

- Your chemical's public name.
- If the chemical is being used in a cosmetic and you are using new animal test data to support your application, you may need to get approval before submitting your application.
- Study reports, and other references that you are using to support your application.
- The **business ID number (beginning with NIC)**, **first and last name** of the person associated with the application at your business, as well as the first and last name of the person who will be the application contact for your business.
- If nominating an agent to act on your behalf, you must have the business ID of the agent's business, as well as the first and last name of the person who will be the contact person at the nominated business agent.
- If the certificate application is a joint application, you must have the business ID of all businesses filing the certificate application, as well as the first and last names of the people who will be the contact agent's at the joint application business(es).
- If someone else is providing chemical data for the application (i.e. a third party), you must have the business ID of the chemical data provider's business, as well as the first and last name of the person who will be the contact agent at the chemical data provider's business. If the chemical data provider is an overseas entity, they will need to register with AICIS to obtain a business ID.

There are some sections in the certificate application process where if you don't have the correct information, the application process will terminate and you will need to restart your application.

Submit the substance dossier to AICIS by either entering the information in the substance dataset or uploading a dossier file (.i6z) in AICIS Business Services. The dossier will be checked at the time of submission (the data validation step) if you enter the information in the substance dataset. We will review this on receipt to confirm that you have correctly completed the substance dataset based on the information requirement for your certificate application type.

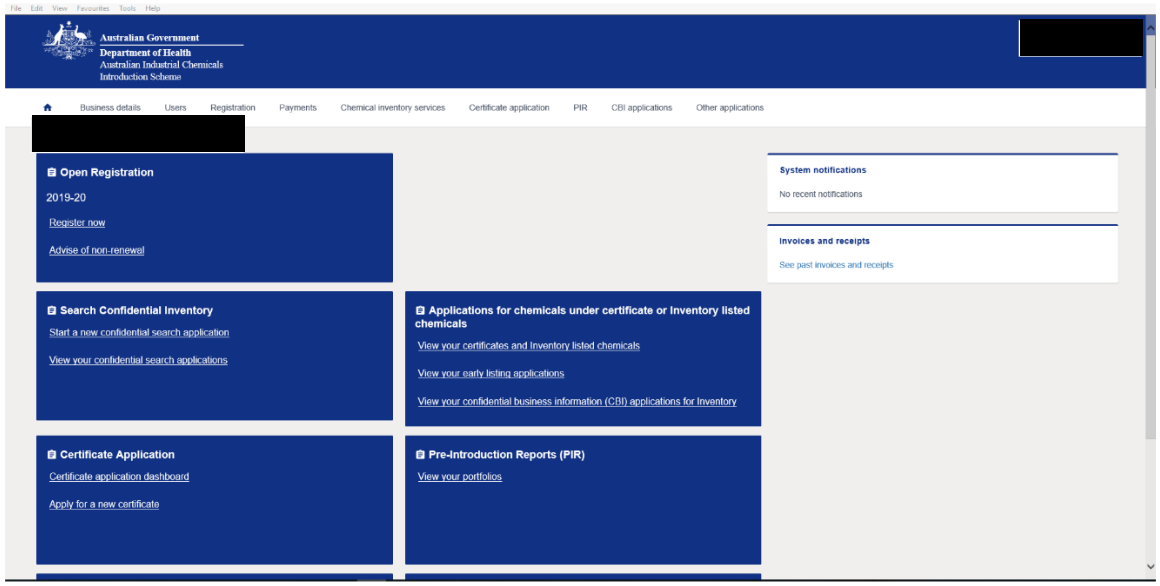
Information regarding business ID

In the application form, you are required to enter the **exact business ID, including the prefix, 'NIC',** of all businesses associated with your certificate application. We require this information to confirm that all the people you nominate in your application are aware of their nomination and understand their obligations.

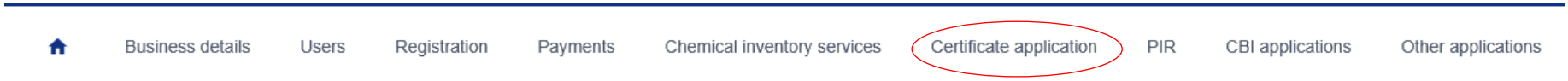
If the application requests you to provide a business ID and you do not have it, you will not be able to proceed with the application or add any chemical related information. You will need to save your application and resume work on the application once you have the business ID.

Starting a new certificate application

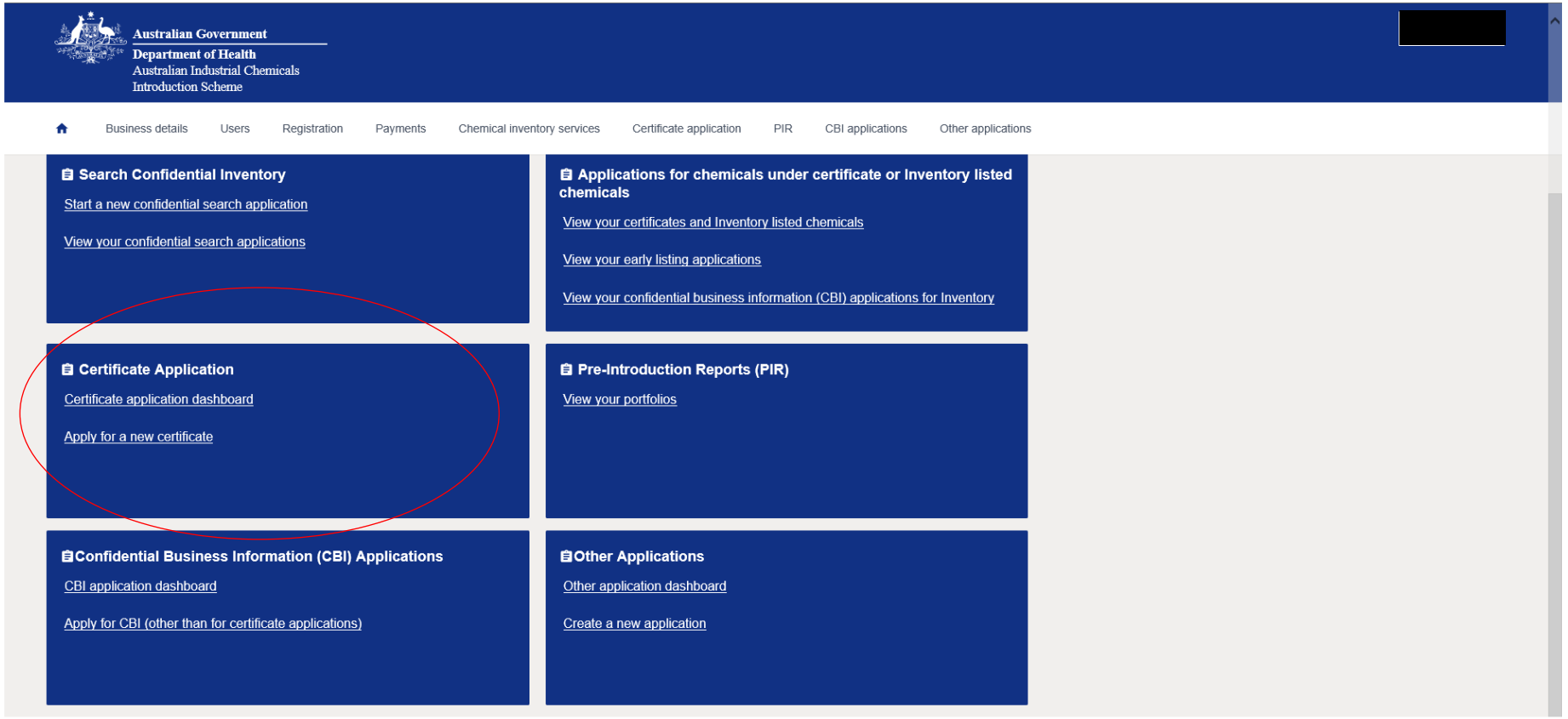
Log into the AICIS Business Services portal.



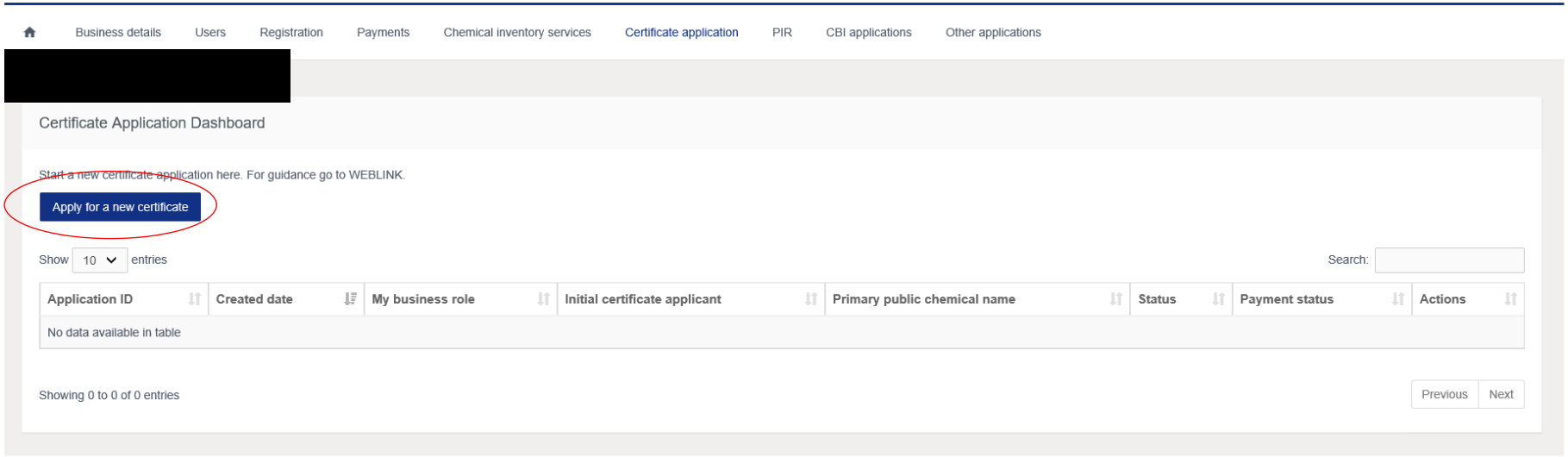
You can submit a new certificate application by clicking on ‘Certificate application’ in the menu banner.



You can alternatively submit it through the main screen.



Once you have clicked on ‘Certificate application’ (through the menu bar or window) you will see the ‘Certificate Application Dashboard’. This dashboard lists all the certificate applications you have made. Clicking on ‘Certificate Application Dashboard’ in the menus will achieve the same thing.



From here, you can also click on ‘Apply for a new certificate’. This will start a new certificate application. You can also click on ‘Apply for a new certificate’ in the main menu.

Certificate applicants and participants

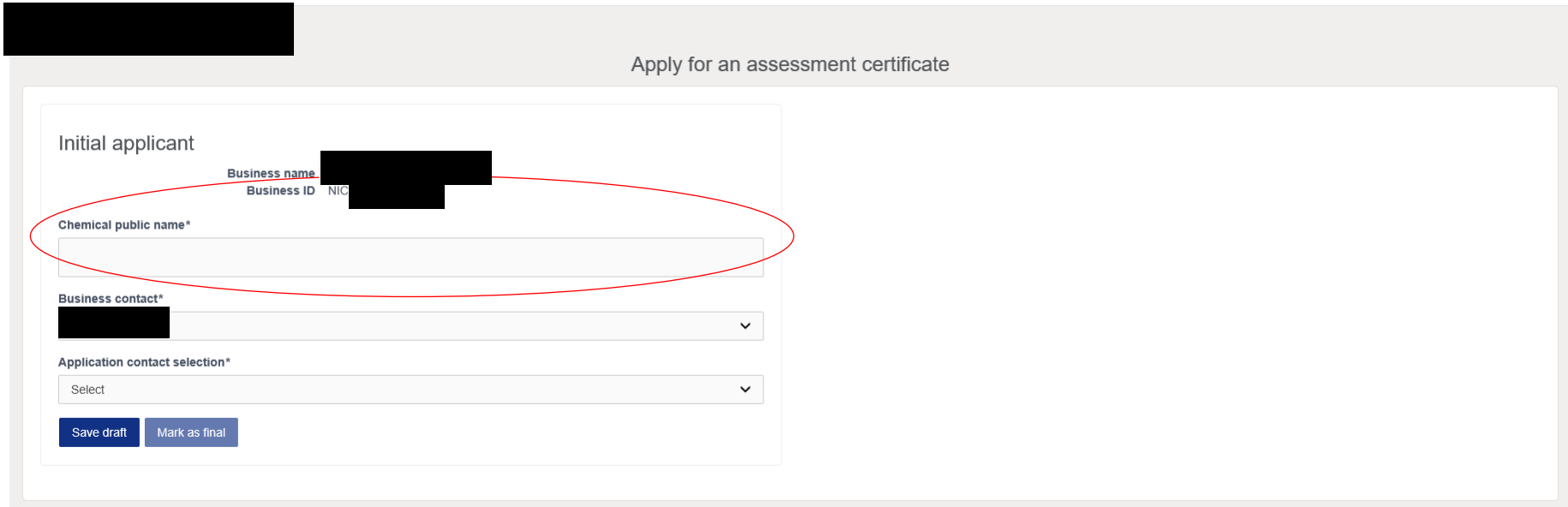
All applicants, participants, agents and chemical data providers must a business ID which they received after signing up with AICIS Business Services. You must know the relevant business ID (starting with NIC) prior to starting your application. We require all applicants, participants, agents and chemical data providers to give their consent to providing information for the application prior to us accepting your submission.

Applicants, participants, agents and chemical data providers are only obliged to provide the information they have been nominated for. For example, if you have arranged for someone else to submit the chemical data, you will not need to complete the chemical dataset. The chemical data provider you have nominated will perform this action.

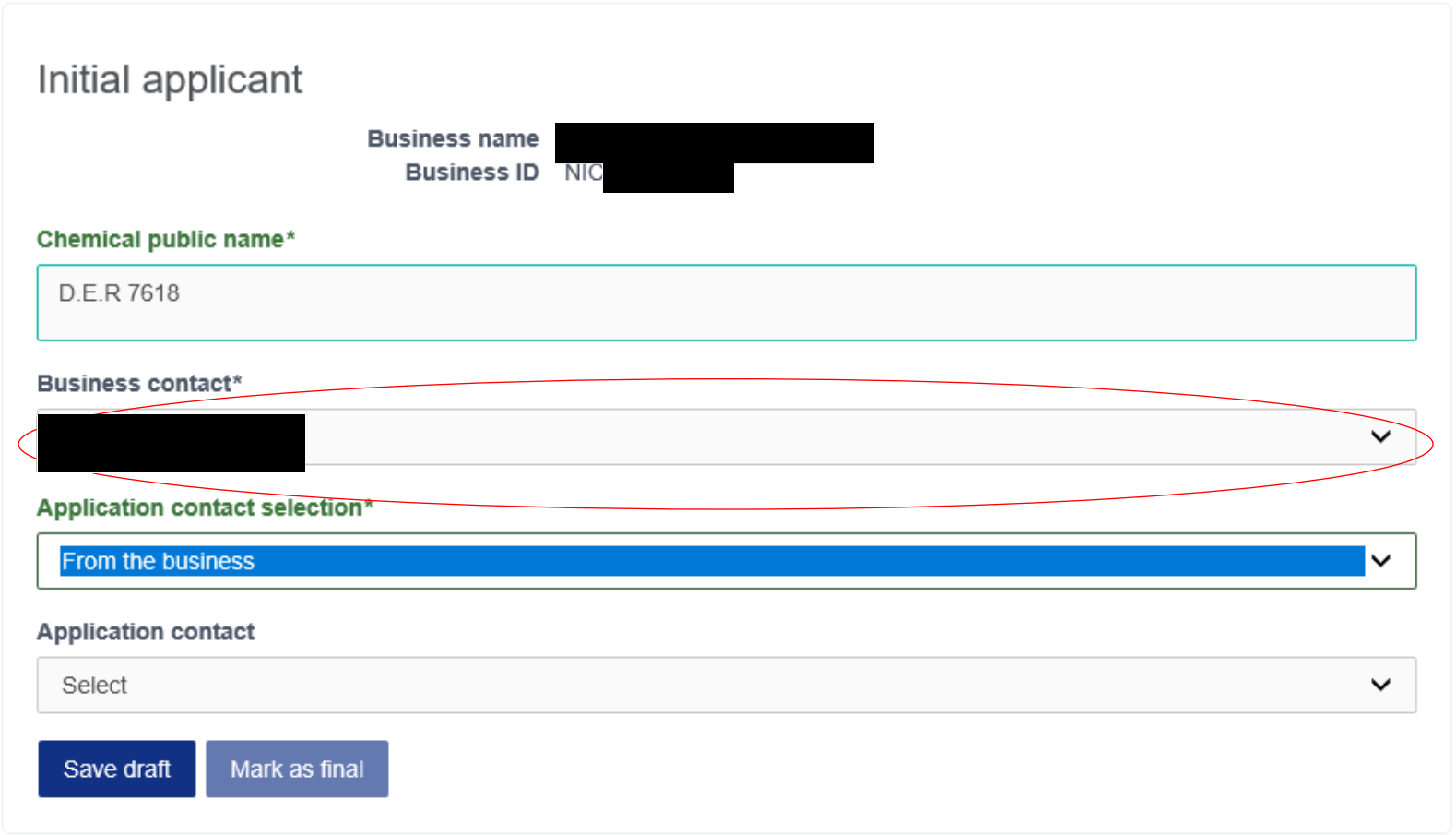
Remember, you will be unable to complete your application if you do not have the following information for people and businesses associated with your certificate:

- Business ID
- business names
- first and last names

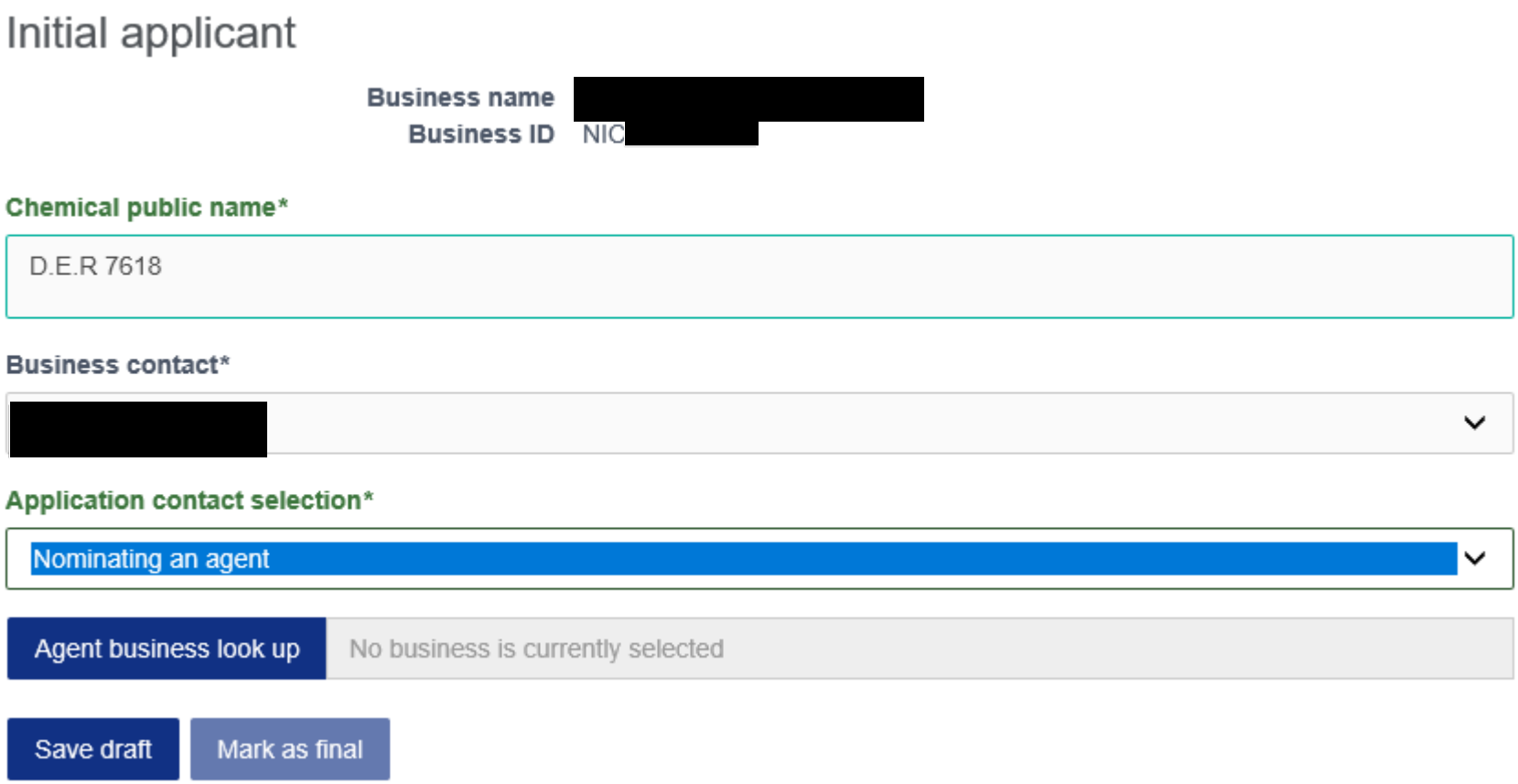
As initial applicant, you will need to enter the chemical public name in the field. This is the name the chemical will be known by all participants in the application.



Then pick ‘Business contact’ from the picklist. This is the person at your business who will be our contact point for any queries. You can only select this information from the picklist. If the name of your business contact is not in the list, they will need to sign up to AICIS Business Services.

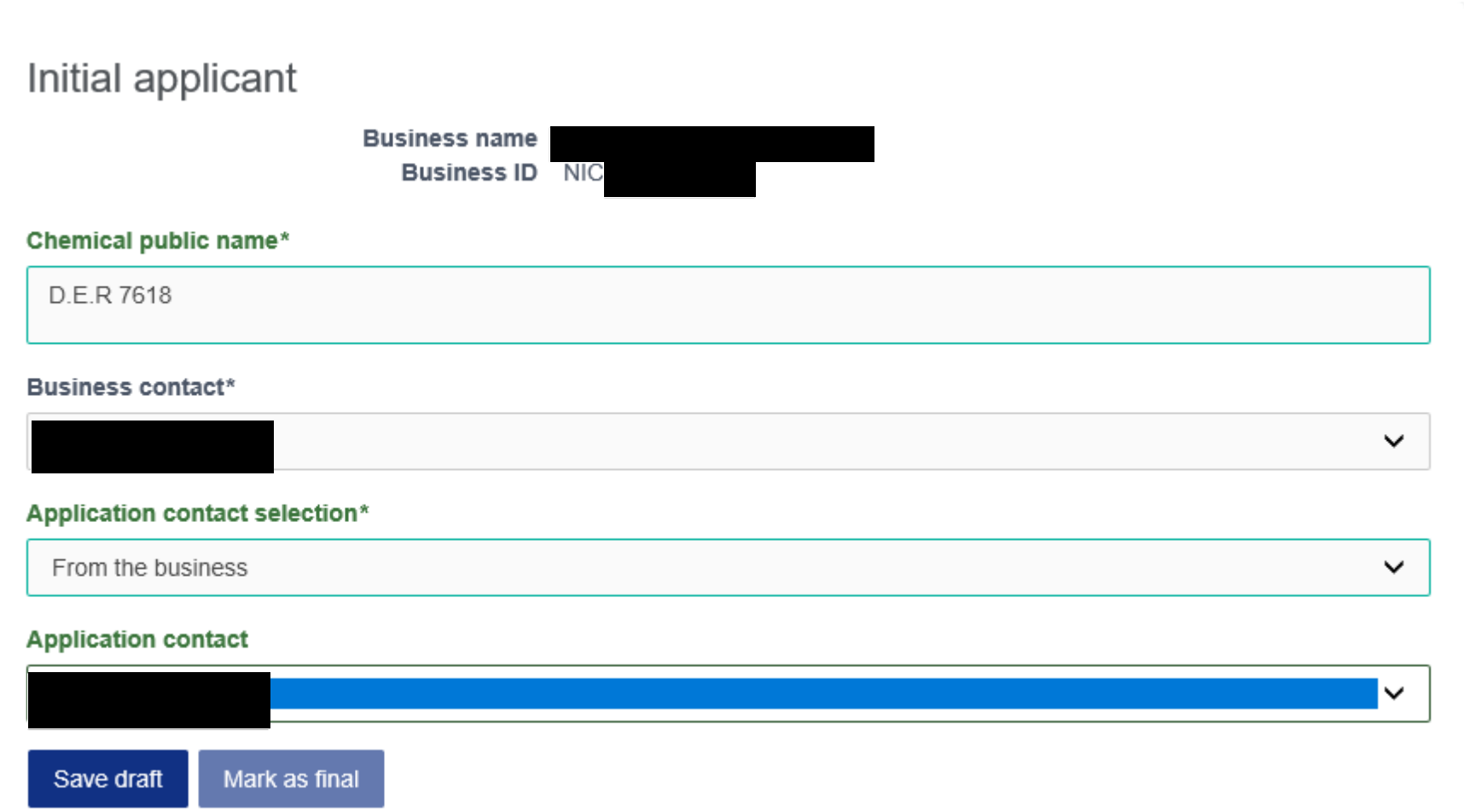


You can select an application contact by clicking on ‘Application contact selection’. The application contact can be from the business or you can nominate an agent by selecting ‘Nominating an agent’.



Once you have selected if your application contact will be from the business or if you will be nominating an agent, you can then look up their details in ‘Agent business look up’.

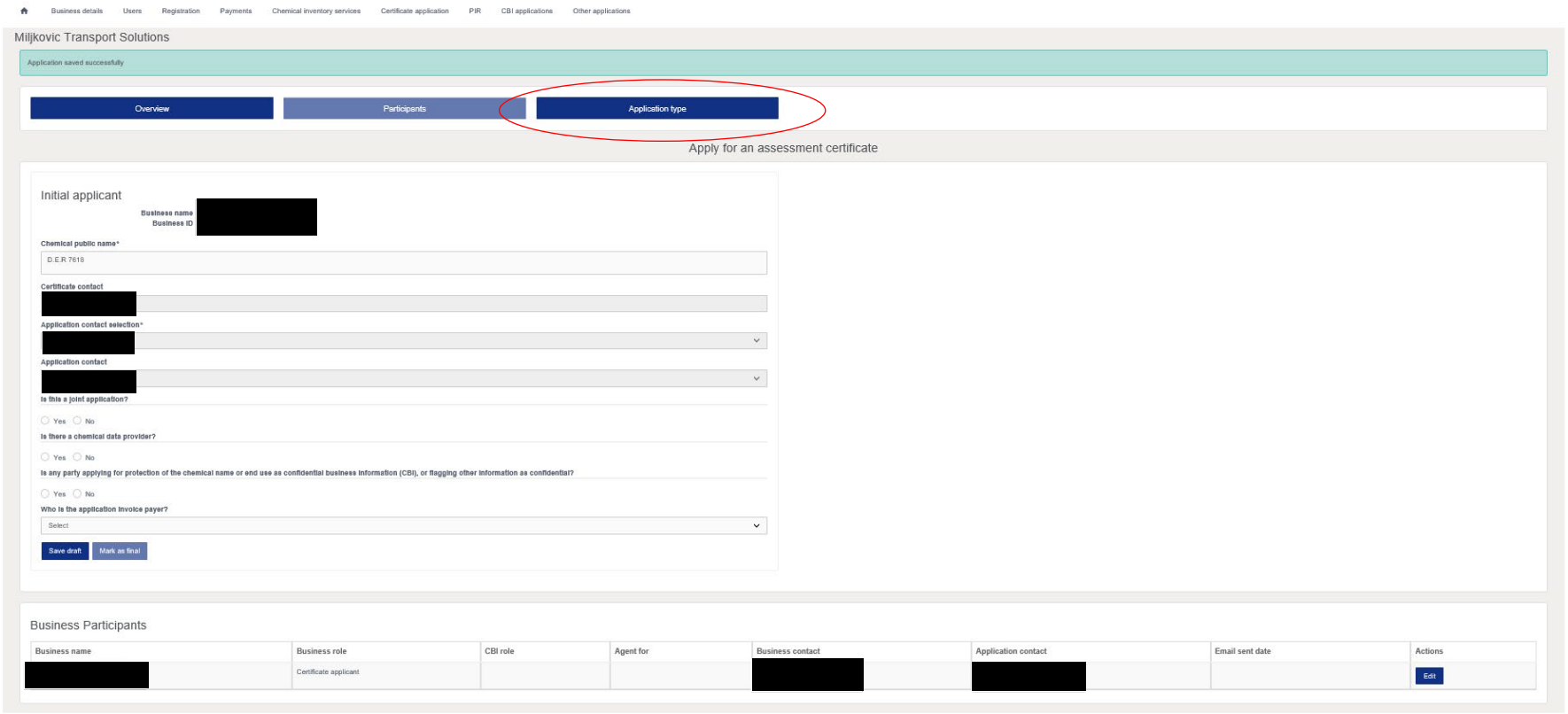
If your application contact will be from your business, only people registered with your business will appear in the picklist.



If you are nominating an agent to act as application contact, you will need to enter their business ID.

Once you have completed all initial applicant details, save the details by clicking ‘Save draft’.

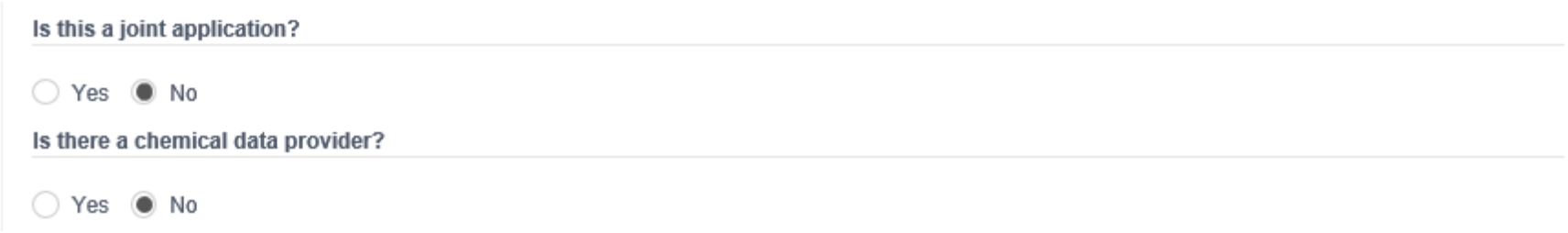
You can now enter in the participant details. The ‘Participants’ tab will open automatically when you have selected ‘Save draft’. If this does not happen, you can click on the ‘Participants’ tab.



You will see your details under ‘Initial applicant details’ and then additional questions that relate to other participants who may be involved in your certificate application.

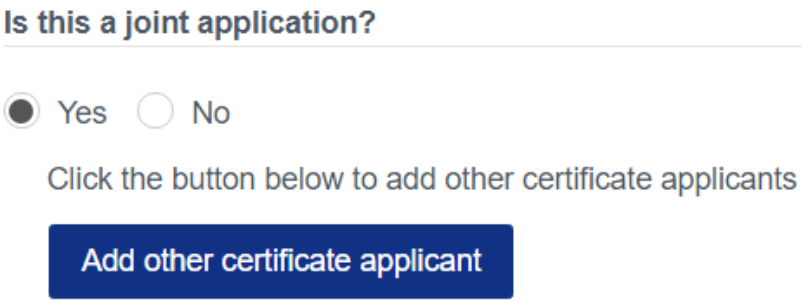
You will be asked to select if the application is a joint one or not. A joint application is where there is more than one applicant.

If you select ‘No’, then the next question to appear will relate to chemical data providers.

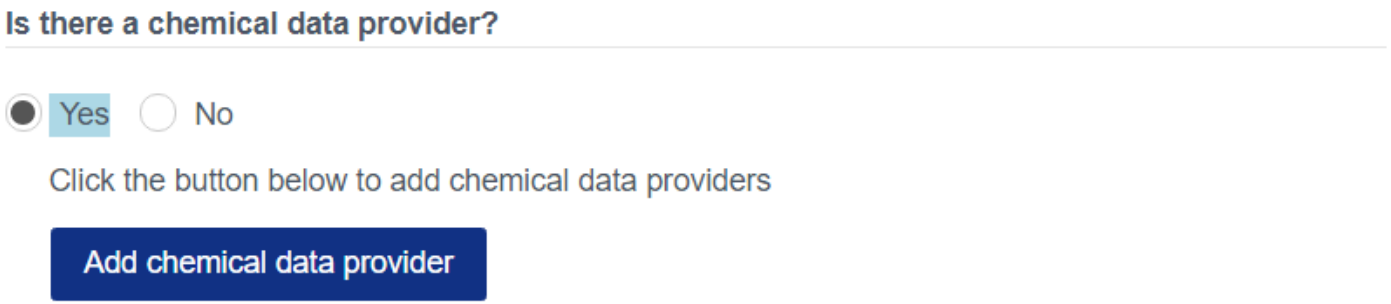


If you are providing the chemical data and there is no external chemical data provider, select ‘No’.

If you select ‘Yes’ to indicate that an application is a joint application, you will be asked to add the other businesses (certificate applicants) to the application.



If you select ‘Yes’ to indicate that you have a chemical data provider, you will be asked to add the other businesses (chemical data providers) to the application.



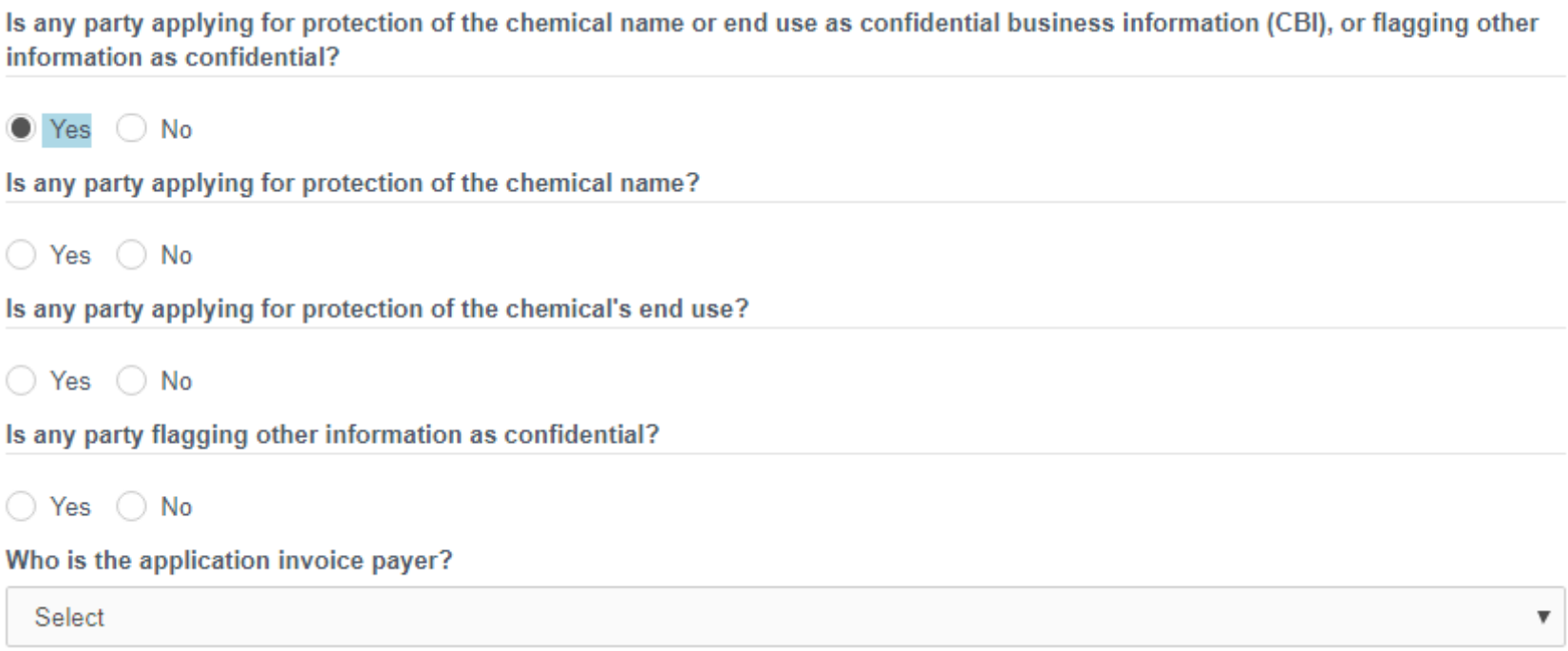
If you will be providing the chemical data, then select ‘No’.

You will then be asked if you or one of the other joint applicants is applying for confidential business information (CBI) of flagging information as confidential. We will only invoice you for CBI applications regarding the chemical name and end use at the start of the application process.

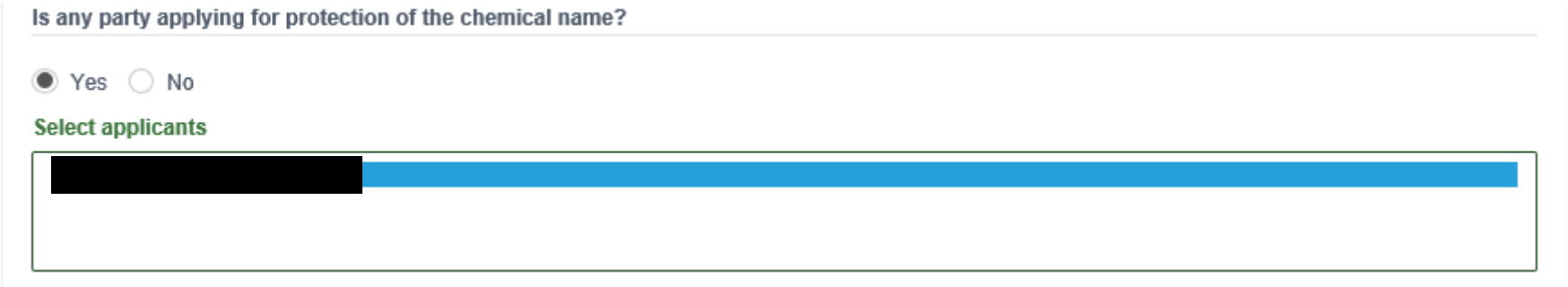
We will consider any information that you flag for consideration as CBI within the chemical dataset on a case-by-case basis. If we determine that we need to publish information flagged within the chemical dataset, we will contact you and you may need to pay an additional fee.

Read about applying for CBI on our website.

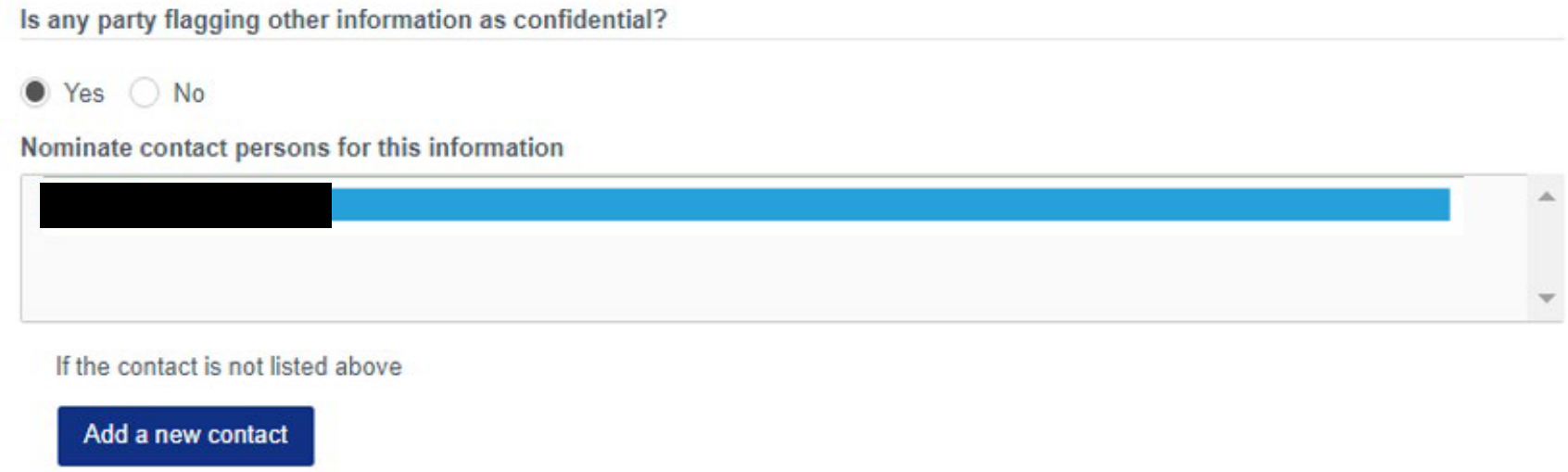
You will then need to select who is applying for the chemical name (or end use) to be CBI. Select the business name from the picklist. The picklist will be populated by the names of those businesses selected as applicants and participants (if applicable) in the certificate application.



You must highlight the name of the business by clicking on it. Even if there is only your business name listed, you must select it. If you don't select a business name, the field will not be recognised as being complete.



Repeat the previous step for the chemical's end use.



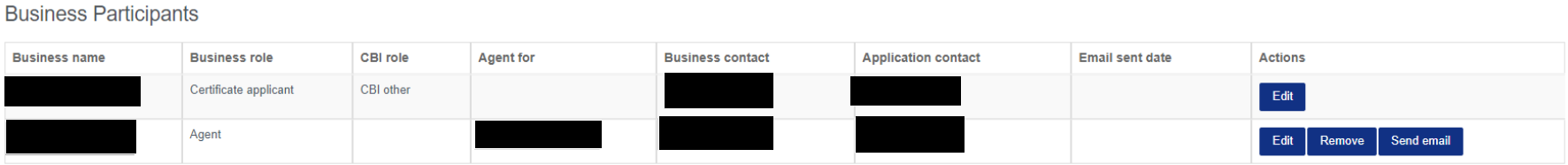
Lastly, select who will be paying the application invoice. The list will be populated by the names of those businesses registered as applicants and participants (if applicable) in the certificate application.

Remember: Only one business can pay the invoice.

You must highlight the name of the business by clicking on it. Even if there is only your business name listed, you must select it. If you don't select a business name, the field will not be recognised as being complete.

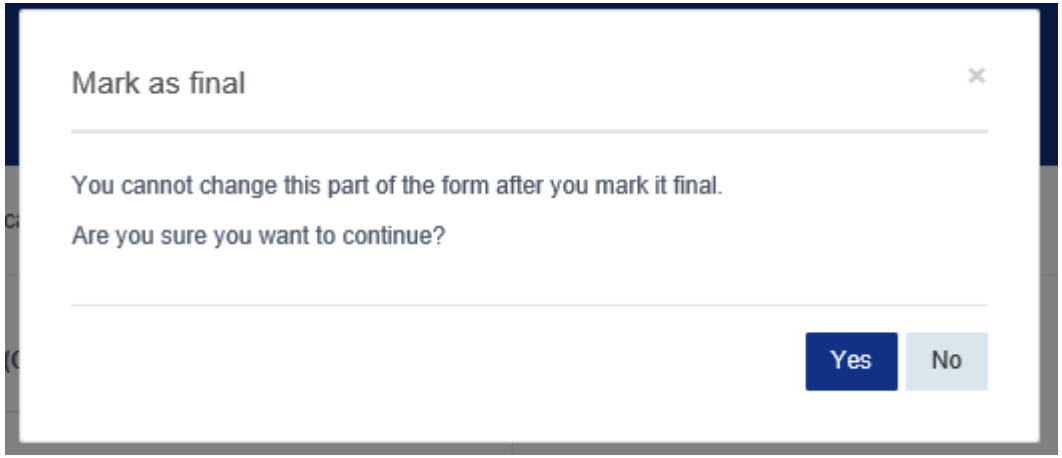
Save the information entered by clicking on 'Save draft'. If you wish to check the details entered, you can do this now.

If your application is a joint application, or has a chemical data provider or an agent, you will need to send them an acknowledgement email by clicking the send email button 'Send email' on each participant in the business participant's page, you won't be able to 'Mark as final' this section until every participant has acknowledged their part of the application.



If you are a single applicant and do not have an agent, save your draft then click on 'Mark as final' to proceed with your application.

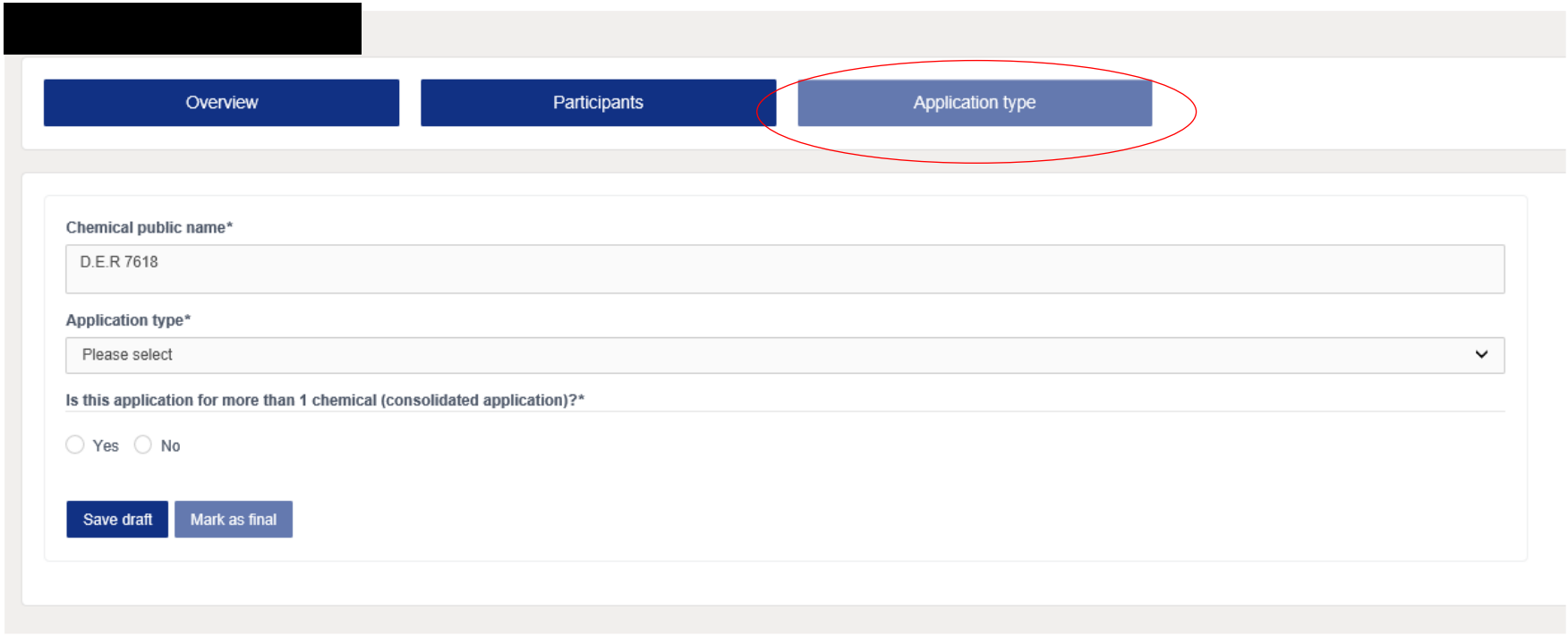
Once you click on 'Mark as final', you will be advised that you cannot make any changes to the applicant, participant and CBI details.



If you click on ‘No’, you will go back to the ‘Overview’ screen and you can confirm the information entered and make any changes if needed.
If you click on ‘Yes’, the applicant, participant and CBI details will be finalised.

Application type

Important: Make sure you understand the 5 different types of certificate applications before you select your ‘Application type’.



The application type is based on the outcome you reached after categorising your chemical introduction. The following table summarises the 5 application types

Application type	Category of Introduction
Health and Environment focus	Introductions where the chemical introduction is considered to present a medium to high risk to health and environment.
Health focus	Introductions where the chemical introduction is considered to present a medium to high risk to health, but a lower risk to the environment.
Environment focus	Introductions where the chemical introduction is considered to present a medium to high risk to environment, but a lower risk to health.

Application type	Category of Introduction
Very low to low risk	Introductions where the chemical introduction is considered to present a very low or low risk to health and environment.
Comparable hazard assessment	Introductions where a comparable hazard assessment (for health or environment) is available.

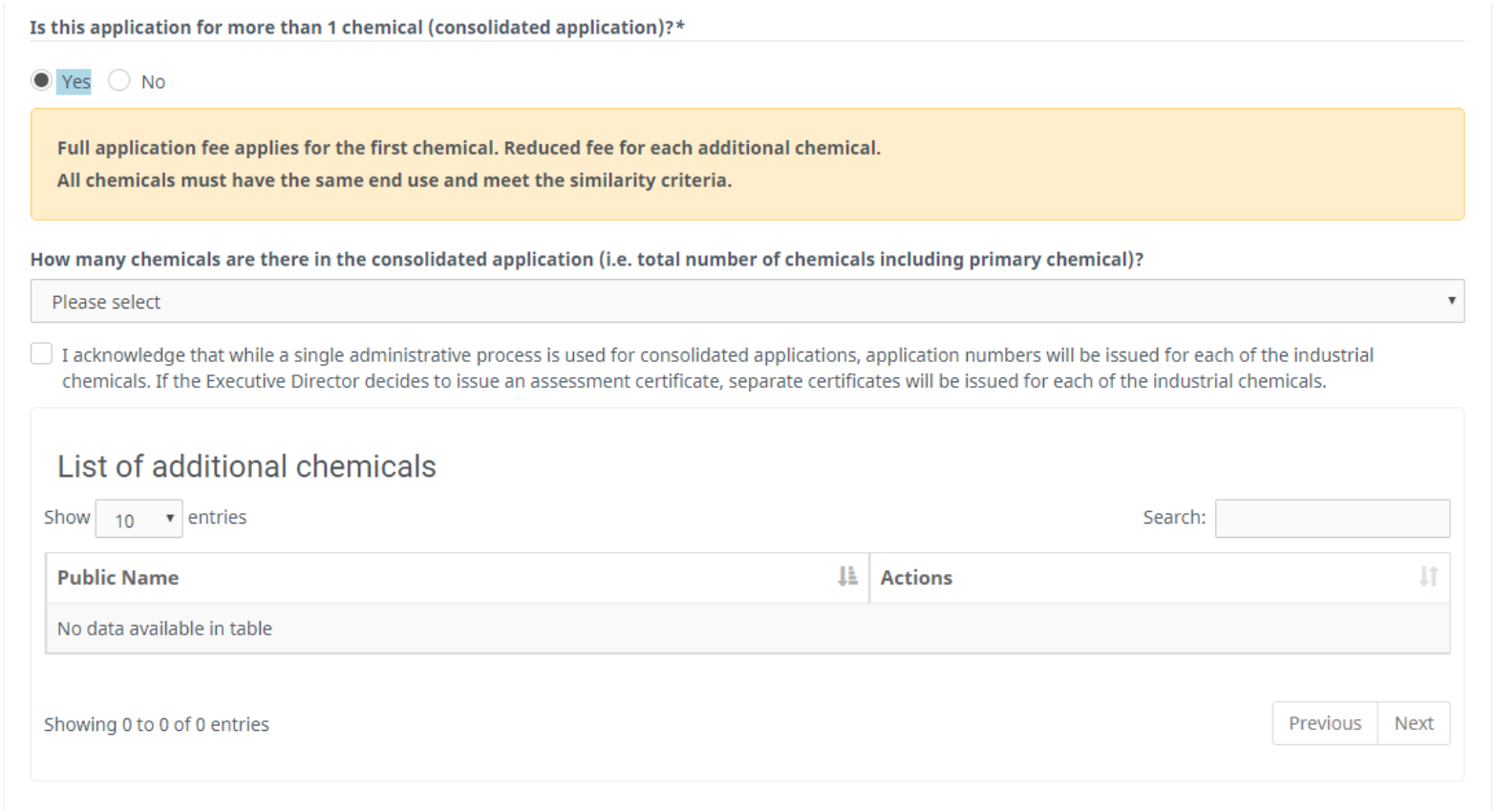
If you are applying for a comparable hazard assessment, you will need to complete an additional form.

If your introduction is a ‘specified class of introduction’, you need to provide extra information.

Highlight the application type from the picklist.

If your chemical application is a consolidated application, click ‘Yes’.

Read about consolidated applications



If you have a consolidated application, you need to:

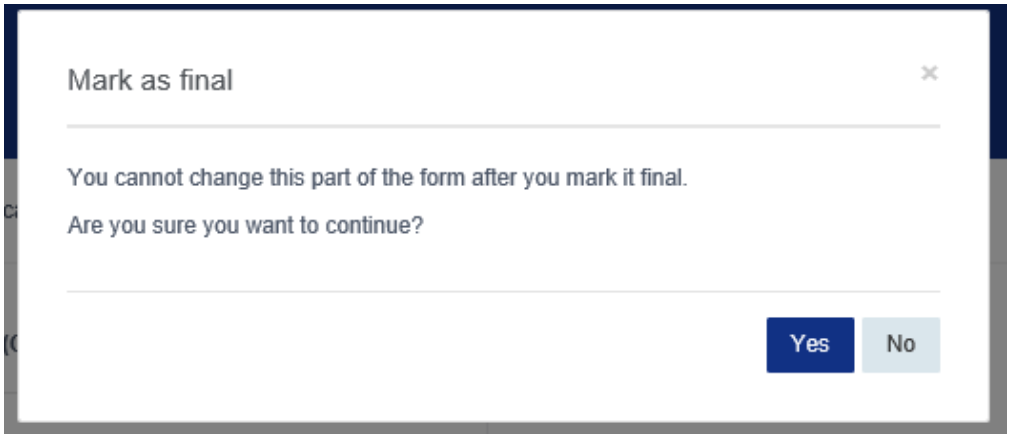
- select the number of chemicals in the application
- list the additional chemicals

When applying for a consolidated application, you need to submit information for each chemical within a single chemical dataset.

You may also need to provide additional information regarding the manufacture, use and exposure scenarios.

If you're only applying for a single chemical, click 'No'.

You can then save the information entered by clicking on 'Save draft'. If you wish to check the details entered, you can do this now. Otherwise, save your draft and click on 'Mark as final' to proceed with your application. Once you click on 'Mark as final', you will be advised that you cannot make any changes to the applicant type.



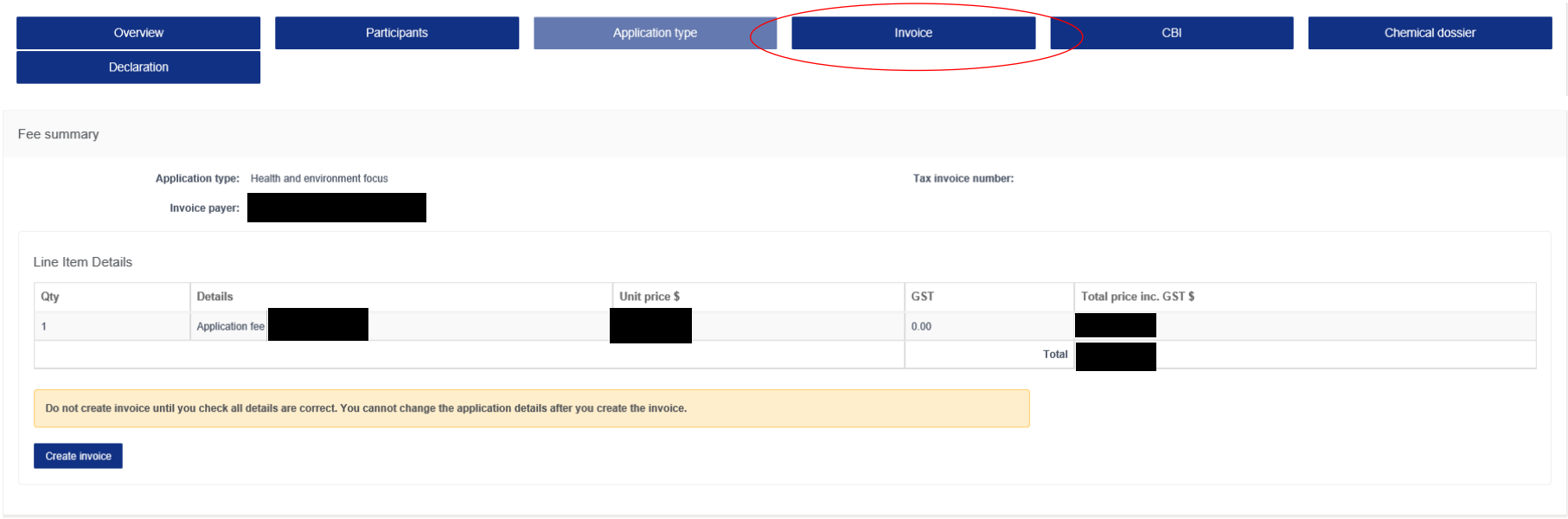
All the remaining tabs will now be available. However, you will not be able to submit your application until you have entered all information and your invoices have been paid.

