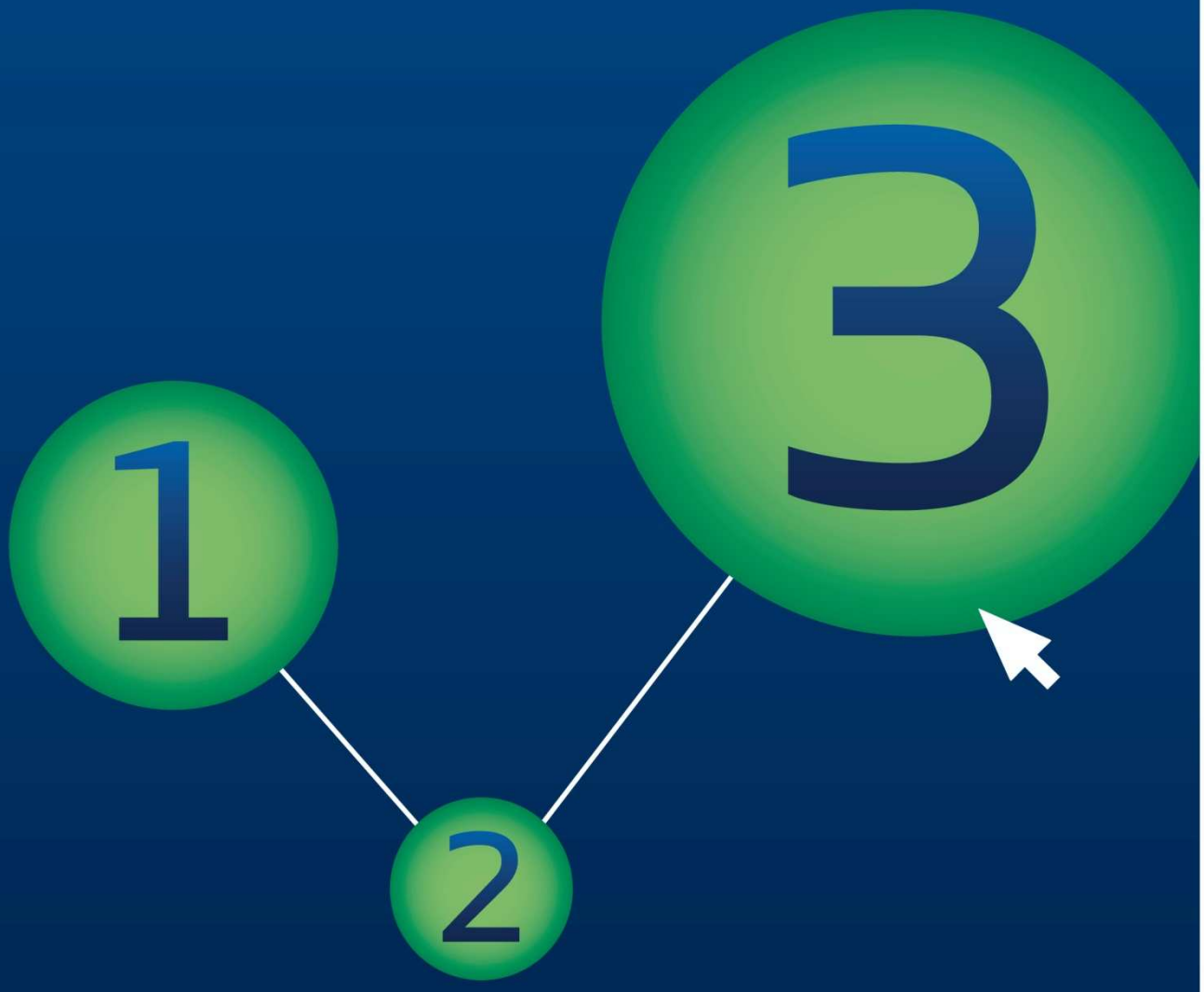
ECHA
EUROPEAN CHEMICALS AGENCY

MANUAL

# Biocides Submission Manual 1

Using IUCLID 5 for biocides applications



| Version | Changes | Date |
|---|---|---|
| Version 1.0 | First version | June 2013 |
| Version 2.0 | Updated to reflect the release of IUCLID 5.5.1, in particular, the inclusion of the 'PBT assessment' in section 13 'Summary and evaluation', and section 12.4 'Packaging' has now changed to section 12.3 'Packaging'.<br><br>In addition, the following areas have been further elucidated in Chapter 2: description and use of supplementary datasets, and IUCLID help functions. | November 2013 |