Invoicing

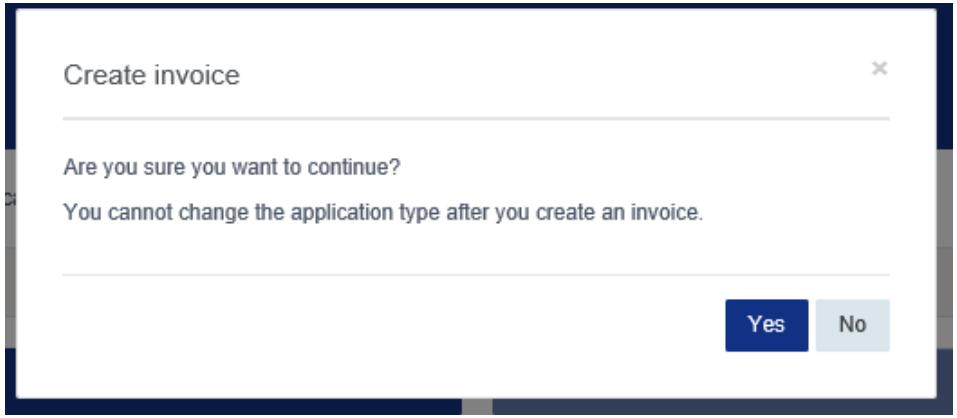
Once you have selected who is paying the invoice(s), they will be responsible for payment. Invoices will be created for the certificate application and any applications to protect the chemical name and/or end-use as confidential business information.

We cannot generate multiple invoices for multiple applicants or split payments. If there is more than one person contributing to the invoice for the certificate application, you must make these arrangements offline.

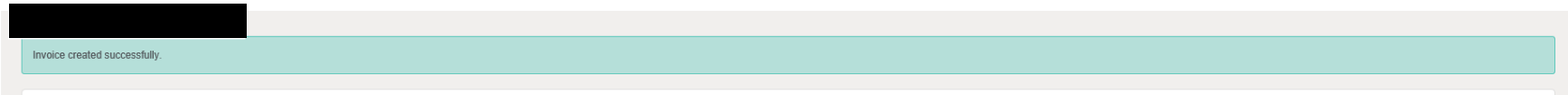
Click on the ‘Invoice’ tab.



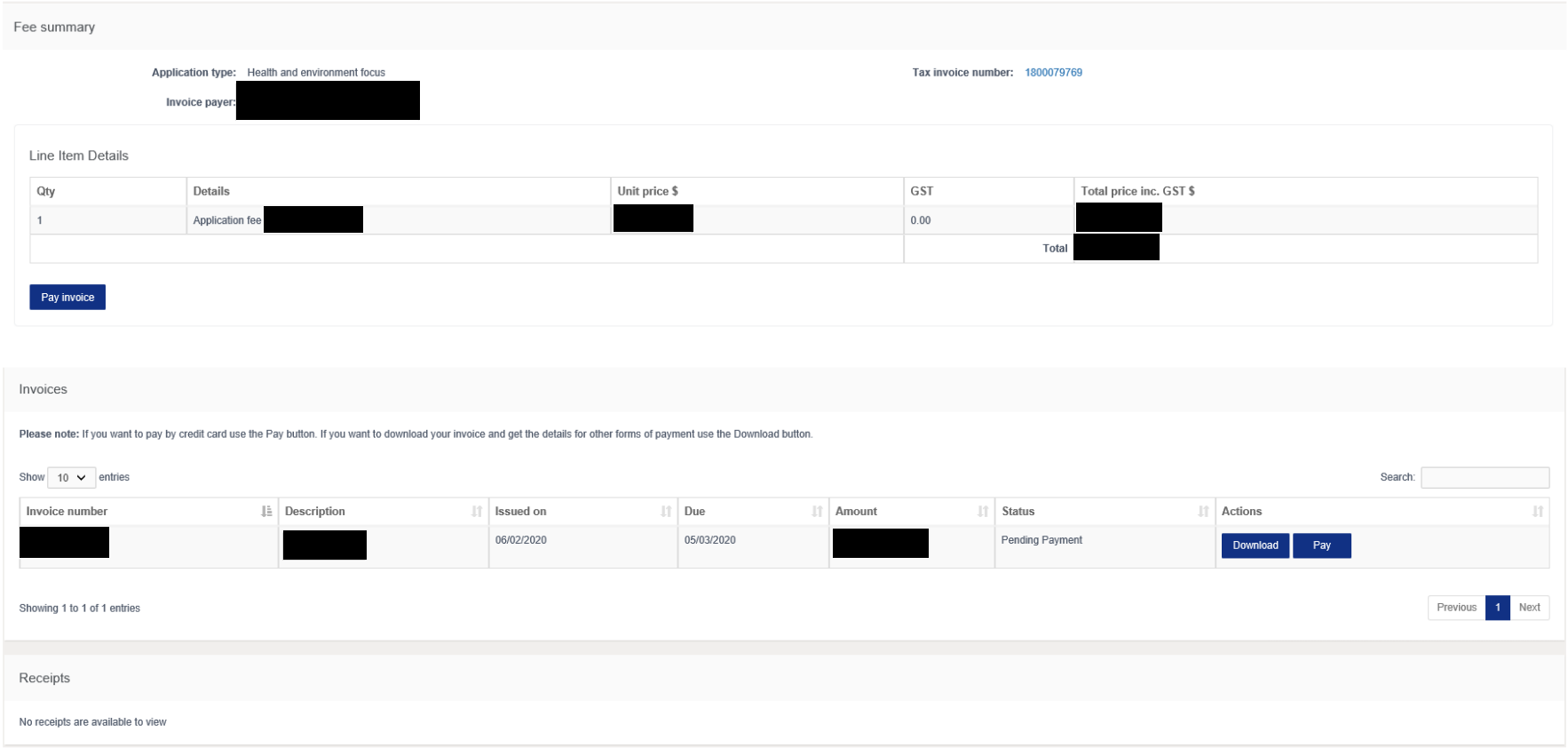
Please note the application fee provided is for demonstration purposes only. If you are also applying for CBI, then you do not need to create an invoice now. You can create it later.



Selecting ‘No’ returns you to the invoice screen, selecting ‘Yes’ will create an invoice for the assessment.

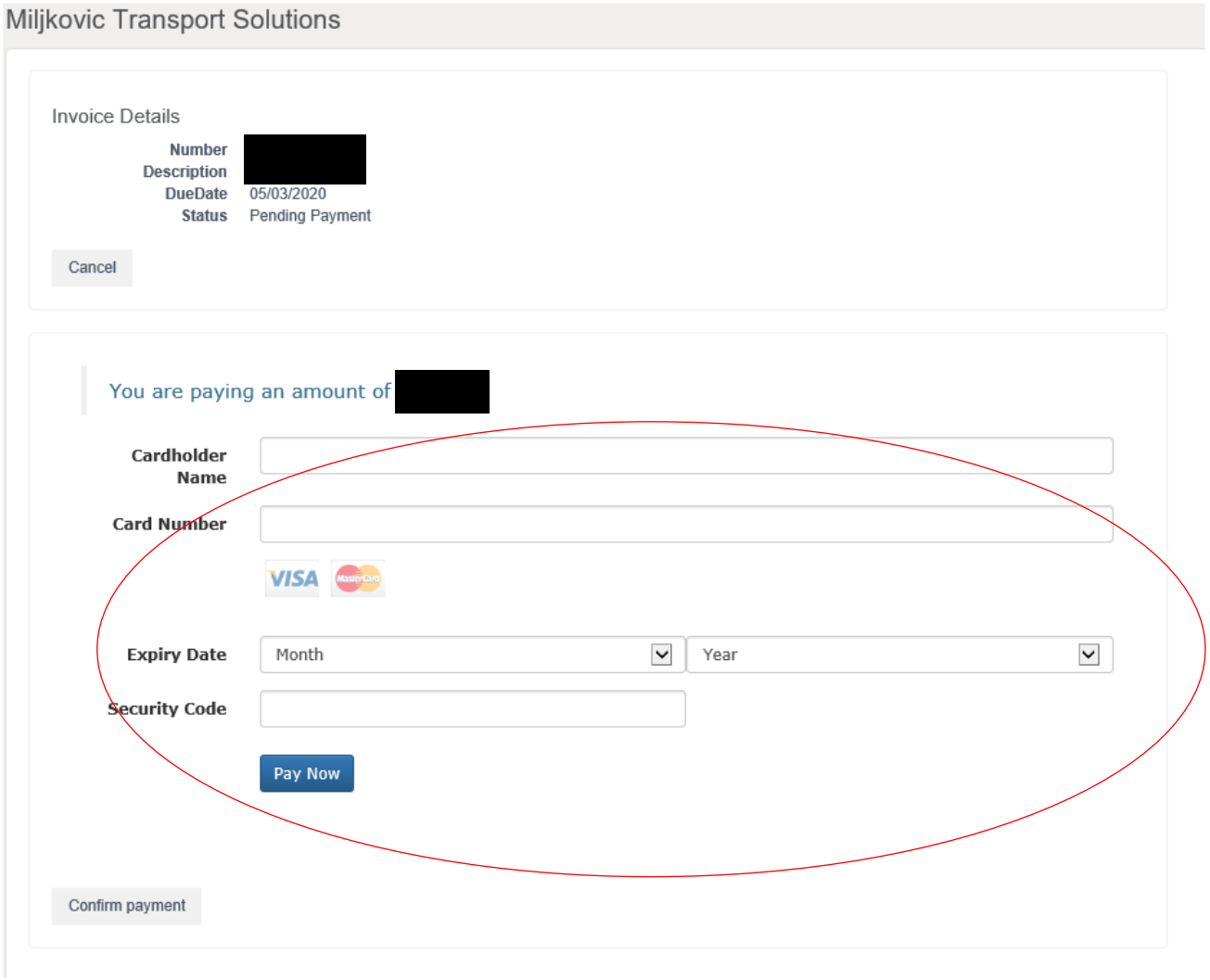


You can then pay the invoice.

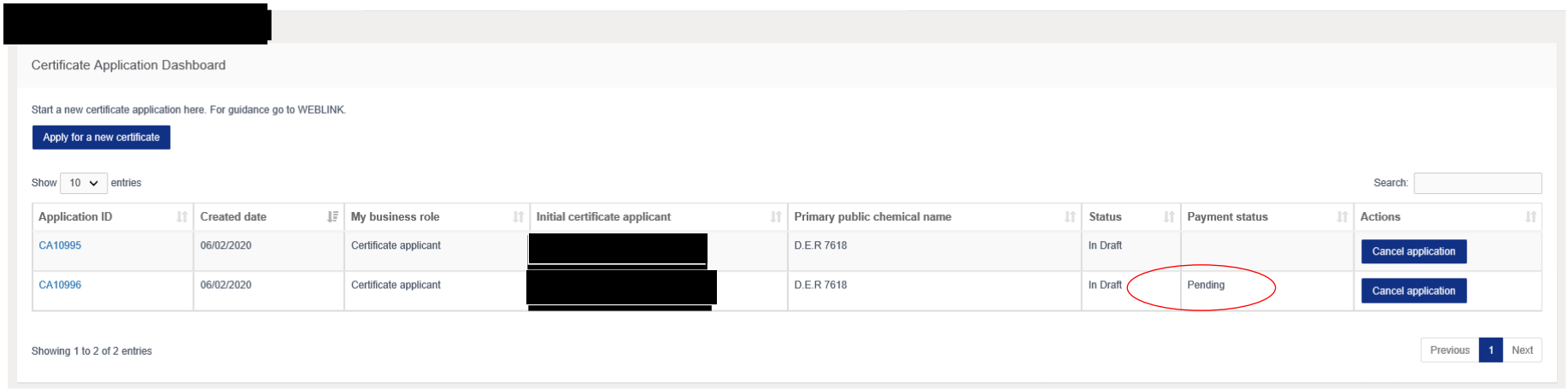


You can download a PDF copy of the invoice by clicking on ‘Download’ or clicking on the hyperlinked invoice number.

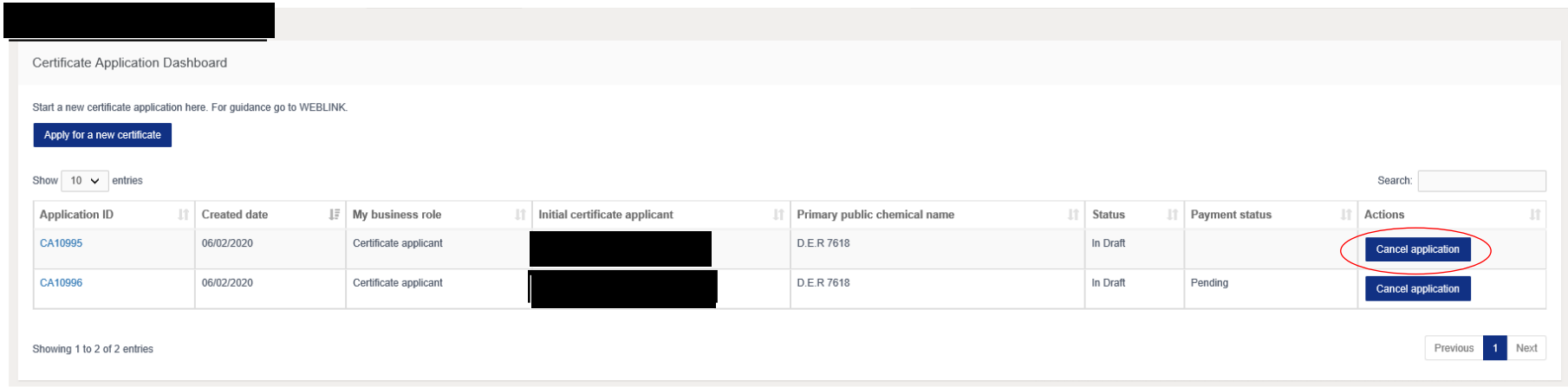
If you are paying for the application with a credit card, you can pay the invoice through the portal.



The certificate application dashboard will show if any invoices are outstanding (pending payment).



If you need to cancel any of your applications or invoices, then you can do this by clicking on ‘Cancel application’.



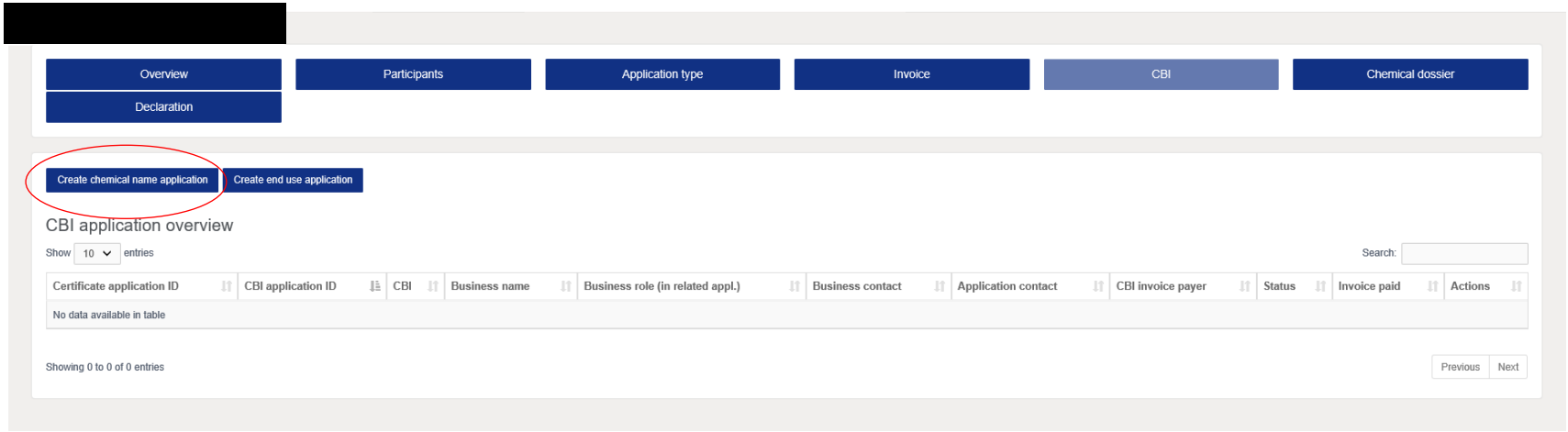
You can continue to complete your certificate application before paying your invoice.

Confidential Business Information (CBI)

If you are applying for both chemical name and end use to be considered as CBI, you will need to create a CBI application for each.

If you are applying for CBI consideration for chemical or end use, but not both, then you will only need to create one application.

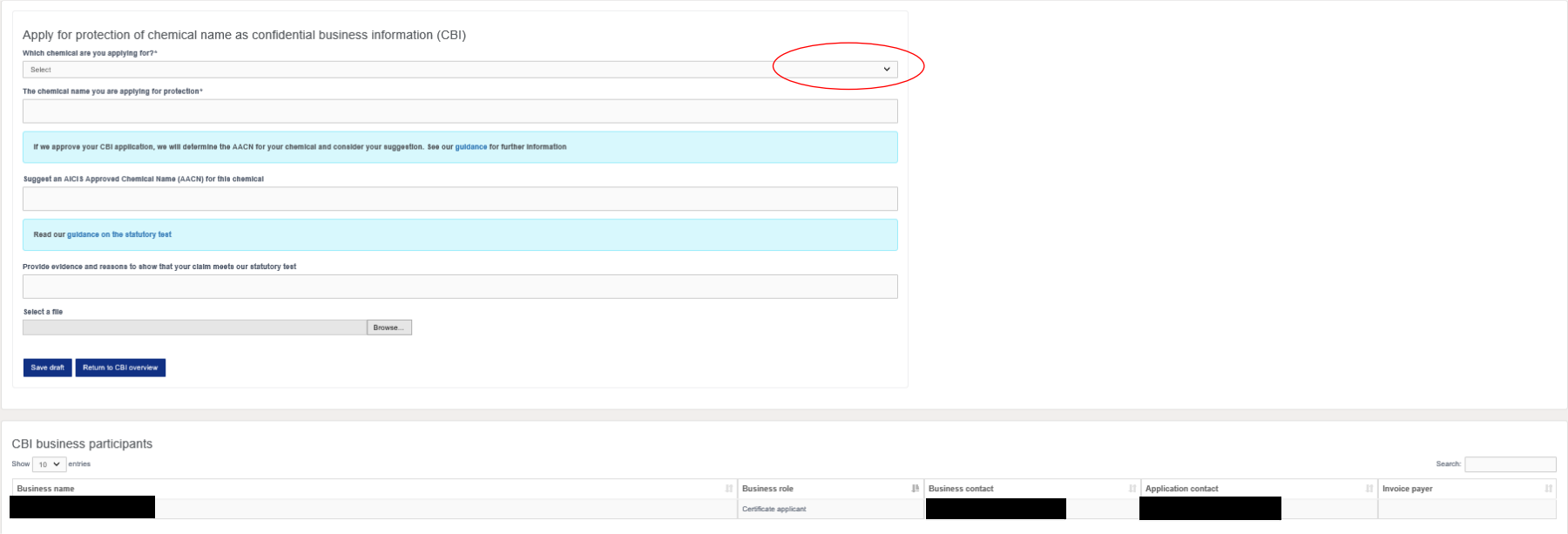
To create a CBI application to protect the name of the chemical, click on ‘Create chemical name application’.



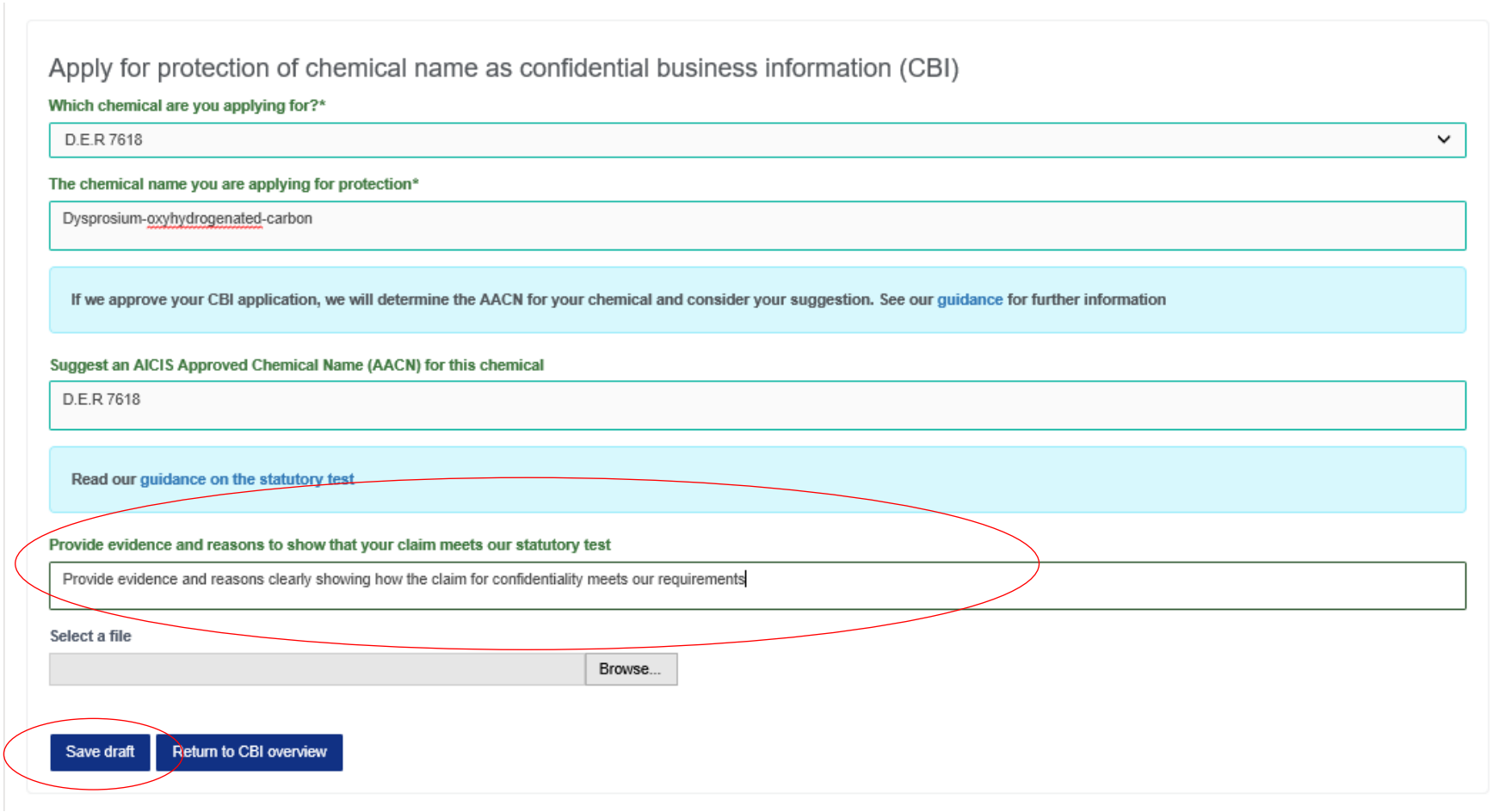
Note: For guidance on applying for other information to be considered as CBI, please see ‘Common Administrative data requirements’ in dataset documents.

Note: The end uses you identify, and information associated with these end uses, will be used by us to work out a defined scope of assessment. More information is available from our website.

Select the chemical whose identity you are protecting from the picklist. The information in the list is based on the details you have entered so far.



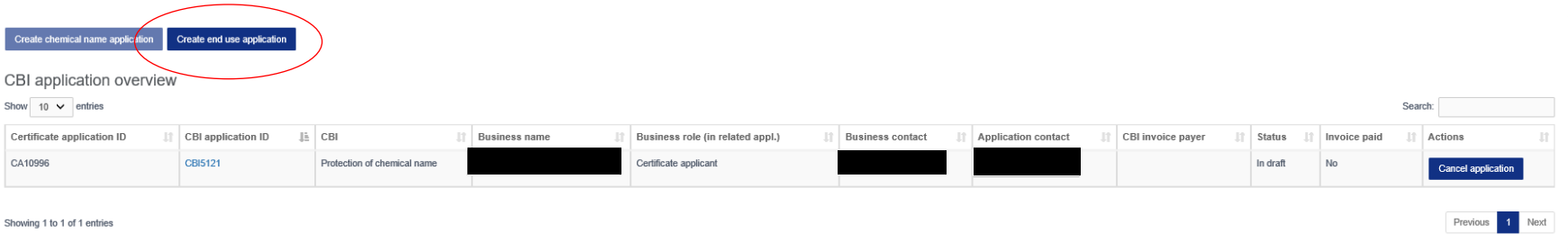
Then enter the chemical name you want to be considered as confidential. The chemical name is that which would be registered with CAS. For example, we would not consider the INCI name as the chemical name.



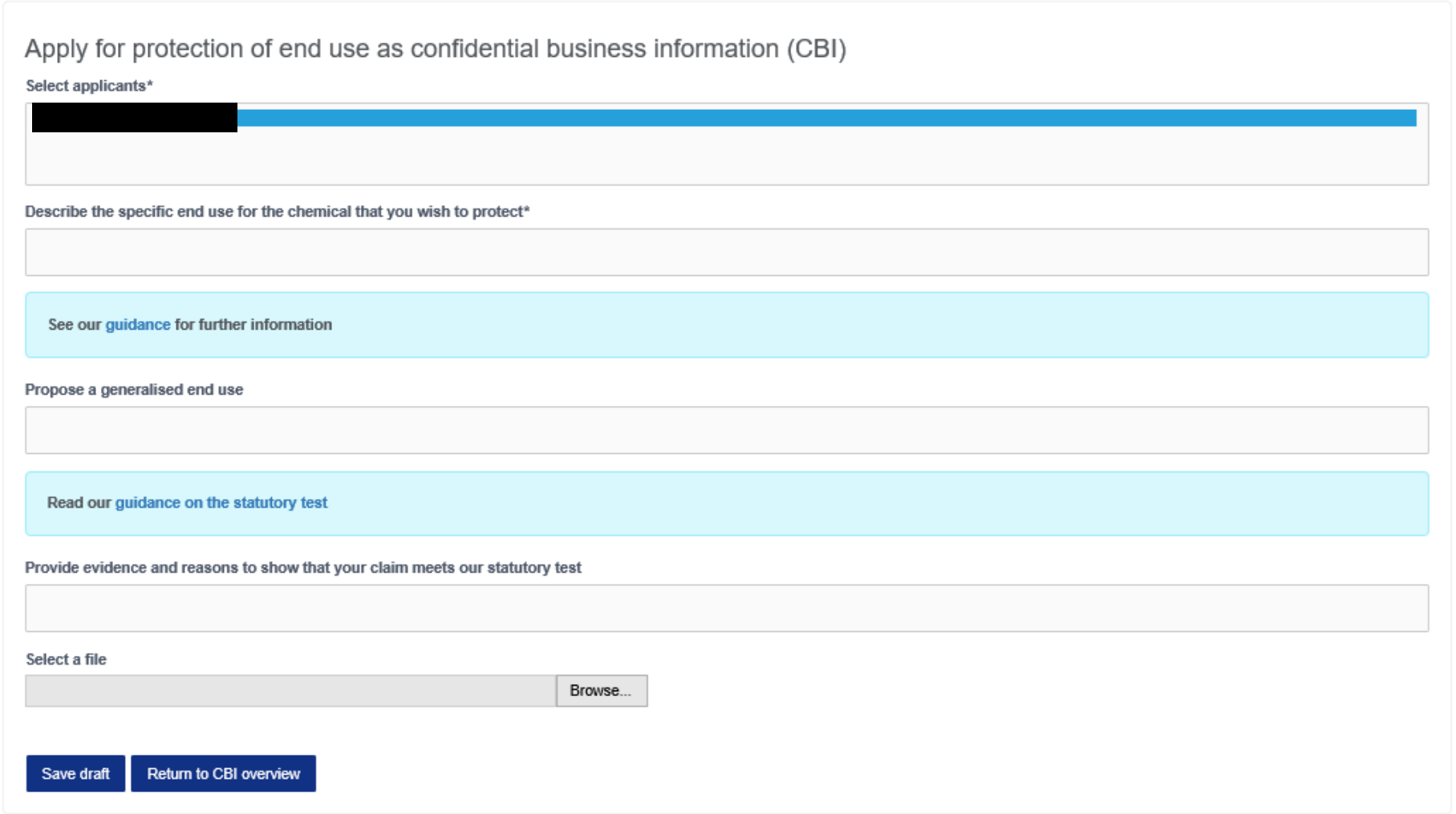
You can provide information and evidence to support your CBI application for protection of the chemical in the field. Alternatively, you can upload a file outlining your evidence and reasons for claiming information to be protected. Once you have completed the application, you must then click ‘Save draft’.

Then click on ‘Return to CBI overview’.

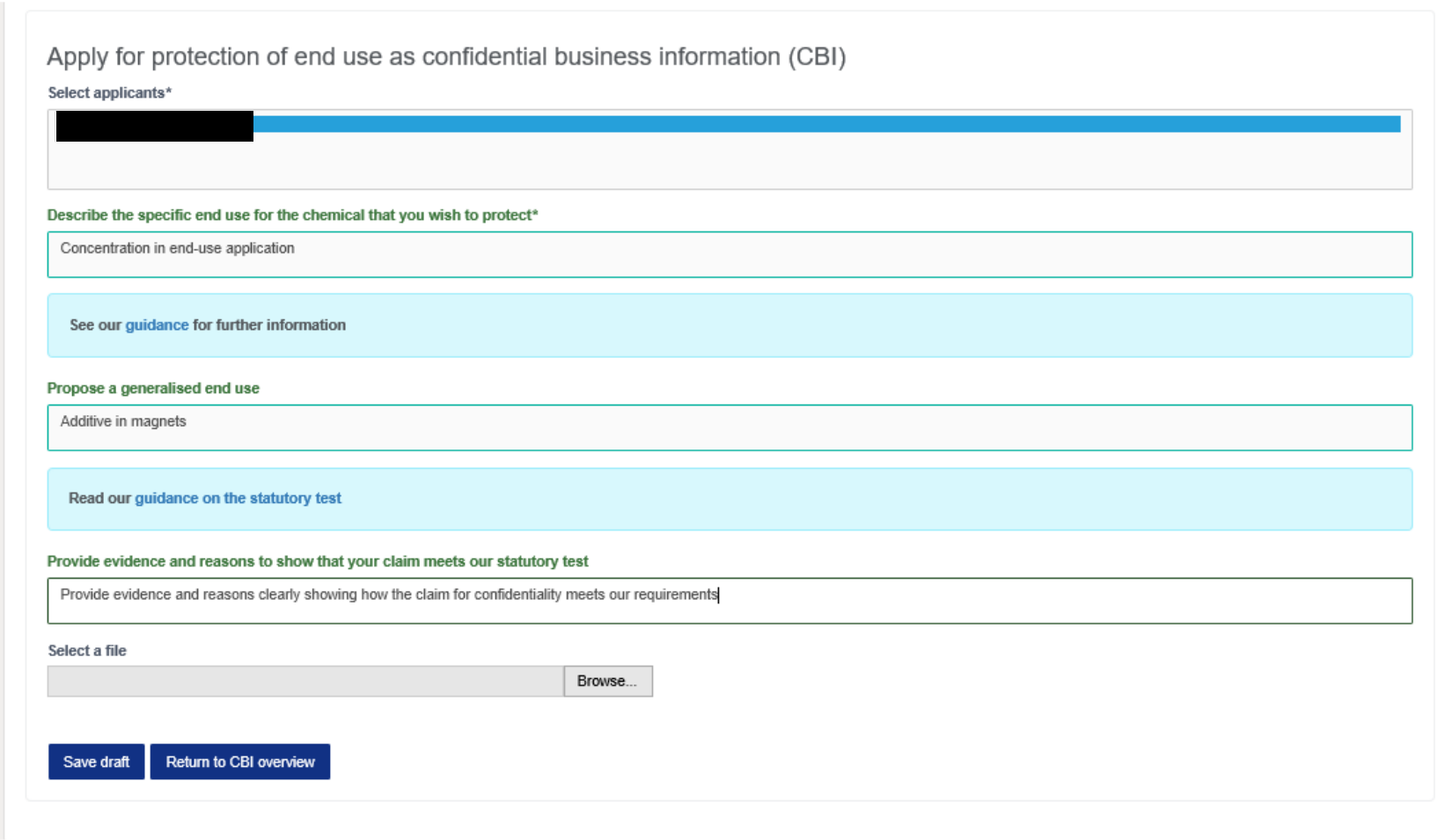
If you are applying to protect the end use application of the chemical, you will need to create an end use application following the same steps described above.



You need to select the name of the business applying. If you do not select the application name by clicking and highlighting it, the applicant name will not be selected. You will then need to describe the specific end use you are protecting and propose a generalised end use in the relevant fields.



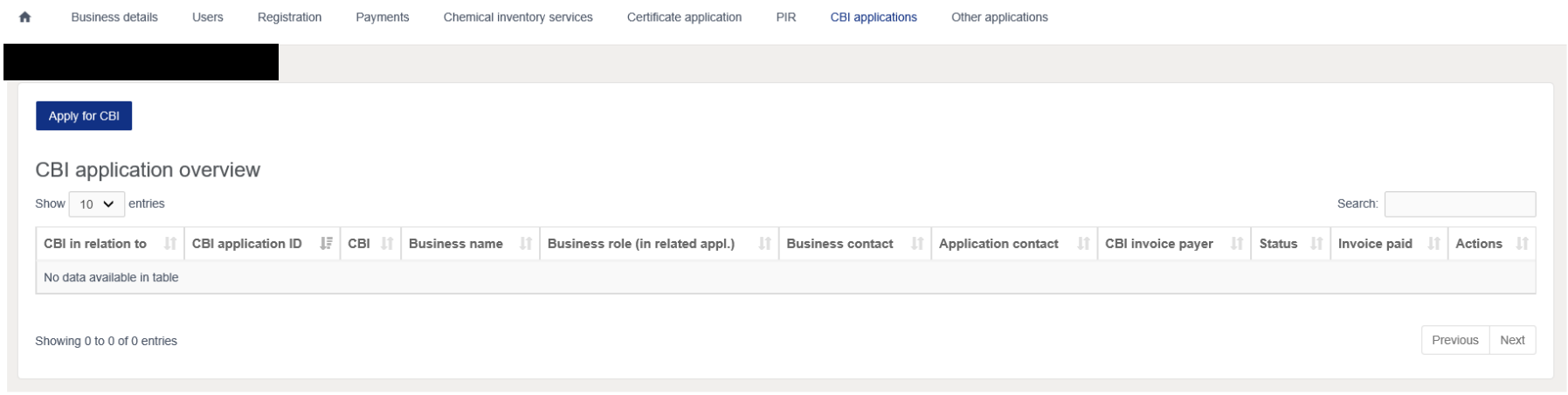
You need to provide information and evidence to support your CBI application directly in the form. Alternatively, you can upload a file outlining your evidence and reasons for claiming information to be protected.



Once you have completed the application, click ‘Save draft’. Then click ‘Return to CBI overview’.

If you have applied for both the chemical name and the end use of the chemical to be considered as CBI, you can use the same document to support both applications. If you have already uploaded the document, in the field under ‘Provide evidence and reasons to show that your claim meets our statutory test’ you can reference the previously uploaded file.

After saving the draft CBI applications and returning to the CBI overview, continue by clicking ‘Proceed to CBI invoice’.



There are 3 things you can apply for:

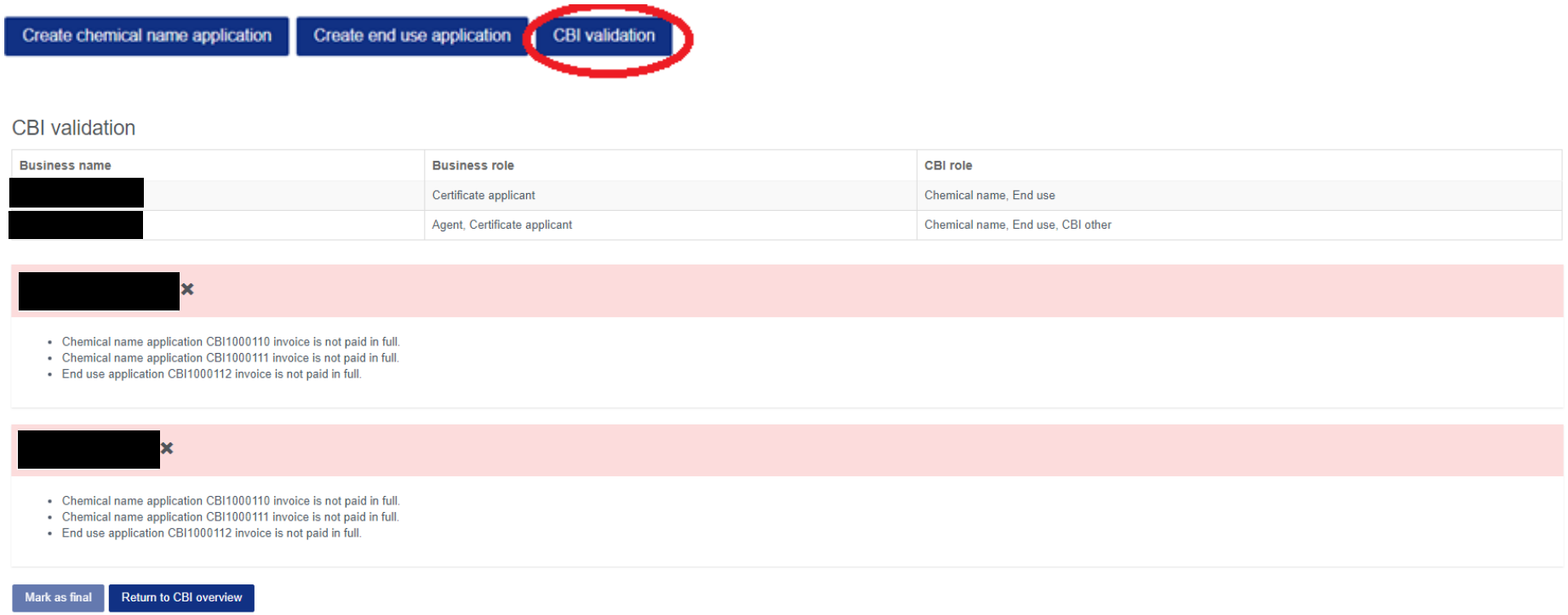
- Protection of chemical name
- Protection of end use
- Protection of other information

You will then be asked to select the application your CBI request relates to.

You'll see all CBI applications and payment status.

CBI validation

Once CBI applications have been created and paid for, click the ‘CBI validate’ button which will take you to a section where you can finalise your CBI application. If there no errors, the ‘Mark as final’ button will be enabled and you can click it.

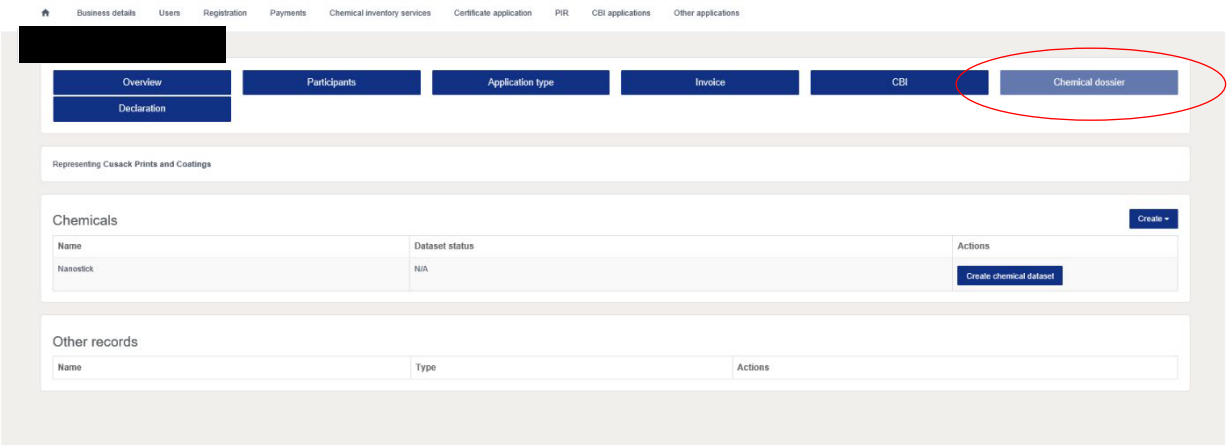


Before you start the Chemical Dataset

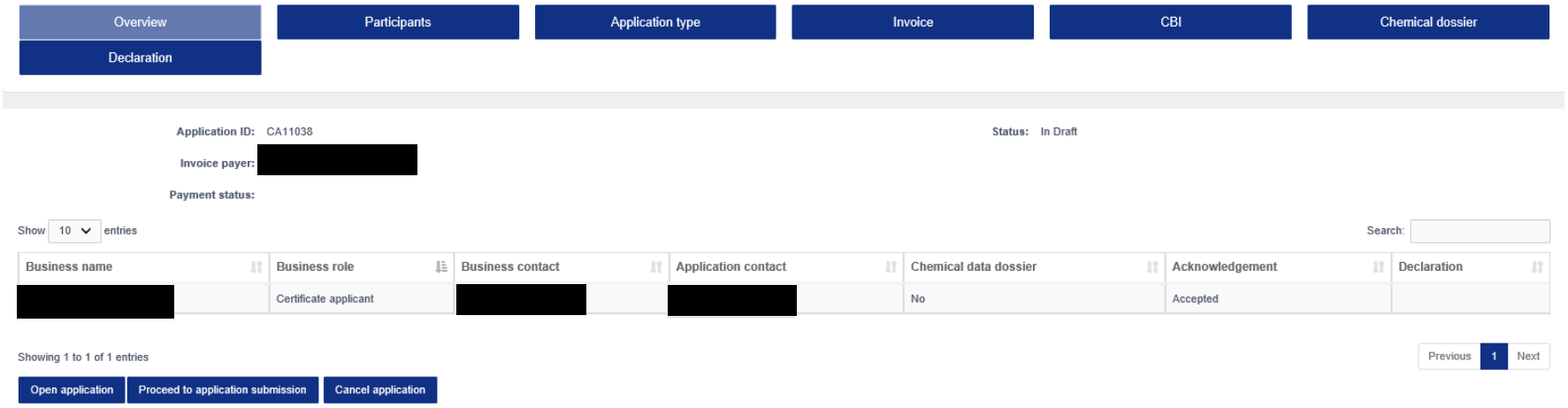
You can complete the chemical dossier through the business portal, or by downloading the IUCLID6 software and entering the information there.

If you are using creating the dataset directly in the portal, click on the ‘Chemical dossier’ tab. In this section you will create a substance dataset which will contain:

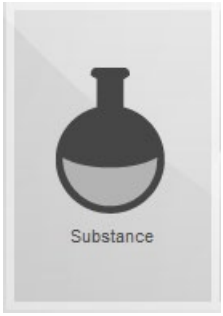
- general information on the chemical
- classification and labelling and PBT information
- manufacture, use and exposure
- physical and chemical properties of the chemical
- a description of the environmental fate and pathways
- ecotoxicological information
- toxicological information
- other information relevant to the class of introduction



If you were nominated to provide any the information for the chemical dataset, you need to acknowledge that agree to provide the information, before entering information into the chemical dataset.



If you are using classic interface of the IUCLID6 software directly, click on the Substance tile.



In this section you will create a chemical dataset which will contain:

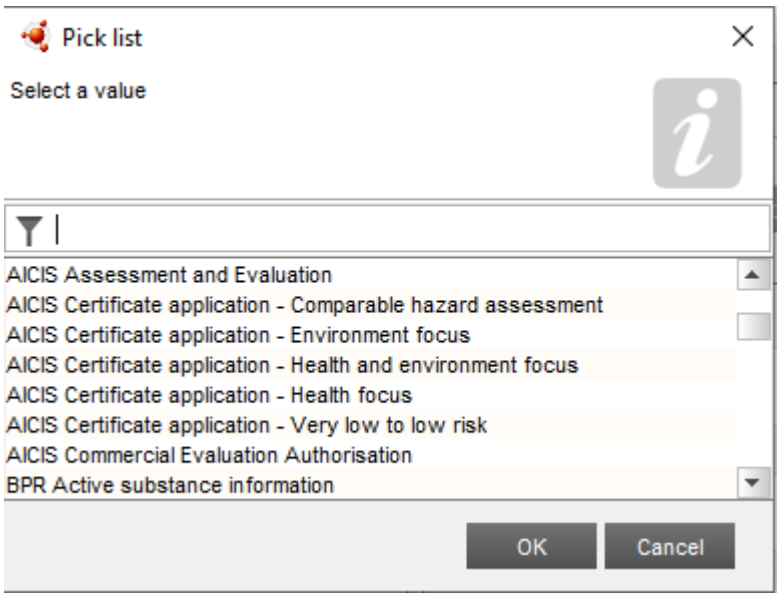
- general information on the chemical,
- classification and labelling and PBT information,
- manufacture, use and exposure
- physical and chemical properties of the chemical
- a description of the environmental fate and pathways,
- ecotoxicological information
- toxicological information
- other information relevant to the class of introduction

In the ‘Navigation panel’ (left hand side of the window), choose the ‘TOC’ (Table of Contents) tab.

The field underneath will have the default entry of ‘REACH Complete’.

Click on the arrow to bring up a picklist of contents tables.

The picklist includes those table of contents specific to the European Union. The templates relevant to new chemical applications are identified with AICIS at the start of the title.



Highlight the relevant certificate application type and click ‘OK’.

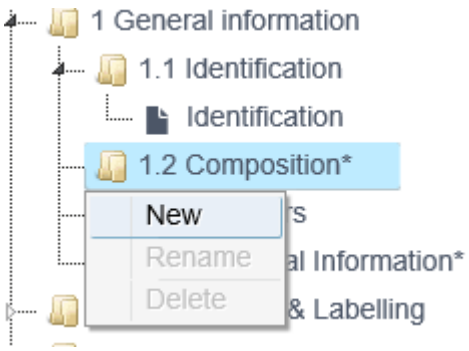
Note: Do not select AICIS Assessment and Evaluation or AICIS Commercial Evaluation Authorisation. These TOCs are **not** certification application types.

Common functions and requirements

Creating and Renaming documents

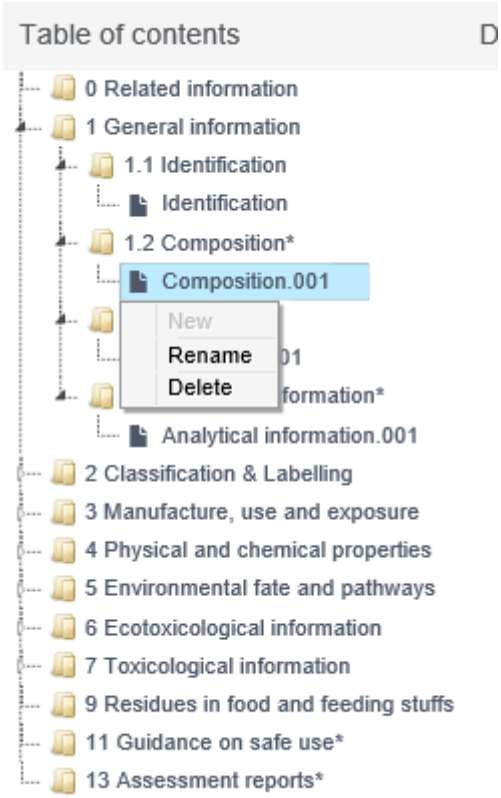
When you open a chapter in the table of contents (by clicking on the +), you will see which documents need to be completed. The documents are named with a generic name which you can change.

To create a document, right click on the chapter head (for example Composition) and select ‘New’.



This will create a document (Composition.001) under this chapter.

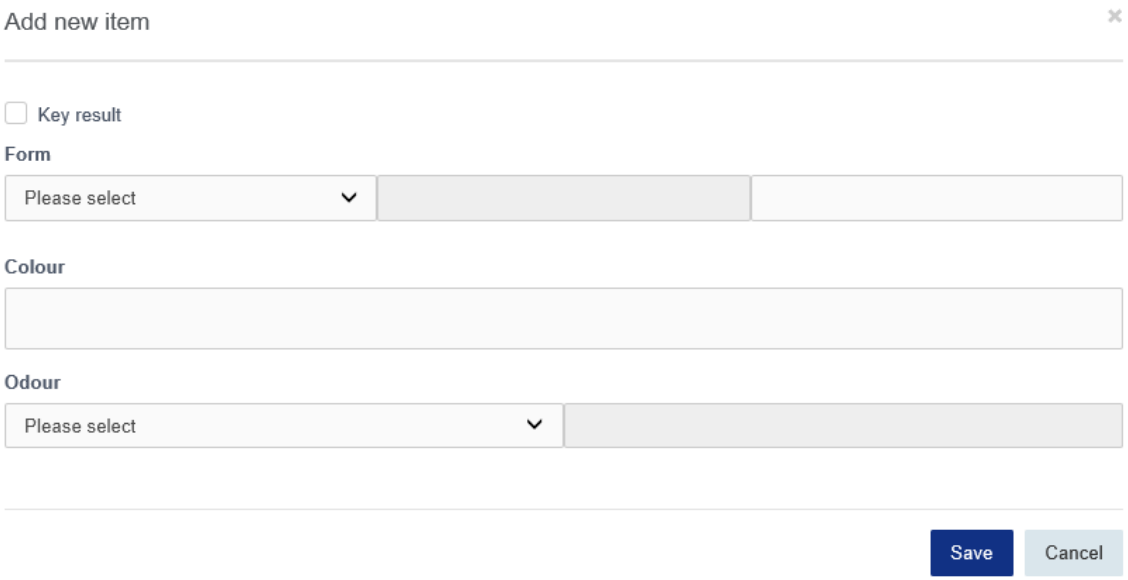
To rename the document, right click on the name of the document (for example Composition. 001) and then choose ‘Rename’. This will allow you to enter in the name you would like the document to be called.



Adding or editing a table entry or document

Many tables can't have information added directly, or be edited directly. You will need to add information to them by completing a pop-up window which outlines the information required for an individual section.

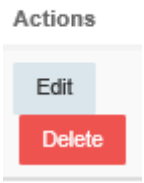
This will bring up an 'Add new item' pop-up window.



You will then need to complete the information in the pop-up window.

Once you have completed entering the information, you will need to click on ‘Save’ to return to the chemical dataset.

The table will be updated with the entries and the ‘Actions’ column will be updated allowing you to edit or delete the entry.



You can make multiple entries by repeating these steps.

Where you need to add a document, click on ‘Add’ to open the ‘Add new item’ pop-up window. Click on ‘Browse’ to find the relevant document and attach it. You can then include any supporting remarks in the relevant field.

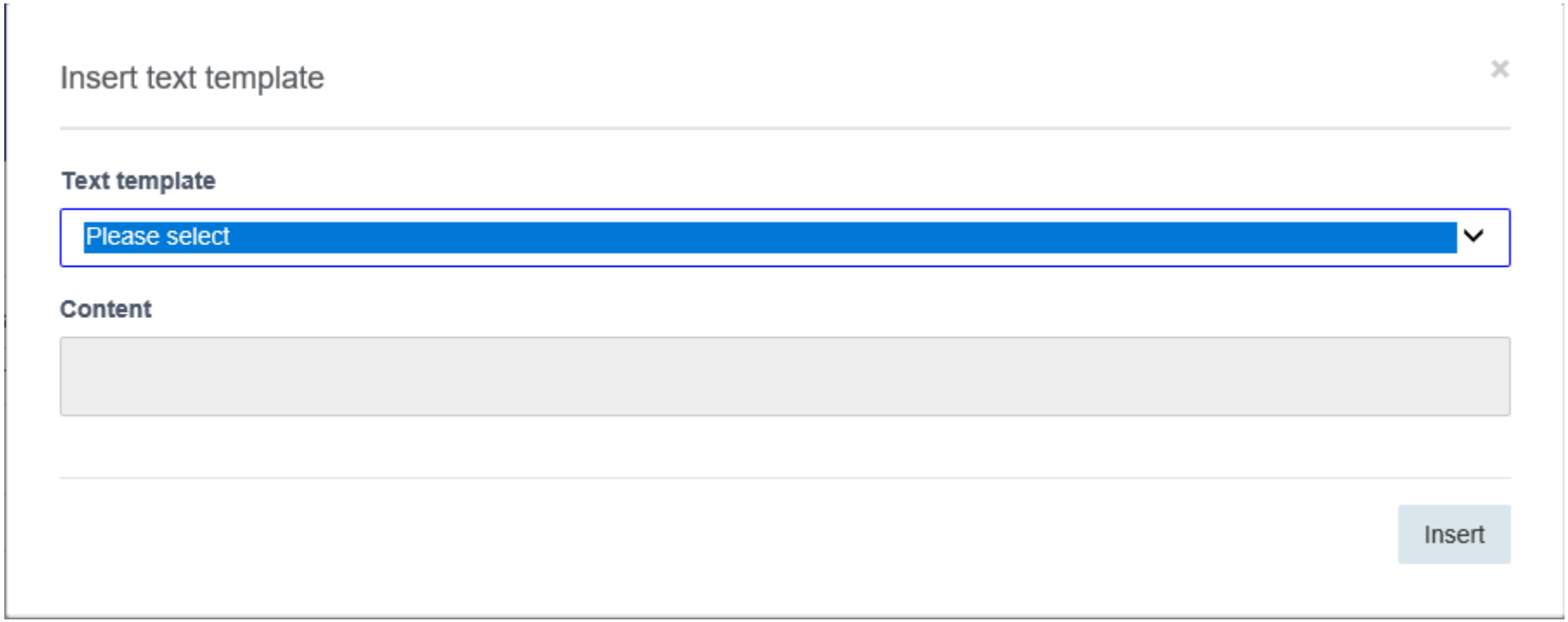
Once you've attached your document and entered any remarks, click 'Save' to save your changes and return to your application.

You can delete documents if you have accidentally added them.

Inserting a template

A template provides a master text that outlines the information required for an individual section.

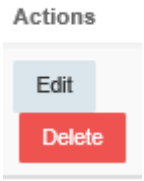
For example, the CBI considerations for information on the use of the chemical may be different to those for the composition of the chemical.



Click 'Insert' to put the text template into the content field. You can then use the template to guide you through the information required.

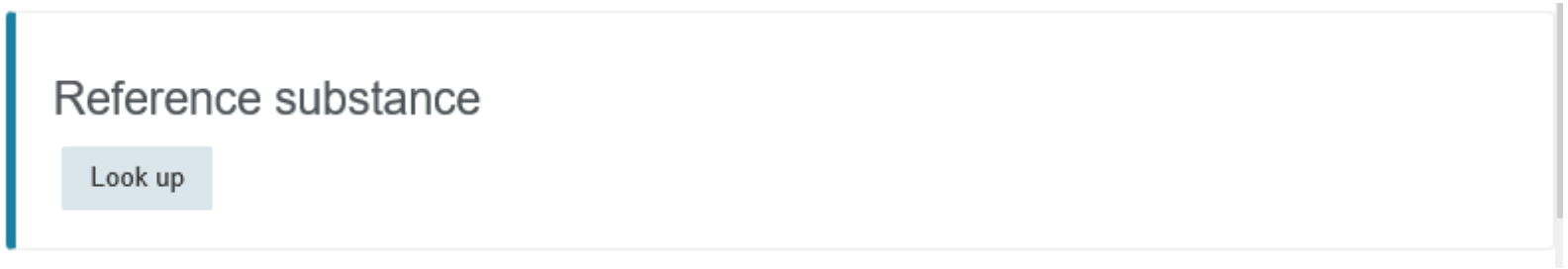
After you have complete the information, click 'Save' and close the pop-up window. When you return to the main application screen, the information will be added to the relevant field.

If the template was part of a table entry, the ‘Actions’ column will be updated allowing you to edit or delete the entry.



Looking up a reference substance

In this section, you are asked to look up a reference substance.



Click ‘Look up’. This will open a pop-up window allowing you to browse and select the reference substance(s) you have created. You can then enter any supporting remarks in the relevant field.

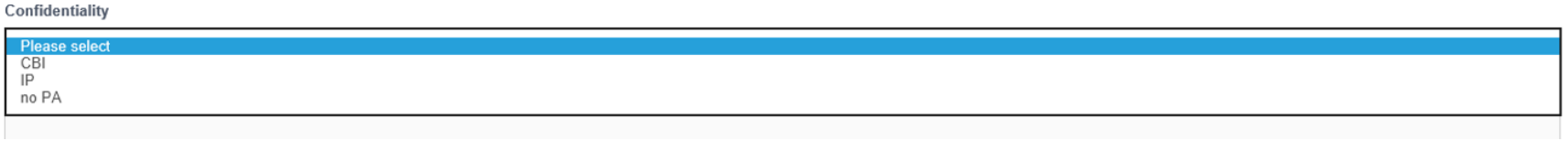
We strongly recommend that you create reference documents for the substances and literature associated with your application prior to creating the chemical dataset. More information is available under the heading ‘Creating reference documents for use in the chemical dataset’.

Select ‘Save’ to save your changes and return to your application

Confidentiality flags and justification

You will need to complete this information throughout the document. This section forms part of the ‘Administrative’ data when entering endpoint information on the chemical.

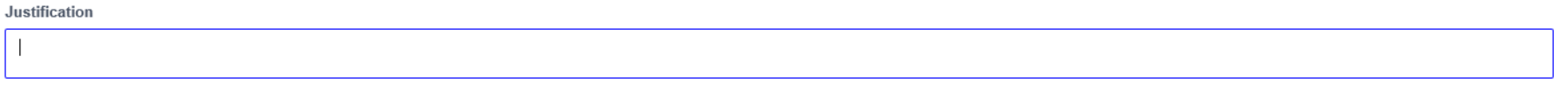
You will need to select a summary which describes your reasons for applying for any items of information to be considered as CBI. From the ‘Confidentiality’ picklist, please select one of the reasons why you consider the information to be confidential.



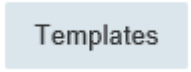
Where ‘CBI’ means the information is confidential business information, ‘IP’ means the information is intellectual property and ‘No PA’ means the information is not publicly available.

If you don’t want the information treated as CBI, don’t select anything.

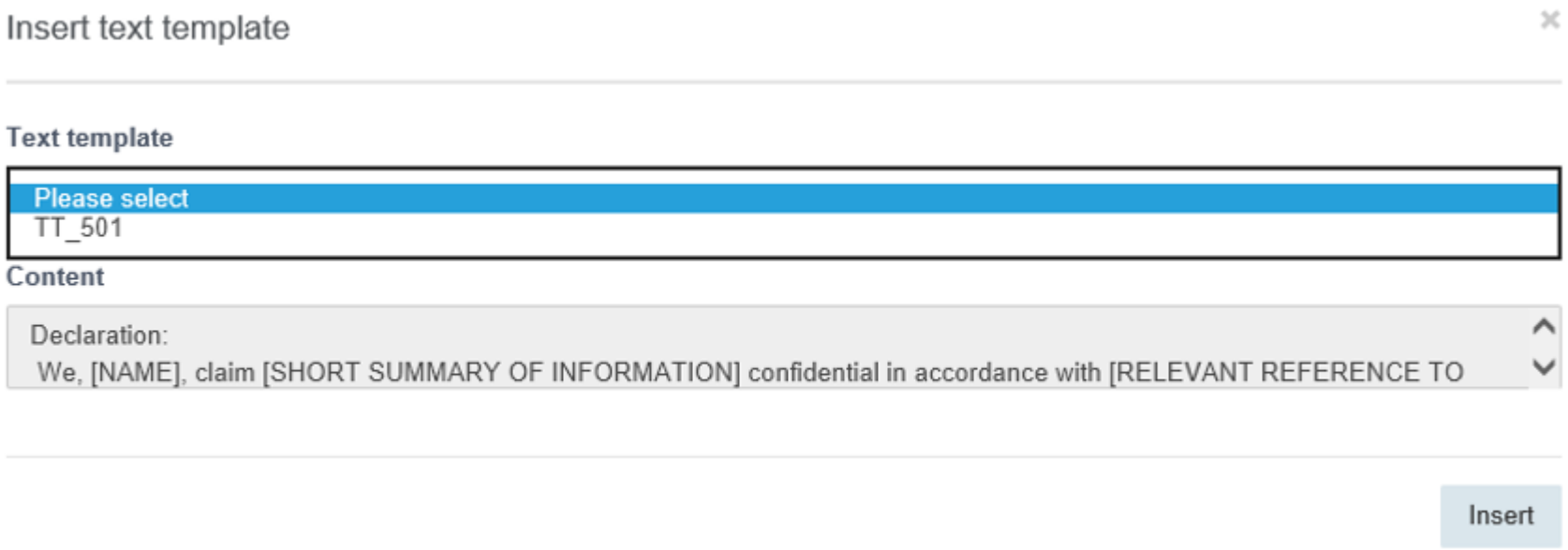
If want information treated as CBI, you will need to provide justification. This information can be directly entered into the ‘Justification’ field.



Alternatively, you can add a template by clicking on the ‘Templates’ button.



This will open the ‘Insert text template’ pop-up window. You can then select the relevant template which will add a text template to the ‘Content’ field. You can then edit the template text with the information relevant to your circumstances.



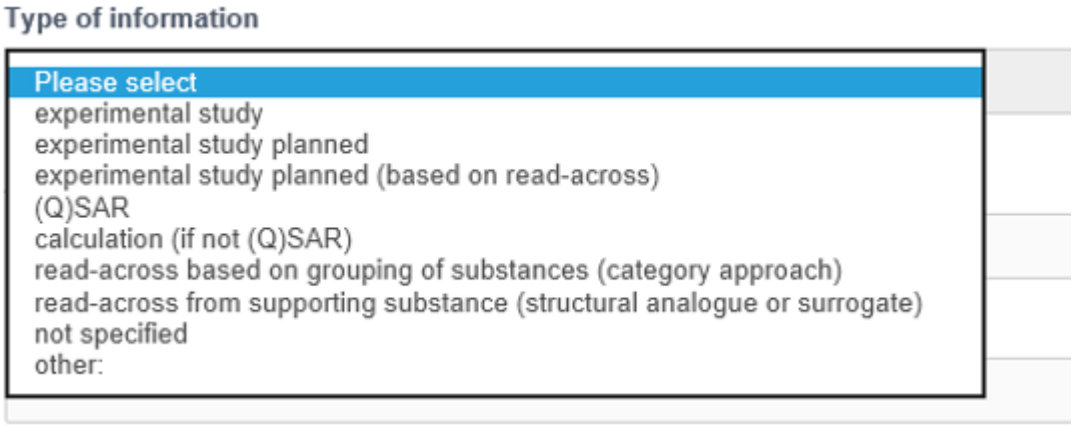
Once you have included all the information, click on ‘Insert’ to insert the text content to the ‘Justification’ field.

If we consider it necessary to publish the flagged information, we will contact you. If we give approval to consider the information as confidential, we may require an additional fee. If we need to publish multiple pieces of information flagged as confidential, you will be charged a fee for each piece of information because we must apply the statutory test to each piece of information separately.

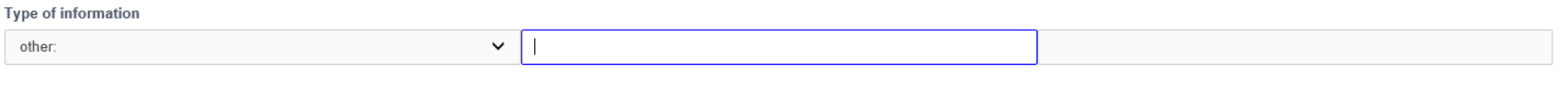
Selecting the type of information an endpoint study is based on

The type of information field allows you to specify what kind of information an endpoint study is based on.

To complete this field you will need to select the type of information most relevant to you from the ‘Type of information’ picklist.



If the type of information you are providing for an endpoint is not on this list, then select ‘other:’ and then enter the study information details into the adjacent field.

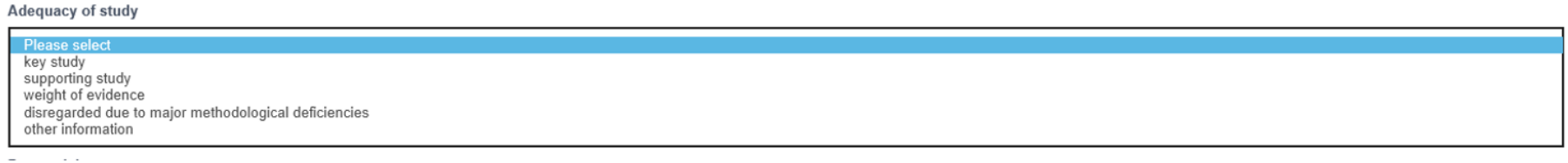


Note: Selecting the options ‘experimental study planned’ or ‘experimental study planned (based on read-across)’, may result in delays to the assessment process due to the information not being available.

Describing the Adequacy of an endpoint study

This field indicates how the study summary you are providing is used to meet the information requirements for the chemical under your category of introduction.

To complete this field you will need to select the adequacy of the study description most relevant to you from the picklist.



Explanations for the study types are in the following table.

Study type	Explanation
Key Study	A study that is relevant, adequate, and reliable. It is expected that they will relate to a robust study summary included with the certificate application. If there is more than one key study, then the study with the highest hazard profile should be used, and reasons describing why this study was chosen as the key study should be included in the Justification for type of information field.
Supporting study	A study that provides additional information supporting the conclusions of the key study.
Weight of evidence	This option should be selected where your submission relies on multiple studies for the same endpoint. This approach suggests that there is no single relevant, adequate, or reliable study available to reach a conclusion and that multiple studies are needed to make a conclusion about the particular property of the chemical. Reasons describing why a weight of evidence approach was chosen should be included in the Justification for type of information field.
Disregarded due to major methodological deficiencies	This option should be selected where a study result shows a higher hazard profile than a key study result, but the methodology or documentation is unreliable, inadequate or irrelevant. Reasons describing why this study was disregarded should be included in the Justification for type of information field.
Other information	This option should be selected where there is information available for the endpoint, but where that information doesn't meet the same considerations the disregarded due to methodological deficiencies option.

Study period

You will need to enter in the study period. This information is especially important when determining if animal test data is an appropriate reference where the chemical is for cosmetic use only.

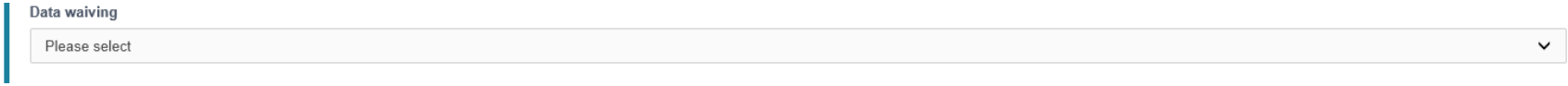
This information should be entered as a date period, for example dd/mm/yyyy – dd/mm/yyyy.

Including justification to support any deviations from the information requirements

You can enter in your justification for any deviations in the field provided. A document can be added to support your justification (see 'Attaching a document').

Including justification to support any data waiving of the information requirements

If you are applying to waiver an information requirement, you will need to provide a rationale.

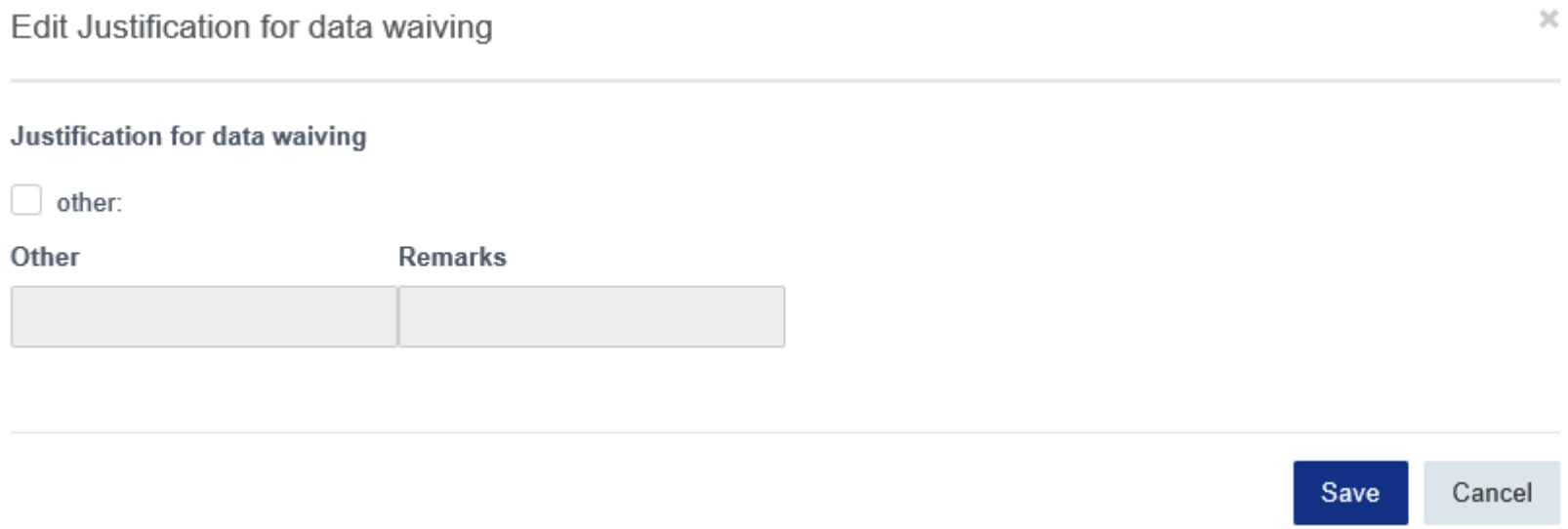


You will need to select a rationale from the data waiving picklist describing why an endpoint study was not performed.

If the standard phrases provided for data waiving do not meet your circumstance, you can select ‘other justification’ and then describe your reasons for waiving the data requirement when editing the justification for data waiving in the related pop-up window.

You will also need to justify why you are waiving the information requirement. You won’t be able to directly edit the Justification for data waiving field. You will need to click on the ‘Edit’ button.

This will open the ‘Edit Justification for data waiving’ pop-up window and allow you to enter your justification for data waiving.



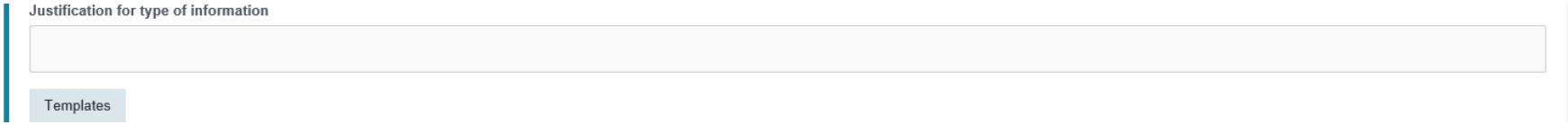
After entering in your justification, click on ‘Save’ to return to the certificate application.

If the type of information you are providing is '(Q)SAR', 'Read-across based on grouping of substances (category approach)', or 'Read-across from supporting substance (structural analogue or surrogate)', you will need to provide justification for submitting this type of information.

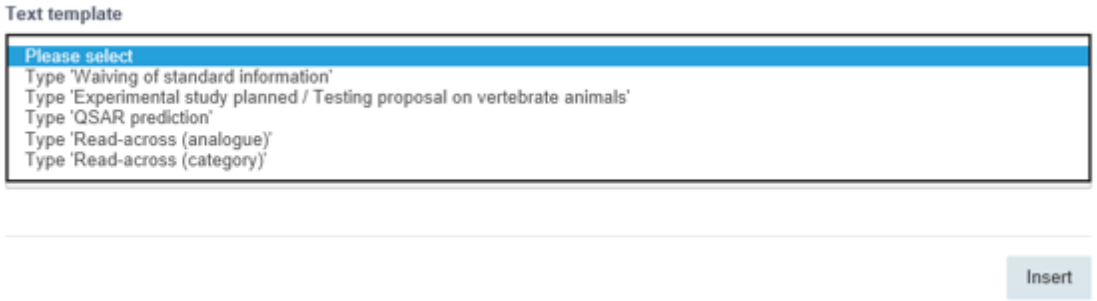
If you have chosen 'Weight of evidence' to describe the adequacy of your study, you should also provide your reasons why under 'Justification for type of information'.

Note: Selecting the options 'Experimental study planned' or 'Experimental study planned (based on read-across)' as your type of information, may result in delays to the assessment process due to the information not being available.

You won't be able to directly edit this field, you will need to insert a template.



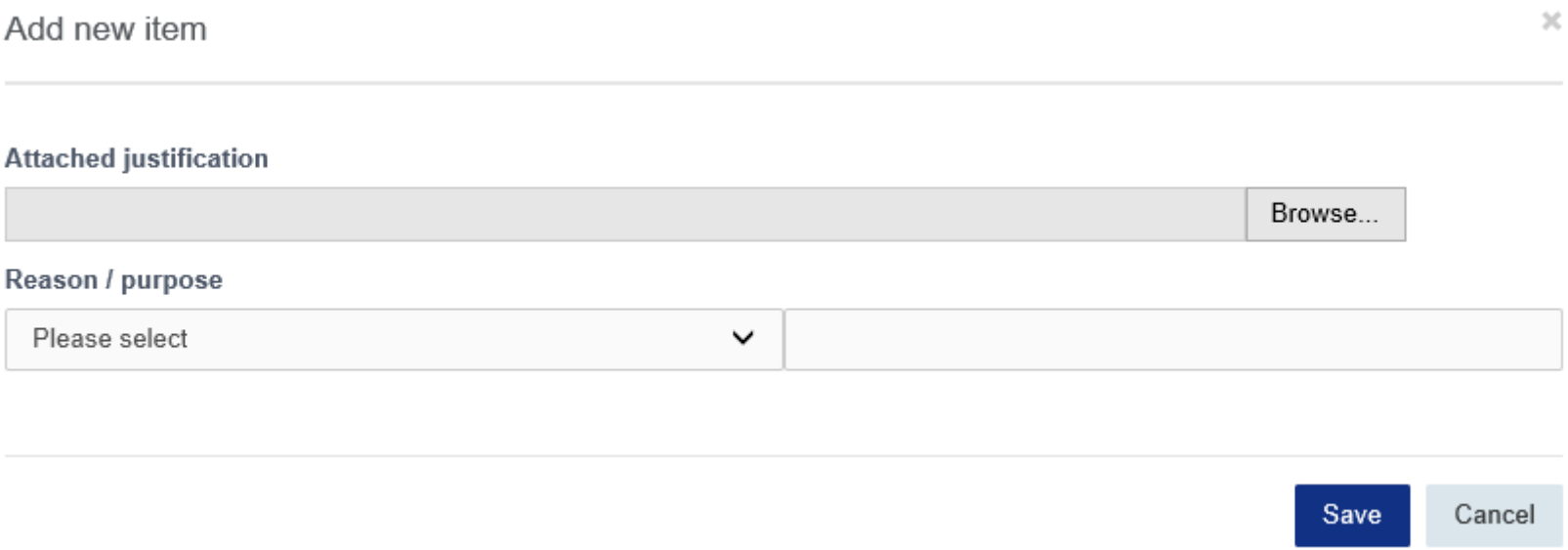
Click on the templates button and select a text template from the picklist.



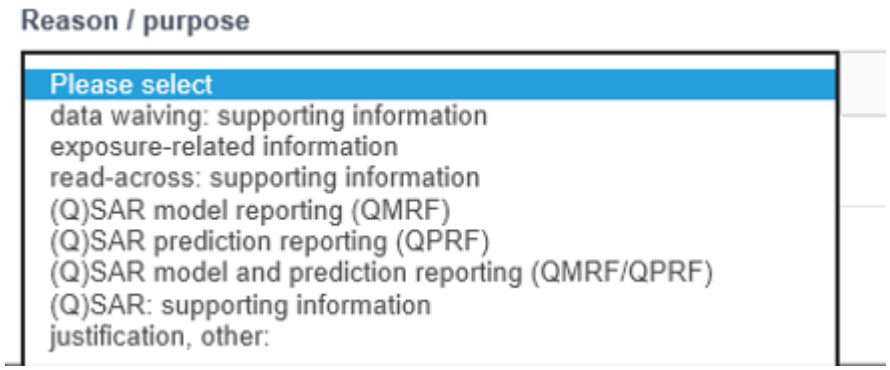
Insert the text template into the content field by clicking on the insert button. You can then use the template to guide you through the information required to justify your choice of information type.

After selecting a template, and completing the information required, click on insert to go back to the main document.

You can add documentation to support your justification in the Attached justification field. You will not be able to add the document directly. Click on the Add button to open the Add new item pop-up window. You can then attach the relevant documentation through the Browse option.



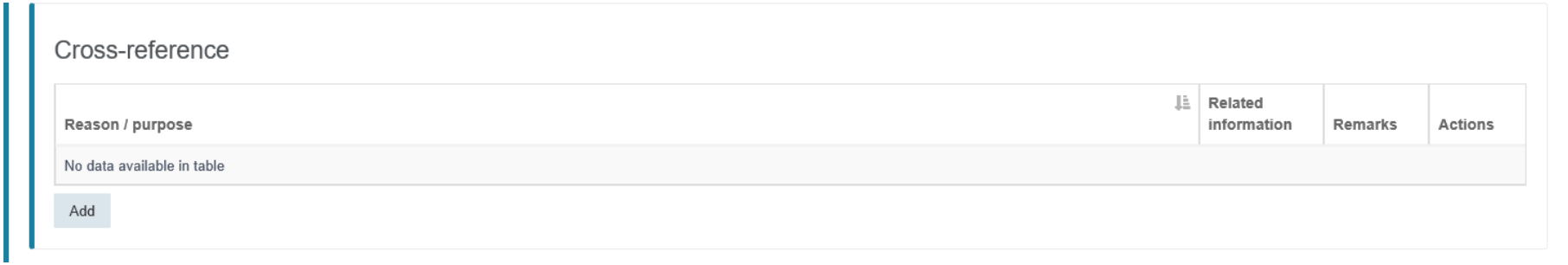
You will also need to provide a reason/purpose describing the attached document from the picklist.



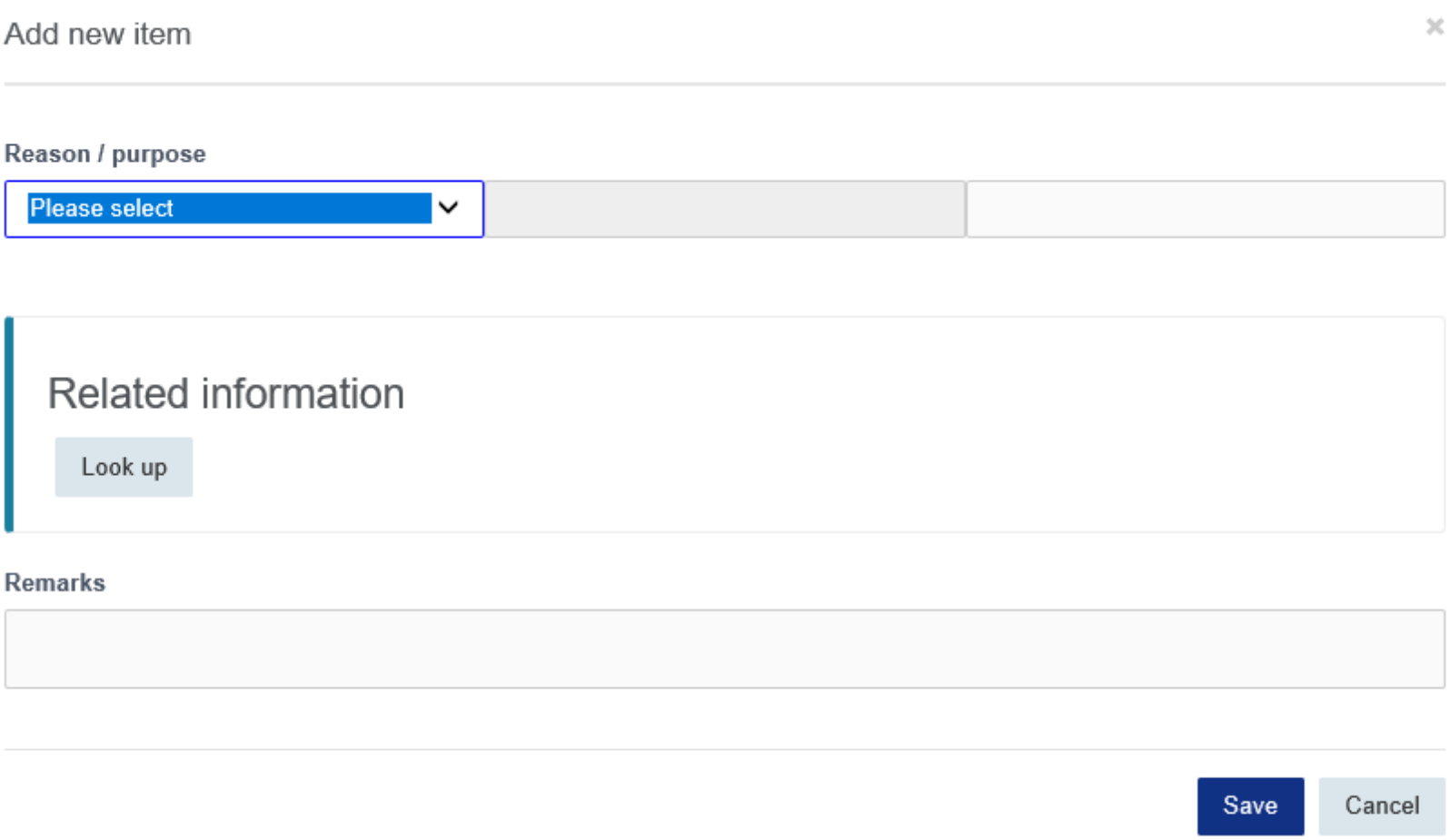
If you select justification, other: you can then enter your reason in the adjacent field.

Adding in a cross-reference

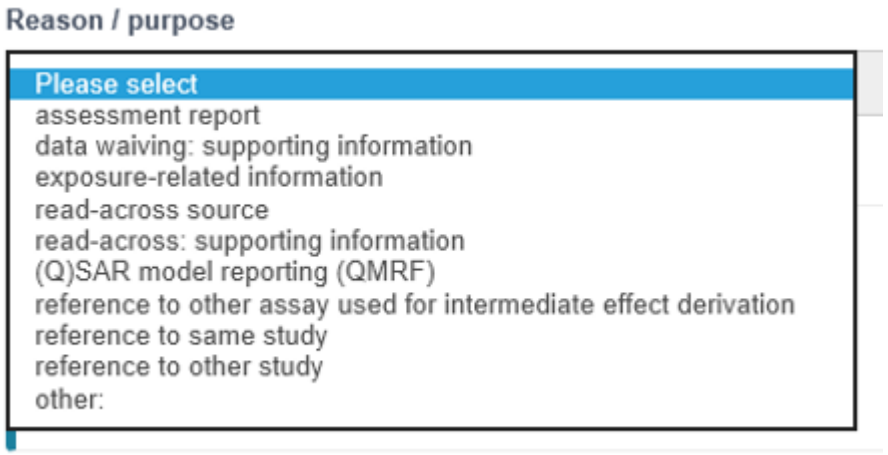
If you want to link an endpoint study record to other records (for example, within the physical and chemical properties section), you can cross reference the study in the ‘Cross-reference’ section.



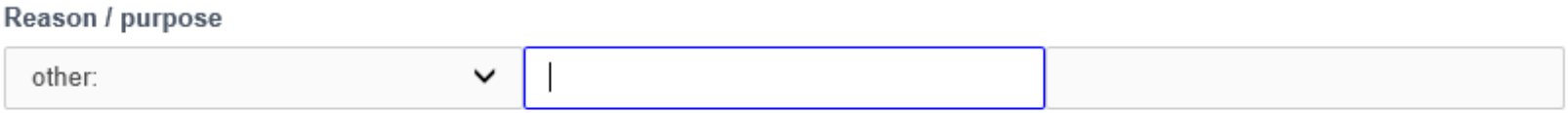
To add a cross reference, click on the ‘Add’ button to open up an ‘Add new item’ pop-up window.



Select a reason/purpose from the picklist.



If you select ‘other:’ you can then enter your reason in the adjacent field.

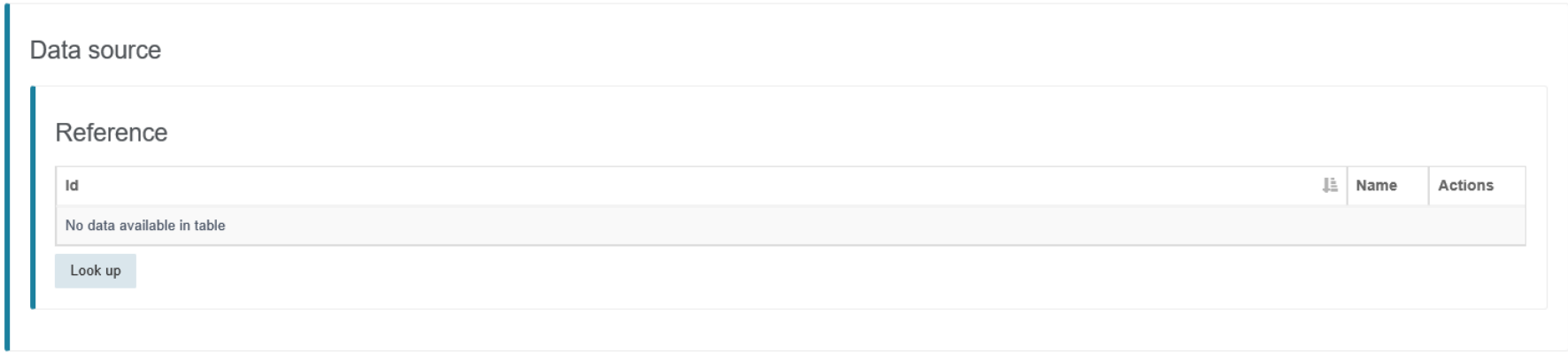


Then click on ‘Look up’ to find the relevant document and directly enter in any additional remarks in the remarks field. Clicking on ‘Save’ will take you back to the certificate application.

You can add as many cross-references as required.

Data sources

Under the ‘Data source’ section, you can click on the ‘Look up’ button to find and attach the relevant document.



A reference to the data source should have been created at the start of the chemical dossier stage, prior to creating a chemical dossier. If not, go back to main screen and add one.

Completing the ‘Results and discussion’ section for an endpoint study

This section should be completed for all endpoint study records that relate to a study summary. The information required will vary depending on the endpoint. The section is made up of one or more tables containing summaries of the results in the study records. The summaries also contain information/observations that relate to the individual endpoint.

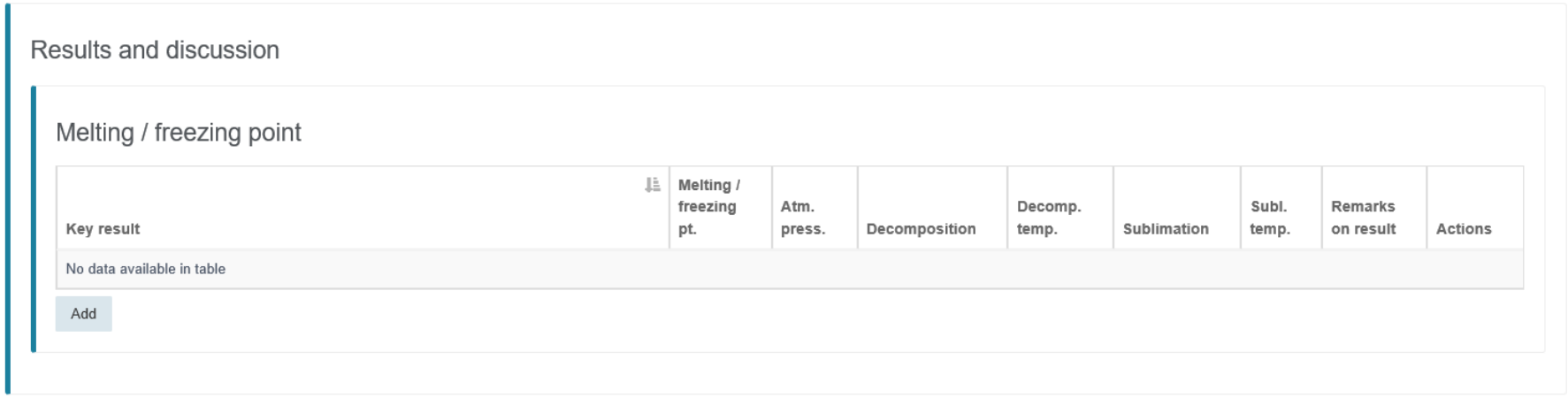
You will be guided through the information you need to provide. To add an entry, click on ‘Add’ which will bring up an ‘Add new item’ pop-up window.

These fields will be a combination of direct text entry and pick lists. You may also be required to insert templates or attach documents. After completing the pop-up window, click on ‘Save’. This will update the results and discussion section table. You will be able to edit or delete any entries made.

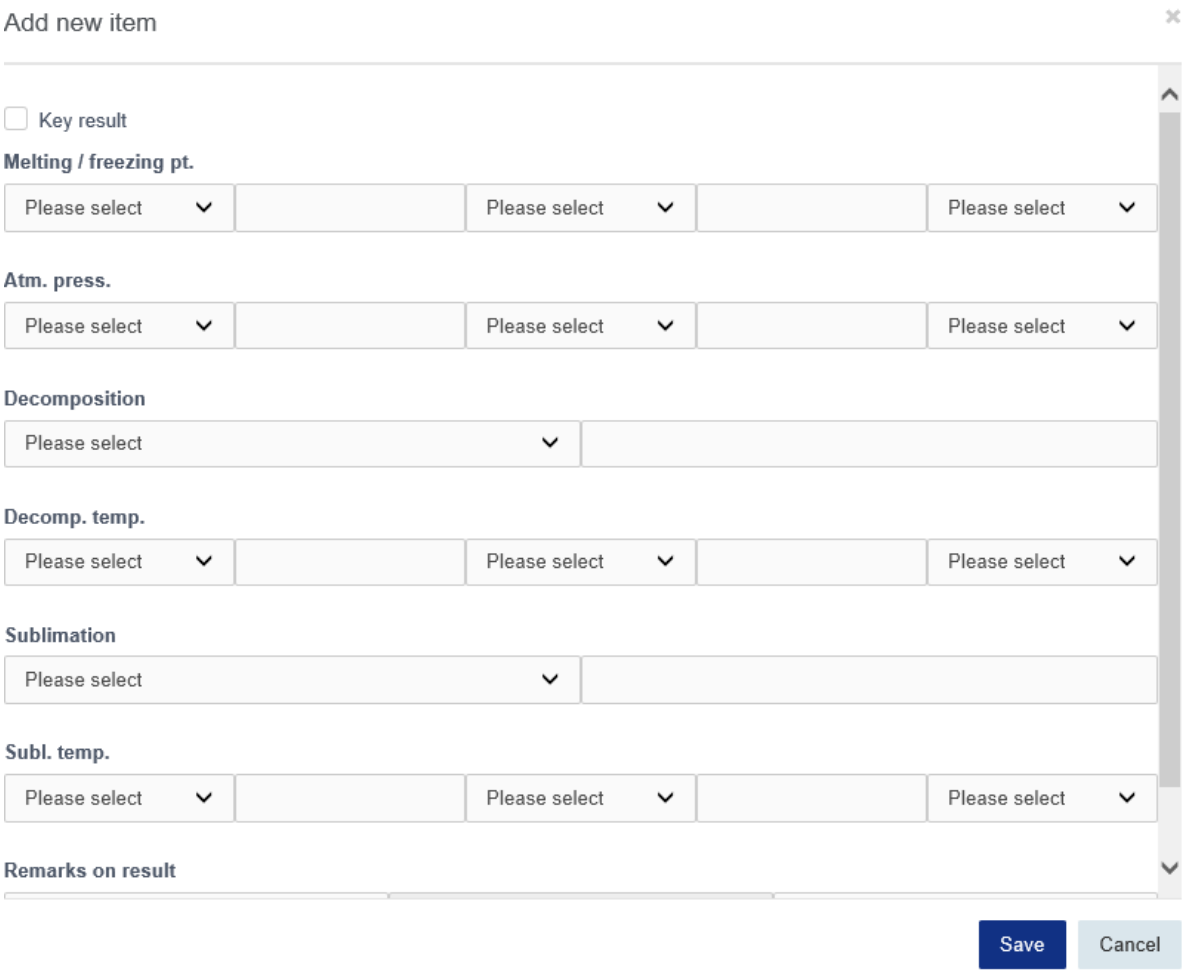
At the start of each add new item window, you will need to check a box marked ‘Key result’ to indicate if the result is a key result. If the study is not a key result, do not click this box.

Multiple study records can be added by clicking on the ‘Add’ button at the base of the table.

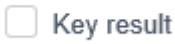
Below is an example for the melting / freezing point.



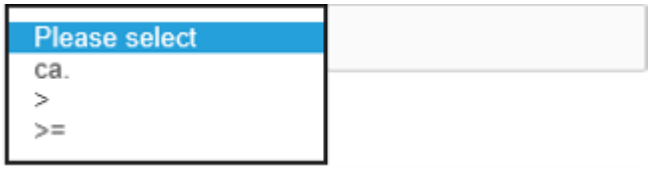
To add results to the table, click on ‘Add’ to bring up the ‘Add new item’ pop-up window.



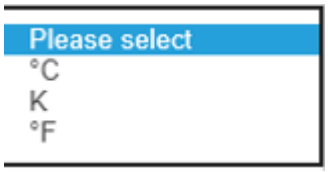
Click the ‘Key result’ box if the study is a key result.



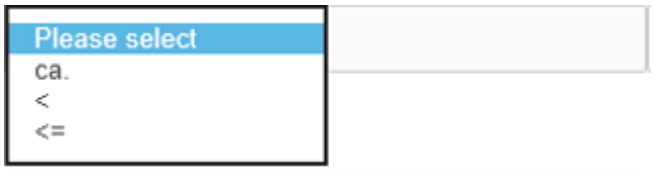
To complete the melting/freezing point entry, enter in the temperature using the relevant picklist and adjacent free text field. You can use both fields if there are a range of values.



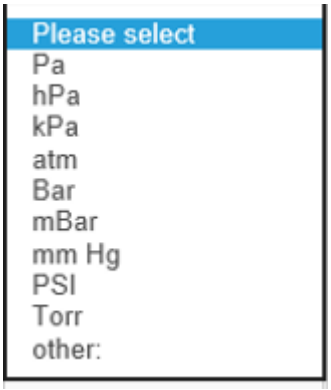
Select the units of measurement from the picklist.



To complete the atmospheric pressure entry, enter in the pressure using the relevant pick list and adjacent free text fields. You can use both fields if there are a range of values.



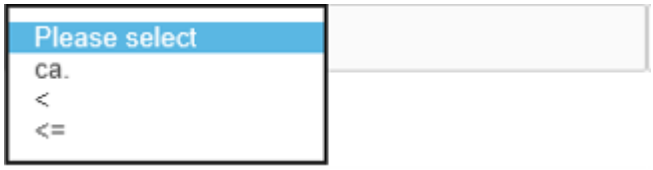
Select the units of measurement from the pick list.



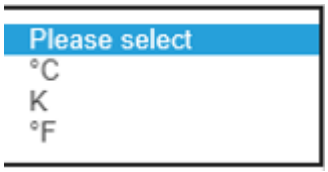
If you select ‘other:’ there is no field for you to enter the measurement value in.

To complete the decomposition entry, select ‘ambiguous’ if it is uncertain if decomposition occurs, ‘no’ if decomposition does not occur or ‘yes’ if decomposition does occur using the pick list.

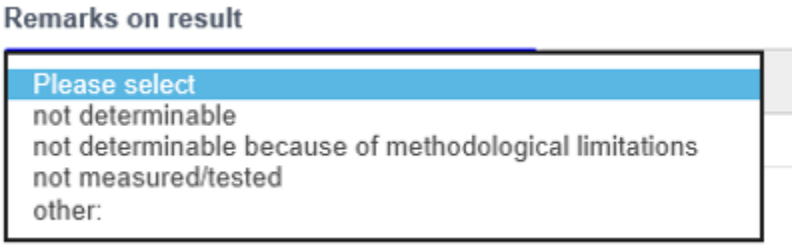
If any decomposition does occur, you can add the decomposition temperature in the same way as completing the melting/freezing point temperature fields.



Select the units of measurement from the picklist.

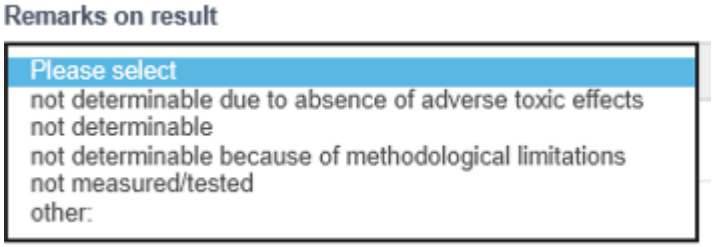


For physical and chemical endpoints, if a test was performed, but no result could be determined, you can select a rationale for this from the pick list under ‘Remarks on result’.

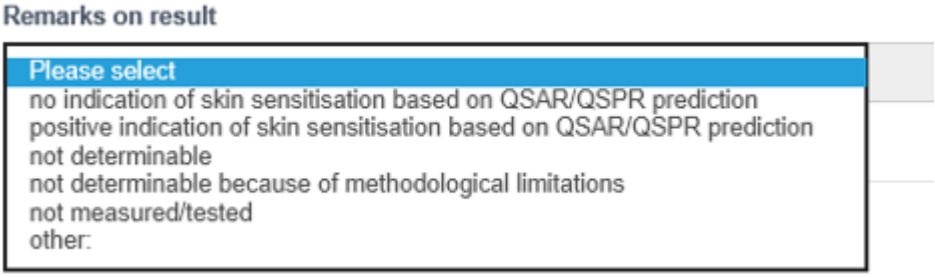


For toxicity endpoints (human health and environmental), if a test was performed, but no result could be determined, the selections available will be dependent on the endpoint.

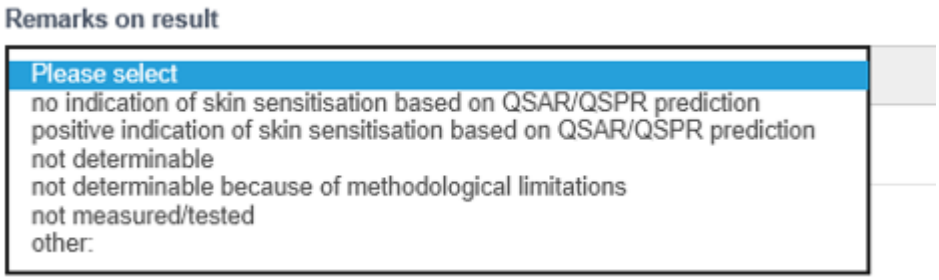
Example – toxicity studies



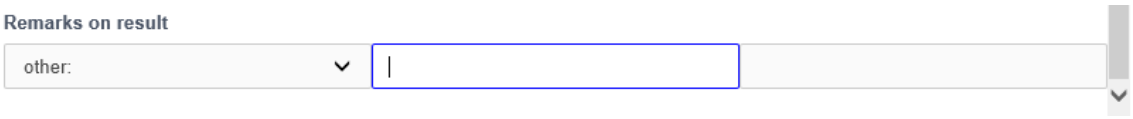
Example – skin sensitisation you’d have the following options



For example, for skin sensitisation you'd have the following options.



In all circumstance, if you select 'other:' in the 'Remarks on result' pick list to describe your remarks on result, then you can enter details in the adjacent free text field.



After completing the information, click on 'Save' to update the relevant field(s).

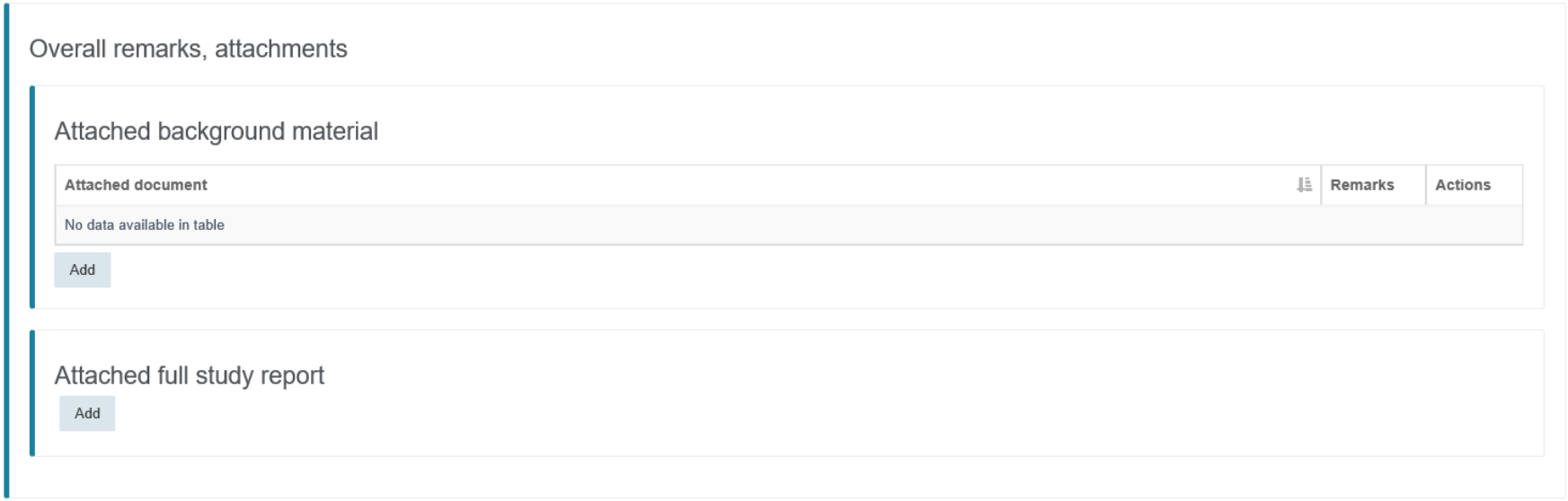
Overall remarks, attachments

After completing the 'Results and Discussion' section for each endpoint, you will then need to add overall remarks and attachments by clicking on the 'Add' button.

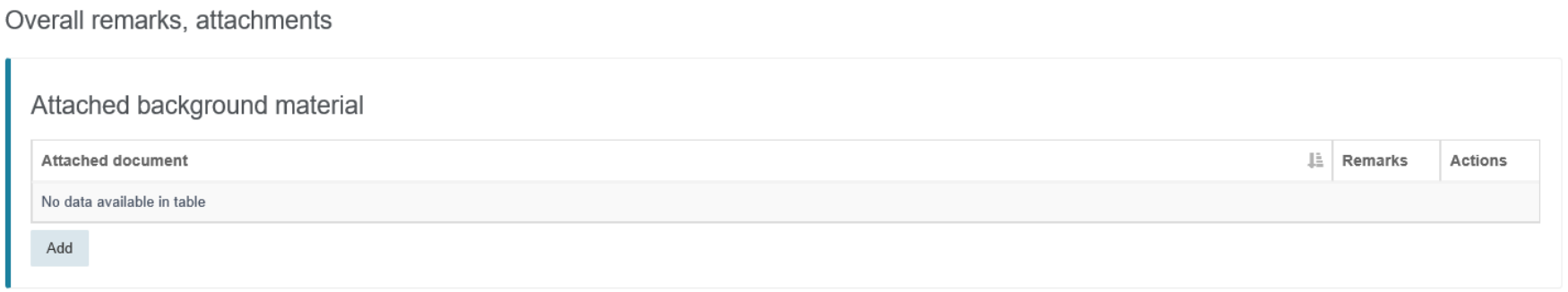
In this section you will provide the interpretation or analysis of the results obtained. You should include an explanation of why you have interpreted your results the way you have. For example:

- based on deviations to the test guideline
- the applicability of the test guideline to the chemical or
- other factors that may have influenced the test result

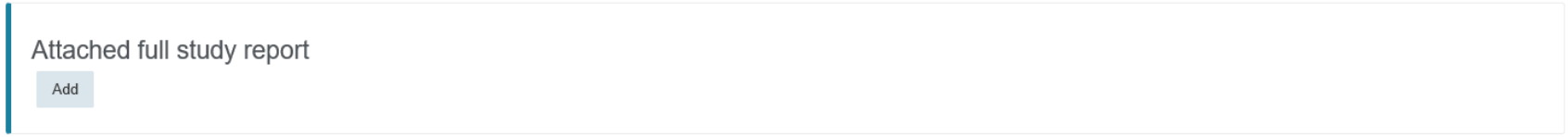
Where you have a choice of endpoint, please note that the information required under results and discussion will be the relevant to the specific endpoint.



You can add background material by clicking on ‘Add’ in the ‘Attached background material’ section.



You can attach the full study report by clicking on ‘Add’ in the ‘Attached full study report’ section.



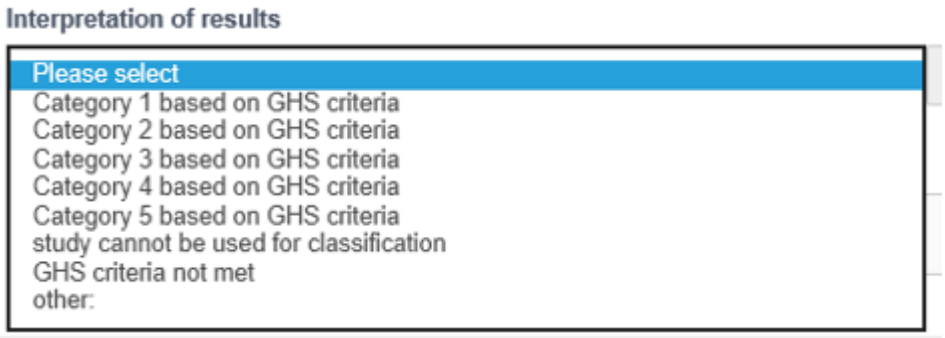
You can delete a report you added accidentally by clicking on ‘Delete’. You can also add additional full study reports by clicking on ‘Add’.

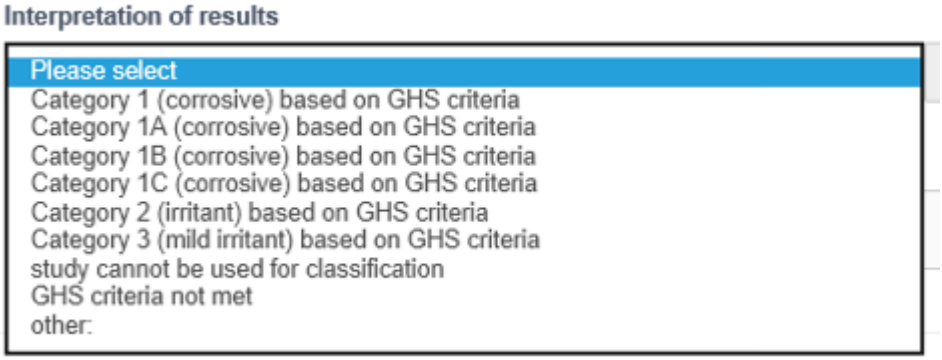
Applicant’s summary and conclusion

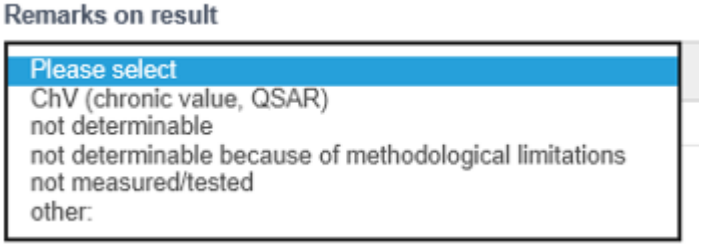
You will need to complete each endpoint by filling in ‘Conclusions’ in the ‘Applicant summary and conclusion’ section. This section describes the main conclusions from the study.

For some endpoints you may need to fill in the ‘Interpretation of results’ section as part of your conclusions.

You may need to indicate if the effects of the chemical relate to its classification and labelling criteria by choosing an option from the ‘Interpretation of results’ or ‘Remarks on result’ pick lists.



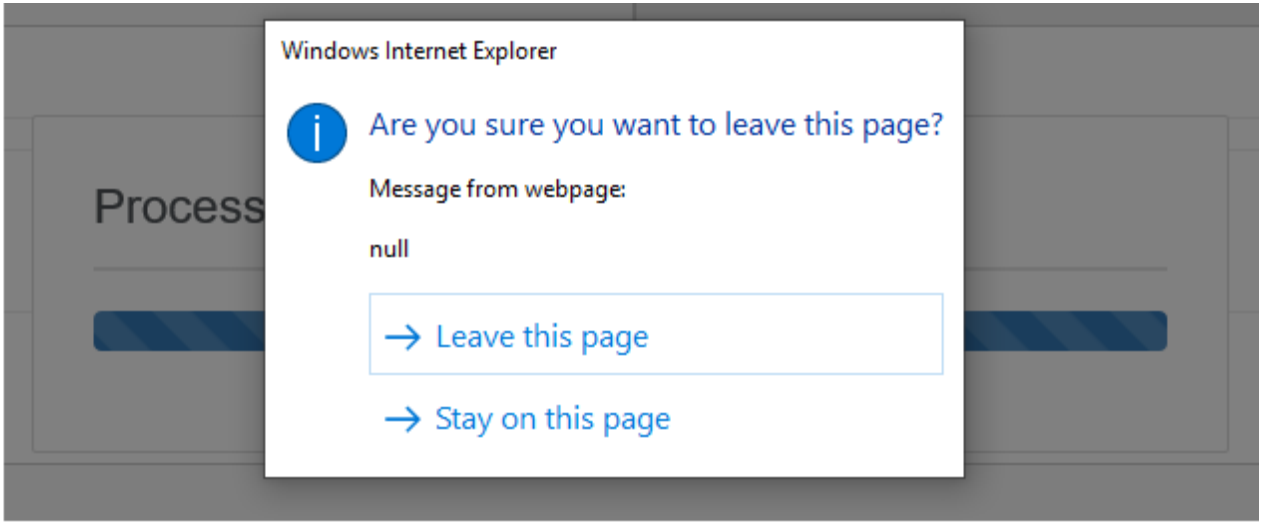




If you select ‘other:’ then you can enter details in the adjacent free text field.

Other messages you may see as you fill in your information

When moving between chapters or documents



If you see this message, click on ‘Leave this page’ to continue.

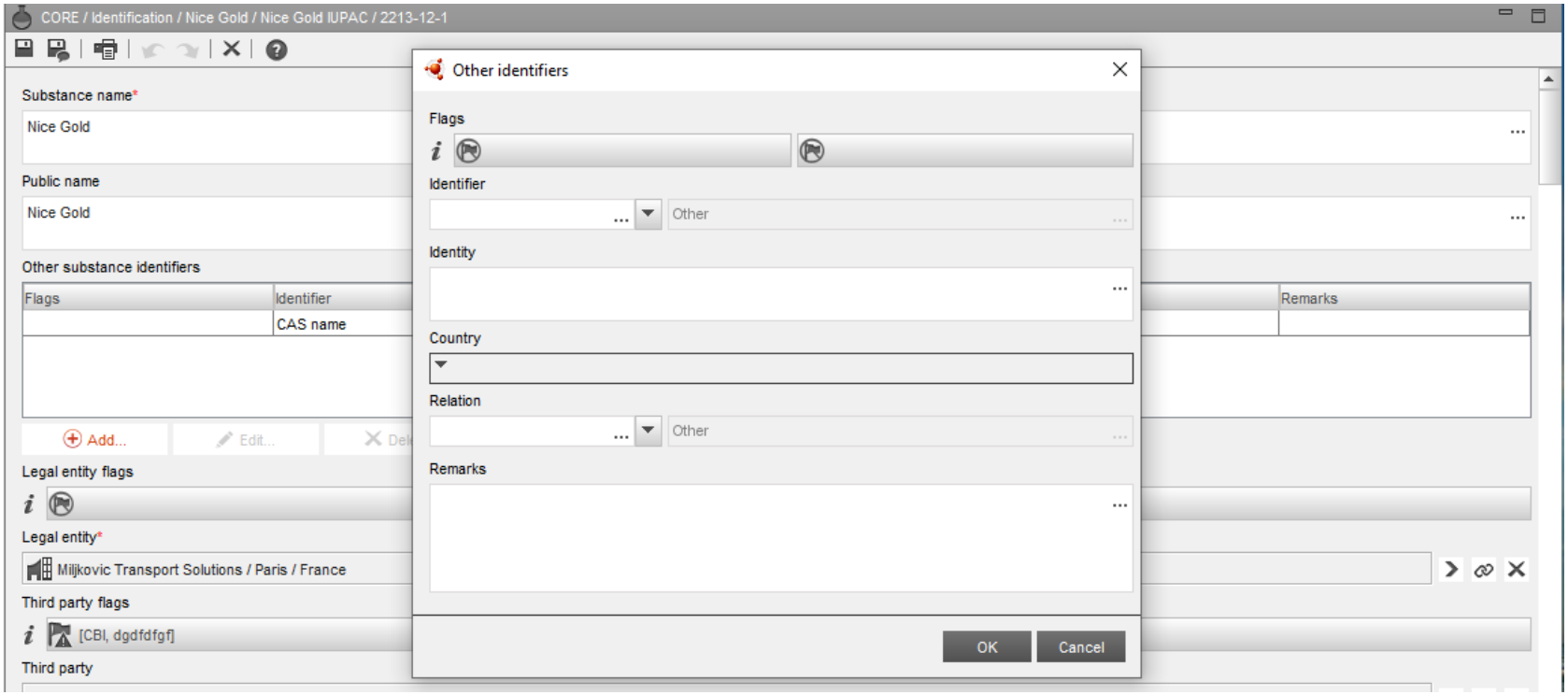
When working in the classic interface of IUCLID6

Note: Not all the fields in IUCLID6 appear in the portal for Applicants to complete. If you are creating chemical dataset from the beginning, we would recommend you use the portal.

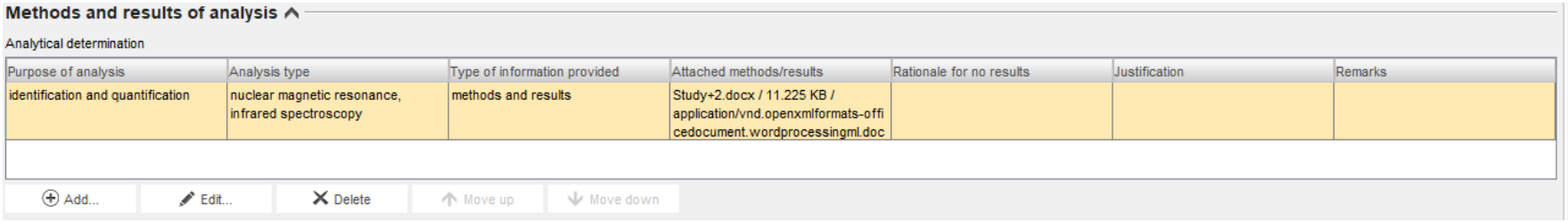
To add information to a table or field in the main window, you can:

- enter the information directly as text or by selecting from a pick list or
- click on ‘Add’ where available

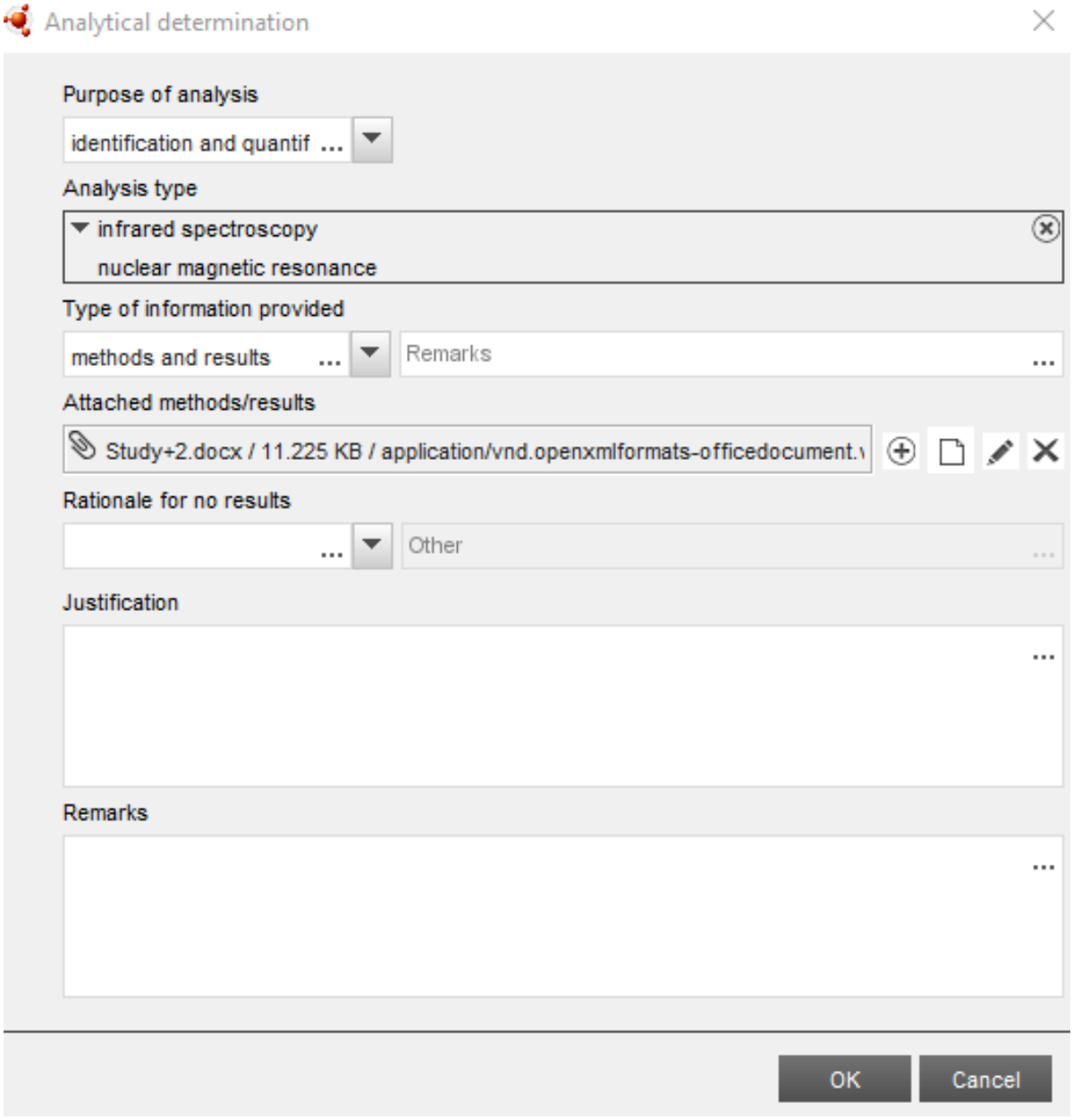
This will open up a pop-up window. Once you have completed the information requested, click on ‘OK’ to save the information in the table.



If you need to enter remarks or edit a table entry, select the table entry you want to look at.

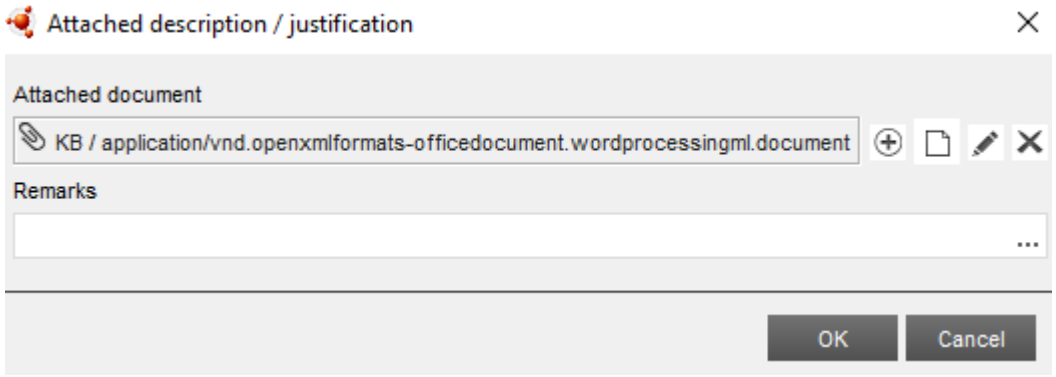


Then click on ‘Edit’ to open a pop-up window where you can see the information submitted.



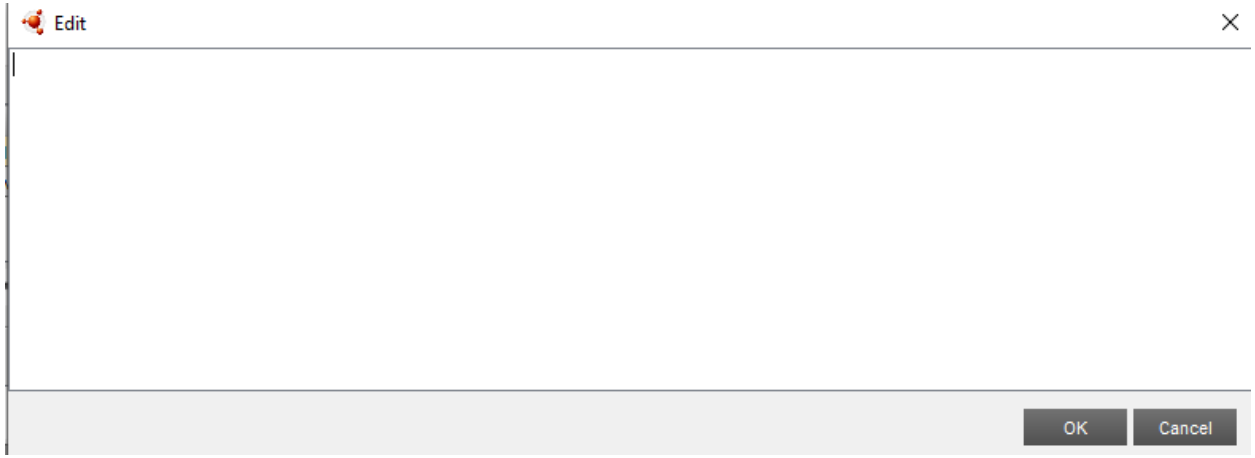
The pop-up window can also be edited by selecting the entry you want to edit and then double clicking.

To add a document to a table, click on ‘Add’. This will open up a pop-up window.



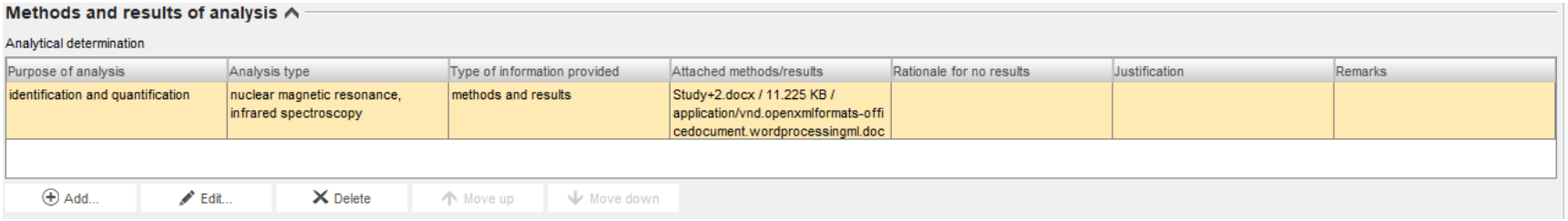
Click on the ‘+’ to attach the document, or the document icon to open the attached document.

You can enter remarks directly into the remarks field, or you can enter them in using the edit function. Click on the ‘…’ to bring up the free text ‘Edit’ window.



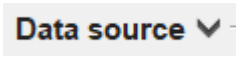
Select ‘OK’ to save your changes to the ‘Edit’ window. Then click on ‘OK’ again to save the information in the field.

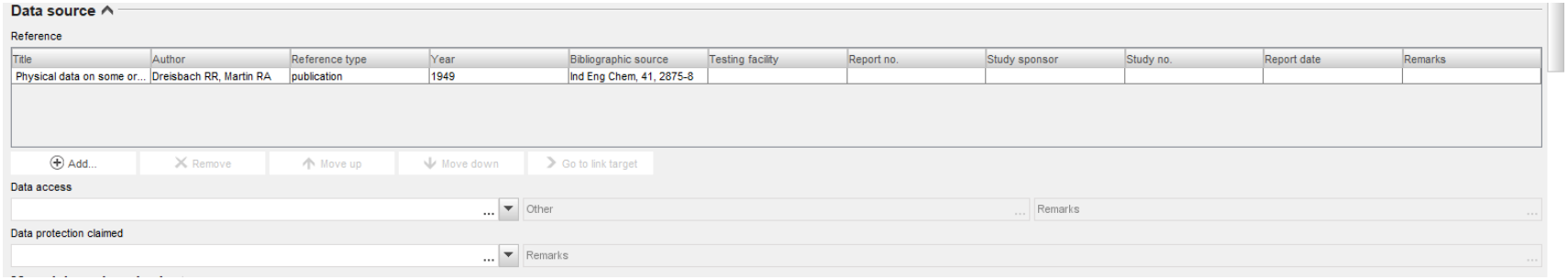
If you need to enter remarks or edit a table entry, select the table entry you want to look at.



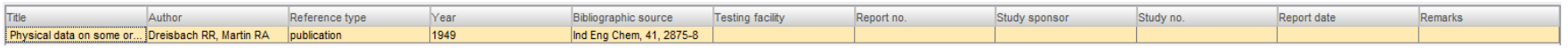
Then click on ‘Edit’ to open a pop-up window where you can see the information submitted.

To open any documents submitted in support of the information entered, open ‘Data source’.

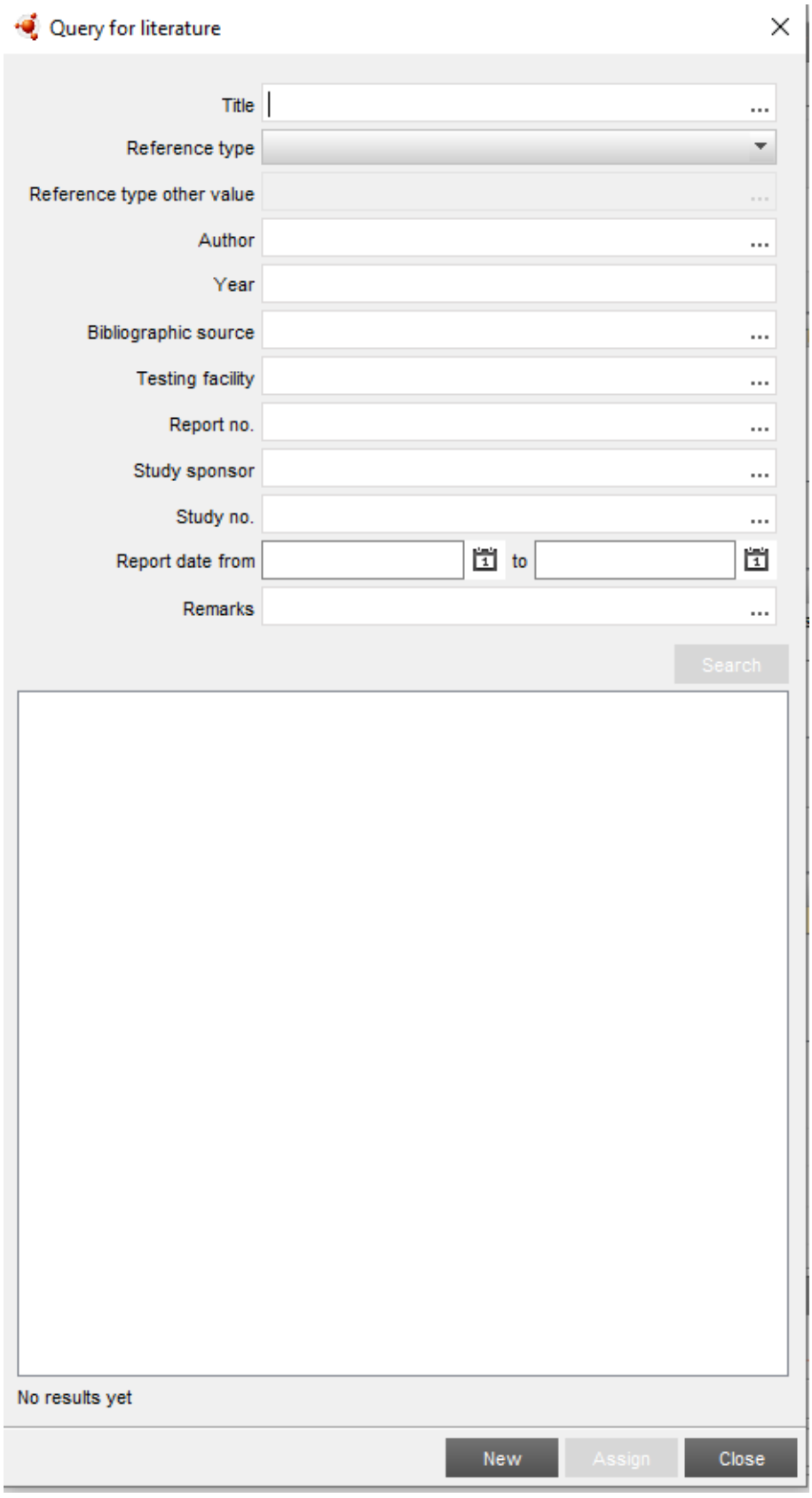




To open any attached documents, click on the ‘Title’ cell of the data source to highlight it and then double click to open it.

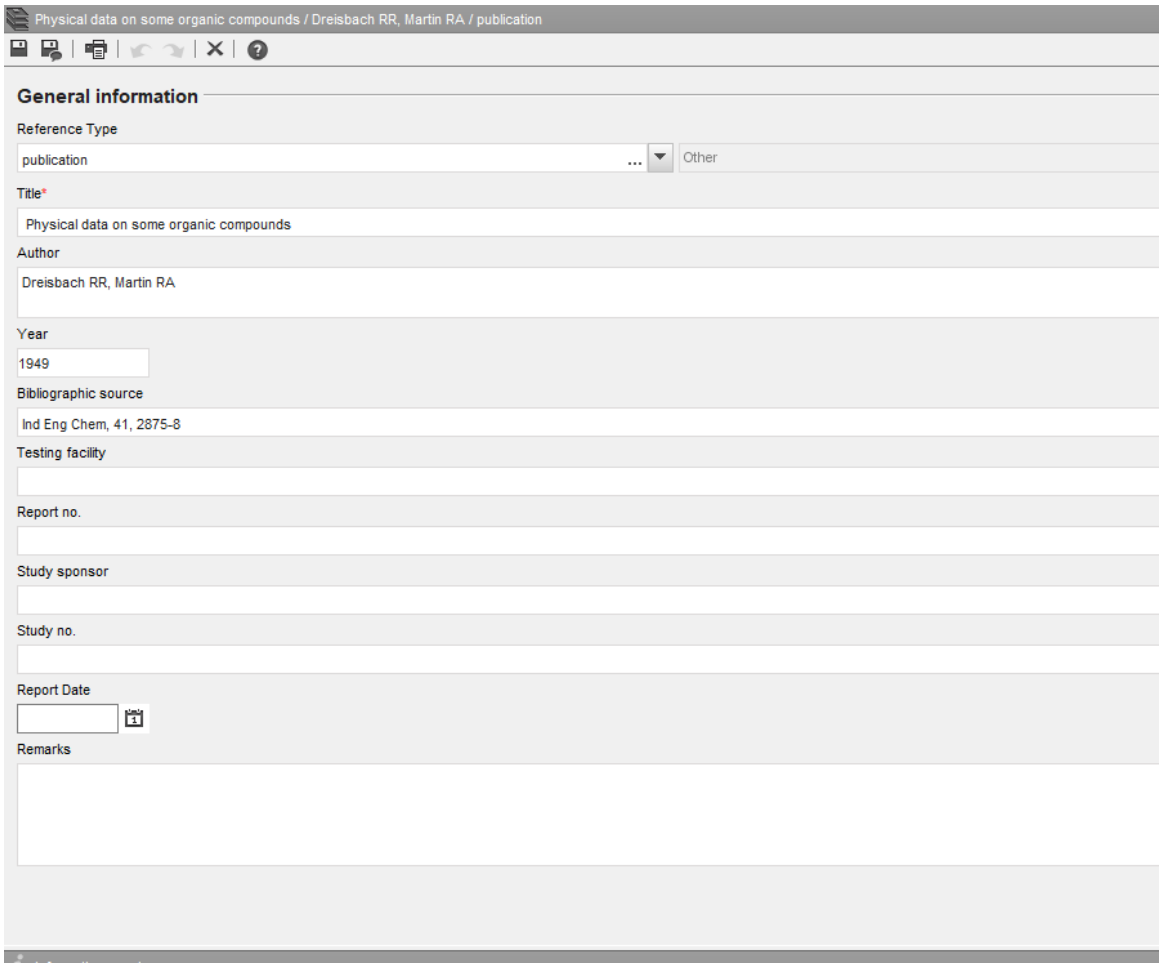


To add another data source, click on ‘Add’. Then, enter in the information required by the ‘Query for literature’ pop-up window.

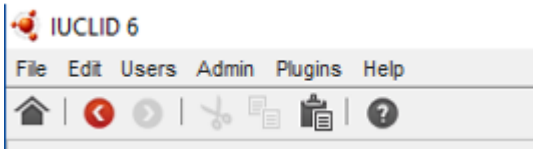


You can remove a reference added by mistake by clicking on ‘Remove’.

To see a summary of the reference, you can click on ‘Go to link target’. This will take you to another window and you can then click on ‘Save’ to save any changes you may have made.

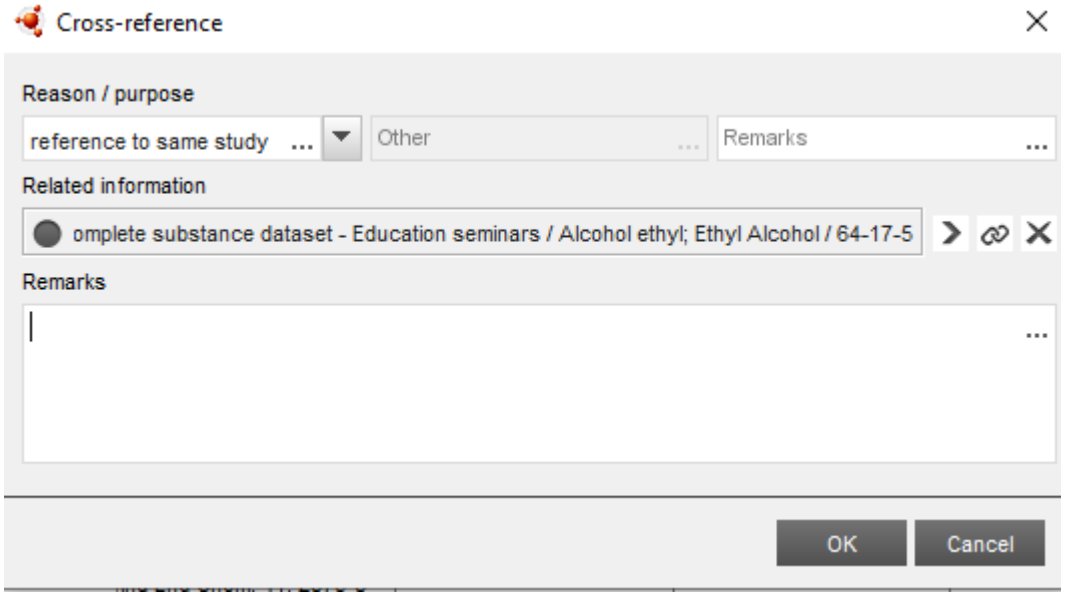


Click on the left facing arrow in the top menu bar to go back to the document you are working on.



You can ‘Cross-reference’ a study under ‘Administrative data’.

Clicking on the link icon between ‘>’ and ‘X’ will allow you to link in other documents. Highlight the document you are linking as a cross-reference, and then click on ‘Assign’ to save the change.

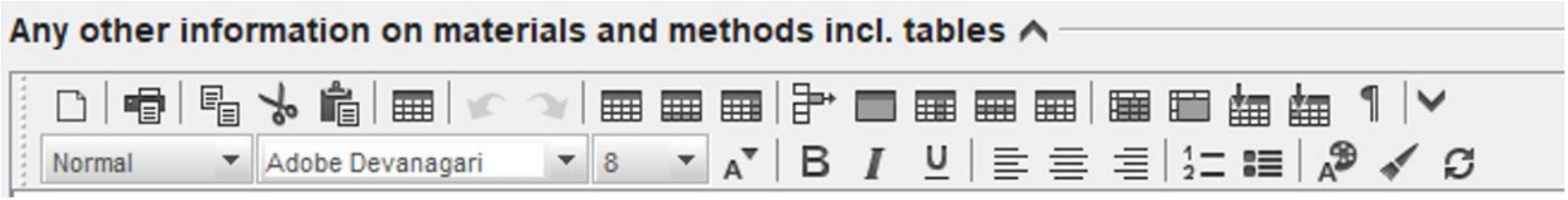


Alternatively, you can click on the ‘…’ at the top right hand side of the window which will bring up an ‘Edit’ pop-up window.

Fields identified with an ‘A’ and an arrow will let you enter text in directly.

 will allow you to add in a template.

Fields with the following menu bar provide a formatting palette allowing you to work in the field in the same way as a word document.

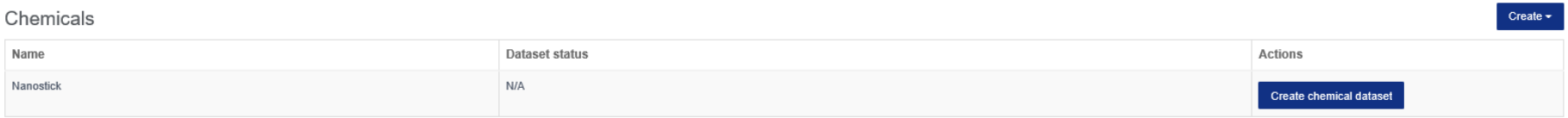


Creating reference documents for use in the chemical dataset

After opening the chemical dossier tab, you will then need to create reference documents by clicking on ‘Create’. It is important to create these documents before the dataset as they will be attached in the relevant sections of the chemical dataset.

> The creation of reference documents **must** occur before you create your chemical dataset.

Do not create a chemical dataset until you have created all the relevant reference information.



Reference substance

These documents allow you to store identification information for your chemical as well as any constituents of the chemical such as impurities, additives, analogues, constituents or surface treatments. This information includes information such as the chemical name (CAS name, IUPAC name, synonyms, etc), any identity codes (CAS number) as well as molecular and structural information.

You should provide the CAS number for the chemical. This is a unique number assigned to it by the Chemical Abstracts Service (CAS) and can be obtained by contacting CAS.

You must provide a molecular formula that gives the identity and number of atoms of each element in the molecule. For example, C6H6 for benzene, H2SO4 for sulphuric acid. When providing the molecular formula for synthetic polymers made using 2 or more monomers, list the monomers in order from the highest carbon number to the lowest.

For example (C8H6O4.C5H12O2.C4H2O3.C3H8O2)x for 1,3-Benzenedicarboxylic acid, polymer with 2,2-dimethyl-1,3-propanediol, 2,5-furandione and 1,2-propanediol.

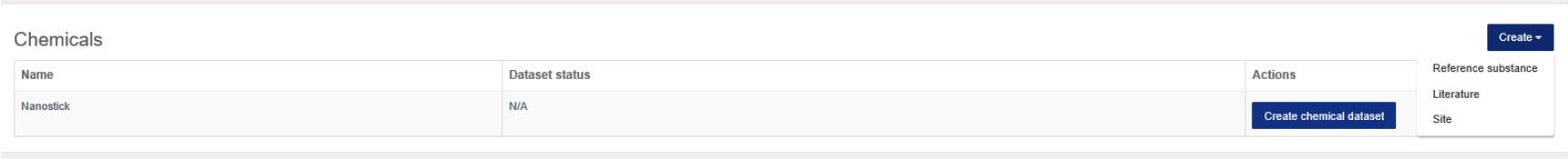
Provide a structural formula indicating the location of atoms, ions or groups and the nature of bonds joining them.

For polymers, depict the probable bonds between monomers in the structural formula.

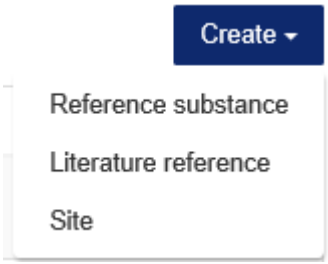
Creating reference substance documents allows you to use the same information for the same chemical identity, avoiding the need to continually re-enter information. These documents act as reusable references. It also allows for the information to be centrally managed and updated. You can also directly maintain documents you create. You can link each reference substance to an unlimited number of substance or mixture datasets. To update information for a reference substance, you can open the 'Reference substance inventory', search for the relevant substance and then update it. Updating the reference substance will impact on all datasets that you have linked to the reference substance.

You must complete all fields identified with a red asterisk (*).

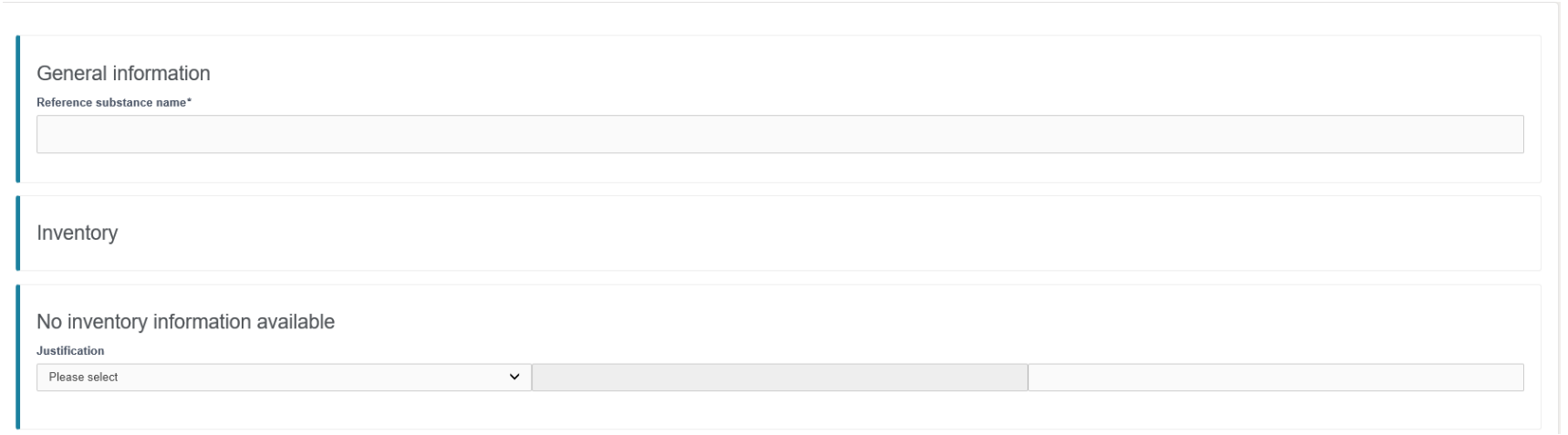
To create a document record for a reference substance, click on 'Create'.



Then select ‘Reference substance’ from the pick list.



Under ‘General information’, enter in the name of the reference substance in the field.



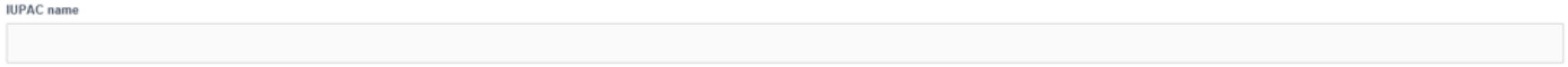
The use of the term ‘inventory’ in IUCLID is not related to the AICIS Inventory. If the reference substance you are creating as part of your application is not on the IUCLID6 inventory, you must select one of the following from the ‘Justification’ pick list:

- not yet assigned
- no previous notification obligation
- previous identifier no longer suitable
- produced, but not marketed in relevant region
- research and development
- not applicable
- other:

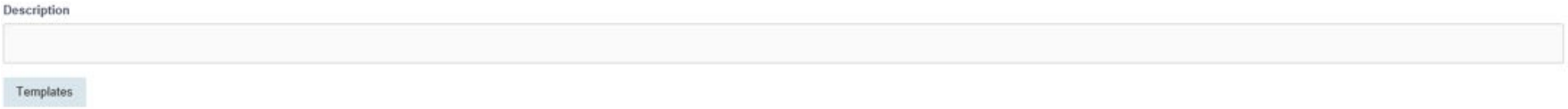
Selecting ‘other:’ activates the adjacent field for you to enter in your justification.

Indicate if you consider the information for this reference substance to be CBI by completing the ‘Confidentiality’ fields.

If the reference substance has an IUPAC name you can enter it in the field. If there is no IUPAC name, you can choose to enter in information defining the chemical name of the reference substance.



Enter in a description of the reference substance in the field if the reference substance does not correspond to a well-defined chemical substance.



You can also choose to insert a template which will guide you through the information required.

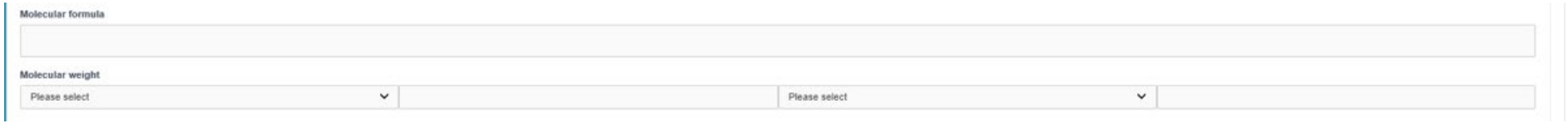
Enter in the CAS number and name of the reference substance in the matching fields.

Then add information regarding identifiers of any related substances. Click on ‘Add’. This will open an ‘Add new item’ pop-up window allowing you to complete the ‘Identifiers of related substances’ field. Enter in any group/category information in the ‘Group / category information’ field.

Then, enter in the molecular and structural information related to the reference substance. Identify if you would like the information to be considered as CBI.

Enter in the molecular formula in the relevant field in the ‘Molecular and structural information’ section. If you can’t derive a formula from the reference substance, you should enter justification in the ‘Remarks’ field located under ‘Structural formula’. After entering in the molecular formula inforamtion, add in the molecular weight range.

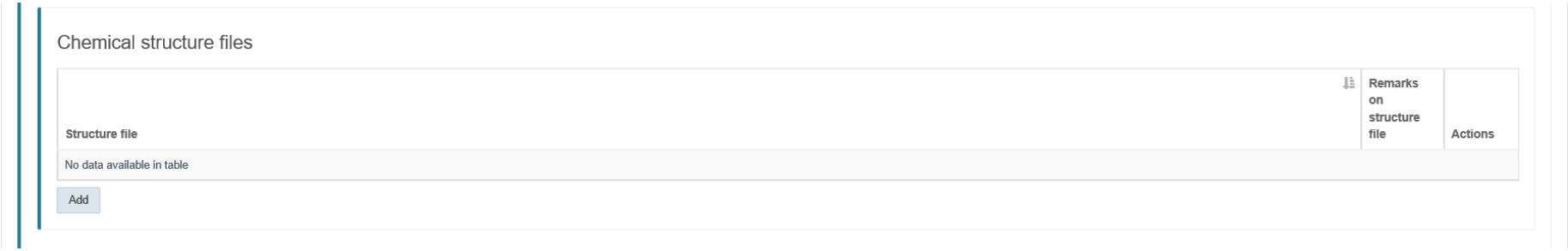
You must provide the gram-molecular weight of the chemical. For polymers, provide both the number-average molecular weight and the weight average molecular weight.



Enter in the SMILES notation and InChi names, if these are available, in the relevant fields.

Lastly, upload the structural formula of the reference substance in the relevant field. Click on ‘Browse’ to add a copy of the structural formula.

Then click on ‘Add’ to add the chemical structure file. You can only attach .jpg files.



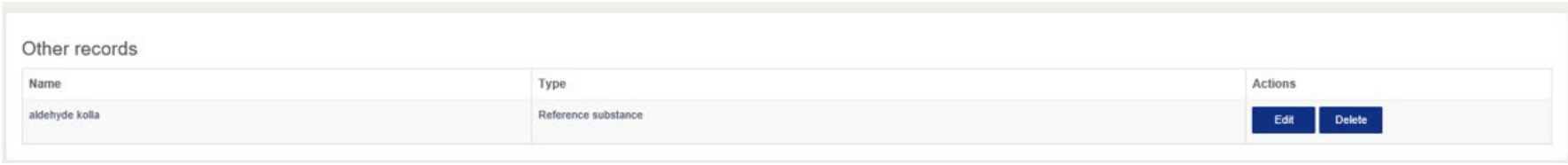
This will open an ‘Add new item’ pop-up window. Click on ‘Browse’ to add a copy of the chemical structure. Enter in any remarks on the structure file in the relevant field.

Click on ‘Save’ to save the chemical structure file in the ‘Structure file’ table.

Then ‘Save’ the information entered for the reference substance.

Repeat these steps for all reference substances you will be referring to in your chemical dataset. You can create records for reference substances at any point when entering the chemical dataset. However, you will need to exit the chemical dataset.

After saving, you will be returned to the main chemical dataset screen where the ‘Reusable references’ table will have been updated to show your new record.



You can edit or delete references by clicking on ‘Edit’ or ‘Delete’.

You must complete a reference substance record for all known (or reasonably anticipated):

- hazardous and non-hazardous impurities (including isomers and by-products) of a chemical
- additives/adjuvants (such as stabilisers, inhibitors and modifiers) incorporated into the main chemical substance

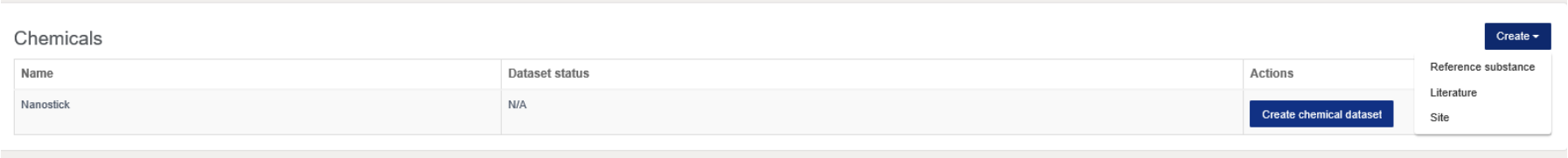
To report unknown impurities, create a generic reference substance and under the IUCLID name enter the phrase ‘unknown impurities’. In the ‘Remarks’ field, specify the nature, number and relative amounts of the impurities where possible. You should also provide typical concentration and concentration range for the unknown impurities.

Literature

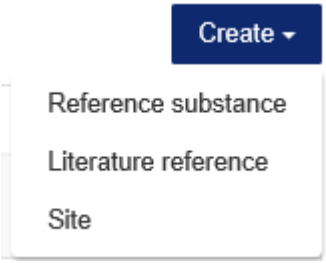
You must provide a complete listing of all publications referred to in your application statement, including:

- references for published and unpublished studies
- references for other information obtained from the scientific literature
- references to standards and codes of practice
- details of test methods used to generate data
- references to other notification and assessment schemes
- references for other reports on the chemical or class of chemicals.

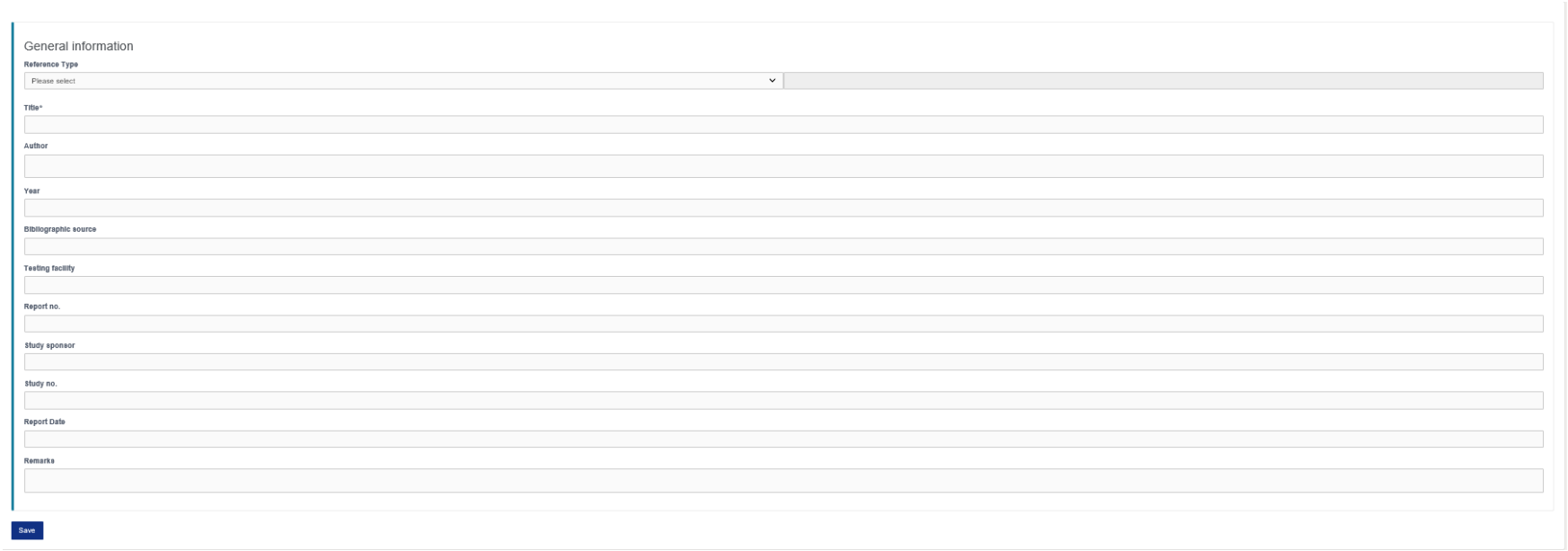
To create a document record for a literature reference, click on ‘Create’.



Then select ‘Literature’ from the pick list.



You can then create reusable references. You can insert and store different types of literature references. This includes the publications and study reports which form the basis of the endpoint study records you will create in the chemical dataset. You can link each literature reference to the endpoint study records in the chemical dataset.



Select a reference type from the ‘Reference Type’ pick list:

- study report
- other company data
- publication
- review article or handbook – what we want the difference to be between a review and a publication, for example, a review that has been published in a scientific journal
- other:
- Bibliographic source.

Then click on ‘Save’ to save the information entered for the literature source.

Repeat these steps for all literature sources you will be referring to in your chemical dataset. You can create records for literature sources at any point when entering the chemical dataset. However, you will need to exit the chemical dataset.

After saving, you will be returned to the main chemical dataset screen. The ‘Reusable references’ table will update with the additional reference information.

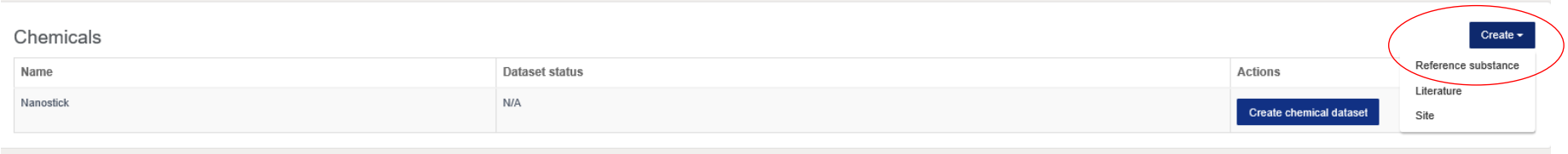
You can edit or delete references as needed by clicking on ‘Edit’ or ‘Delete’.

Site

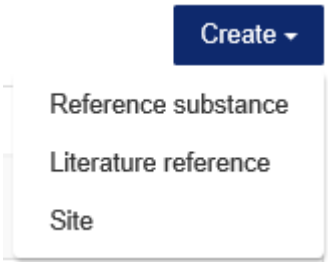
Site details are required if the chemical information is being manufactured in Australia. The information includes the name of the site, the address and other contact details of the site.

You must complete all fields identified with a red asterisk (*).

To create a document record for a site, click on ‘Create’.



Then select ‘Site’ from the pick list.



Identify if you would like the information to be considered as CBI.

In the ‘General information’ fields, you must enter in the site name. Enter in any remarks about the site in the ‘Remarks’ field if required.

Then fill in any relevant fields in the ‘Contact address details’ section, again identifying if you would like the information to be considered as CBI.

After completing the contact details for the site, click on ‘Save’.

Repeat these steps for all sites you will be referring to in your chemical dataset. You can create records for sites at any point when entering the chemical dataset. However, you will need to exit the chemical dataset.

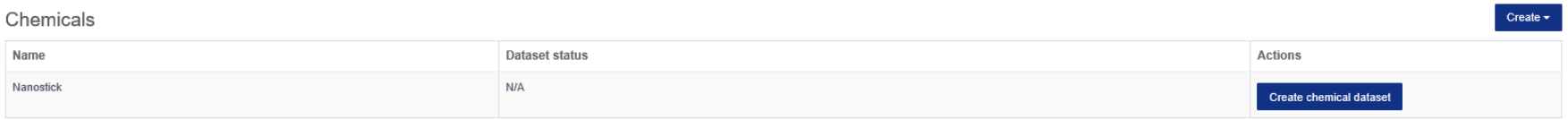
After saving, you will be returned to the main chemical dataset screen. The ‘Reusable references’ table will update with the additional reference information.

You can edit or delete references as needed by clicking on ‘Edit’ or ‘Delete’.

Creating a chemical dataset

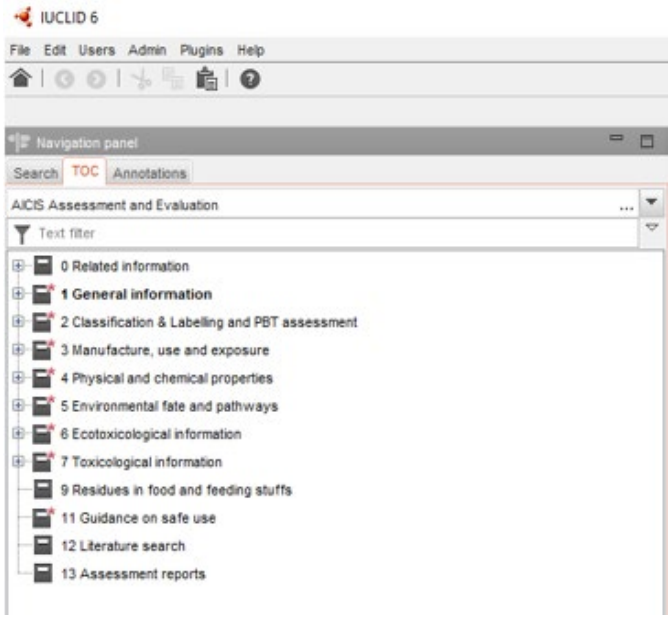
If you are creating a chemical dataset through the portal, click on ‘Create a chemical dataset’.

We strongly recommend that you do this step after you have created records for all the references you will be referring to in your dataset.



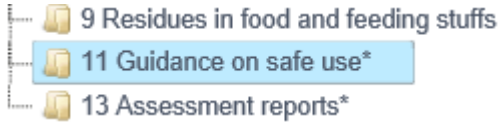
After creating the chemical dataset, you will see a table of contents. It will list a number of chapters and sub-chapters to guide you through entering the information required for your chemical and its category of introduction.

If you are creating the dataset directly in IUCLID6, your screen will be similar to this. However, the chapters listed will be described based on the application type you have selected under TOC.



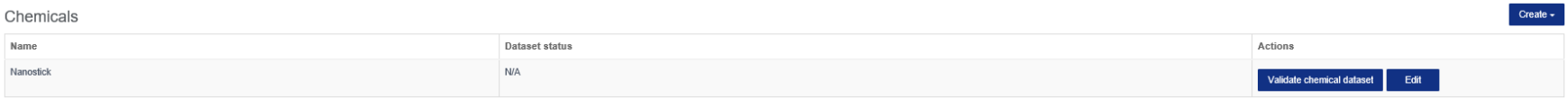
You must complete any chapters and sub-chapters that are marked with an asterisk (*) unless otherwise indicated by the Categorisation Guidelines.

Chapters marked with an asterisk do not contain sub-chapters. For example, Chapter 11 ‘Guidance on safe use’ and Chapter 13 ‘Assessment reports’. If a chapter is marked with an asterisk, you must also complete it.

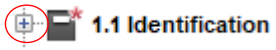


The chapters and sub-chapters that you need to complete will vary depending on your category of introduction. The guidance provided here covers all information requirements for those applications where the indicative risk for human health and the environment is medium to high. Other categories of introduction will have different chapters you need to complete and the table of contents will automatically reflect them.

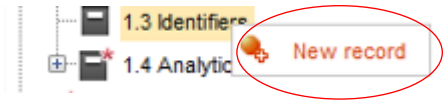
If you need to close the chemical dataset after it has been created, you can edit it by opening the certificate application and then go to the Chemical dossier tab. You can then click on Edit to open the chemical dataset.



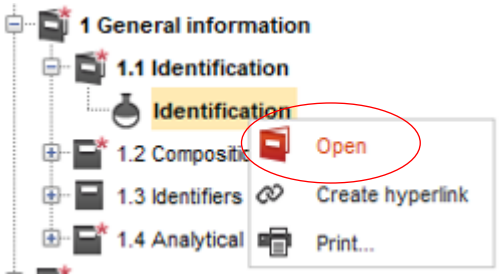
If you are creating a chemical dataset directly in IUCLID6 to send to AICIS, right click on the '+' of the chapter you would like to add a new record to.



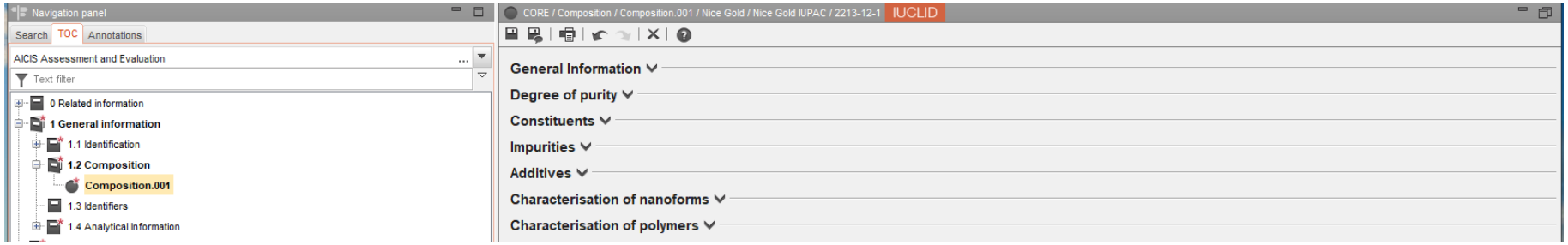
Then, select 'New record'.



Once the record has been created you can then open it.



The right hand side of the window will then bring up the fields you will be required to complete.

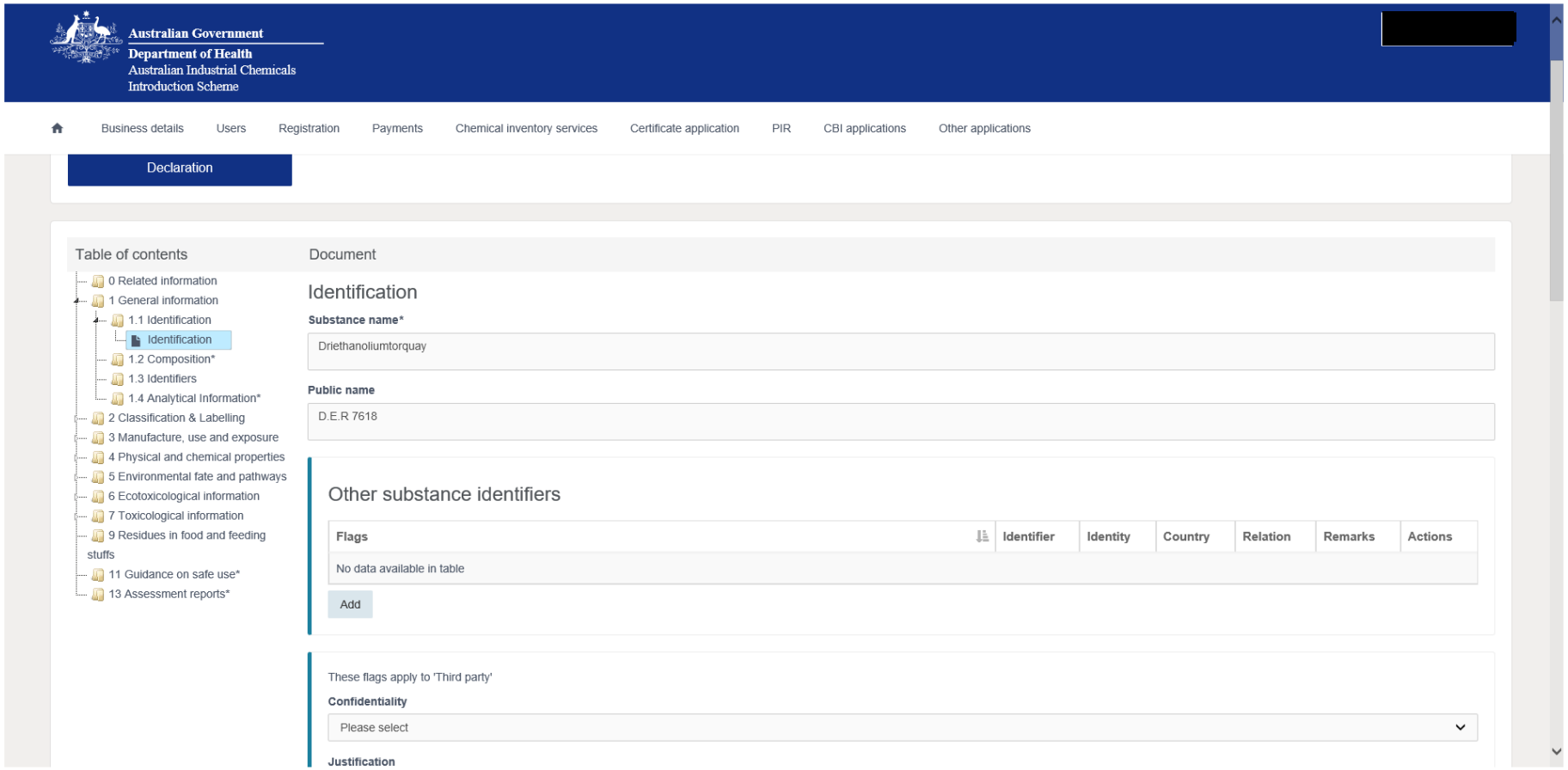


General information

This chapter describes the identity of the chemical including chemical identity, composition, other identifiers and analytical information.

Identification

You must provide a complete and unambiguous identification of the chemical.



Enter the substance name directly into the relevant field. The substance name is the name of the chemical the dataset relates to. You must provide the chemical name that will be used in the AICIS Inventory, the Chemical Abstracts CA Preferred Index name. If this is not available, provide the International Union for Pure and Applied Chemistry (IUPAC) name.

For substances that are not pure chemicals, describe the chemical name as completely as possible. This includes chemicals of unknown or variable composition, a complex product of a chemical reaction or a biological material.

In the case of a synthetic polymer, provide the information listed under the relevant paragraphs below, for the constituent monomer/s.

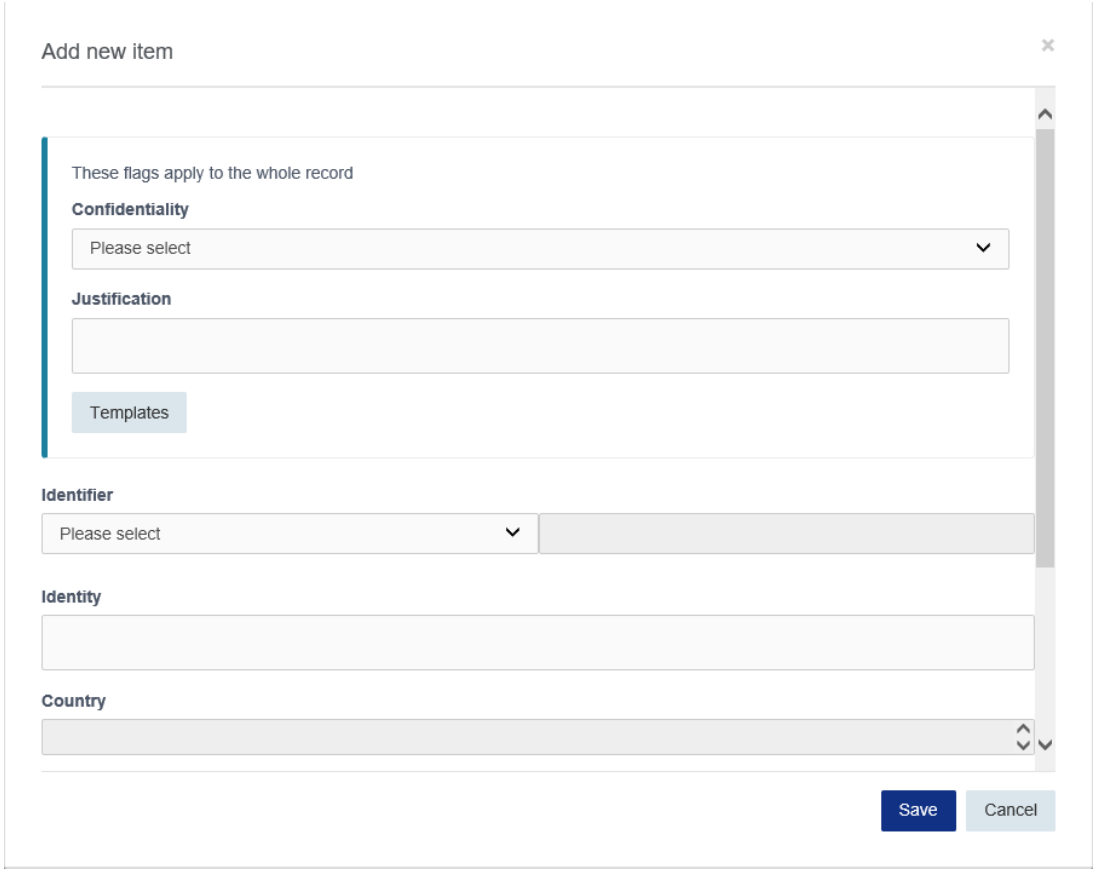
You can include other substance identifiers here. These identifiers can include:

- Other names: for example, common names by which the chemical is known or identified in the scientific or technical literature. For example, 2-propanone is commonly known as acetone, International Nomenclature of Cosmetic Ingredients (INCI) names or names which are used to identify the chemical in other regulatory schemes.
- Marketing name of the chemical: for example, those names under which the chemical has been, or will be, marketed including trade names. Specify if these names will be used for marketing purposes in Australia.

If you have applied for the chemical name to be considered as CBI and we have approved the application, we will use the AICIS approved chemical name (AACN) in the Assessment Statement.

You should include chemical (scientific) synonyms in the reference substance information created earlier.

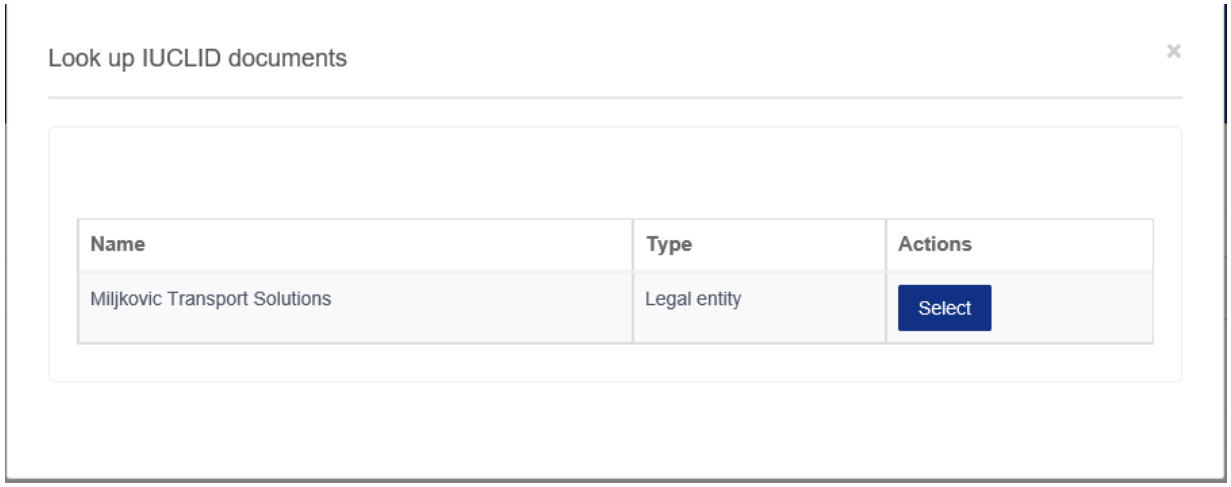
You will not be able to enter in information on other substance identifiers directly into the table. To add information into the table you will need to click on ‘Add’ to bring up an ‘Add new item’ pop-up window.



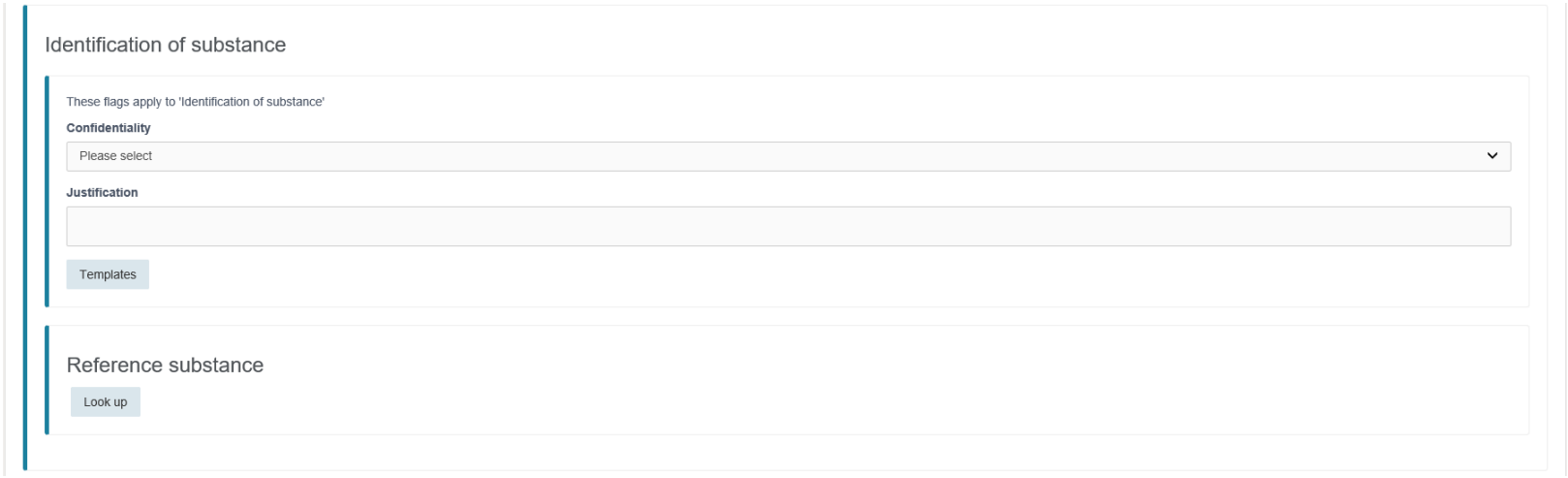
Enter in the relevant information and then click on ‘Save’ to save the information in the table.

If applying for confidentiality in relation to third party and/or the identification of the substance, you should choose CBI (Confidential Business Information).

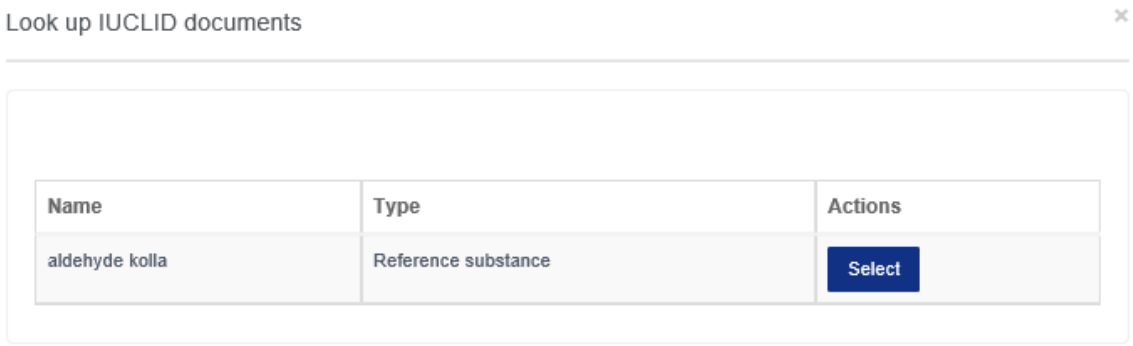
Select ‘Look up’ to find the relevant ‘Third party’.



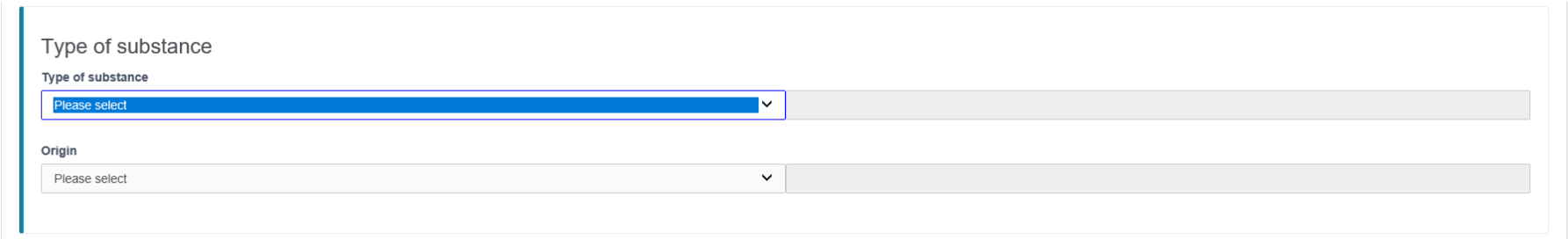
Then enter in details about the chemical you are introducing in the ‘Identification of substance’ section.



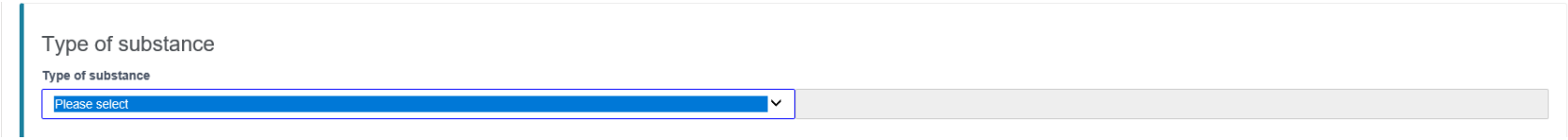
Then, click on ‘Look up’.



Then, click on ‘Select’ to select the chemical you are introducing before describing it. Select the appropriate type of substance from the pick list.



For ‘Type of substance’, you have to select if it is a mono-constituent chemical, a multi-constituent chemical, a UVCB, a polymer or a microorganism or toxin produced by a microorganism. Selecting ‘other:’ activates the adjacent field.



A mono-constituent substance is a well-defined substance where the substance is named according to the chemical name of that main constituent. If your chemical is a mono-constituent chemical, assign the reference substance corresponding to the main constituent.

UVCB substances (i.e chemical of Unknown or Variable composition, Complex reaction products or Biological materials) are substances that cannot be sufficiently identified by their chemical composition. If your chemical is a UVCB substance, assign a reference substance corresponding to the UVCB substance.

The UVCB criteria only define a proportion of chemicals that contain more than 1 component and are manufactured, brought into Australia and used together. There are chemicals that do not meet the UVCB criteria because they comprise components which are identifiable and present in fixed proportions but, like UVCBs, those components are not separated during their introduction and use. Alternatively, purification or analysis can lead to identification of all components in a chemical and the ratios at which they are present. This can lead to the individual components being named separately.

If the chemical is none of these then you can select ‘other:’ and the adjoining field will be activated. You can then enter in the chemical type.

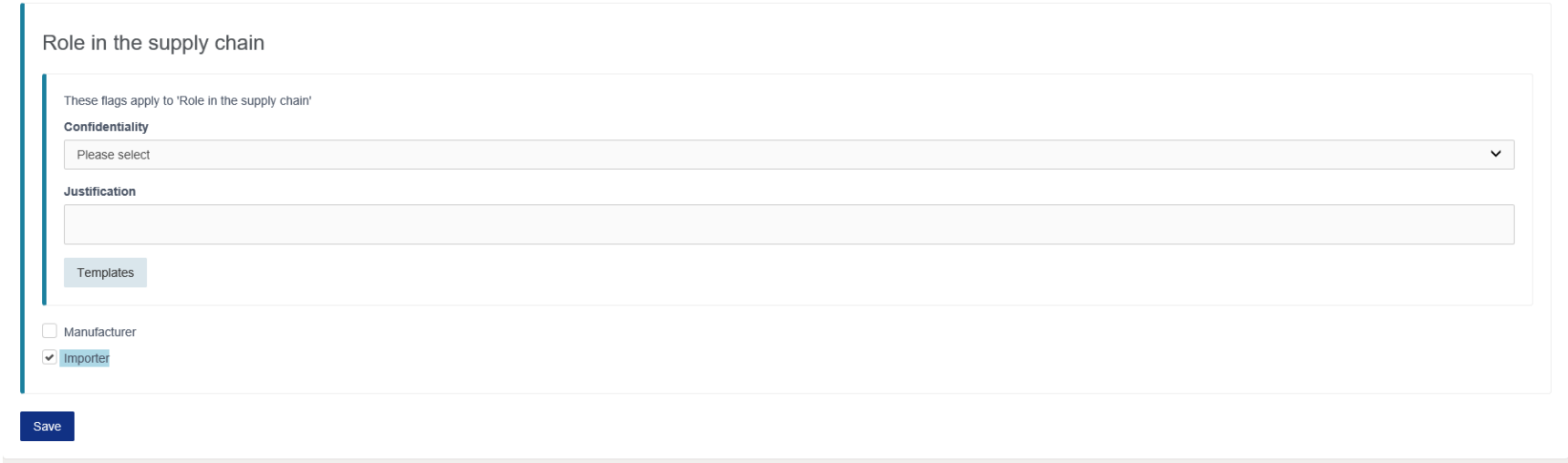
Then select the origin of the chemical from the pick list. You have to select if it’s an element, inorganic, organic, organometallic or a petroleum product.

Note: In this context, organic relates to chemicals which are carbon-containing compunds. It does not relate to the use of:

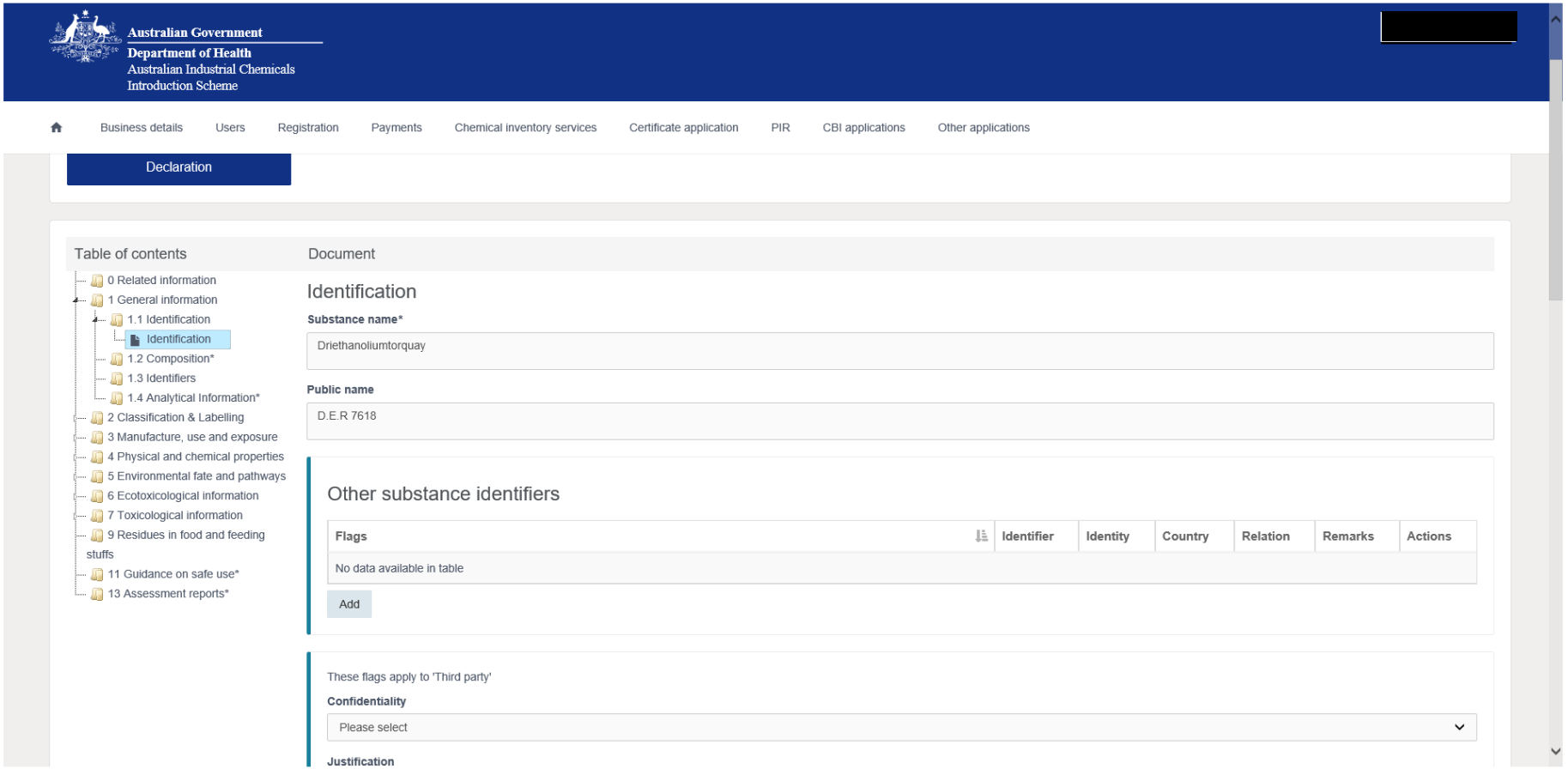
- manufacturing processes such as those that emphasise sustainability
- non-synthetic chemicals or artificial fertilisers

Selecting ‘other:’ activates the field.

Choose if you are the manufacturer or importer. You can also flag if this information should be considered as CBI.



Then click on ‘Save’ to save the information in the chemical identification document.



You can only create one identification document per chemical dataset.

Composition

This section contains information on the identity and concentration of the constituents of the chemical, including any impurities and additives, as well as the state and form of the chemical.

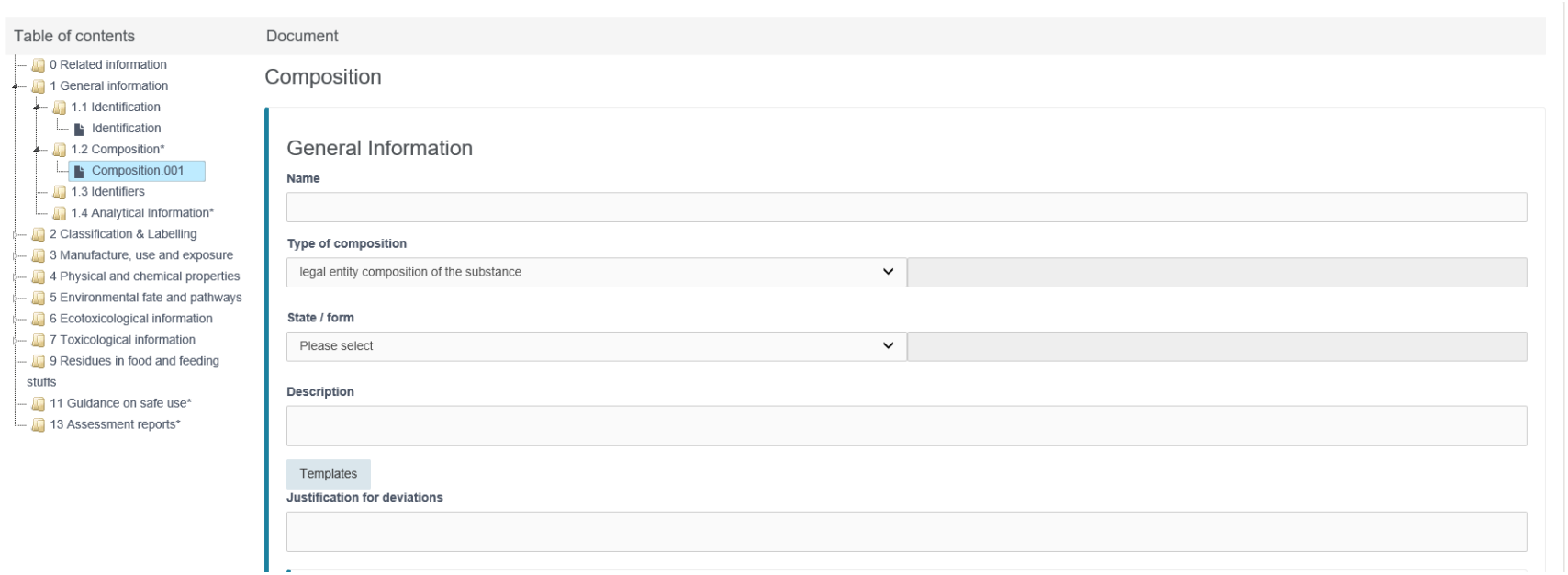
If your chemical is considered to be at the nanoscale, you will be able to enter information on the characterisation of the chemical and any associated nanoforms. If your chemical is at the nanoscale, you must provide additional information/data. See guidance about this on our website:

https://www.industrialchemicals.gov.au/help-and-guides/guide-applying-online-assessment-certificate

If your chemical is a polymer, you will be able to enter information on the molecular weight and any low molecular weight species.

If your chemical is a polymer, or is considered to be at the nanoscale, go to the section on ‘Additional information for polymers, and chemicals considered to be at the nanoscale’ before completing the analytical and composition information.

Create a new document under Composition (Chapter 1.2).



Then enter in general information about the composition of the chemical you are introducing.

Enter in the name of the chemical and then select the type of composition. This refers to a composition manufactured, imported or used by the applicant. The default selection is **legal entity composition of the substance**.

If you select ‘other:’ then the adjacent field will open.

You will also need to select the physical state/form of the chemical. If the chemical covers different physical states or forms, then you should create a separate composition record for each state/form of the chemical.

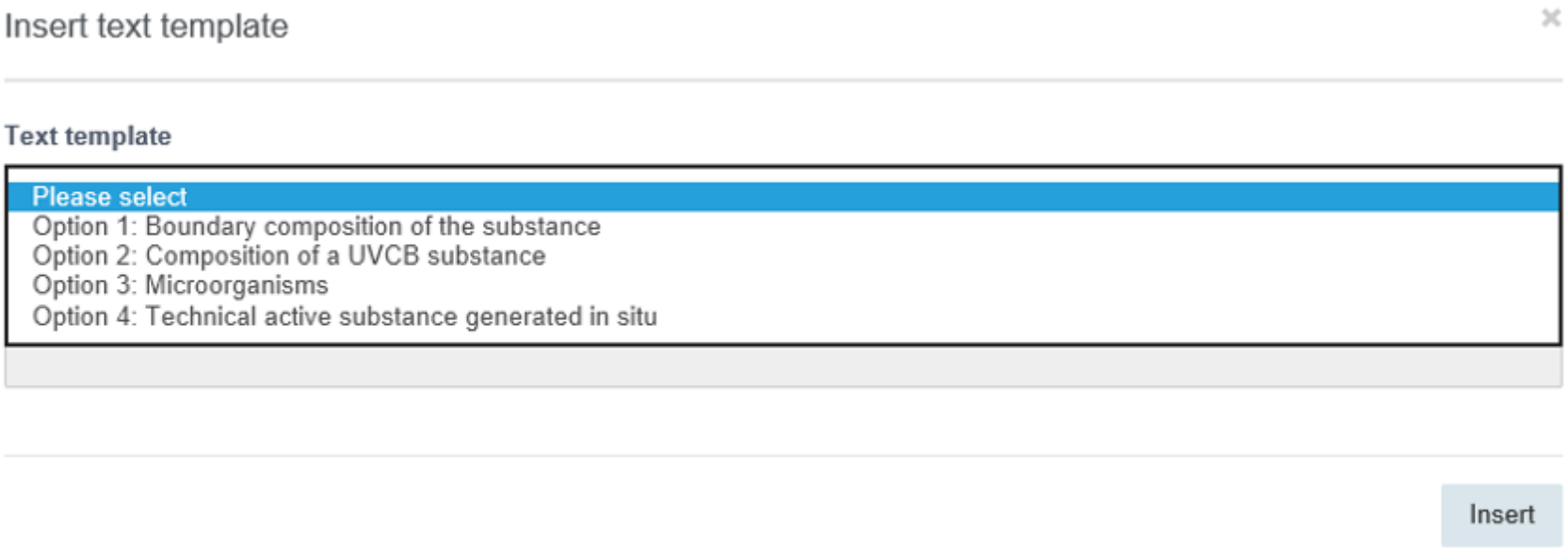
If your chemical is considered to be at the nanoscale, then select ‘solid: nanoform’.

If you select ‘other:’ then the adjacent field will open.

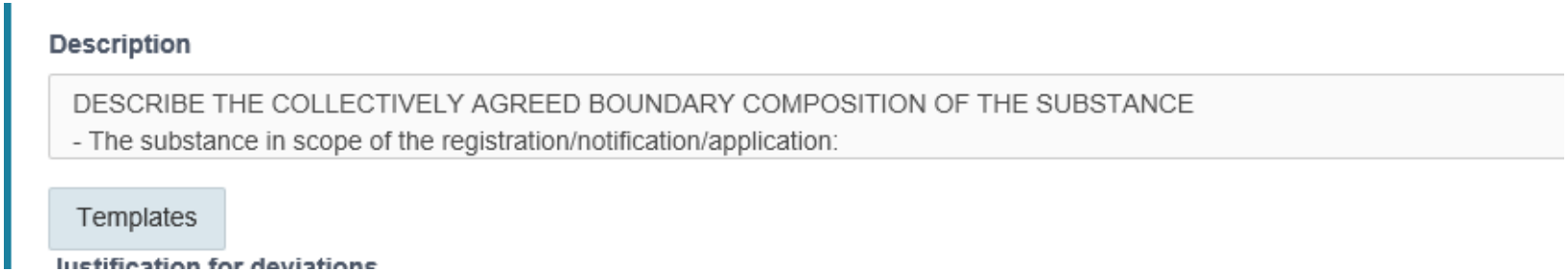
You can also enter more detailed information on the type of composition in the description field. This is especially important if you need to clarify between several compositions. Additional descriptions of the chemical may also be required where the chemical covers a wide range of polymorphs or isomers.

You can also include further information identifying the composition of the chemicals, such as UVCBs, where you may not be able to define or quantify the constituents.

You could also select a text template option for guidance on the sort of information to be included.



Select the template from the pick list that best describes the composition of your chemical and then choose ‘Insert’.

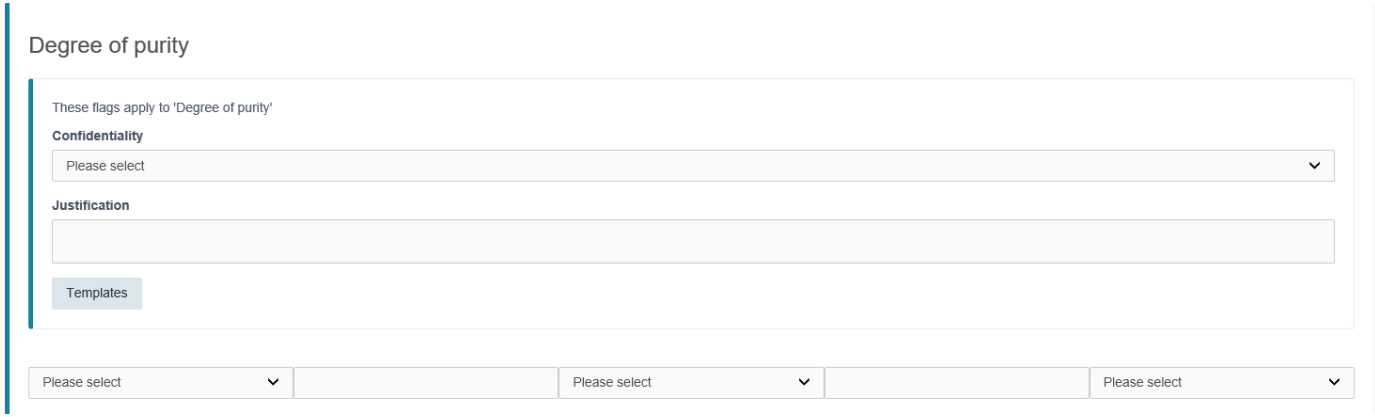


Boundary composition of the substance allows joint applicants to provide:

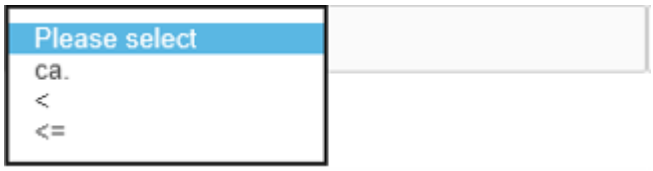
- chemical identity information that should be common to the legal entity compositions they are jointly applying for
- the related classification and assessments

If you are unable to enter in the information on composition required, you must provide justification for not providing this information.

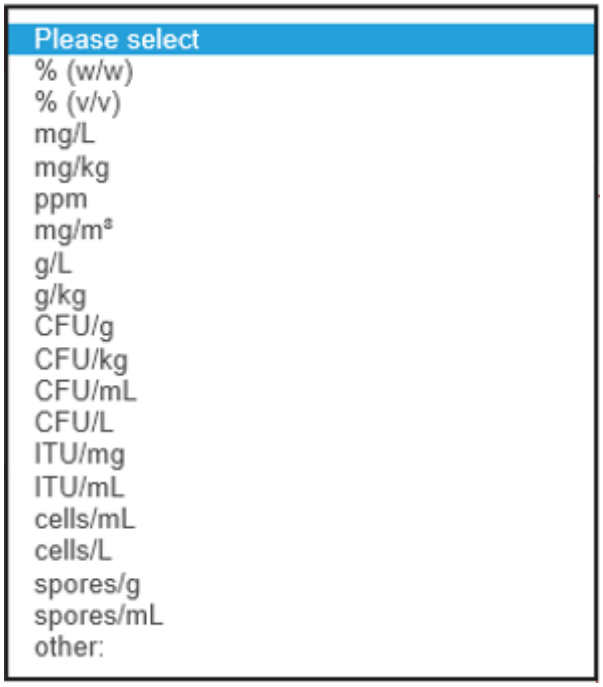
You will then need to provide the degree of purity. This should relate to the overall concentration of the chemical (or main constituents in the composition) and its associated unit of measurement (i.e. as a weight percentage). For chemicals containing water, give the weight percentage for the dried substance, unless water is an integral part of the chemical’s composition.



Enter in the degree of purity using the pick lists and adjacent fields.



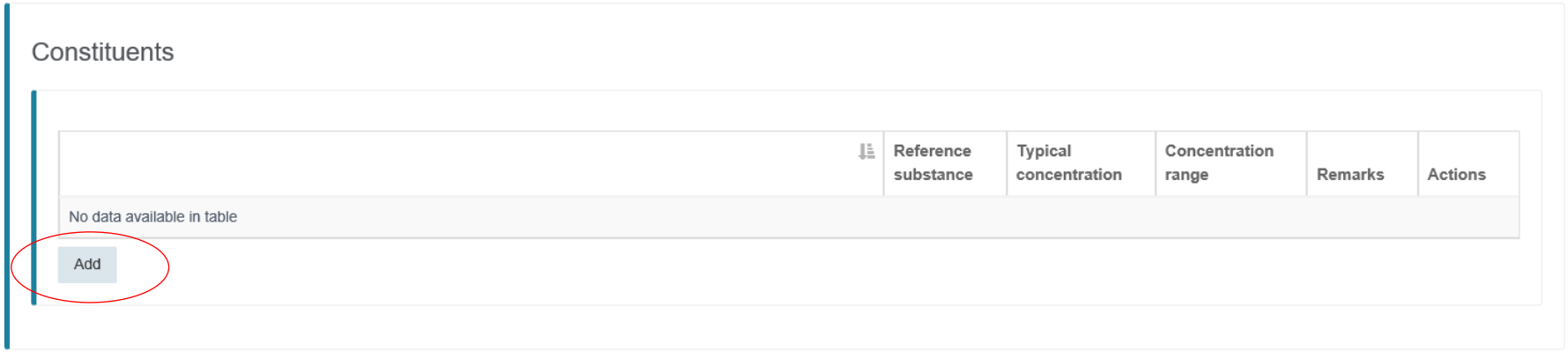
Then select the units of measurement from the pick list.



If you select ‘other:’ no adjacent field will open to enter in the measurement units.

For UVCB chemicals that do not have any additives, you should record the degree of purity as 100%.

You will not be able to directly enter in information about the chemical constituents. You will need to add this information as a new item in the ‘Constituents’ table.



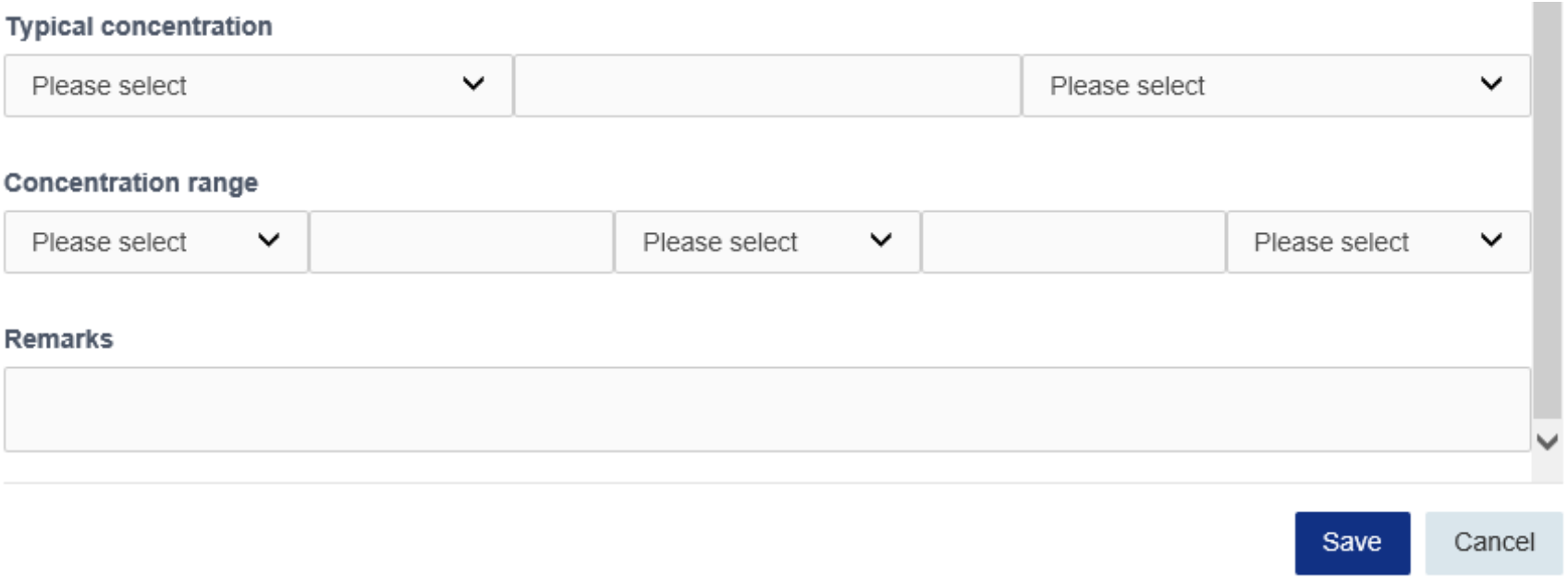
Each chemical composition must have a minimum of 1 constituent. If there is more than 1 constituent in the chemical, you will need to add a separate record for each constituent chemical.

You should have already entered in information on the constituents of the chemical as part of creating reference substances. If you have not already done so, you will need to complete this step before you can complete the ‘Constituents’ table.

You will need to flag if you will be applying for the constituents of the chemical to be considered as CBI.

You will need to provide information on the typical concentration and concentration range of the constituent in the chemical. You can also enter any remarks directly into the ‘Remarks’ field.

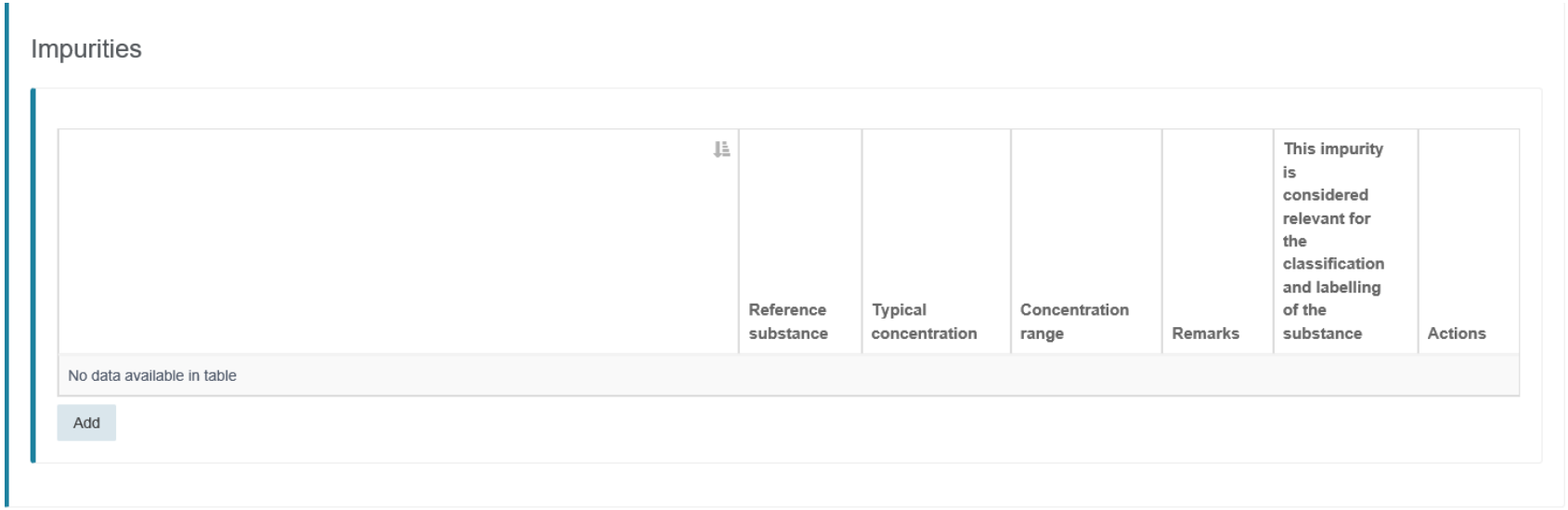
When entering information for mono-constituent chemicals, record the information for the main constituent. If your chemical is a multi-constituent chemical, record the information for the main constituents (≥ 10% in the chemical) and report any constituents < 10% as impurities.



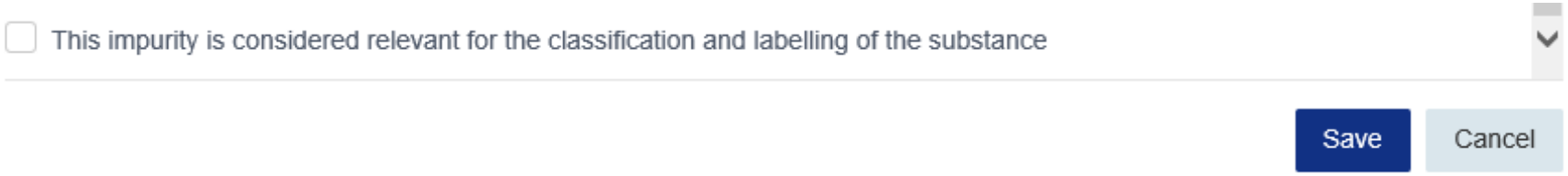
Once you have completed the entries, click on ‘Save’ to save your changes and return to the ‘Constituents’ table.

Repeat these steps for all the constituents of your chemical.

Use the same approach to enter information on impurities and additives.



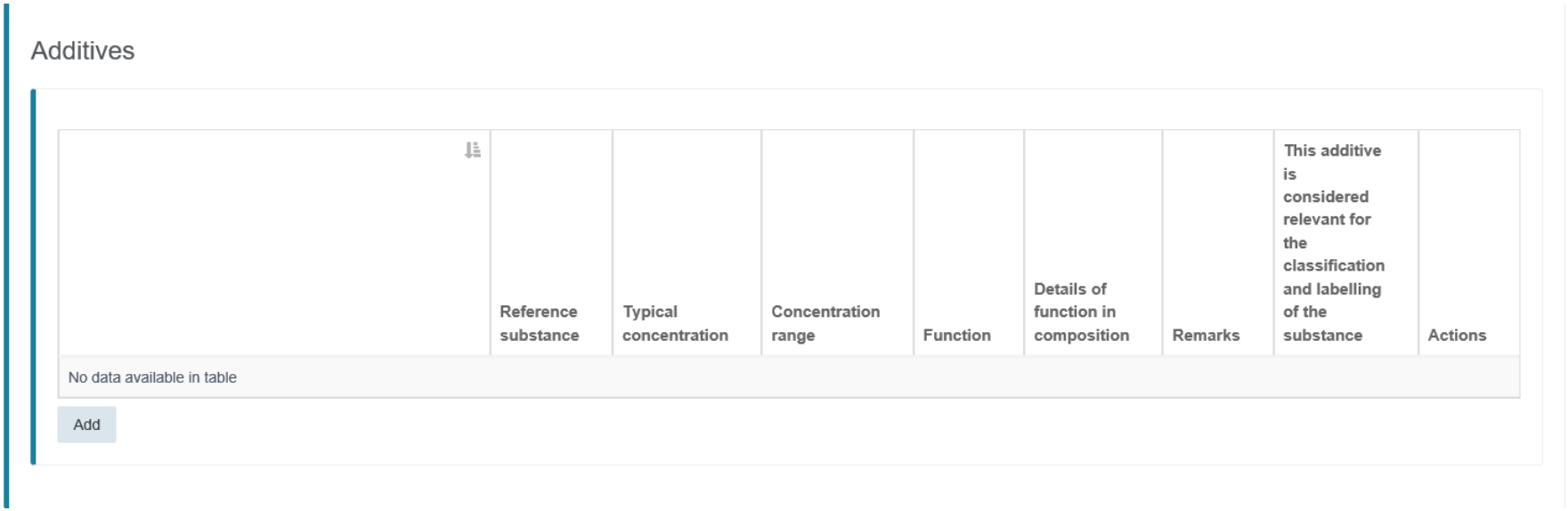
In addition to adding the relevant reference substance, concentration details and any remarks, you also need to indicate if the impurity is considered relevant to the classification and labelling of the substance by clicking in the check box.



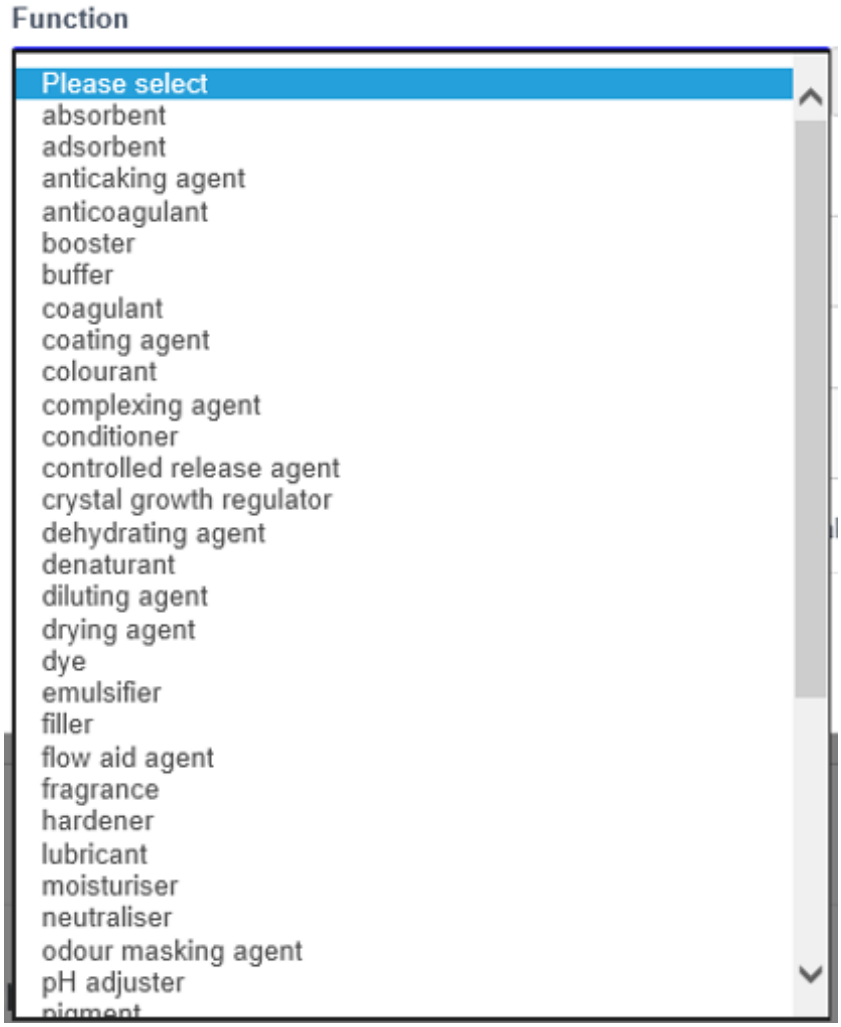
If your chemical is a UVCB, you should report chemical constituents in the ‘Constituents’ table and not in the ‘Impurities’ table.

Once you've completed the information required in the 'Impurities' table, you will need to click on 'Save' to save the changes and return to the 'Impurities' table. Repeat these steps for all the impurities in the chemical.

When completing the 'Additives' table, in addition to adding the relevant reference substance, concentration details and any remarks, you will also need to provide information on the function of the additive in the composition of the chemical.



Select the function of the additive in the chemical from the pick list.



If you select ‘other:’ the adjacent field will open and you will be able to enter information in this field.

If your chemical is a UVCB, you should report any additives used to stabilise the chemical constituents in the ‘Additives’ table. You should also include the stabilising function of the additive.

You can then enter in details of the additive’s function in the chemical and any remarks in the relevant field. You will also need to indicate if the additive is considered relevant to the classification and labelling of the substance by clicking in the check box.

Once you have completed the information required in the ‘Additives’ table, you will need to click on ‘Save’ to save the changes and return to the ‘Additives’ table. Repeat these steps for all the additives in the chemical.

If your chemical is not a polymer or is not considered to be at the nanoscale, you can now save the information you have entered. Scroll down to the bottom of the ‘Composition’ page and then click on the ‘Save’ button at the bottom left hand side (under ‘Combined functional group equivalent weight’).

For polymers, the monomers should be mentioned in the components table.

If your chemical is a polymer, or is considered to be at the nanoscale, you will need to provide additional information under the ‘Composition’ chapter. The information required is described under Additional information for polymers, and chemicals considered to be at the nanoscale.

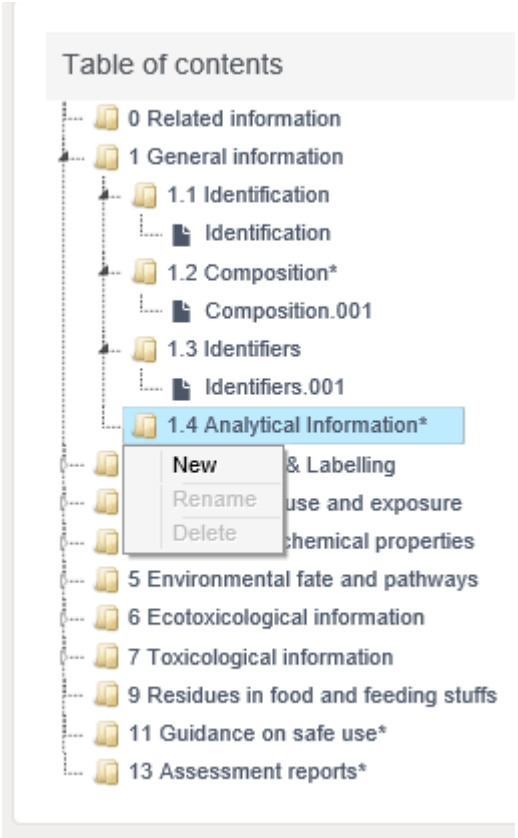
Analytical information

This section includes the information used to confirm the identity of your chemical and includes methodology, spectra or chromatograms. You should create a document for each analytical method used to characterise the identity of the chemical.

You must provide copies of spectra to confirm the structural formula. For example, from infra-red spectroscopy, nuclear magnetic resonance spectroscopy, mass spectroscopy and ultraviolet-visible spectrophotometry. Indicate principal wavelengths and/or other significant data. Provide analytical details, such as the solvent used or the infrared matrix used. For example, nujol mull or potassium bromide disk.

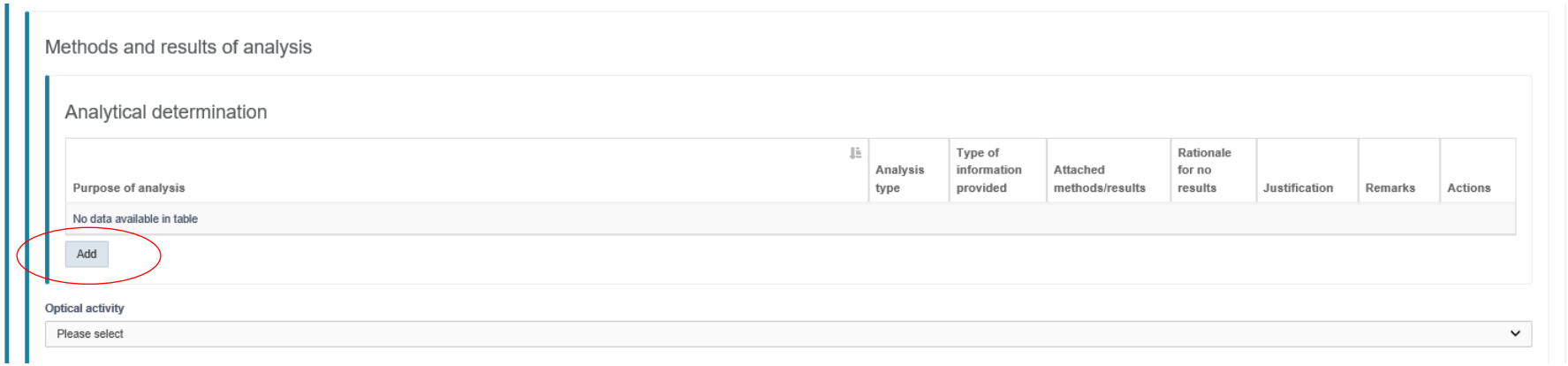
If your chemical is a polymer, or is considered to be at the nanoscale, go to the section on ‘Additional information for polymers, and chemicals considered to be at the nanoscale’ before completing the analytical and composition information.

Create a new document in the ‘Analytical information’ subchapter.

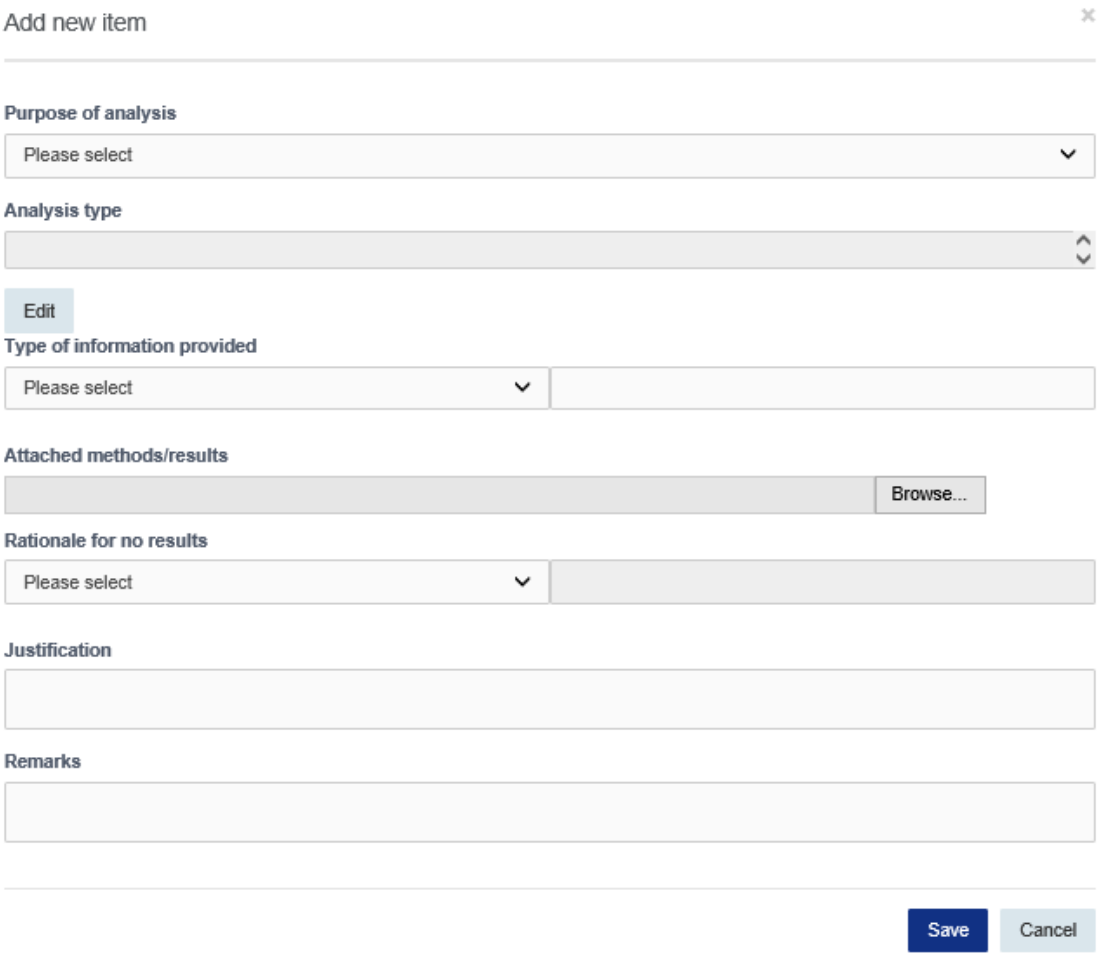


Flag if you will be applying for the analytical information of the chemical to be considered as CBI. You will then need to provide information on the methods and results of analysis used to characterise the chemical.

You will not be able to directly enter in information about the analytical determination of the chemical. You will need to add this information as a new item in the ‘Purpose of analysis’ table.



Click on ‘Add’ to add an entry to the purpose of analysis table.



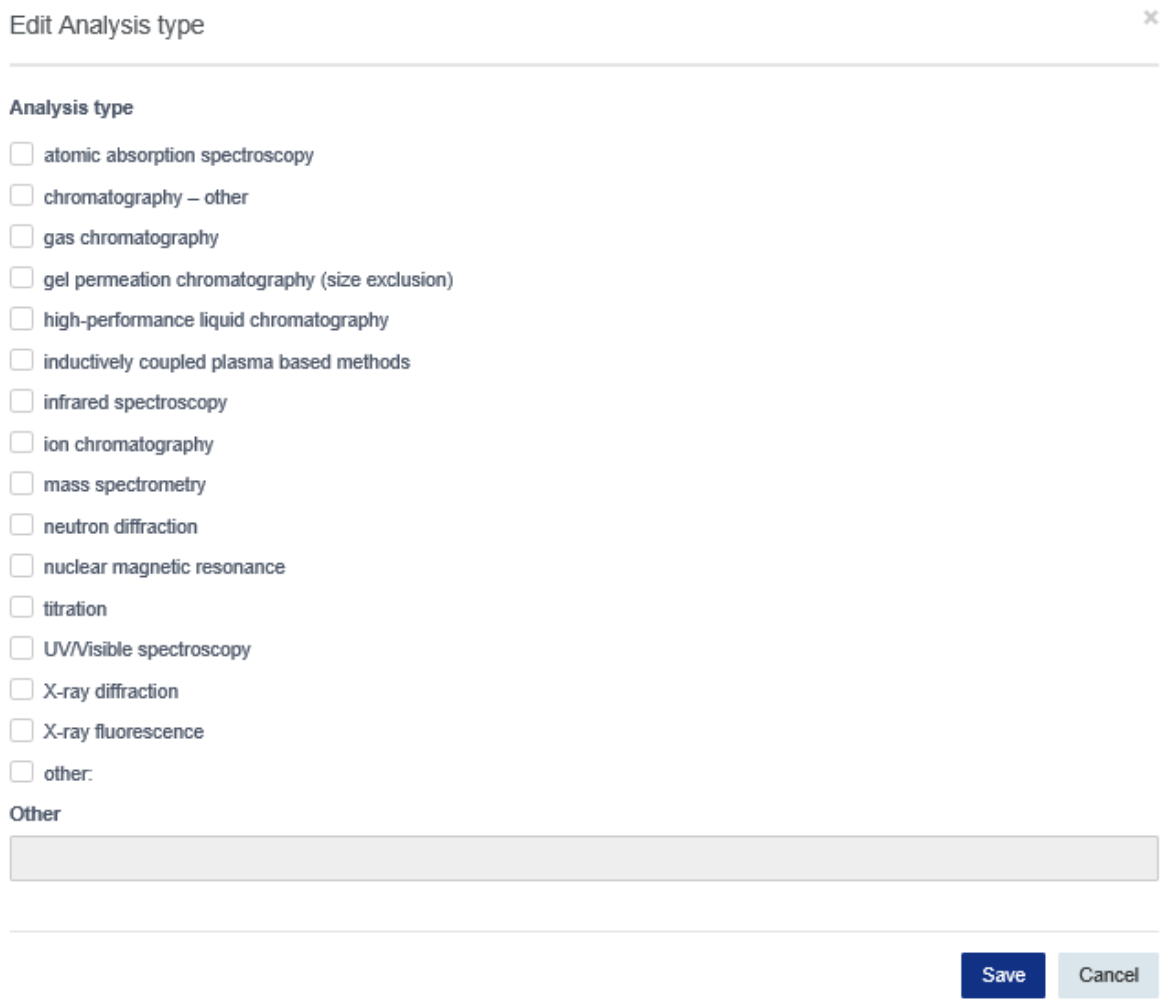
To describe the purpose of analysis, make a selection from the ‘Purpose of analysis’ pick list.

Tests performed to confirm the identity of a chemical and its constituents are considered to be **identification** analyses. Examples include spectroscopic tests such as UV or IR.

Tests performed to confirm the concentration of the chemical and its constituents are considered to be **quantification** analyses. Examples include chromatographic tests, elemental analysis and titration.

Some tests can be for identification and quantification purposes.

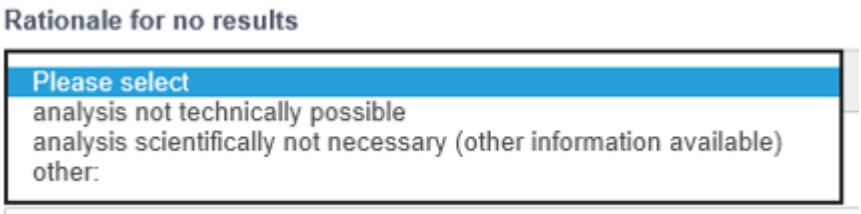
You can edit the analysis type by clicking in the ‘Analysis type’ field. Alternatively, you can select an analysis type by clicking on the ‘Edit’ button which will bring up a pop-up window with a list of analysis types.



Select ‘Save’ to save your changes before going back to the ‘Add new item’ window. Or select ‘Cancel’ to go back without saving your changes.

You must then attach a copy of the study record describing the methods and results.

If you do not have a study record, you can select one of the following rationale from the ‘Rationale for no results’ pick list.



If you select ‘other:’ the adjacent field will open and you will be able to enter information.

You must then provide a justification supporting your rationale for no results. For example, why the analysis was considered not technically possible.

You can also enter in any general remarks you have in relation to the analysis record.

Once you have entered in the information required, click on ‘Save’ to save your changes before going back to the ‘Purpose of analysis’ pop-up window.

Once you’ve completed the information required in the purpose of analysis table, you will need to click on ‘Save’ to save the changes and return to the ‘Analytical determination’ section.

You can add more analyses to the table by clicking on ‘Add’.

You will also need to select ‘yes’, ‘no’ or ‘not relevant for Optical activity’.

If your chemical is considered as at the nanoscale for the purposes of introduction you will have additional information to complete. See the information under ‘c’ for more details on completing these steps.

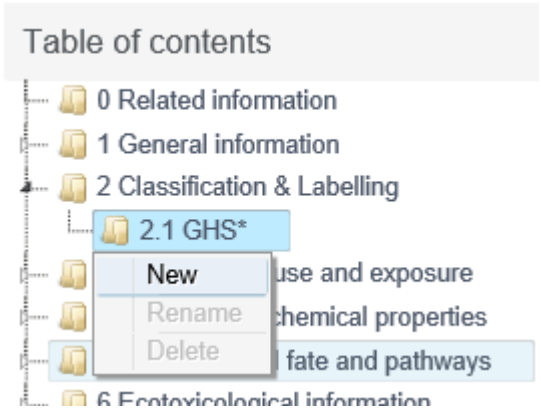
Classification and Labelling

In your application, you must state if the notified chemical is a hazardous chemical. If it is, you must provide the hazard classification for it, determined in accordance with the GHS. This must include the GHS hazard statement with the relevant code and the basis of the classification for the endpoint you considered.

The Safety Data Sheet (SDS) on the chemical should include statements of the hazardous nature, for instance:

- Hazardous according to the GHS
- Not classified as hazardous according to the GHS or
- Not classifiable according to the GHS (limited hazard data)

Open Chapter 2 ‘Classification & Labelling’, and right click on subchapter 2.1 ‘GHS’ to create a new document.



If asked to leave this page, select ‘Leave this page’. You can then enter in the GHS information as described on the chemical’s SDS.

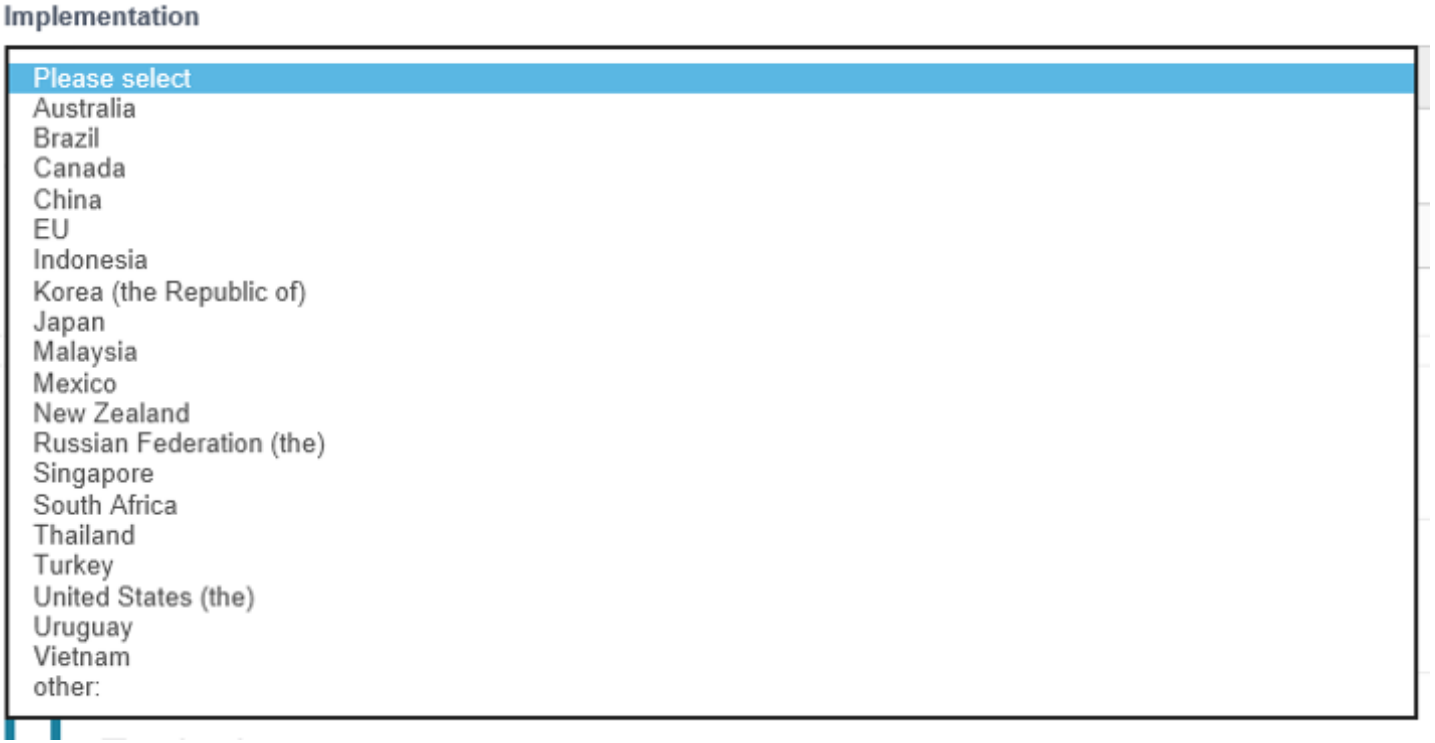
You can create documents for each constituent in the chemical or forms of the chemical where different classification and labelling requirements apply.

You will need to flag if you wish this information to be considered as CBI (see Chapter 3).

Under ‘General Information’ you will need to provide the name of the chemical as it appears on the SDS.

If you are creating more than 1 document, the name should allow for the different records to be distinguishable from each other.

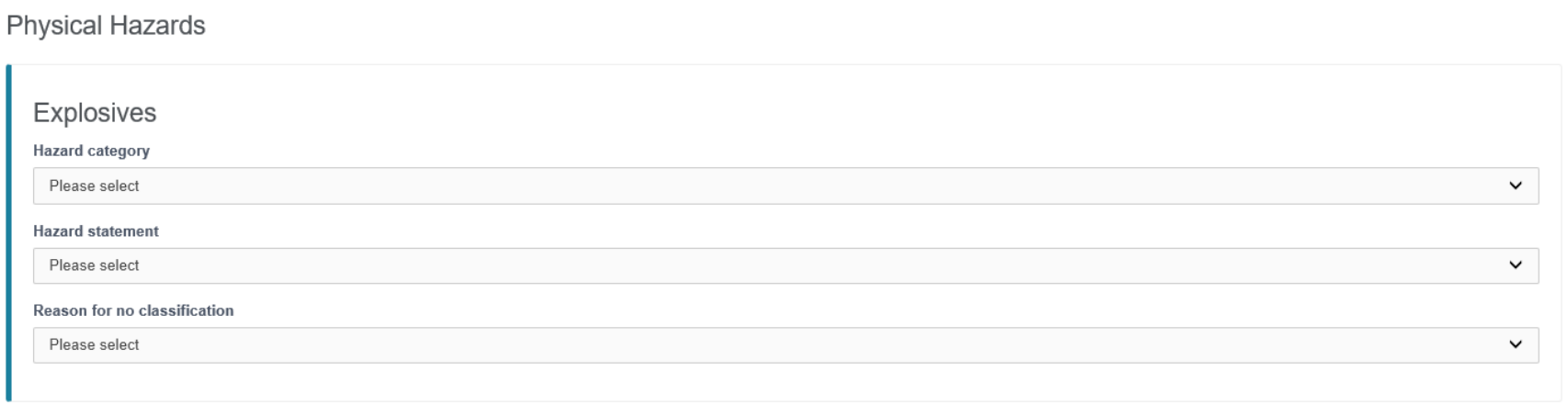
Select ‘Australia’ under ‘Implementation’.



You will also need to indicate the type of classification using the ‘Type of classification’ pick list. Select if the chemical classification was based on self-classification or harmonised classification (provide definitions for these).

You will then enter in the information that the classification is based on. Select the relevant hazard category, statement or reason for the chemical not being categorised with that physical hazard from the pick lists.

You must either select a hazard category and hazard statement for each hazard class or select a reason for no classification.



Reasons for no classification are as follows.

Select ‘data lacking’ if there are no relevant data, or other information that can be compared with the classification criteria.

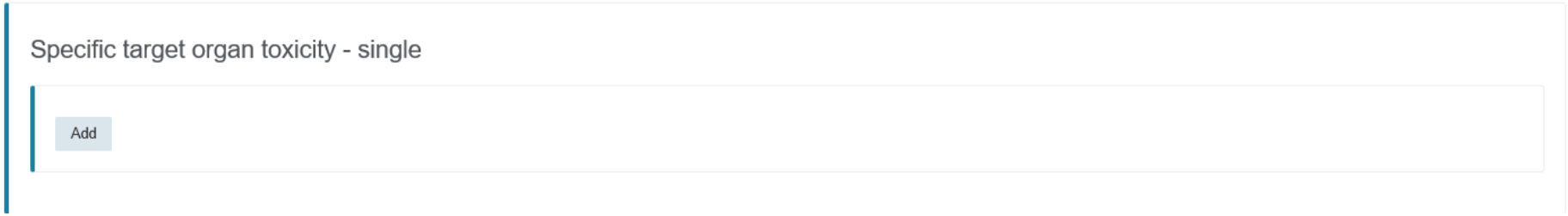
Select ‘inconclusive’ if the data or information you have is not reliable or if there are several equivocal study results or information.

Select ‘data conclusive but not sufficient for classification’ if the chemical has undergone a high standard of testing, or where high-quality information is available, but the classification criteria have not been fulfilled.

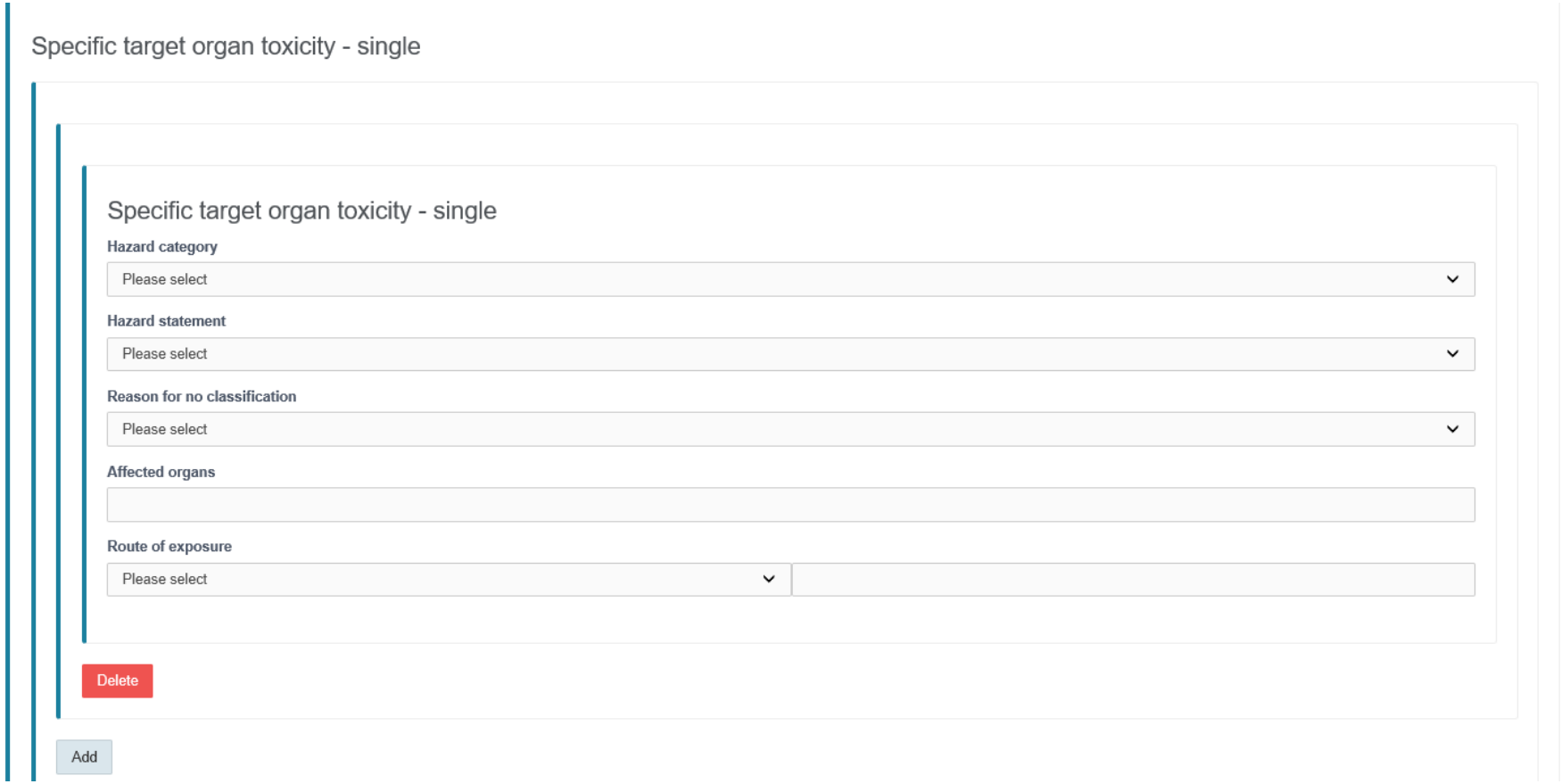
Where required, a justification needs to be provided for each classification (or no classification).

You can complete the fields for physical, human health and environment hazards by selecting the relevant hazard category from the pick lists. When completing the ‘Reproductive toxicity’ sections, if the chemical has been categorised, you must also provide information on the specific effect and route of exposure (oral, dermal, inhalation or a combination of 2 or more of these). For germ cell mutagenicity and carcinogenicity, a route of exposure also needs to be selected.

If you have information on specific target organ toxicity – single, you can add records in the ‘Specific target organ toxicity – single’.



If the chemical has been categorised as specific target organ toxicity – single, you must also provide the affected organs and the route of exposure (oral, dermal, inhalation or a combination of 2 or more of these).

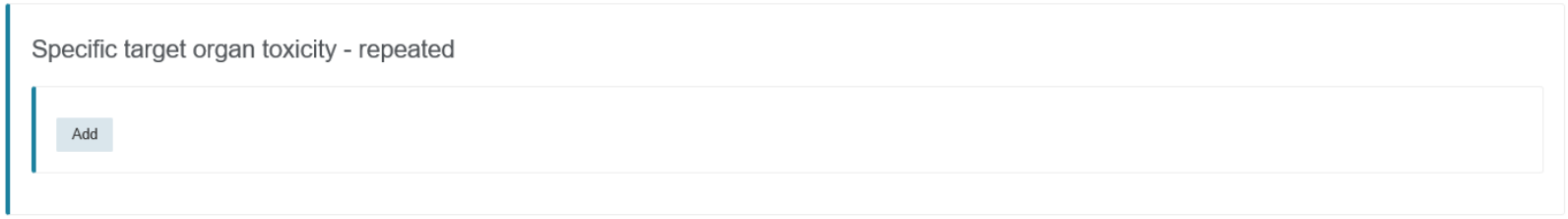


You can add additional records if the chemical:

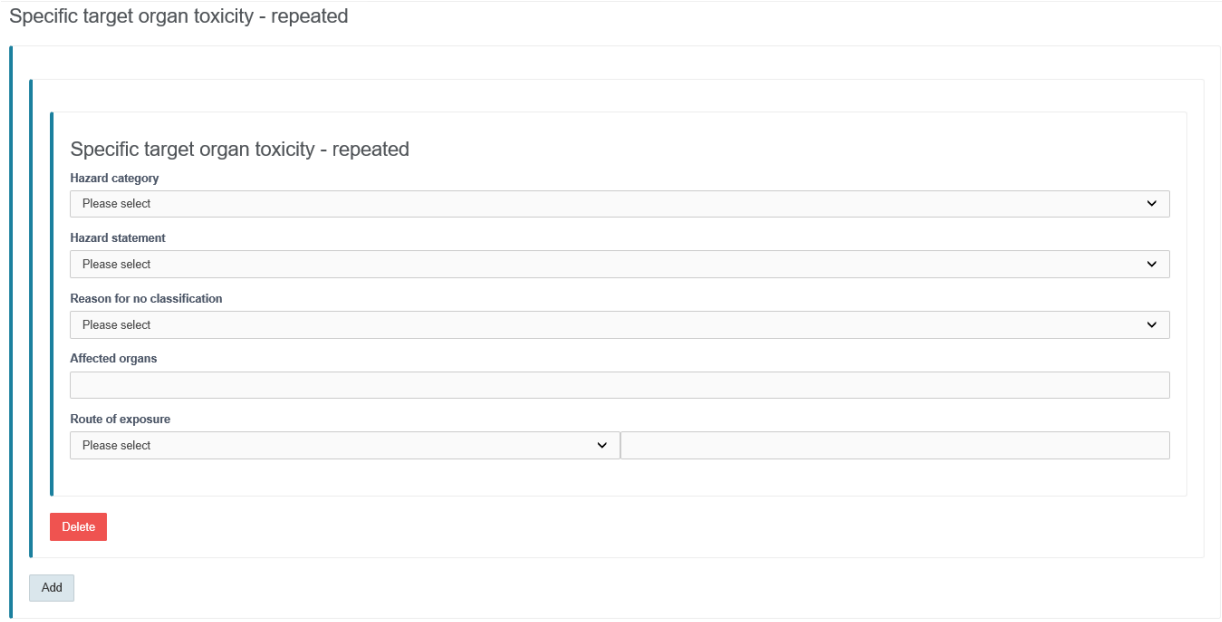
- has been categorised with multiple specific target organ toxicities
- has been categorised with more than 1 exposure route or

- has multiple studies available

If you have information on specific target organ toxicity – repeated, you can add records in the ‘Specific target organ toxicity – repeated’.



If the chemical has been categorised as specific target organ toxicity – repeated, you must also provide the affected organs and the route of exposure (oral, dermal, inhalation or a combination of 2 or more of these).

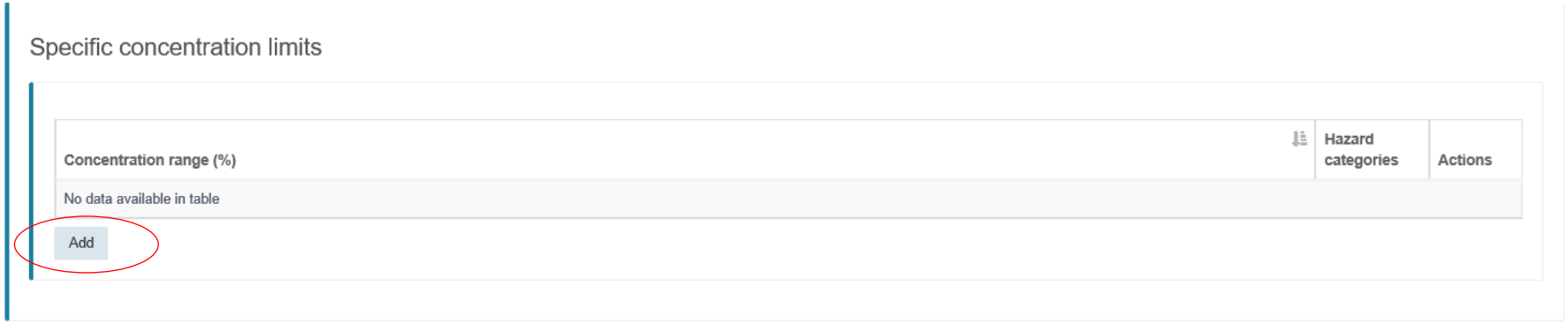


You can add additional records if the chemical:

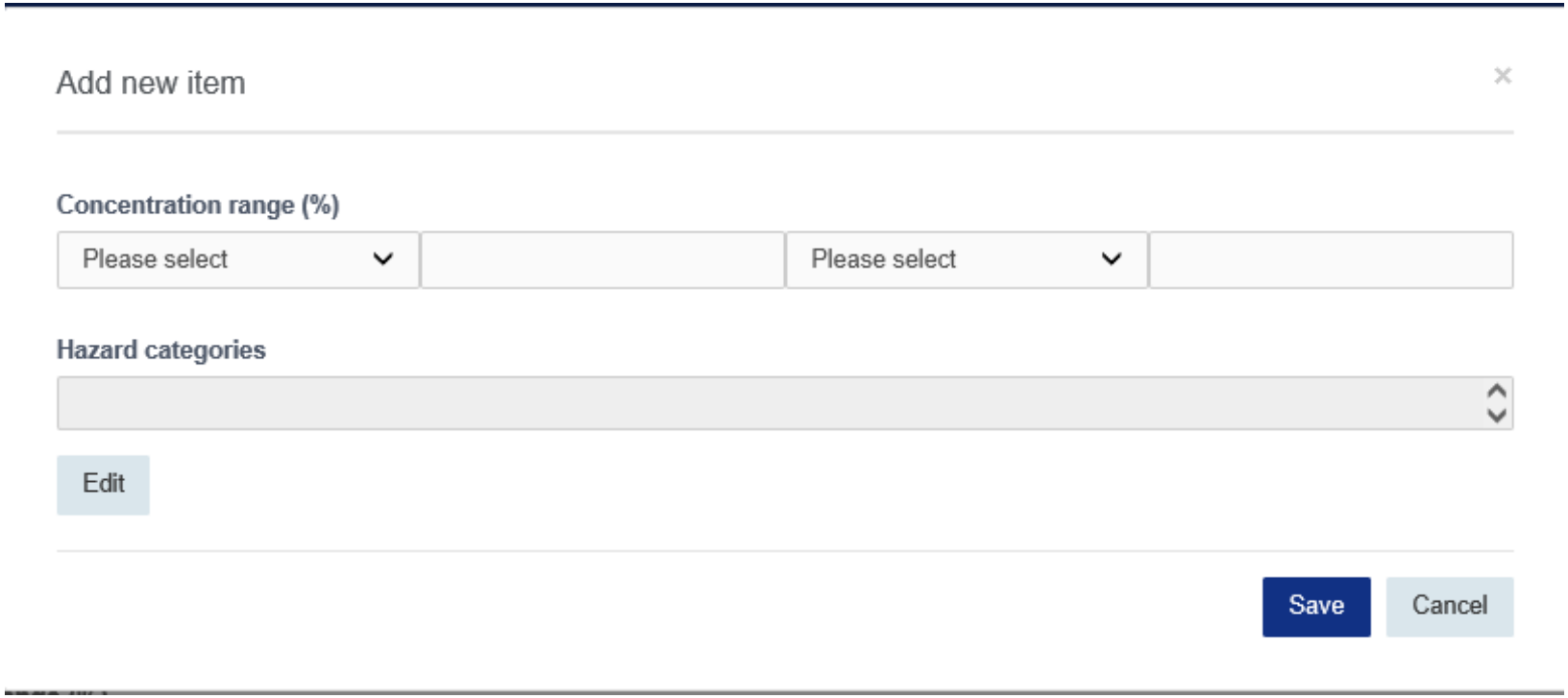
- has been categorised with multiple specific target organ toxicities
- has been categorised with more than 1 exposure route or
- has multiple studies available

If you create a record by accident, you can delete the record.

You will then need to provide information on the specific concentration limits. You will not be able to directly enter in information about the specific concentration limits. You will need to add this information as a new item in the ‘Concentration range’ table.

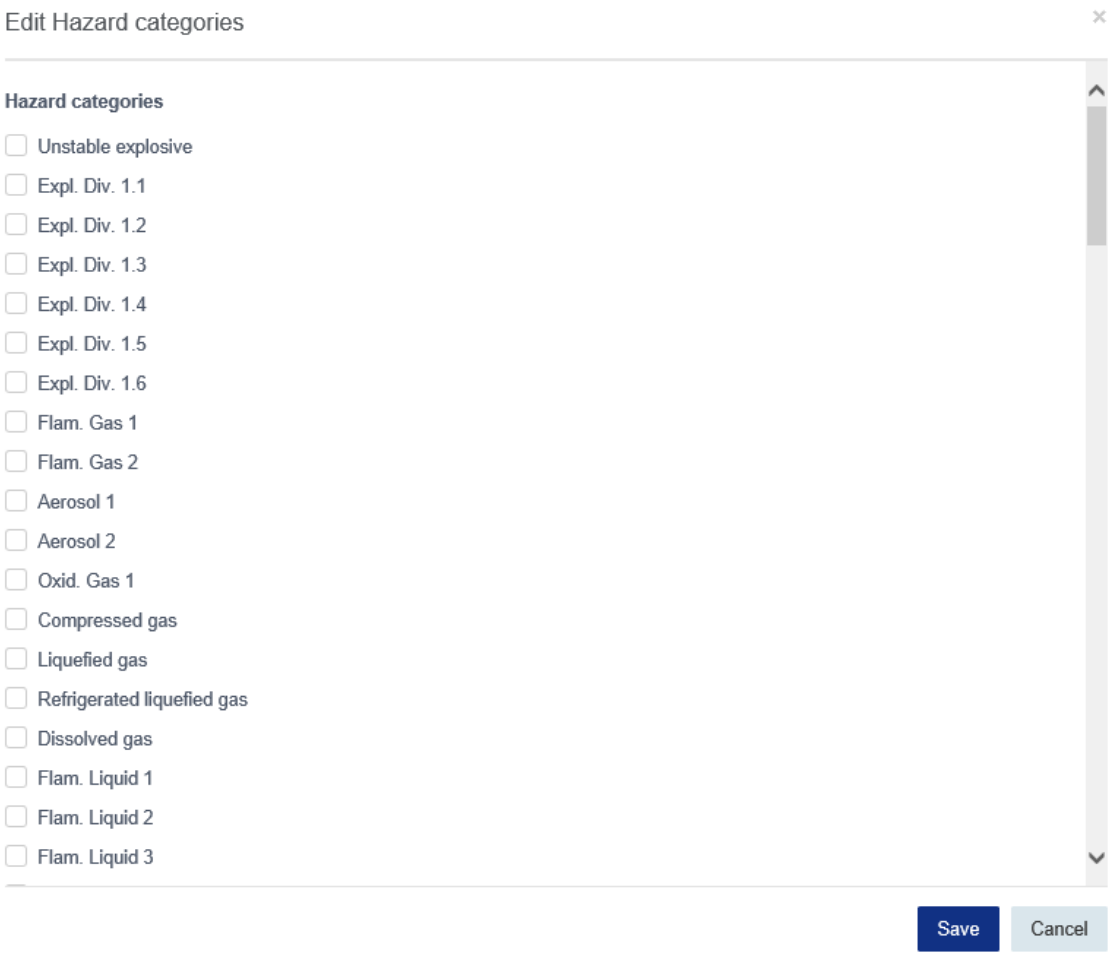


You will not be able to directly enter in information about the concentration range. You will need to add this information as a new item in the ‘Concentration range’ table.



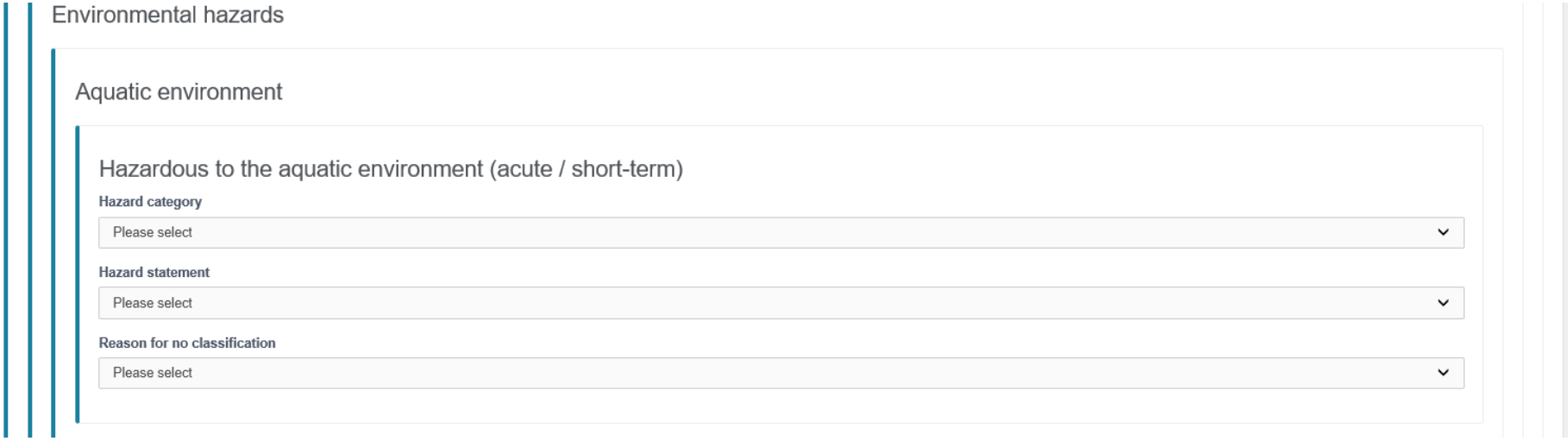
Enter in the concentration range using the pick lists and adjacent fields

You will not be able to directly enter in the hazard categories. To edit this field, you will need to click on ‘Edit’ to open the hazard categories window. Scan down the list and click on each of the relevant hazard categories. Once selected, click on ‘Save’ to save your changes and return to the ‘Add new item’ pop-up window.



Then click on ‘Save’ again to return to the ‘Classification’ page.

You will then need to enter in the information on environmental hazards in the ‘Environmental hazards’ section using the same approach.

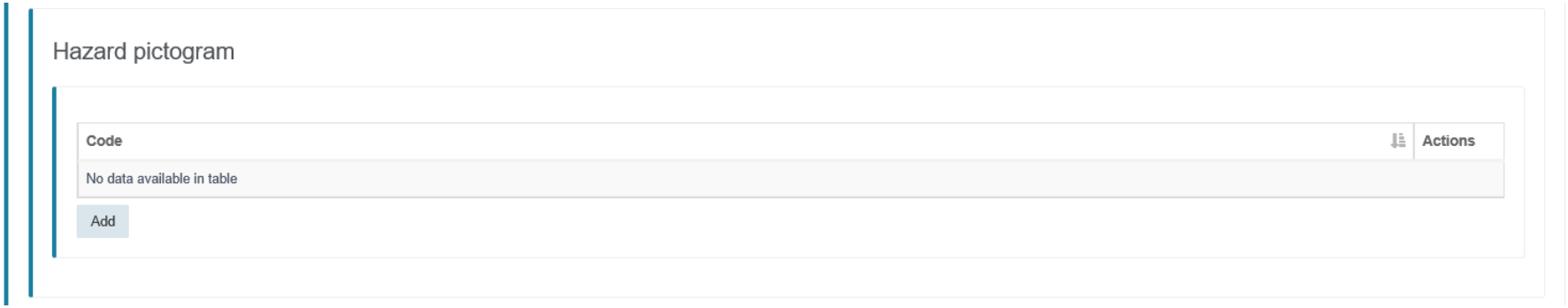


If your chemical has been classified with any additional hazard classes relevant to the classification of the chemical for physical-chemical characteristics, health hazards or environmental hazards, you can enter these in the additional hazard classes and statements fields.

You must select a Signal word from the pick list. You will not be able to directly enter in the signal word under labelling. To edit this field, you will need to select the relevant signal word from the pick list.

If there is no signal word, then select ‘No signal word’.

You will not be able to directly enter in information about the code for the hazard pictogram. You will need to add this information as a new item in the ‘Code’ table.



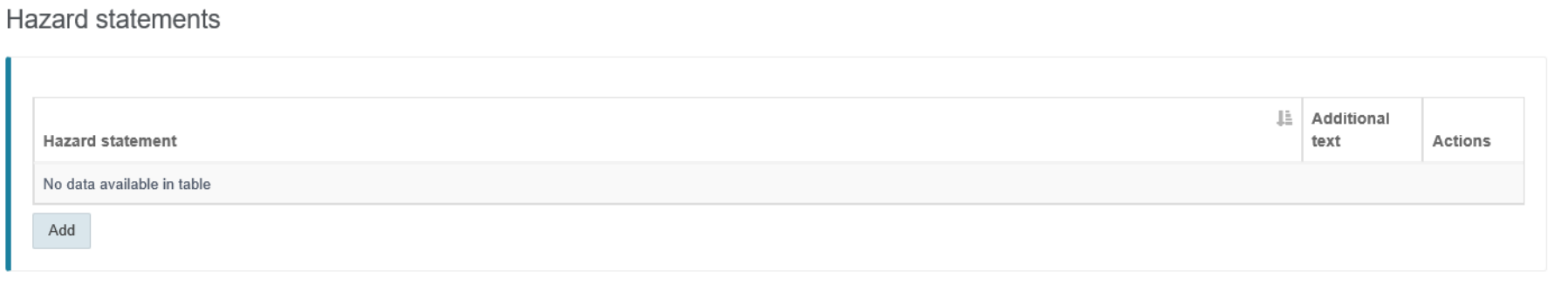
You will not be able to directly enter in the hazard pictogram under code. To edit this field, you will need to select the relevant pictogram from the pick list.

Select from 1 of the following text descriptions of the hazard pictograms.

GHS Pictogram	GHS Classification	Text description of pictogram
	GHS01: Explosive	GHS01: exploding bomb
	GHS02: Flammable	GHS02: flame
	GHS03: Oxidizing	GHS03: flame over circle
	GHS04: Compressed Gas	GHS04: gas cylinder
	GHS05: Corrosive	GHS05: corrosion
	GHS06: Toxic	GHS06: skull and crossbones
	GHS07: Harmful	GHS07: exclamation mark
	GHS08: Health hazard	GHS08: health hazard
	GHS09: Environmental hazard	GHS09: environment

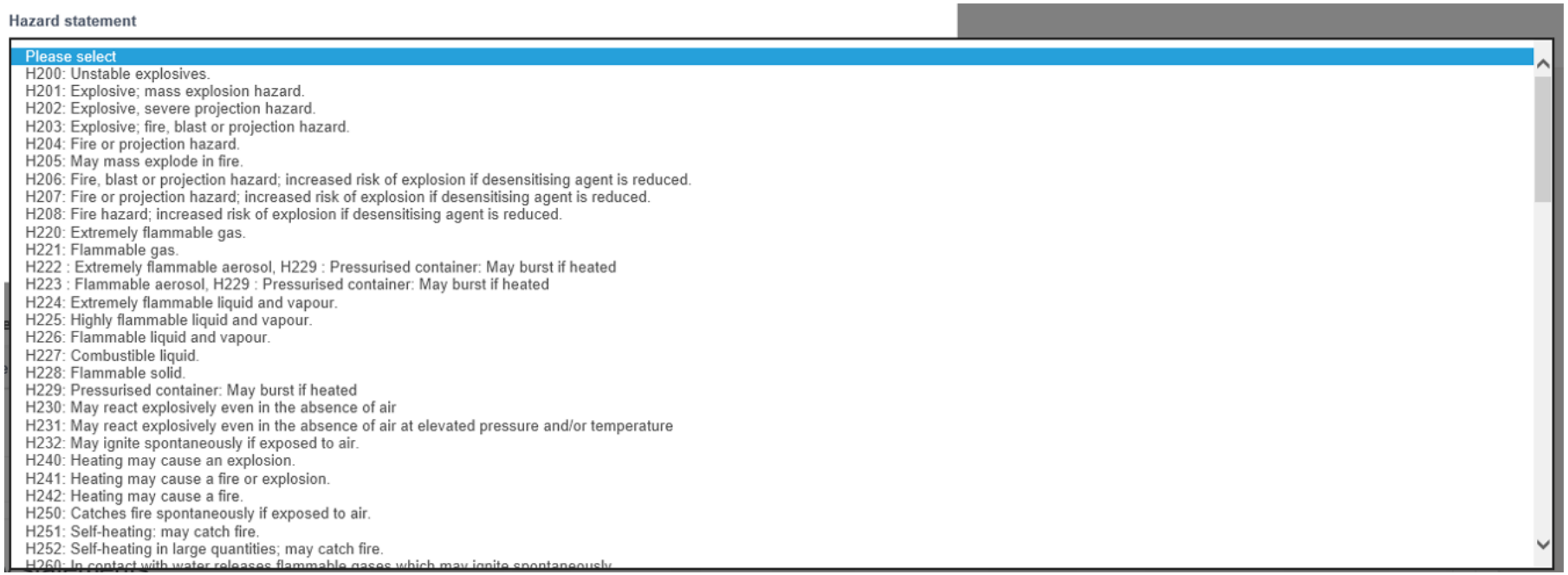
Click on ‘Save’ to save your changes and return to your application. If there are a number of hazard pictograms associated with your chemical, you can add additional records. If you create a record by accident, you can delete the record.

You cannot enter information directly into the ‘Hazard statements’ table. To add an entry to this table, you will need to click on the ‘Add’ button.



This will bring up an ‘Add new item’ pop-up window.

Select the relevant hazard statement from the pick list.



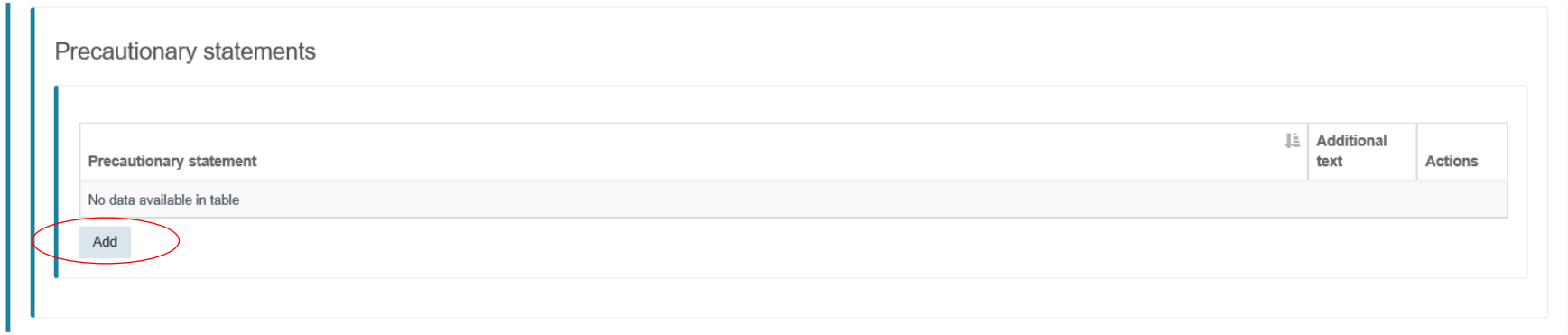
You can enter any additional text related to the hazard statement directly into the ‘Additional text’ field.

Once you have completed the hazard statement information, click on ‘Save’.

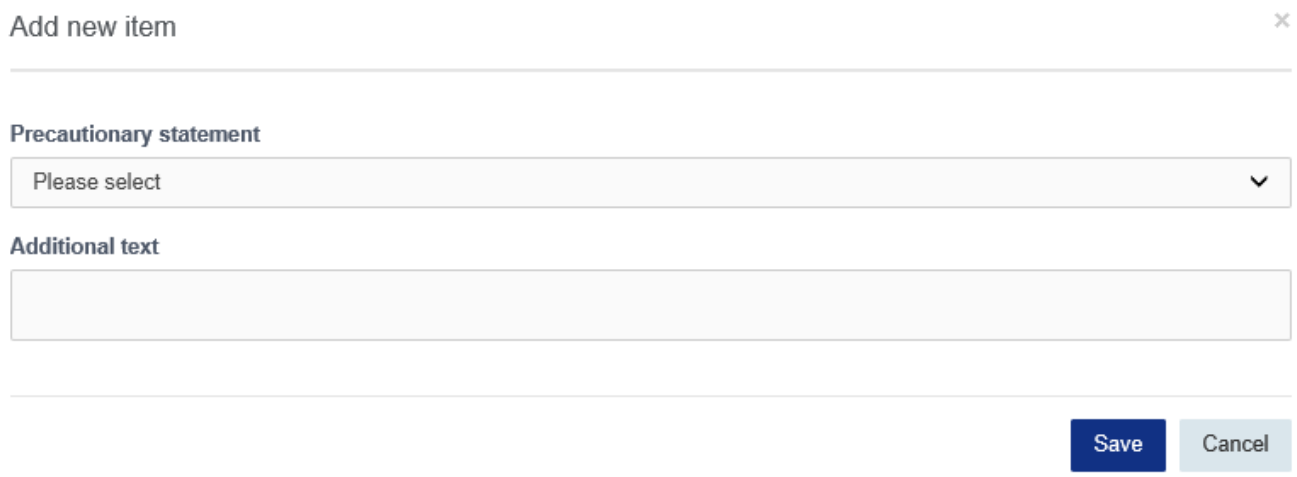
If more than 1 hazard statement applies to your chemical, you can add multiple entries to the table by repeating these steps.

You can then add additional entries to the table.

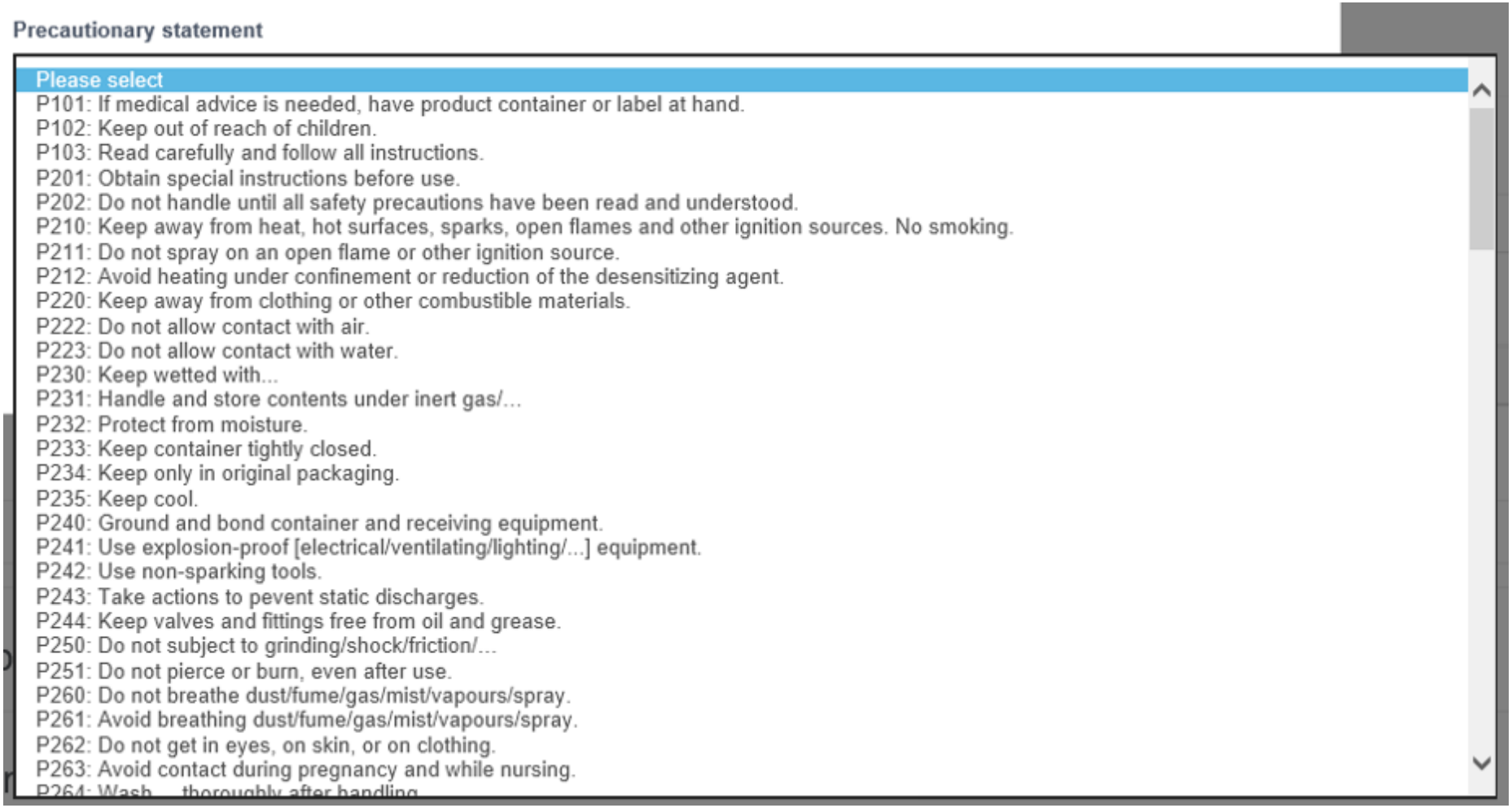
The same steps are used to enter information into the ‘Precautionary statements’ table. To add an entry to this table, you will need to click on the ‘Add’ button.



This will bring up an ‘Add new item’ pop-up window.



Select the relevant precautionary statement from the pick list.



You can enter any additional text related to the hazard statement directly into the ‘Additional text field’.

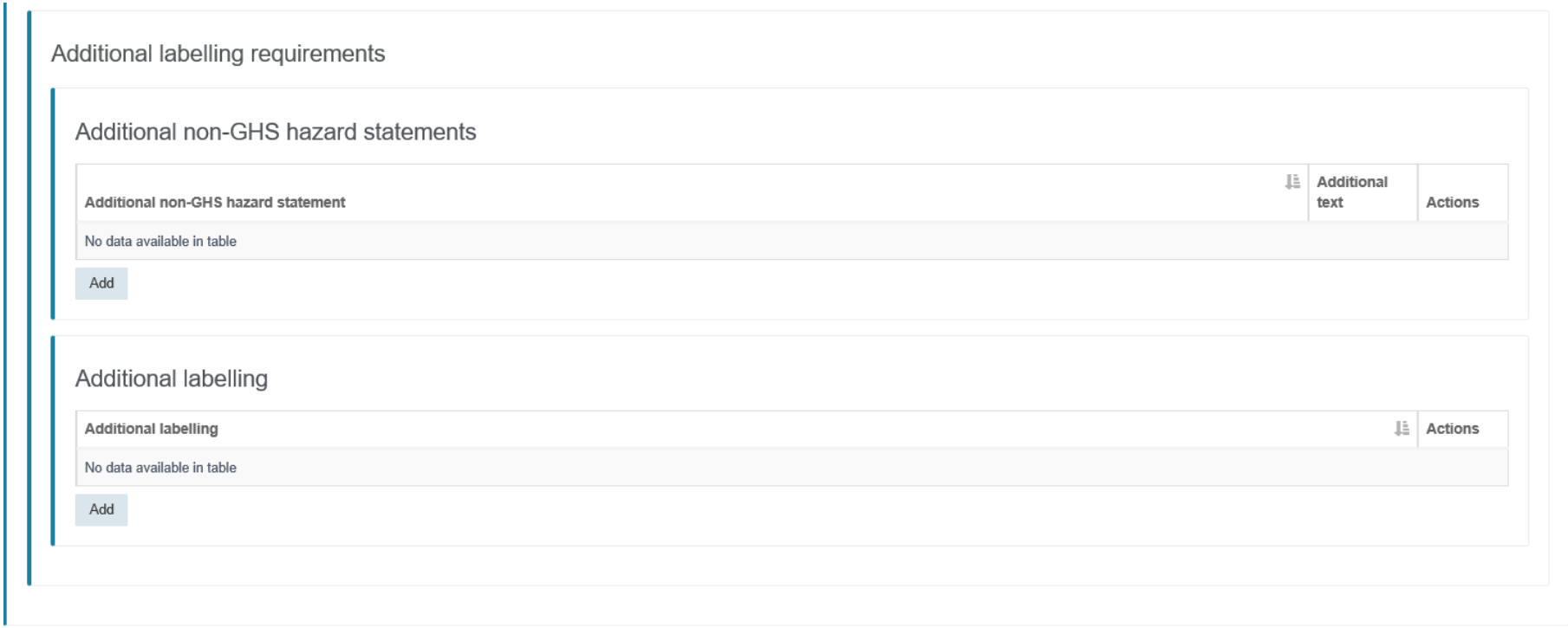
For example, if an open precautionary statement applies, such as ‘P302: IF ON SKIN:’, add in the additional information in the ‘Additional text’ field. The same concept applies if a statement such as ‘P370+P378: In case of fire: Use… to extinguish’ applies, record the appropriate extinguishing media in the additional text field.

Once you have completed the precautionary statement information, click on ‘Save’.

If more than 1 precautionary statement applies to your chemical, you can add multiple entries to the table by repeating these steps.

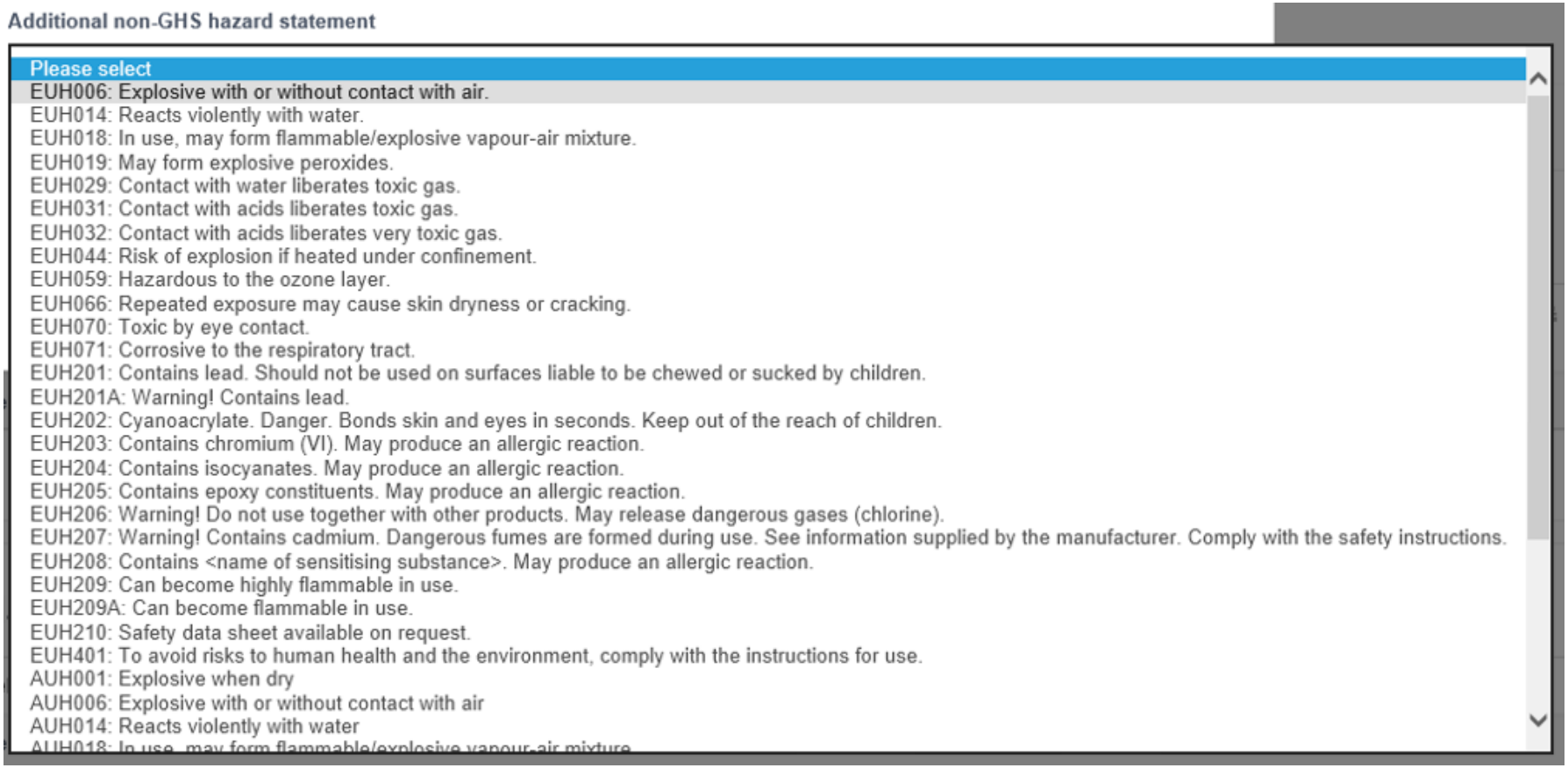
More guidance on the use of precautionary statements is available on the Safe Work Australia website.

If your chemical has additional labelling requirements, you will need to add them here. You cannot enter information directly into the additional non-GHS hazard statement or additional labelling tables. To add an entry to 1 of these tables, you will need to click on the ‘Add’ button associated with each table.



To add additional non-GHS hazard statements to the relevant table, click on ‘Add’ to add a new item.

Select the relevant non-GHS hazard statement from the pick list.



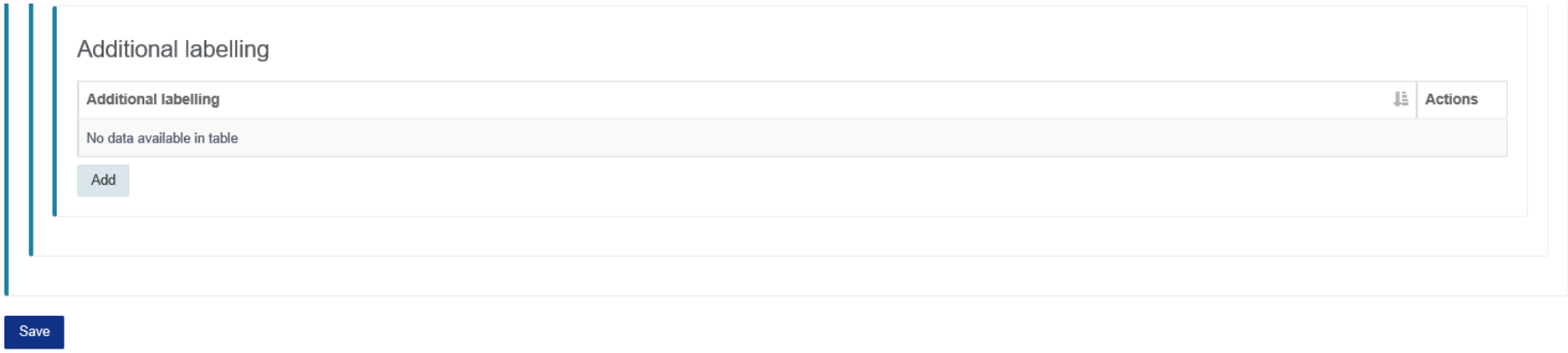
You can enter any additional text related to the hazard statement directly into the ‘Additional text’ field. Once you have completed the hazard statement information, click on ‘Save’.

If more than one non-GHS hazard statement applies to your chemical, you can add multiple entries to the table by repeating these steps.

To add additional labelling information to the relevant table, click on ‘Add’ to open the ‘Add new item’ pop-up window and enter in the additional labelling information in the field.

After adding in the additional labelling information, click on ‘Save’ to save your changes and return to the GHS page.

Click on ‘Save’ at the end of the page to save your changes.



Manufacture, use and exposure

You will need to provide a range of information on the manufacture, use and potential for consumers and environment to be exposed to the chemical.

Manufacture, use and exposure information is used to support any regulatory actions or information that may be required to protect human health and the environment.

You will need to complete the chapters on:

- ‘Estimated quantities’
- ‘Sites’
- ‘Manufacture’
- ‘Formulation or re-packing’
- ‘Uses at industrial sites’
- ‘Widespread uses by professional workers’
- ‘Consumer uses’

It is optional to provide information on the ‘Article service life’.

You will be able to insert a template into this field to guide you through the information required.

You will be prompted to provide information on the following.

- The industry in which the chemical is to be used (for example, paper and pulp).
- All proposed uses of the chemical (for example, solvent, dyestuff, adhesive, plasticiser or detergent), and to insert a template for each use. For each use, indicate the approximate percentage of the chemical used as part of the total amount of chemical manufactured in or imported into Australia.
- The fields of use and methods of application (for example, a spray-on paint stripper in the painting industry)
- The concentration of notified chemical in the mixture or product for all forms of the notified chemical, including final end-use products. This information is critical for the risk assessment.

If you are not manufacturing the chemical in Australia, then you do not need to create a record under ‘Manufacture’.

If you are not formulating or re-packaging the chemical in Australia, then you do not need to create a record under ‘Formulation or re-packing’.

Describing manufacture and reformulation processes

When describing manufacture and reformulation processes, you should include:

- **Identity of the site/s where the chemical will be manufactured or reformulated.** Provide details of the location/s of each industrial site (manufacturing, processing or any other operation) you control and details of sites where repacking and/or reformulating the chemical is carried out.
- **Process description.** Describe the process for each operation you control, including a diagram of the major unit operation steps and chemical conversions, the identity and entry points of all feed-stocks, including reactants, solvents and catalysts, and the location of the points of release of the chemical to the environment.
- **Details of the release of chemicals at each site.** For each release point, include an estimate of the amount and concentration of chemical released directly to the environment or into control technology (in kg/day), the media to which the chemical is released (air, soil or water), a description of any control technology used to limit release, and the destination/s of releases to water, (for example, sewage treatment plant).

You should also consider and describe the release of the chemical to the environment for each use you have identified. For each specific use or application identified, provide:

- information on the estimated number of sites for each use
- broad process descriptions
- descriptions of situations in which environmental release of the chemical may occur

Examples of the chemical being released to the environment include:

- equipment cleaning
- ambient air (for example, through smoke stack emissions, car exhaust fumes, incineration gases, aerosols and fugitive refrigerant gases)
- water (for example, natural waterways or ground water, including release to waste water treatment facilities) or
- surrounding land (for example, through over-spray of paints, general wear and tear and deposition)

You should provide the quantity, concentration and media of release for each situation.

When describing transport and storage, you should:

- define the safe storage requirements (for example, location, temperature or incompatibility) for the chemical and its classification under the Australian Code for the Transport of Dangerous Goods by Road and Rail
- describe all intended storage facilities (including size, type and capacity of containers and potential for environmental exposure) as well as transport between storage facilities, including the quantity of chemical to be transported, mode of transport and potential for environmental exposure.

When describing disposal, you should describe:

- all disposal procedures, including for all contaminated packaging, by providing route of disposal (for example, landfill or incineration)
- quantities to be disposed of by each route (including residues in contaminated packaging if applicable, and not previously addressed)
- the identity of any hazards of degradation products resulting from disposal

You should also state how disposal of the chemical is in accordance with government regulations.

Occupational exposure

A comprehensive description of occupational exposure factors should be included to allow for an adequate assessment of any risks to work health, safety. If you do not use the chemical, you should source the relevant information from the people who will be using the chemical (i.e. downstream users).

For chemicals that have been in use overseas, you can submit relevant occupational exposure information (for example, monitoring data for a similar use).

We would consider useful the following information and any other relevant information relating to occupational exposure.

Category of workers

You should describe the category of workers likely to be exposed to the chemical or any product containing the chemical. Examples are workers employed in:

- maintenance tasks involving equipment using chemicals or
- packaging and storing the chemical

Include all workers involved from the manufacturing process or importation onwards, and those involved in storing, handling, transporting and disposing of the chemical. Include workers using the final products. For example, beauticians and hairdressers for cosmetic products and construction workers for building materials).

Nature of work

You should indicate the nature of the work carried out, or to be carried out, for each category (type) of worker exposed to the chemical.

For each category, briefly describe the:

- nature of work carried out with the chemical (i.e. the operation description)
- maximum duration of exposure (hours per day and days per year)
- frequency of exposure
- activities requiring protective clothing and equipment, indicating the physical form/s of the chemical during exposure (for example, hot liquid or fine powder)

Safety procedures to be observed when handling the chemical

You should provide information on methods and procedures to minimise or prevent worker exposure. Principles and procedures for the effective control of chemicals in the workplace are available from the Safe Work Australia website.

You should provide examples of the isolation procedures and engineering controls used, or to be used, in minimising worker exposure to the chemical. This may include:

- isolation of a hazardous operation by the use of sealed reformulation apparatus
- modifications to the working environment, for example, ventilation or fume extraction
- enclosure, for example, spray painting within booths
- preventive maintenance schedules designed to maintain plant, equipment and extraction systems to a high standard.

You should provide a description of any safe work practices to be observed by workers in handling the chemical. This may include:

- precautions during routine handling
- precautions during storage and transport
- precautions in handling spills

- practices with good housekeeping
- introduction of procedures to reduce duration and frequency of exposure for employees

Where applicable, you should specify the protective clothing and equipment required for routine and non-routine tasks, including the following types of equipment.

- Respiratory equipment, in accordance with Australian Standards AS 1716 Respiratory Protective Devices and AS 1715 Selection, Use and Maintenance of Respiratory Protective Devices or equivalent internationally acceptable standards
- Protective clothing (for example, gloves, eye protection and/or footwear). Be specific (for example, flame-proof cotton overalls). The general description of 'impervious gloves', for example, is not sufficient, but the more precise 'nitrile gloves' is. Consult the relevant Australian Standards (or equivalent). For example, AS 2161.2—Occupational Protective Gloves Part 2: General Requirements, AS 1336—Eye Protection in the Industrial Environment and AS 3765.1—Clothing for Protection against Hazardous Chemicals Part 1: Protection against General or Specific Chemicals.

Australian and international standards are updated from time to time, so you should also check that you have consulted the most recent versions of each standard.

Training of workers

You should provide a brief description on any core training conducted for employees so that they become proficient in safe working practices. You should also include details on any training required to introduce the new chemical into the workplace.

The information you should include can cover:

- instructions on health and safety hazards of the chemical, including routes of entry into the body
- instructions on the correct use of all protective equipment required during handling of the chemical
- instructions on the correct use of relevant equipment
- instructions for emergency situations
- information on labelling of the chemical
- availability of the SDS

You should also include the duration and frequency of training.

Prevalence of work-related injuries and diseases related to workers exposed to the chemical

You must detail, for chemicals already in use overseas, any known effect on the occupational health and safety of workers exposed to the chemical before they are introduced to Australia.

Describe the type, frequency and severity of all work-related injuries and diseases resulting from worker exposure. Examples are incidences of health effects or disease and total work time lost.

Where possible, detail the duration, frequency and levels of exposure of workers. Where effects in workers have been seen, mention mitigating factors (such as concomitant exposure to other chemicals) that could have caused the observed effects as well as other relevant factors.

Fully describe adverse health effects experienced by workers exposed to the chemical, as required by Paragraph 6(b), Part B of the schedule, Health Conditions.

Other occupational hazards

You should also provide any additional information on occupational hazards that may occur during the complete life-cycle of the chemical within Australia.

Include information on conditions that could increase the hazard of the chemical. This includes such items as:

- adverse working conditions (for example, heat or cold)
- work in confined spaces
- potential exposure to other hazardous substances
- possibility of reaction (for example, with other substances or with water)
- any other interaction (for example, interaction of chemicals and heat)

Health conditions

You should include information with respect to health conditions included if available (these may only be available for chemicals already in use in another country). You should also include a list of health conditions reported or known. For example, health conditions indicating that the chemical should not be used in circumstances where exposure is too great.

You should provide information on health conditions, such as asthma, broken skin, dermatitis, or therapeutic or recreational drug use.

You should also submit any evidence of specific health conditions associated with the chemical that might suggest it must not be used without special precautions (for example, exposure may cause severe dermatitis).

You should list any health conditions that could reasonably be expected to occur. For example, by analogy with structurally similar chemicals, or analogues.

You should also mention any health conditions aggravated by the chemical. For example, exposure to the chemical may increase the incidence of asthma in susceptible workers.

Occupational health monitoring

Include details of both atmospheric and biological monitoring procedures to be used to measure worker exposure to the chemical. For chemicals already in use, you can obtain the methodology for the monitoring procedures from international sources. For new chemicals, you can develop a methodology by considering existing methodology for structurally similar existing chemicals.

If you propose no monitoring procedures, then you should provide justification with regards to health and safety hazards and extent of worker exposure.

You can also provide information on existing or proposed exposure limits and known methods of atmospheric or biological monitoring of the chemical.

Atmospheric monitoring

Where relevant, include information on the type/s of atmospheric monitoring you proposed, such as:

- personal monitoring, indicating the time-weighted average concentration of actual worker exposure to the chemical
- automatic continuous monitoring, indicating the location in the work area where peak-level concentrations and time-weighted average concentrations of the chemical occur

- fixed-point monitoring, indicating time-weighted average concentrations of the chemical over a set period (for example, an eight-hour shift) for a fixed location in the work area
- grab sampling, indicating where instantaneous concentrations of the chemical occur

You should:

- detail any sampling techniques and sampling equipment (for example, passive monitor badges may be used for personal monitoring)
- provide a brief description of the analytical method/s used, including the principal technique (for example, gas chromatographic or gravimetric analysis)
- detail the type of instrumentation the analytical method/s used

Biological monitoring

This involves the quantitative measurement of the chemical or its metabolite in the appropriate body tissue, fluid or excretion product. For example, in blood, urine or expired air.

You must provide information on the:

- test/s to be used, the program of activities
- relevant collection procedures
- analytical methods and instrumentation

Observations on human exposure

Where available, provide information held or reasonably obtainable on studies or observations of the effects of the chemical on humans. In particular, provide observations of health problems or adverse symptoms in humans exposed to the chemical. This may include information on specific incidents, such as acute exposure resulting from an accidental spillage.

You may also provide information on any epidemiological studies on workers who have been exposed to the chemical. Where possible, you can also provide their health conditions (either positive or negative) relating to exposure levels.

Public health exposure

Public exposure may occur:

- during industrial use as the result of contamination of air, water, soil or food
- as the result of an industrial accident
- by domestic use of the chemical

Describe any potential public exposure to the chemical, based on the:

- proposed uses of the chemical
- physical and chemical properties
- site of manufacture or reformulation in Australia and the release of the chemical into the environment at that site
- quantity, concentration and frequency of release of the notified chemical for each use of the chemical
- conditions of safe storage
- disposal procedures
- consequences of accidental spillage

Where it is possible (such as for cosmetics applied to the skin), quantify the exposure in terms of number of applications per day and amount used per application.

When estimating the amount of chemical manufactured in Australia, imported or both, you should provide the estimated amount in tonnes per year for each. For example, if the chemical is manufactured and imported into Australia, you should provide the amount of the chemical manufactured in Australia in tonnes/year and the amount of chemical imported into Australia in tonnes/year.

Remember to estimate the quantities of the chemical you are introducing and not the quantity of the product or formulation the chemical is contained in.

Environmental impact

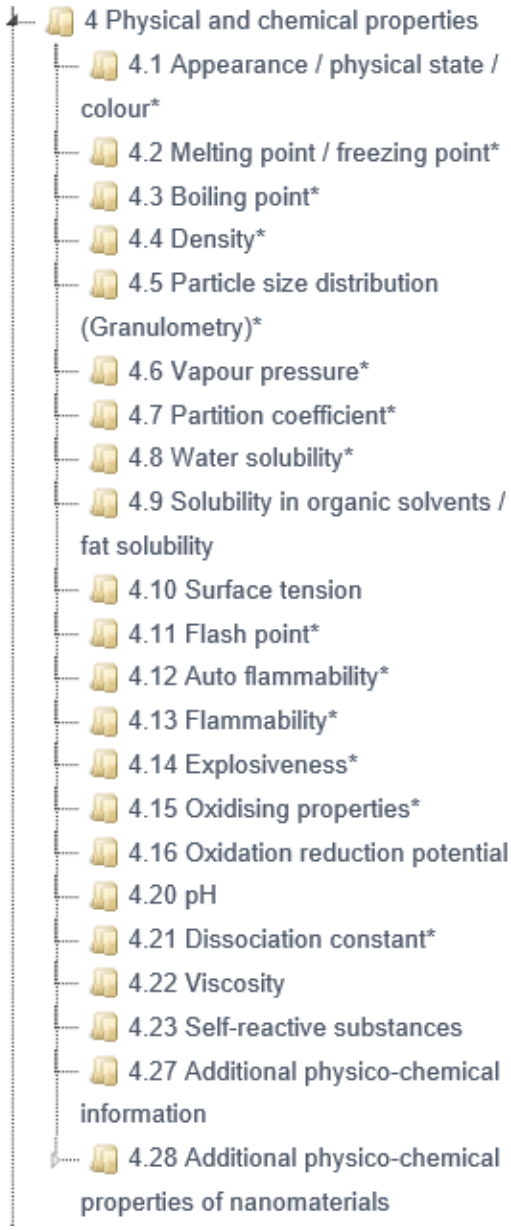
You should include an assessment of the environmental impact of the chemical with information on the following points:

- manufacturing process
- release to the environment for each use, including from manufacturing, reformulating, repackaging and end use
- storage and transport
- disposal

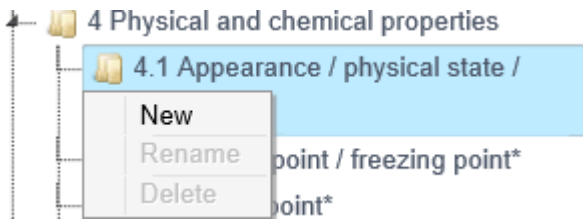
If you do not use the chemical, get information on the environmental impact from the user/s of the chemical.

Physical and chemical properties

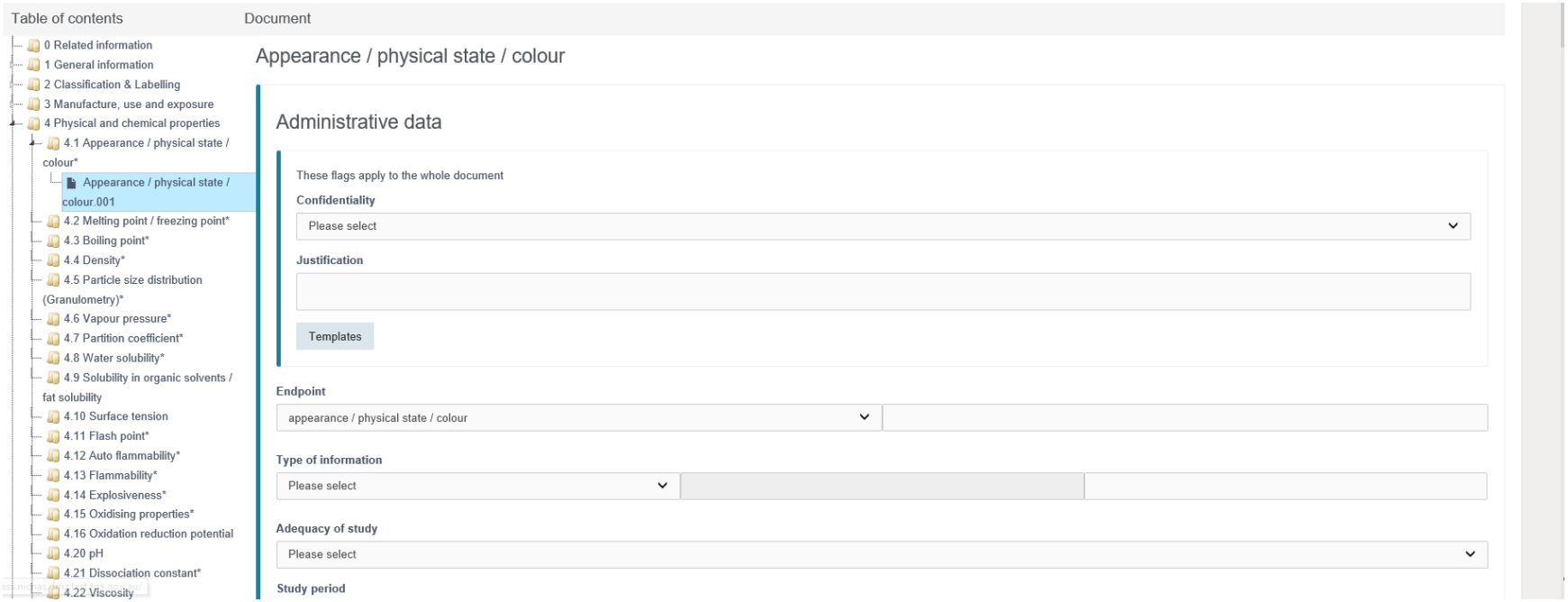
Where you are required to submit or hold data on the physical and chemical properties of the chemical you are introducing, this data should be in accordance with the Organisation for Economic Co-operation and Development's (OECD) Guidelines for the Testing of Chemicals.



For each endpoint, you will need to create a new document.



This example will guide you through entering information on the appearance/physical state/colour of your chemical.



If the correct endpoint under ‘Appearance / physical state / colour’ has not already been selected in the endpoint field, you will need to select the endpoint being described.

In this example, select ‘appearance / physical state / colour’.

Where more than 1 endpoint is available from the pick list, choose the study that best describes the study you are describing.

Things to consider when completing information on physical and chemical information

Melting point or boiling point: For non-pure chemicals, a temperature range may be more appropriate to report. For some chemicals the freezing point is more appropriate than the melting point.

Specific gravity or density: For gases, please provide the specific gravity (air = 1), to help indicate the tendency of the chemical to settle or disperse when discharged at high concentrations into the atmosphere. For liquids, please provide both the liquid and vapour densities.

Vapour pressure: In addition to the vapour pressure of the chemical, please describe any potential effect on the measurement by impurities.

Vapour pressure is important for estimating the chemical's potential for inhalation exposure and for determining the application route/s for toxicity testing. It’s environmentally relevant because it helps estimate the chemical's distribution between the environmental compartments. That is, the phase transitions between soil and air, soil and water, and (with water solubility) water and air. It can also help predict atmospheric concentrations.

Water solubility: If the substance is insoluble in water, indicate the detection limit of the analytical method used and any water accommodated fraction of the chemical determined.

Water solubility is significant environmentally because:

- it largely determines the mobility of the chemical within and between air, soil and water compartments
- it can be important in determining appropriate emergency services responses
- water-soluble chemicals gain ready access to humans and other living organisms
- it significantly effects potential for bio-accumulation

Hydrolysis as a function of pH: Hydrolysis is one of the main modes of abiotic degradation of substances in the environment.

Partition coefficient (n-octanol/water): The partition coefficient of a substance between water and a lipophilic solvent (n-octanol) can:

- indicate its potential for skin absorption or
- be used to estimate the chemical's bio-accumulation potential in aquatic organisms

Adsorption and desorption: These data are necessary for evaluating the tendency of chemicals to migrate into the air, water and soil or sediment compartments of the environment. Adsorption and desorption processes also have an effect on the transport of chemicals and on their bio-availability.

Dissociation constant: The extent of dissociation of a chemical in water governs the forms it will take in the aquatic environment. Knowledge of the dissociation constant, together with the pH of the systems in which a chemical is likely to be found, makes it possible to estimate the extent to which dissociated and un-dissociated forms will be present.

Particle size (distribution) or fibre length: This is one factor influencing the distribution and mass transport of insoluble and non-volatile particles in water, air and, in some cases, the upper soil layer. Furthermore, the tendency of a chemical to settle and penetrate biological tissue (for example, inhalation characteristics) depends on particle size.

Flammability limit: Do not overlook the distinction between flammable and combustible. For example, sodium chloride, carbon tetrachloride and carbon dioxide are non-combustible and non-flammable, but sugar, cellulose and ammonia are combustible and non-flammable. Details on the nature and identity of toxic and hazardous combustion products is also useful.

Auto-ignition temperature: This is the temperature required to initiate or cause self-sustained combustion in any substance in the absence of a high-temperature ignition source, such as a spark or flame.

Explosive properties: When providing details on the explosive properties, you should also consider providing details on the nature and identity of hazardous explosion products.

Reactivity – Oxidising properties: For the majority of substances, oxidising properties are not a concern and testing can be waived based on a consideration of the structure. The table below shows a non-exhaustive list of chemical classes associated with oxidising properties.

Chemical class	Formula
Nitrates (salts or esters)	$NO_3^-M^+$ O_2N-O-R
Nitrites (salts or esters)	NO_2-M^+ ON-O-R
Fluorodinitro	$(NO_2)_2$-C-(F)-
Metal oxides	MO_n

Chemical class	Formula
Metal oxometallates	$M^{+}MO_n^{-}$
N – Halogen compounds	N-X
N – Haloimides	-C(O)-NX-C(O)-
Difluoroamino	- NF_2
Difluoroaminopolynitroaryl	$(NO_2)_n$-Ar-NF_2
Organic nitro compounds	
Nitroalkyl	NO_2-R
Nitroaryl	NO_2-Ar
Oxohalogen compounds	
Acyl hypohalites	R C(O)-OX
Hypofluorites	FO^{-}
Bis(fluoroxy)perhaloalkanes	$F_3CCl(OF)_2$ etc
Perchlorates	ClO_4^{-}
Chlorates	ClO_3^{-}
Chlorites	ClO_2^{-}
Hypochlorites	ClO^{-}
Perbromates	BrO_4^{-}
Bromates	BrO_3^{-}
Bromites	BrO_2^{-}

Chemical class	Formula
Hypobromites	BrO^-
Periodates	IO_4^-
Iodates	IO_3^-
Difluoroperchloryl salts	$F_2ClO_2^+Z^-$
Dioxygenyl polyfluoro salts	$O_2^+ [MF_n]^-$ or $O_2^+ [EF_n]^-$
Interhalogen compounds	
Metal polyhalohalogenates	$M^+ [XX'n]^-$

Chemical classes associated with oxidising properties adapted from Bretherick's Handbook of Chemical Reactive Hazards.

Additional information for polymers and chemicals considered to be at the nanoscale

Composition of polymers

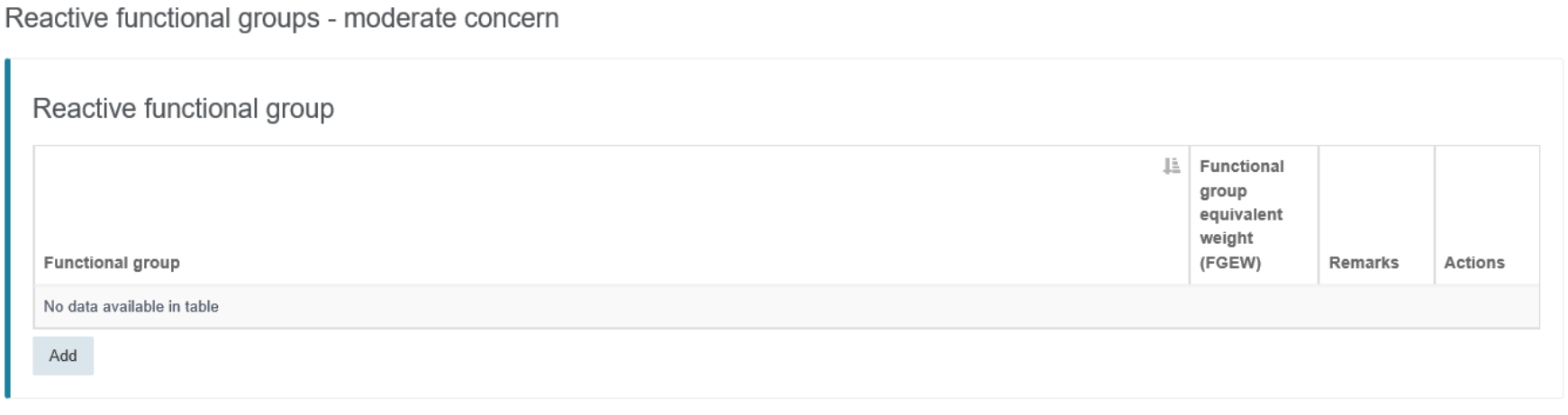
If your chemical is a polymer you will need to provide information on:

- its number average molecular weight (NAMW)
- its weight average molecular weight (WAMW)
- its polydispersity index
- the percentage of low molecular weight species < 1,000 g/mol
- the percentage of low molecular weight species < 500 g/mol

You can enter values directly into the relevant fields.

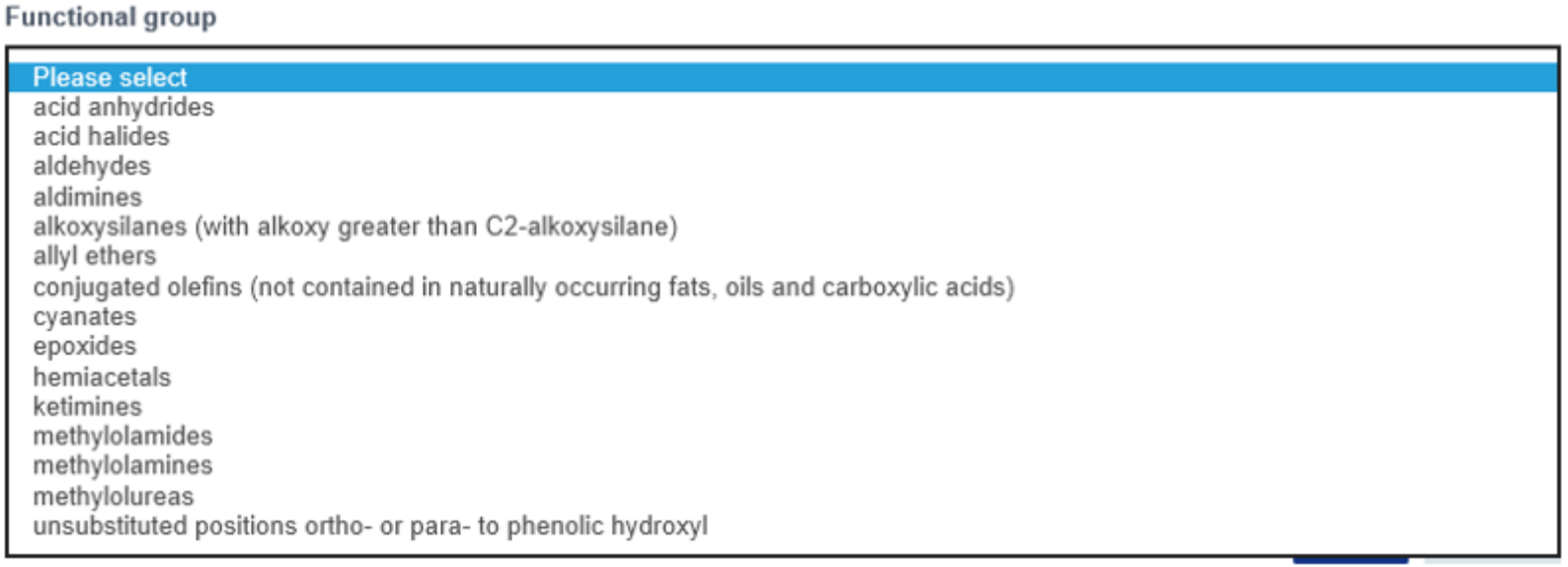
If the polymer only contains reactive functional groups of low concern, you can check the box with the text ‘Polymer contains only low concern reactive functional groups’.

If the polymer contains reactive functional groups of moderate and/or high concern, then you will need to add information to the relevant tables. You cannot enter information directly into the table. To add an entry, you will need to click on the ‘Add’ button.



Clicking on ‘Add’ will bring up an ‘Add new item’ pop-up window.

Select the functional group from the pick list.

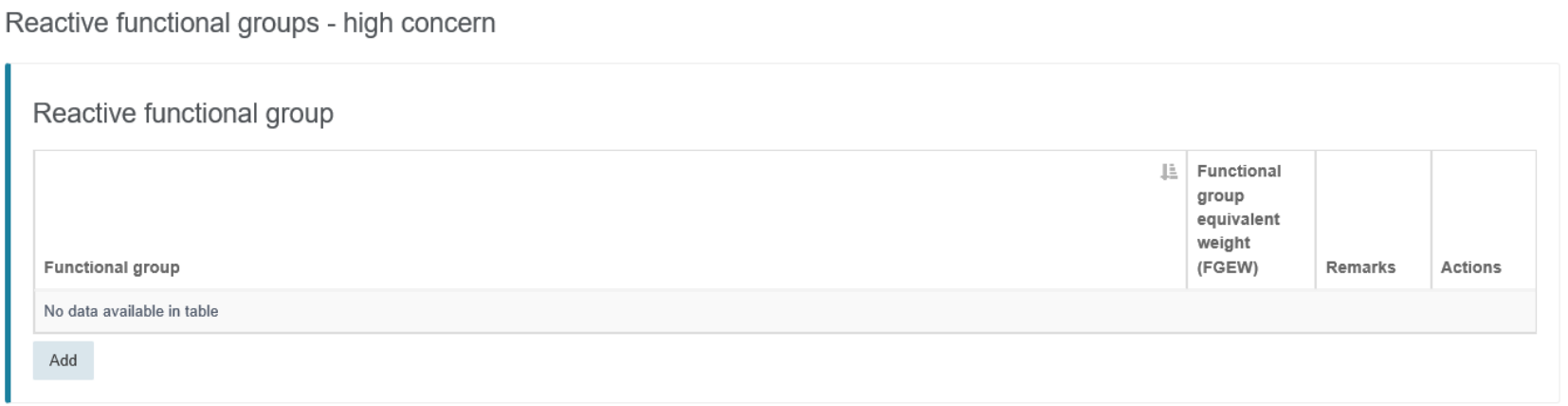


The functional group equivalent weight (FGEW) and any associated remarks can be directly entered into the relevant fields.

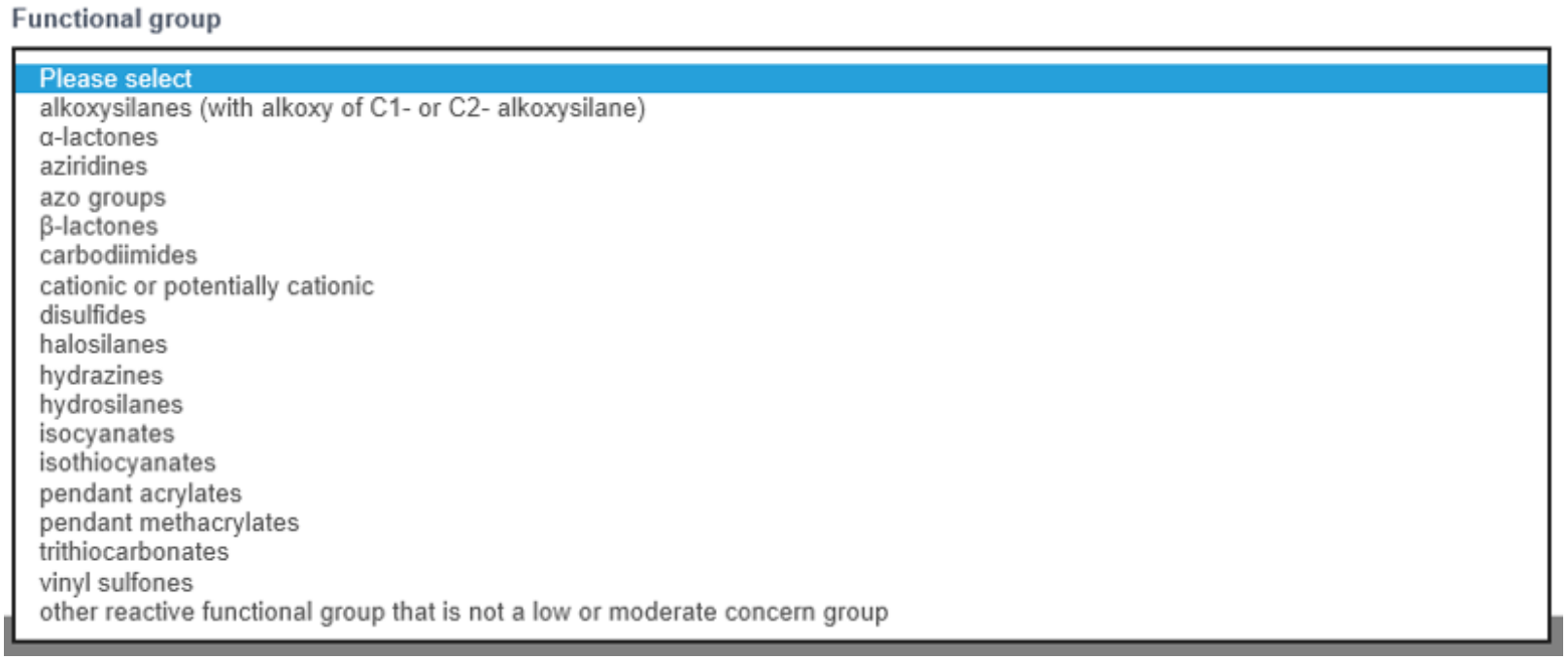
Click on save to save your changes to the table and return to the ‘Reactive functional groups’ fields.

You can add additional reactive functional groups to the table by clicking on the ‘Add’ button.

The same process is repeated where the functional groups are considered to be of high concern.



After opening the ‘Add new item’ pop-up window, select the functional group of concern from the pick list before entering the functional group equivalent weight (FGEW) and any associated remarks directly into the relevant fields.



Click on ‘Save’ to save your changes to the table and return to the ‘Reactive functional groups’ fields.

You can add additional reactive functional groups to the table by clicking on the ‘Add’ button.

You can directly enter the combined functional group equivalent weight into the relevant field, as well as any remarks you may want to include.

When you have completed all the relevant fields. Click on ‘Save’ to save the information entered.

Composition of chemicals considered to be at the nanoscale

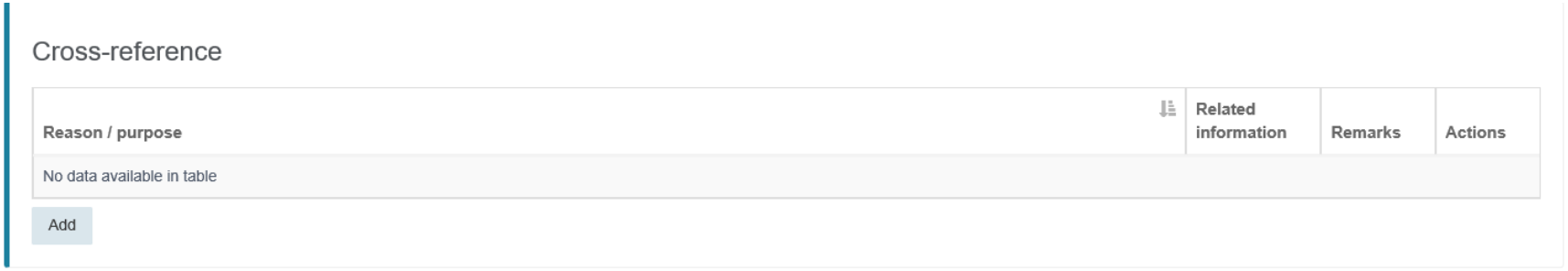
If your chemical is considered to be at the nanoscale, you will need to provide additional information on the composition of the chemical, and any nanoforms you may be using to support your certificate application.

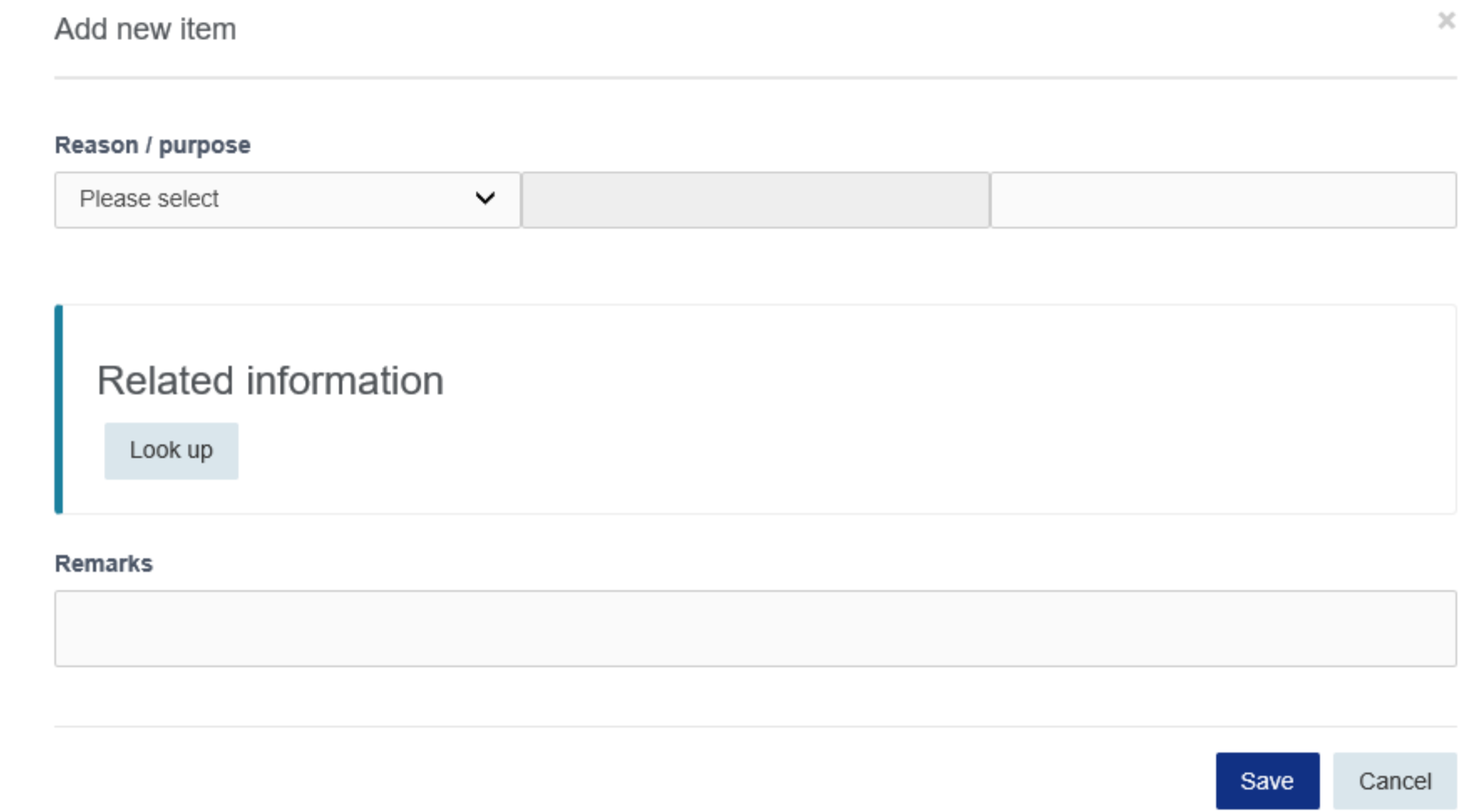
You should read guidance on our website which outlines data requirements for chemicals at the nanoscale:

https://www.industrialchemicals.gov.au/help-and-guides/guide-applying-online-assessment-certificate

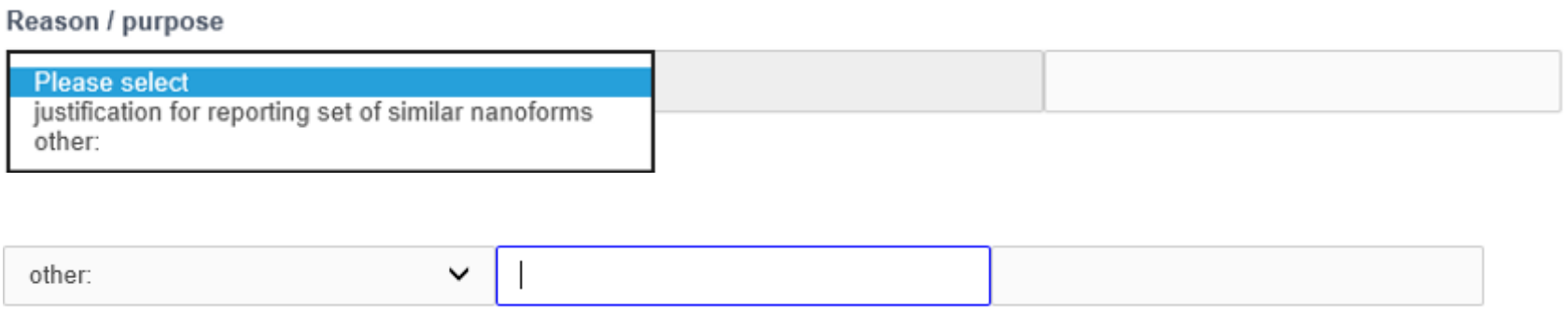
Select if you are reporting a single nanoform or a set of nanoforms.

If you are submitting a set of similar nanoforms, you will need to provide justification why you consider these nanoforms as a set.
You can enter your justification directly into the ‘Justification’ field, or you can insert a template.
Select ‘Save’ to save your changes before going back to the main window. Or select ‘Cancel’ to go back to the main window.




Add new item
Reason / purpose
Please select
Related information
Look up
Remarks
Save
Cancel

You will need to select the reason/purpose for the cross-reference from the ‘Reason / purpose’ pick list.



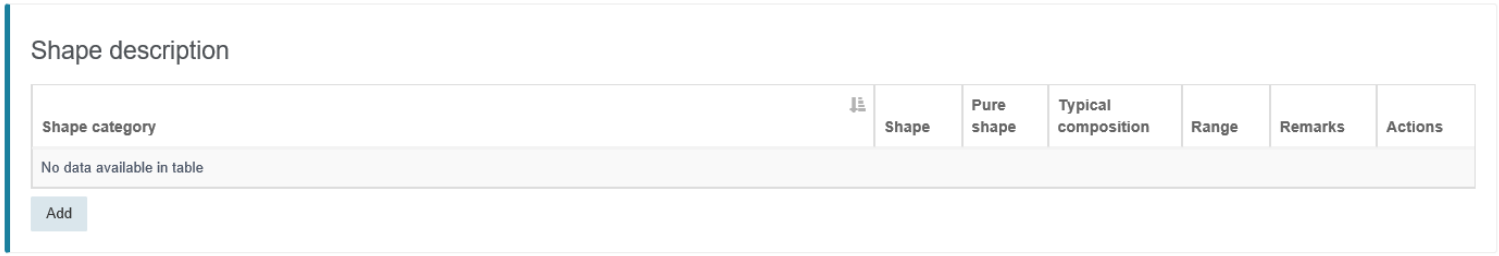
Select ‘Save’ to save your changes before going back to the main window or select ‘Cancel’ to go back to the main window.

You will need to provide information on:

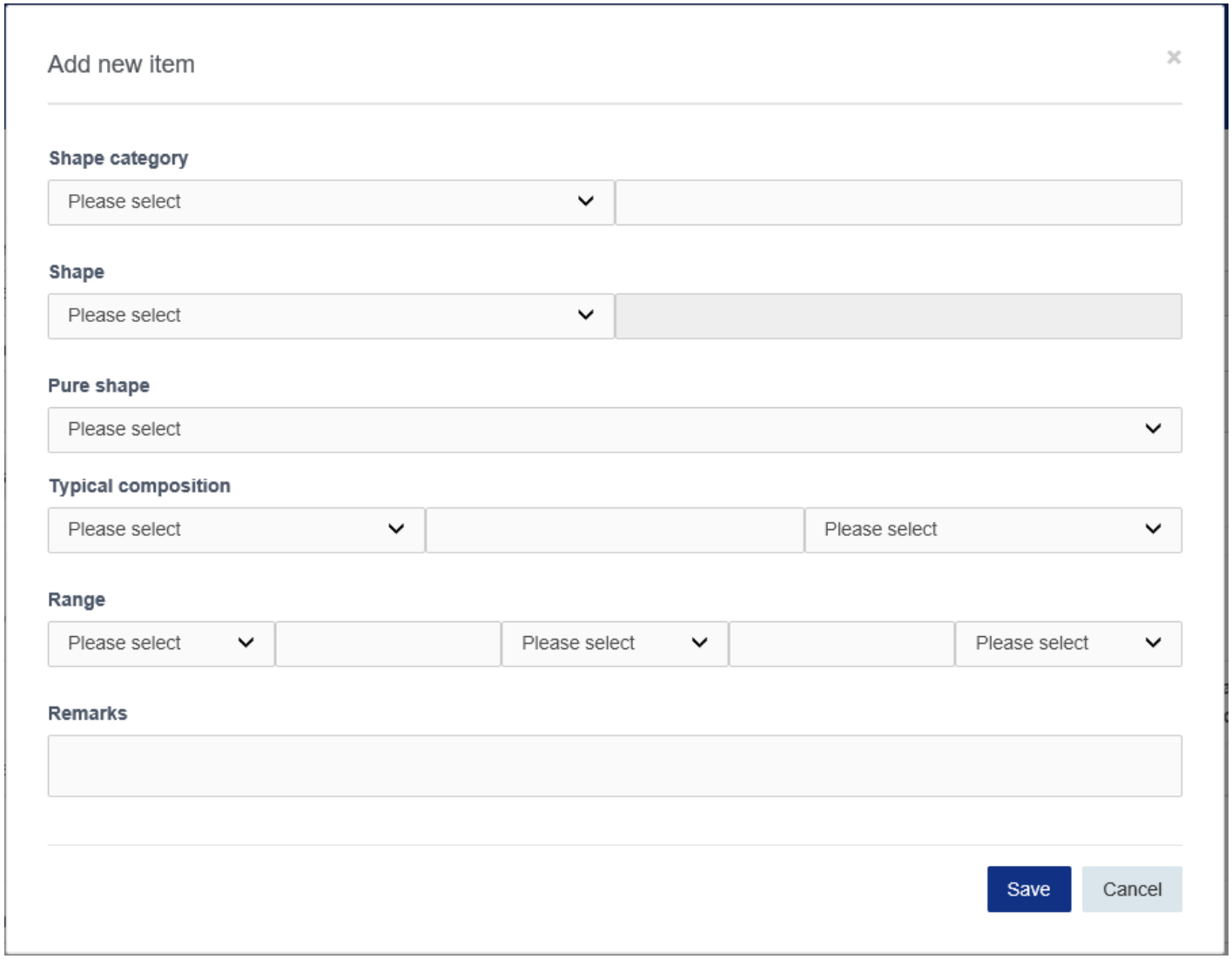
- the shape of the chemical
- the particle size distribution and range
- crystallinity
- specific surface area
- any surface functionalisation or treatment

You can flag any of these endpoints for consideration as CBI.

To add an entry to the ‘Shape description’ table, you will need to click on ‘Add’.

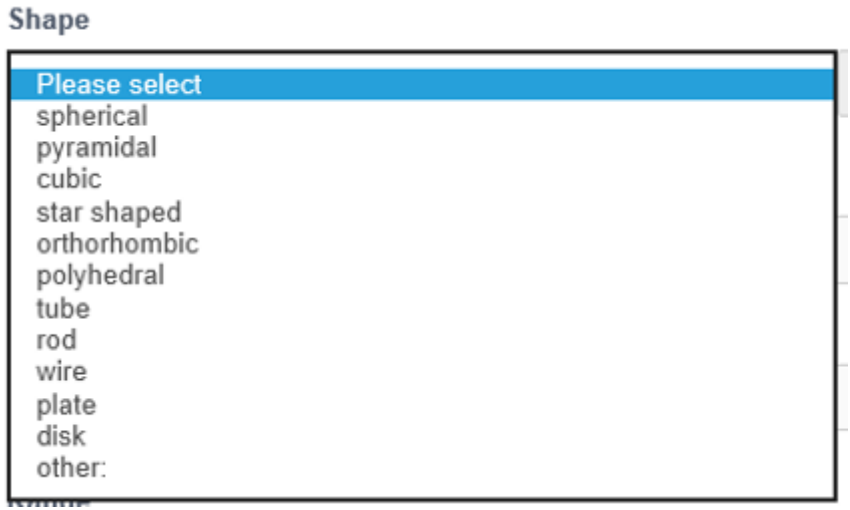


After clicking on ‘Add’, an ‘Add new item’ pop-up window will open.



You will need to select a shape category from the pick list.

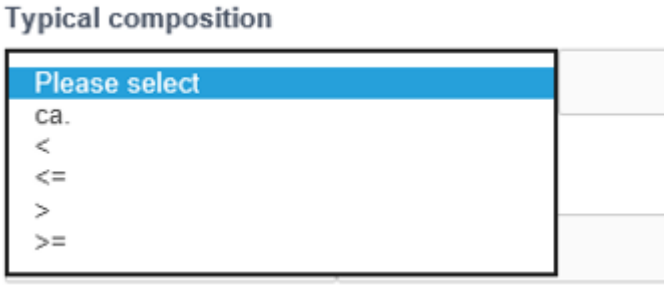
You will need to select a shape from the pick list.



If you select ‘other:’ the adjacent field will open and you will be able to enter information in it.

You need to indicate if the shape of the chemical is a pure shape in the relevant pick list.

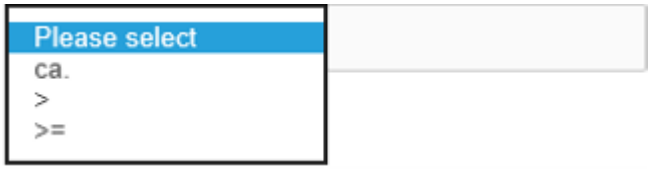
Under ‘Typical composition’, in the first cell you can choose from the following options.

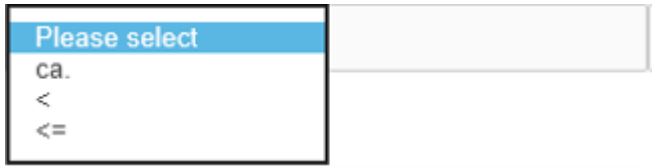


Enter in your value in the second cell (a field), followed by the unit of measurement.

Note: There is no additional field available to enter in a description of the measurement if you choose ‘other:’. You should include this information in the remarks field.

Enter in the range using the pick lists and adjacent fields.





Then, select the units of measurement from the pick list.

Note: There is no additional field available to enter in a description of the measurement if you choose ‘other:’. You should include this information in the remarks field.

You can directly enter in any remarks or other comments on the shape of the chemical in the ‘Remarks’ field.

Save your changes by clicking on ‘Save’ before going back to the ‘Characterisation of nanoforms fields’ section.

The table will be updated with the entries and the ‘Actions’ column will be updated allowing you to edit or delete the entry. You can then add additional entries to the table by clicking on ‘Add’.

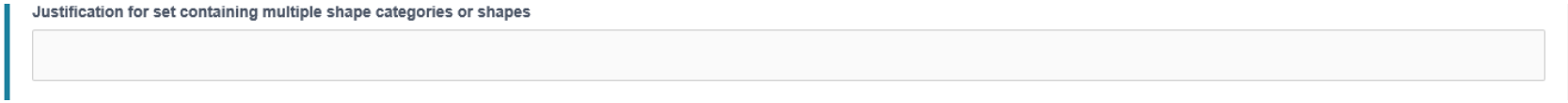
You will need to justify your choice of analogue or use of nanoforms in a set if:

- you are reporting a chemical at the nanoscale and using read-across to support your dataset
- the dataset you’re using includes nanoforms with multiple shape categories or shapes

You should read guidance on our website which outlines data requirements for chemicals at the nanoscale: https://

www.industrialchemicals.gov.au/help-and-guides/guide-applying-online-assessment-certificate

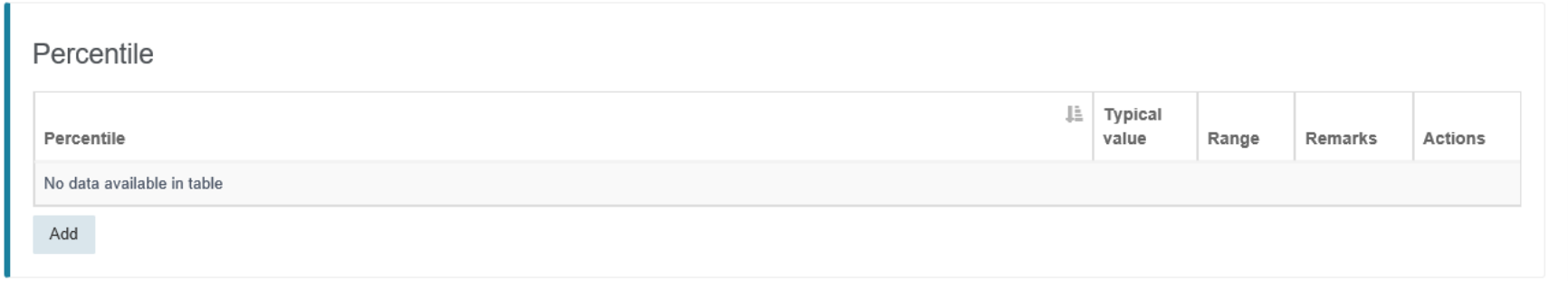
You can directly enter this information into the ‘Justification for set containing multiple shape categories or shapes’ field.



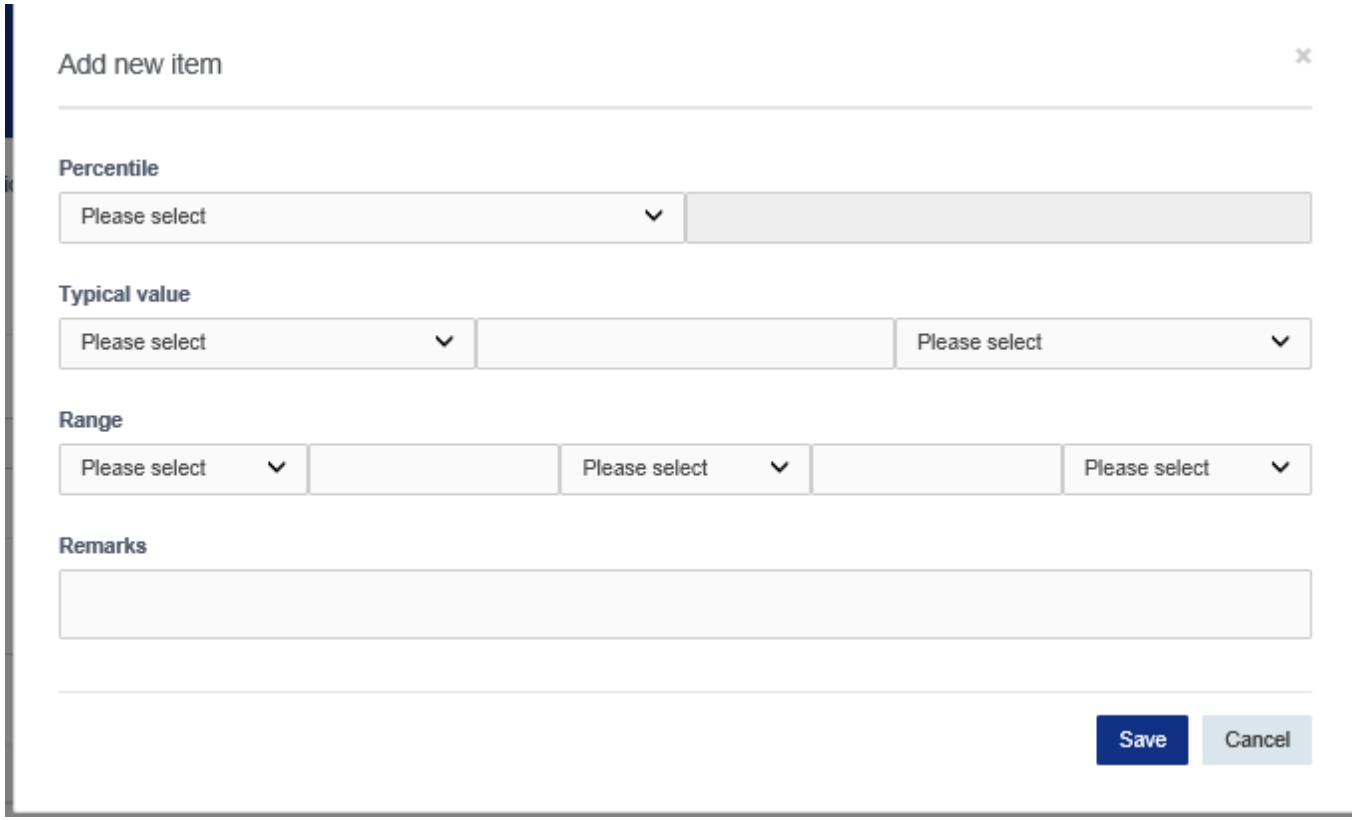
To add information on the particle size distribution and range, you will need to add new fields by clicking on ‘Add’.

Select a shape category from the relevant pick list.

Then add information on the percentile values to the ‘Percentile’ table. To do this you will need to add a new item. Click on ‘Add’ under ‘Percentile’.



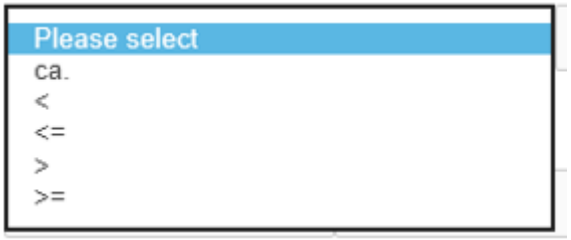
This will open an ‘Add new item’ pop-up window.



Under ‘Percentile’, select the relevant D value from the following options.

If you select ‘other:’ the adjacent field will open and you will be able to enter information in it.

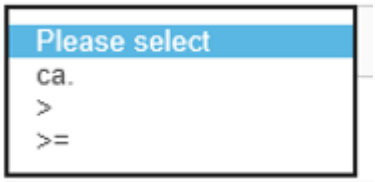
Under ‘Typical value’, you have the following options for the first cell.



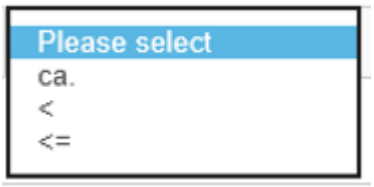
Enter your value in the second cell. Select the relevant measurement in the third cell.

Note: There is no additional field available to enter in a definition for ‘other:’.

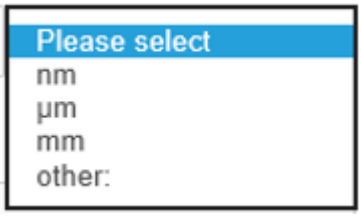
Under ‘Range’, in the first cell select from the following options



Enter in your lower value in the second cell, then select from the following options.



Enter in your upper value in the fourth cell. In the fifth cell you can select the relevant measurement.



Note: There is no additional field available to enter in a definition for ‘other:’.

You can also enter in any remarks in the ‘Remarks’ field.

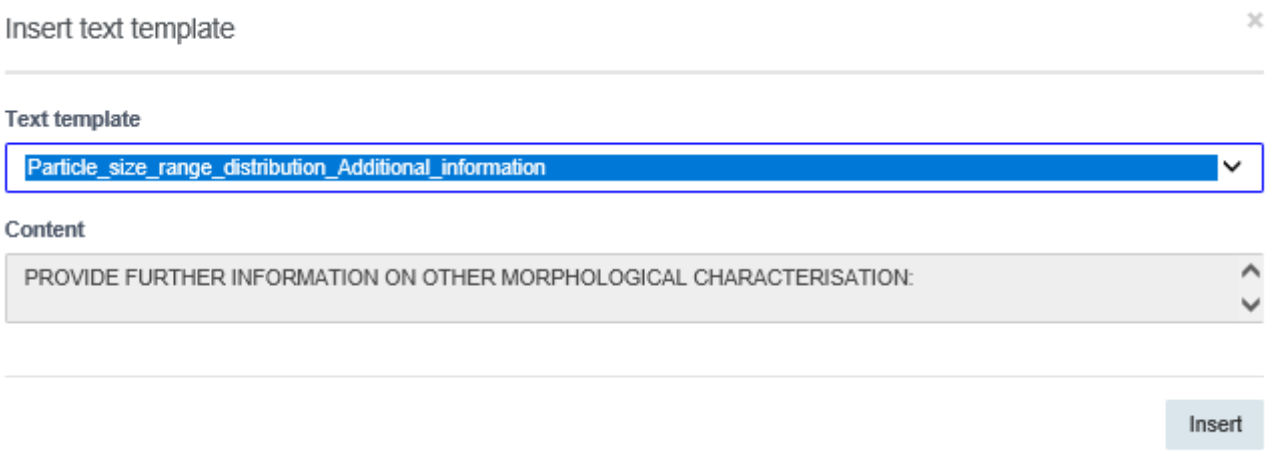
Select ‘Save’ to save your changes before going back to the main window or select ‘Cancel’ to go back to the ‘Characterisation of nanoforms’ fields.

You can then enter in any information you have regarding the typical:

- length of the particle and range of particle lengths
- lateral dimensions and range of lateral dimensions
- aspect ratio and range of aspect ratio values

You can also provide additional information regarding the particle size and distribution by entering information directly into the ‘Additional information’ text box.

Alternatively, you can insert a text template under the ‘Insert text template’ section.



You will then need to provide the values for the fraction of constituent particles in the size range 1-100 nm.

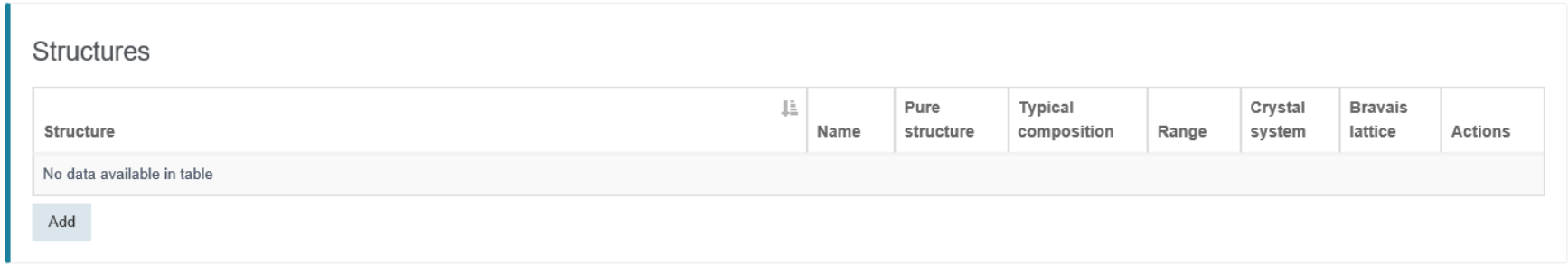
Choosing ‘Delete’ will delete the information entered under particle size distribution and range.

Choosing ‘Add’ will allow you to add in the particle size and distribution information for any other nanoforms that may be present within the ‘Particle size distribution and range’ fields.

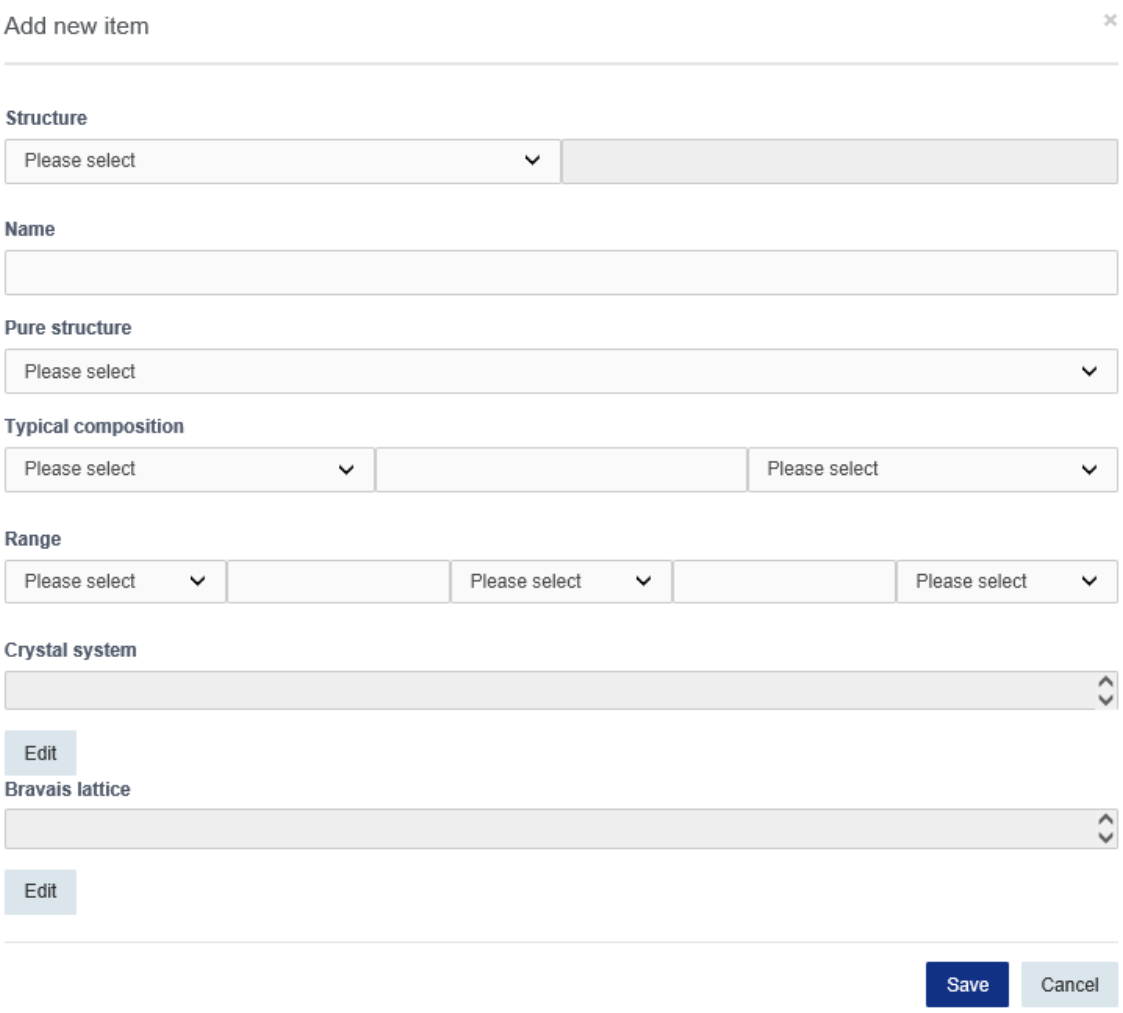
To provide information on the crystallinity of the chemical at the nanoscale, you will need to add information on the structures present in the ‘Structures’ section.

You should read guidance on our website which outlines data requirements for chemicals at the nanoscale:

https://www.industrialchemicals.gov.au/help-and-guides/guide-applying-online-assessment-certificate



You will not be able to enter the required information directly into the table. To add an entry to a table, you will need to click on the ‘Add’ button.

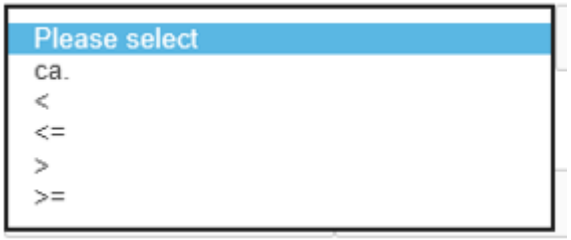


Under ‘Structure’, you can select from the following options.

If you select ‘other:’ the adjacent field will activate and you will be able to enter an appropriate description of the structure in it.

Enter in the name of the structure, then indicate if it is a pure substance by selecting ‘Yes’ or ‘No’.

Under ‘Typical composition’, in the first cell select from the following options.



Enter in your value in the second cell, and in the third cell you can select ‘%’ or ‘other:’.

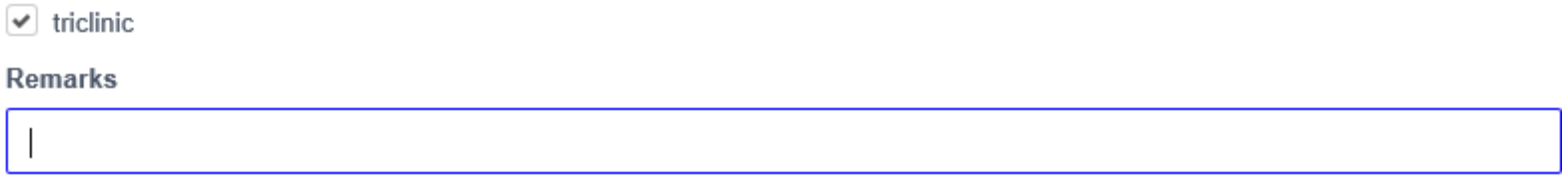
Note: There is no additional field available to enter in a description of the measurement if you choose ‘other:’. You should include this information in the remarks field.

You will then need to provide the range of values for the typical composition of particles.

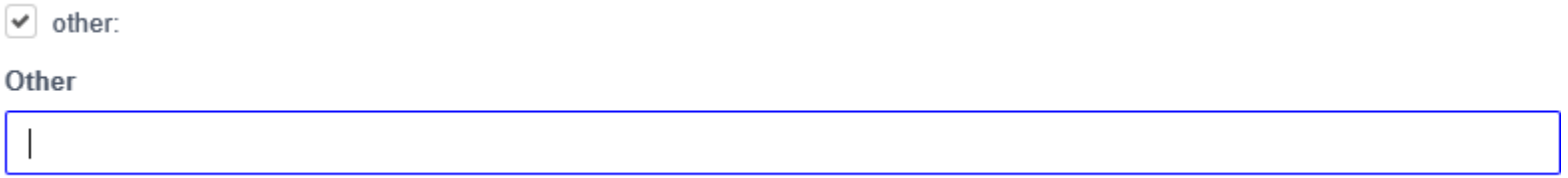
Note: There is no additional field available to enter in a description of the measurement if you choose ‘other:’. You should include this information in the remarks field.

To edit information on the ‘Crystal system’ and ‘Bravais lattice’, you will need to complete the ‘Edit’ pop-up window.

Click on the ‘Edit’ pop-up window to open the ‘Edit Crystal system’ or ‘Edit Bravais lattice’ pop-up windows. Click on the relevant check box(es) and enter any remarks into the ‘Remarks’ field directly under the check box.



If the crystal structure of your chemical is not included in the list, you can click on ‘Other’ and enter the appropriate description in the ‘Other’ field.

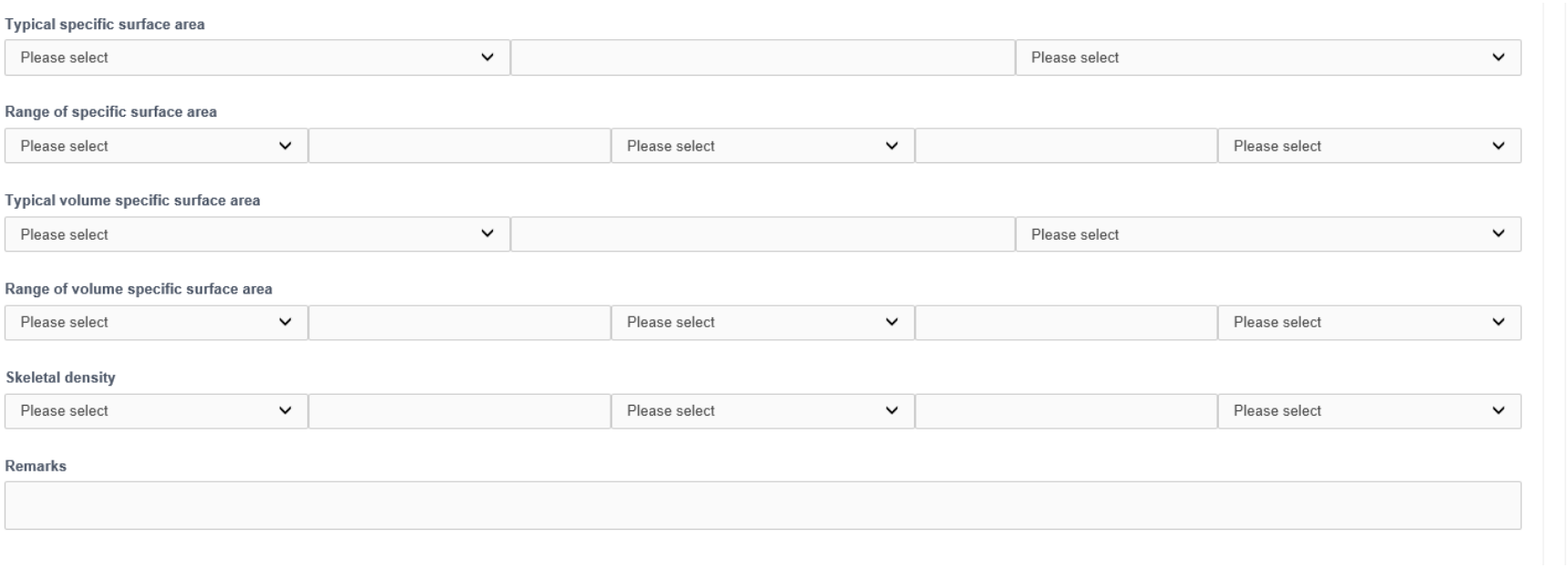


You can also enter in any overall remarks in the ‘Remarks’ field.

Once you have completed entering information on the ‘Crystal system’ and/or ‘Bravais lattice’, you must click on ‘Save’ to save your changes before returning to the ‘Add new item’ pop-up window

After entering in the information required in the ‘Add new item’ pop-up window, click on save to ‘Save’ your changes before going back to the ‘Characterisation of nanoforms fields’. Click on ‘Add’ if you need to add more items to the ‘Structures’ table.

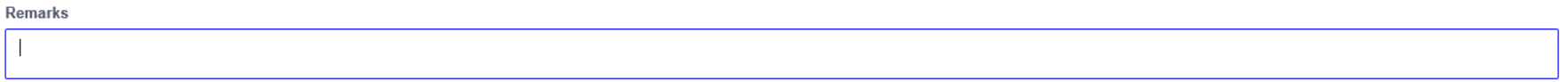
Information regarding the specific surface area of the chemical can be entered into the fields under the ‘Specific surface area’ heading.



You can enter in any information you have regarding:

- the typical specific surface area of the particle and range of specific surface area measurements
- the typical volume specific surface area and range of volume specific surface area measurements
- any information on the skeletal density of the particles

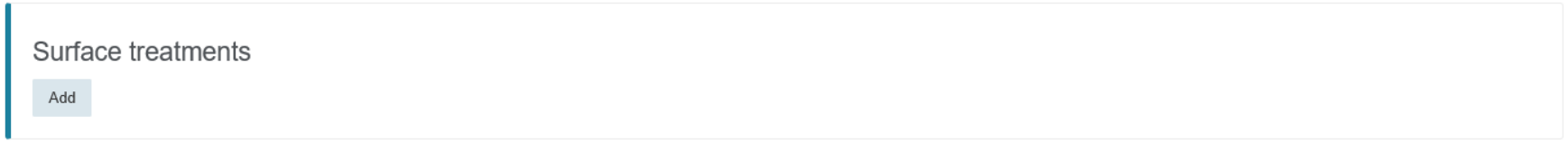
You can also provide additional information regarding the particle size and distribution by entering information directly into the ‘Remarks’ text box.



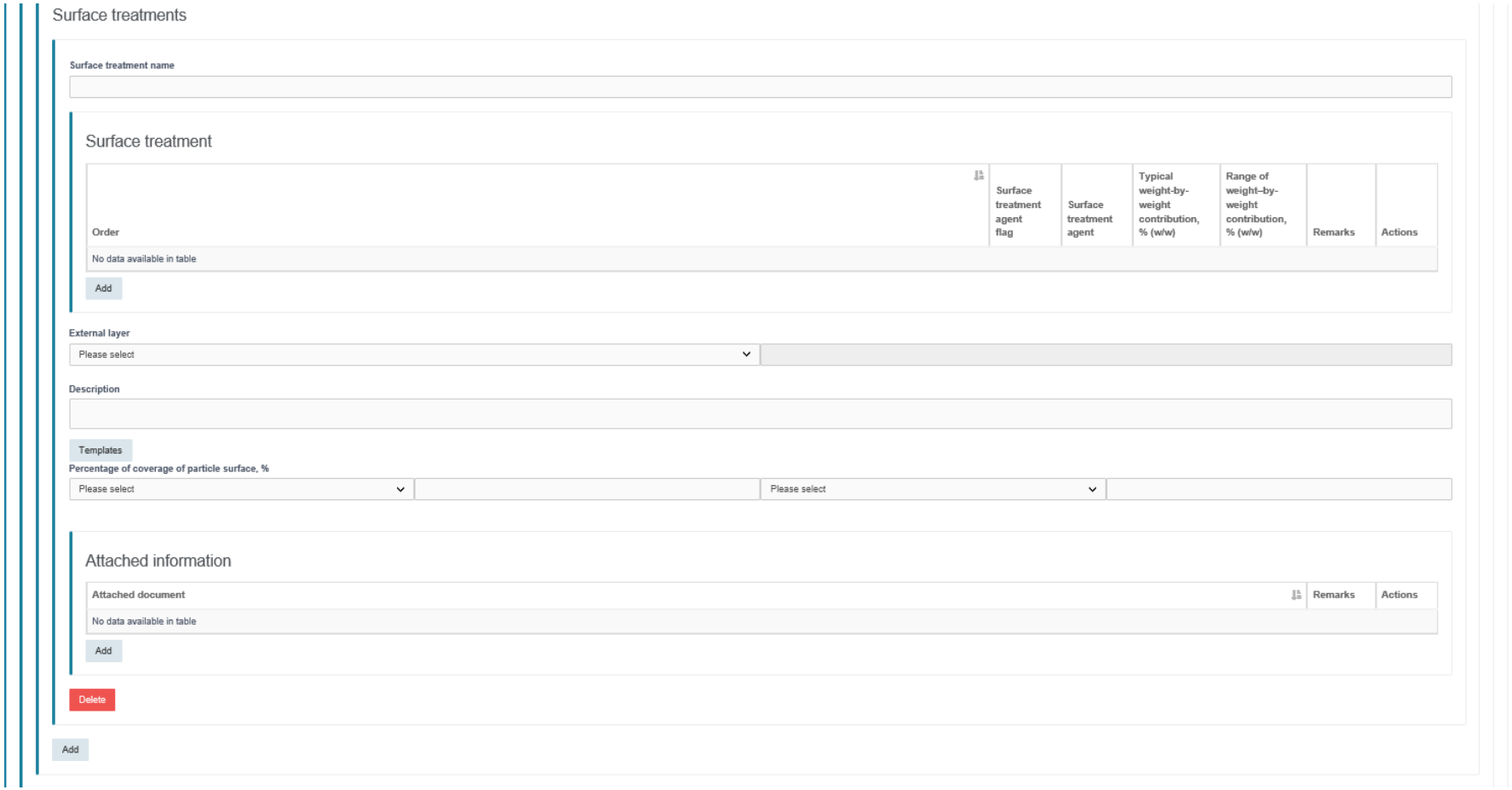
If your chemical has had any surface functionalisation or treatments to it, you will need to provide information on these.

You will need to provide information on the surface treatment applied to the particles and if the chemical or set of nanoforms being used contain both treated and non-surface treated nanoforms.

If surface treatments or functionalisation has been applied, you will need to add information on these.

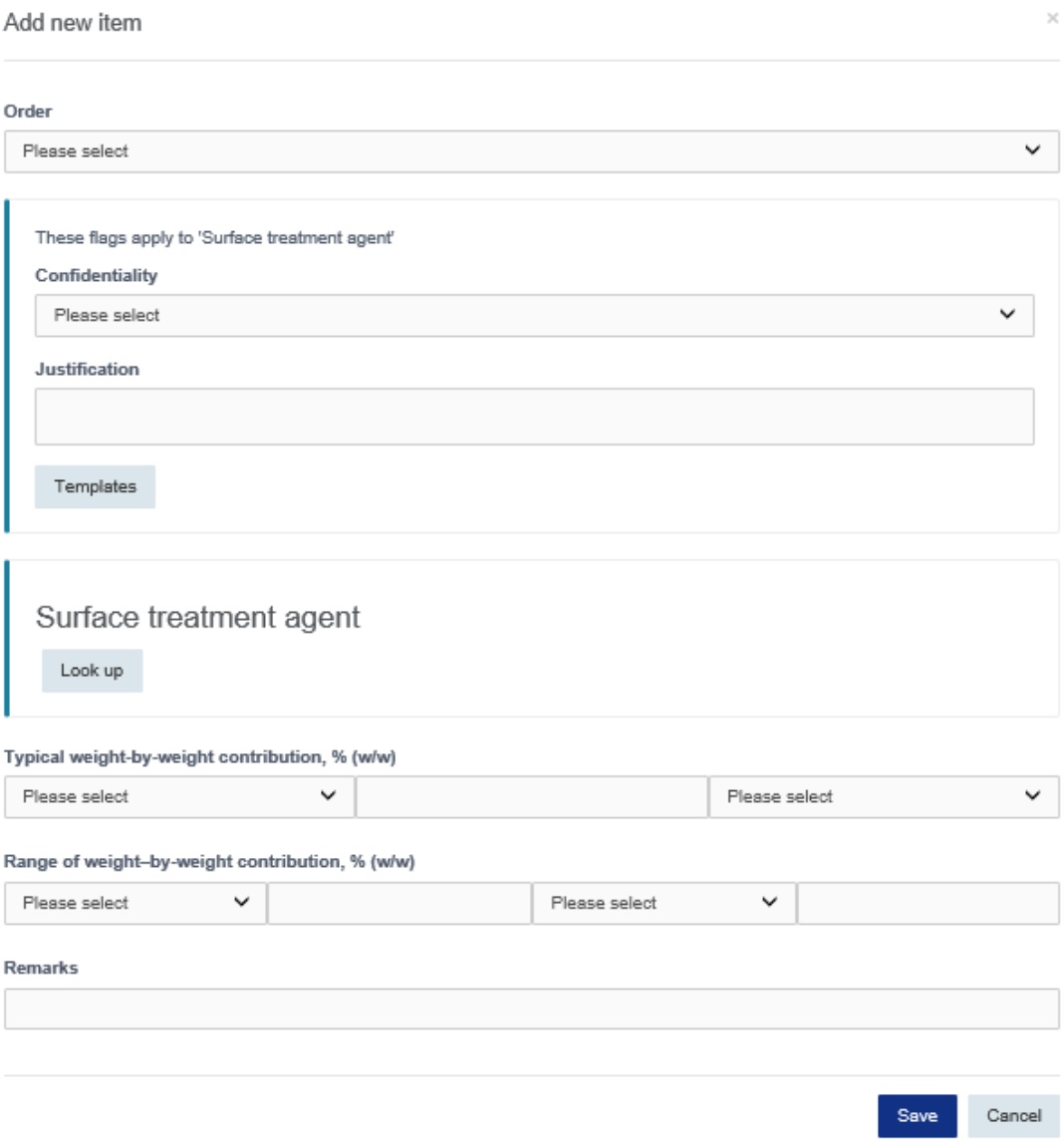


Selecting ‘Add’ will open new fields within the ‘Characterisation of nanoforms’ fields.



After directly entering in the name of the surface treatment, you will then need to add information to the order of the surface treatments. You cannot enter information directly into a table. To add an entry to a table, you will need to click on the ‘Add’ button.

This will bring up an ‘Add new item’ pop-up window.



Select the order number of the surface treatment and flag if you would like the information to be considered as confidential.

You will also need to look up the details of the surface treatment agent(s). The chemical details of any surface treatment agent(s) should have been created as part of creating reference substance records. If not, you will need to go back to the main chemical dossier window and create a substance reference for the surface treatment agent(s).

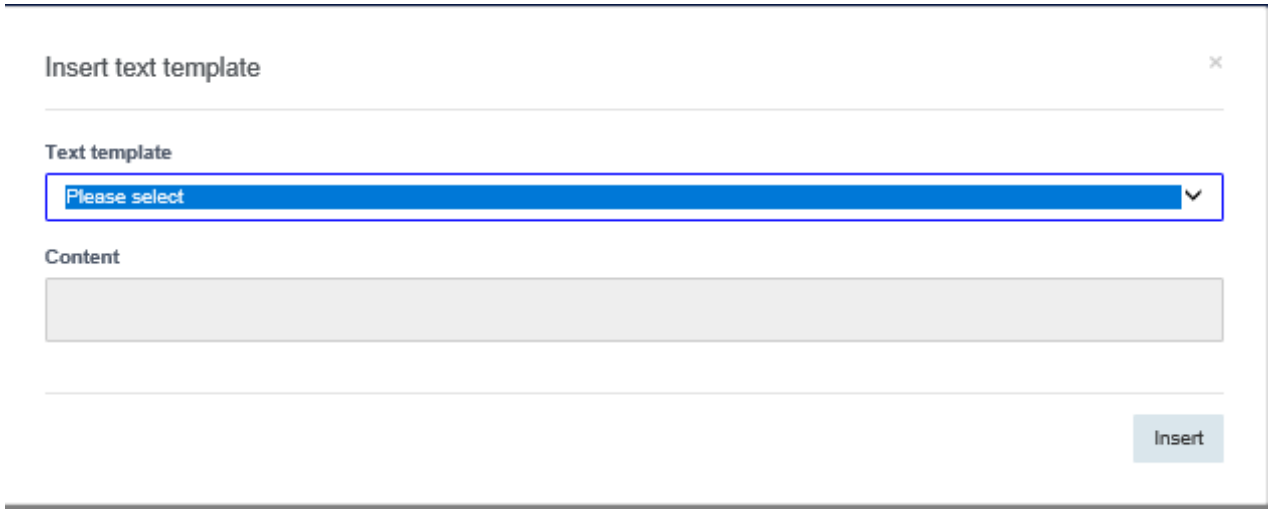
After completing all fields, select ‘Save’ to save your changes before going back to the ‘Surface treatment’ fields.

Select a description of the external layer from the pick list.

If you select ‘other:’ the adjacent field will open and you will be able to enter information in it.

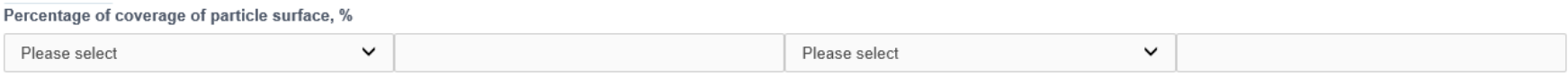
Then you will need to describe the external layer. You can directly enter a description of the external layer into the ‘Description’ field, or you can insert a template text.

Click on ‘Templates’ to open the ‘Insert text template’ pop-up window.



Select the relevant text window and then click on ‘Insert’ to add it into the ‘Description’ field. You can then enter in the information relevant to your chemical by following the template.

You will also need to indicate (as a range of values) how much of the chemical’s surface is covered by the treatment (in percent).

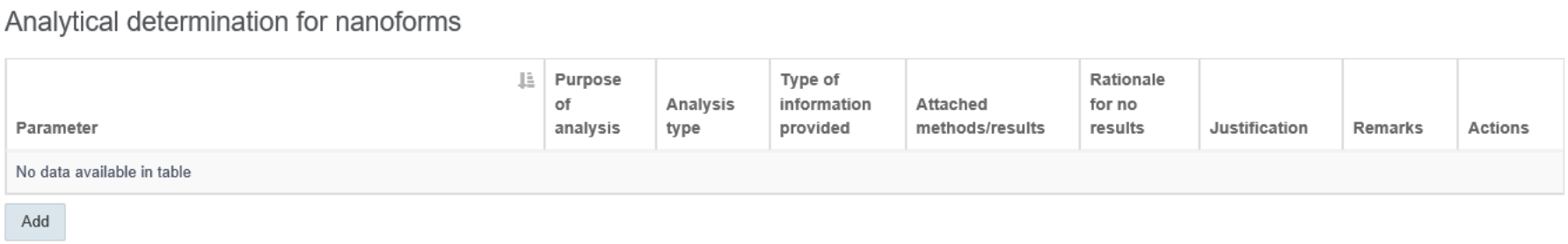


You can also attach a document by clicking on ‘Add’.

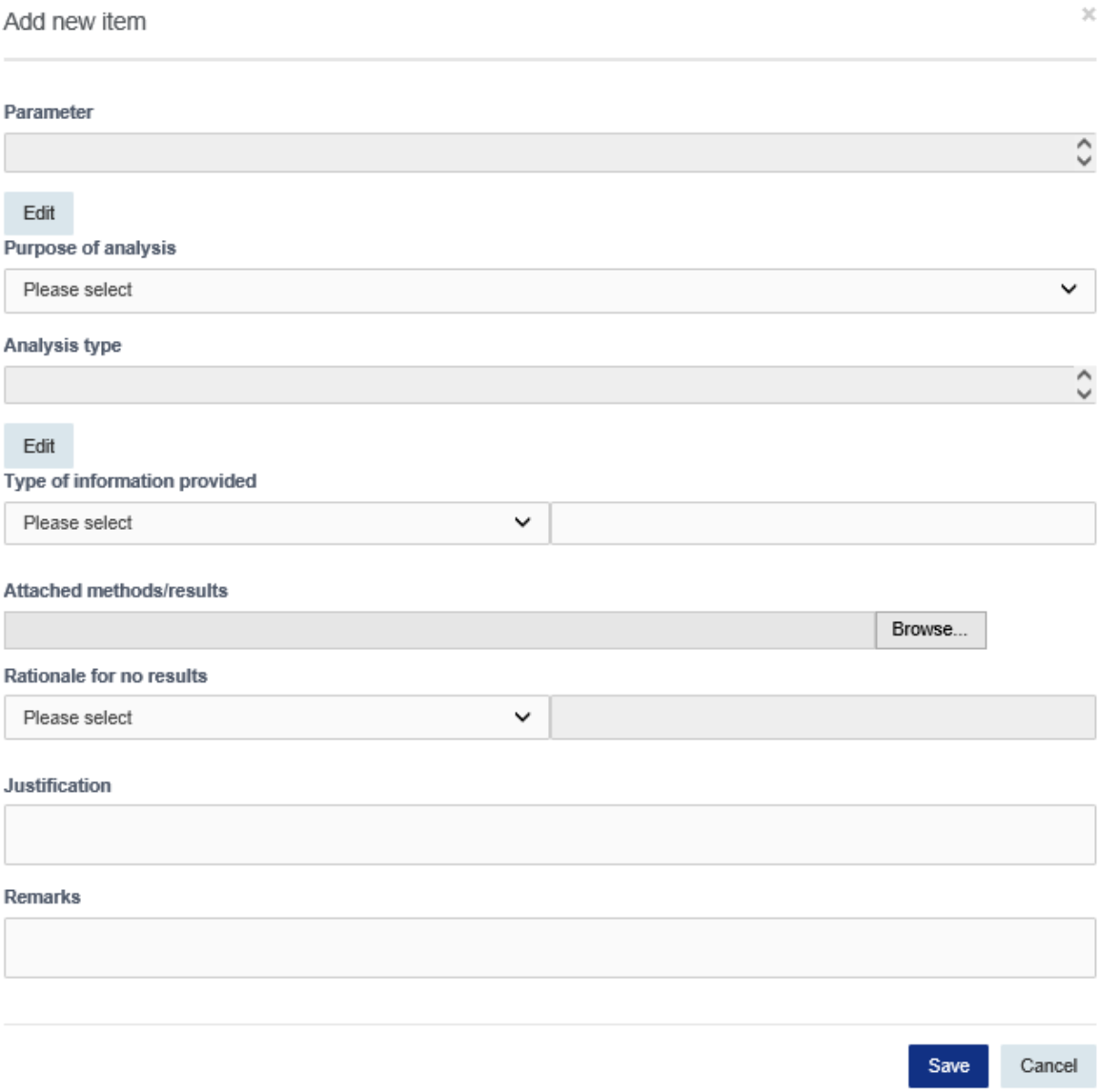
You can then add more surface treatment records by clicking on the ‘Add’ button at the end of the record.

Analytical information of chemicals considered to be at the nanoscale

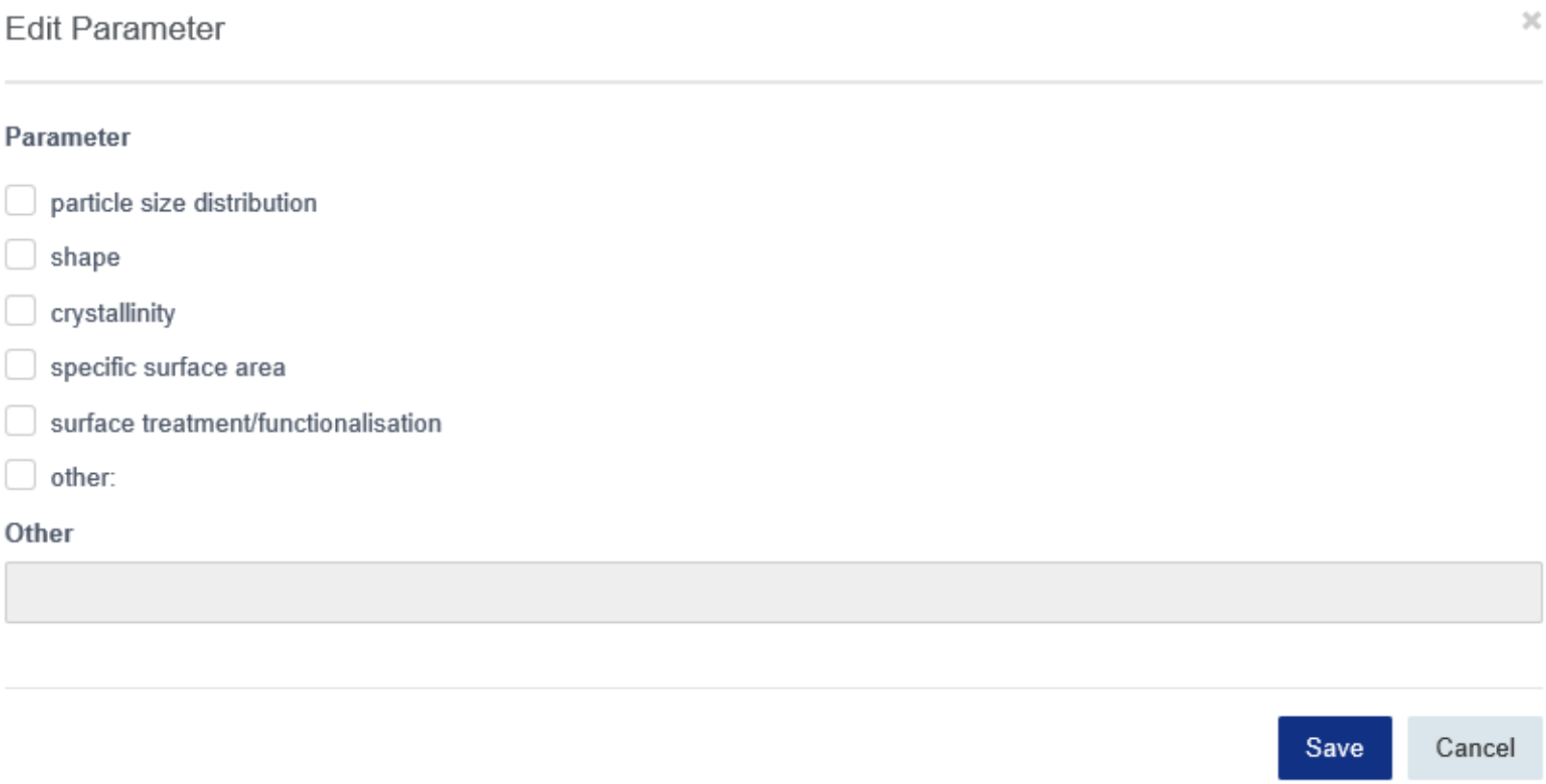
You cannot enter information directly into the analytical determination for nanoforms table. To add an entry to the table, you will need to click on the ‘Add’ button.



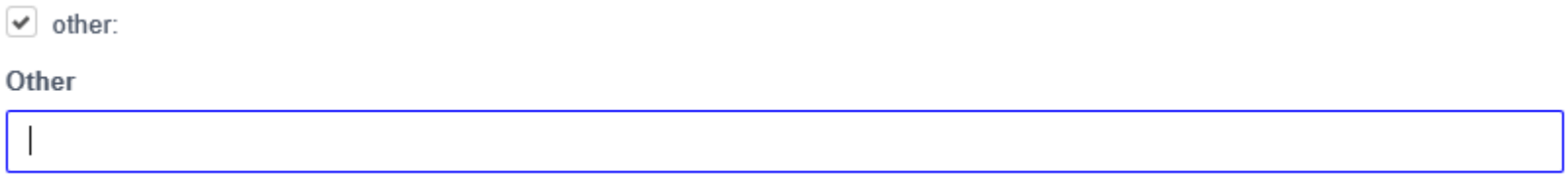
Click ‘Add’ to make a record for each analytical test.



You can enter the parameter being measured by clicking in the field. Alternatively, you can select from one of the following options.

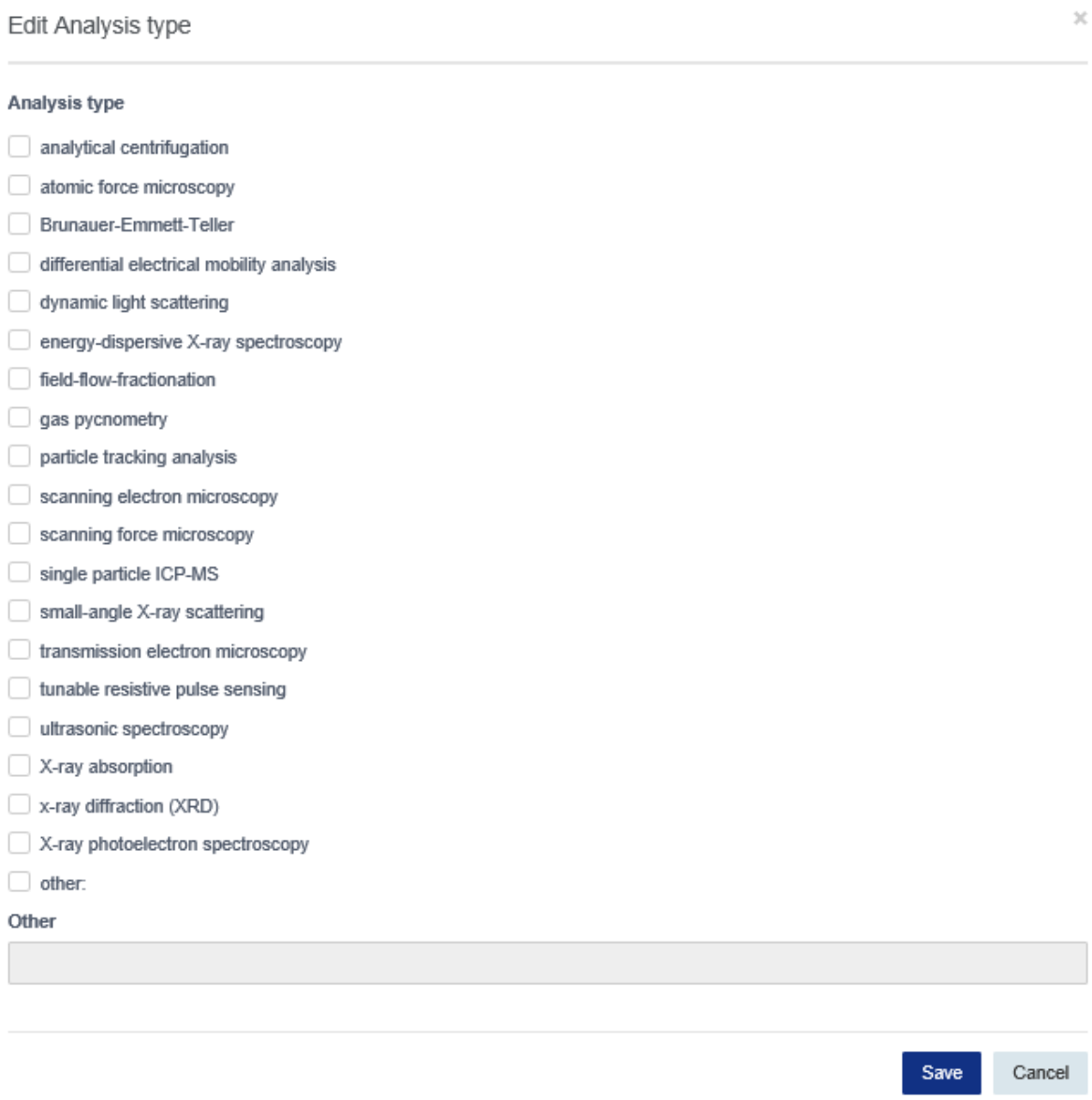


Selecting ‘other:’ will allow you to enter the parameter being measured in the field.

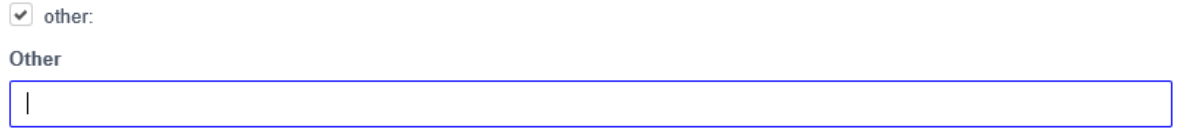


To describe the purpose of analysis, select from the following options in the ‘Purpose of analysis’ pick list.

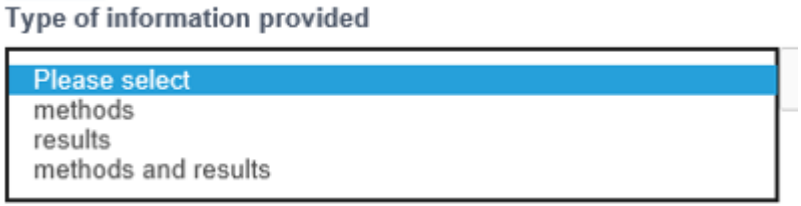
You can enter analysis type by clicking in the ‘Analysis type’ field. Alternatively, you can select an analysis type by clicking on the ‘Edit’ button which will bring up a pop-up-window with a list of analysis types.



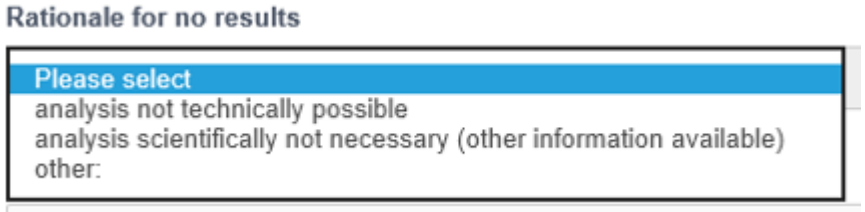
Selecting ‘other:’ will allow you to enter the analysis type used in the field.



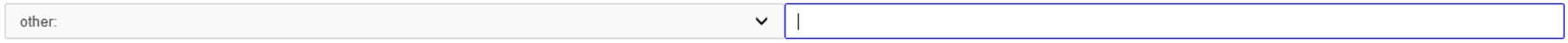
Select ‘Save’ to save your changes before going back to the Add new item window or select ‘Cancel’ to go back to the Add new item window.
You then need to describe the information provided by selecting from the following options.



There is also a field available if you need it.
After you have described the information, attach a copy of the study record describing the methods and results.
If you do not have a study record, you can select one of the following rationale for no results from the ‘Rationale of no results’ pick list.



If you select ‘other:’ the adjacent field will open and you will be able to enter information in it.



You must then provide a justification supporting your rationale for no results. For example, why the analysis was considered not technically possible.

You can also enter in any general remarks you have in relation to the analysis record.

Once you've completed the information required in the 'Parameter' table, you will need to click on 'Save' to save the changes and return to the 'Analytical determination for nanoforms' section.

You can add more analyses to the table by clicking on 'Add'.

If you have any overall remarks, you can enter these directly into the 'Remarks' field.

Click on 'Save' to save the information entered under 'Analytical information'.

Completing Environmental Fate, Ecotoxicity, and Toxicological endpoint information

Where required, for each endpoint you are providing information on based on your category of introduction, you will need to complete:

- the administrative data
- overall remarks
- attachments
- summary and conclusion

You should always confirm that the 'Endpoint' field relates to the endpoint the study is describing.

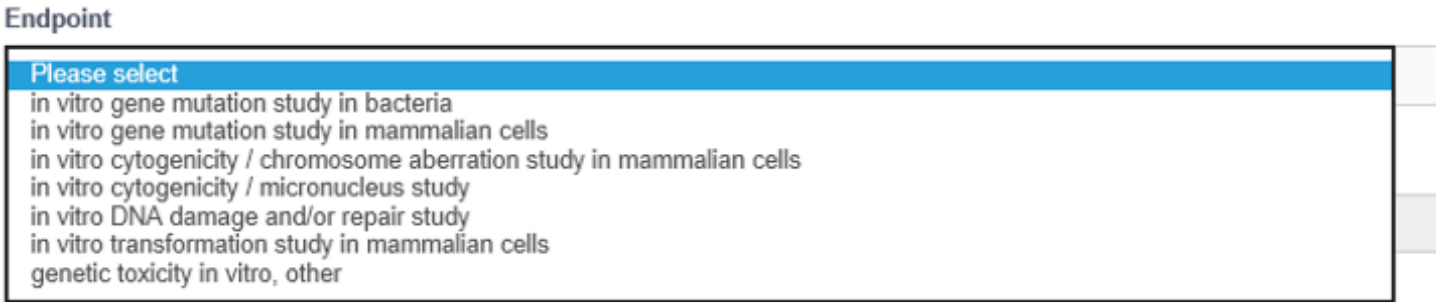
If your introduction is a specified class of introduction you will need to provide additional information with your application. Refer to our website for further guidance.

Where multiple test guidelines are available for an endpoint, you will be required to select the appropriate endpoint.

Example – Skin irritation/corrosion

Example – Skin sensitisation

Example – Genetic toxicity in vitro



Example – Short-term toxicity to fish

Not all endpoint records will require you to complete a results and discussion section. For example, basic toxicokinetics.

Completing information on Residues in food and feeding stuffs, Guidance on safe use and Assessment reports

Residues in food and feeding stuffs

You only need to complete this section if you have information available, and where the chemical will have a use in food contact articles.

Guidance on safe use

You will need to insert text using the template(s) provided for:

- first aid measures
- fire-fighting measures
- accidental release measures
- handling and storage
- exposure controls/personal protection
- stability and reactivity
- disposal considerations

Assessment reports

You can attach any assessment reports or other documents you have referenced during your certificate application here. Comparable hazard assessment reports and a copy of the letter you received from AICIS (confirming our receipt of the comparable hazard assessment report) can also be attached here.

If you are submitting the information for a comparable hazard assessment application type by uploading a validated IUCLID6 dossier, this information can be attached in the Assessment reports section of the IUCLID6 data file.

Validating your certificate application

Once you have completed the chemical dataset, you will need to validate the information you provided. Under this step the information provided will be checked to confirm that the substance dataset has been completed correctly based on your application type.

To complete this step, see the guidance on our website.

Note: You will also need to answer a question about whether your introduction is a specified class of introduction, and if so let us know which class of introduction.

Declaration Step

You can complete this section of the certificate application after the chemical dossier has been validated and you have edited any inconsistencies in the information.

The certificate applicants (initial and joint) and data providers must make this declaration. You must declare that the information you have provided is true and correct before you can submit the certificate application for assessment. All participants in the certificate application must not:

- provide false or misleading information
- withhold information

All applicants, agents and chemical data providers you nominated as part of the certificate application process must submit their declaration before we can receive application.

You will be responsible for ensuring that a nominated person or business submits their declaration.

If a nominated person or business refuses to submit a declaration, you must cancel the application and start again.

Please note, The Assessment and Evaluations Team do not have access to your certificate application until after you have submitted the certificate application. As such they will not have the capacity to assist you with making changes to nominated businesses or people associated with those businesses.

Submission

The certificate application can be submitted by the initial applicant or their nominated agent after:

- all CBI applications are completed
- all invoices (for certificate and CBI applications) have been paid in full
- all certificate applicants (initial and joint) and chemical data providers have provided a chemical dossier
- all certificate applicants and chemical data providers have made a declaration

There are a number of validation steps to assist you in confirming you have made available to us all the information required.

Once you have submitted the valid certificate application, it will be assigned to a team within AICIS.

We will initially screen your certificate application and contact the applicant contact (or nominated agent where appropriate) email if there is insufficient information available, or if we require clarification on information you provided. This step is independent of the 'Data Validation' step you performed prior to submitting your certificate application.

If we confirm the application as being valid and complete, you will not receive any correspondence from us.

Summary of sections to be completed for each certificate application type

Check that the test data you are proposing to use is sufficient to support your application.

We have a table on our website that summarises the sections that you will need to complete for each application type.

The information requirements used to support your application can vary depending on the indicative risk of your chemical and the category of introduction.

We strongly recommend that you review these requirements prior to starting the chemical dossier section of your application.