**Biocides Submission Manual 1 – Using IUCLID 5 for biocides applications**

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# 1. Introduction

## 1.1 Objective

The purpose of this manual is to describe the key steps in creating a dossier related to biocidal active substances and to biocidal products. A dossier is required as part of some applications under Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, hereinafter referred to as the BPR. The dossier that needs to be submitted with those applications should be prepared in IUCLID format (Article 79 of the BPR).

## 1.2 Conventions and terminology

The following icons are used throughout this manual:

 Useful information, guidance, assistance

 Very important note

The following text conventions are used throughout this manual:

| | |
|---|---|
| BPR | Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products |
| BSM | Biocides Submission Manual |
| CLP | Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 |
| C&L | classification and labelling |
| DPD | Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations |
| DSD | Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances |
| ECHA | European Chemicals Agency |
| GHS | Globally Harmonised System |
| IUCLID 5 | International Uniform Chemical Information Database, version 5 |

| | |
|---|---|
| PBT | persistent, bioaccumulative and toxic |
| R4BP 3 | Register for Biocidal Products, version 3 |
| REACH | Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH) establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC |
| UUID | Universally Unique Identifier |

## 1.3 Definitions and concepts

For the purposes of this manual, the definitions in Article 3 of the BPR apply.

| | |
|---|---|
| Active substance | A substance or a micro-organism that has an action on or against harmful organisms (Article 3(1)(c) of the BPR). |
| Applicant | The legal entity that is the 'applicant' as per the BPR. The applicant is indicated as the 'asset owner' in R4BP 3. |
| Biocidal product | Any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action.<br><br>Any substance or mixture, generated from substances or mixtures that do not fall under the first indent, to be used with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action.<br><br>A treated article that has a primary biocidal function must be considered as a biocidal product (Article 3(1)(a) of the BPR). |
| Letter of access | An original document, signed by the data owner or its representative, stating that the data may be used for the benefit of a third party by competent authorities, ECHA, or the Commission for the purposes of the BPR (Article 3(1)(t) of the BPR). |
| R4BP 3 | Register for Biocidal Products, version 3, established and maintained by ECHA, as per Articles 71 and 79 of the BPR. |

# 2. What is IUCLID?

IUCLID is a software program installed on your local IT environment. It is used to enter, store, maintain and exchange data on substances, compositions and micro-organisms, including active substances and biocidal products. This data is entered and stored in 'datasets' and can be exported from a IUCLID dataset in a file called a 'dossier' (.i5z file) and then uploaded as part of an application, to be submitted through the Register for Biocidal Products (R4BP 3). IUCLID is essential for applicants to be compliant with, amongst others, the BPR legislation, by submitting data in the correct format (Article 79 of the BPR).

To use the IUCLID application, you must first sign-up on the IUCLID website (http://iuclid.eu) and register details about your legal entity. When a legal entity is registered, a Universal Unique Identifier (UUID) is generated and assigned to that legal entity. Legal entity information, such as contact details provided by the party and the UUID assigned by the IUCLID website, are stored in a Legal Entity Object (LEO). For more information about creating an LEO, please see BSM 2: Using R4BP 3 for biocide applications.

ECHA has provided guidance documents to assist you in fulfilling the information requirements under the BPR - Guidance documents. In addition, please consult the appropriate Biocides Submission Manual for more information on what documents should be included in an application and how to submit an application.

The latest version of IUCLID, version 5, can be obtained free of charge from the IUCLID website at the following address: http://iuclid.eu.

For more details about the installation and use of IUCLID 5 go to the Support tab of the IUCLID website, and see its built-in help function and the manuals located in the documentation section.

## 2.1 Dataset types

A dataset is the central core of information in IUCLID 5, which contains information on the intrinsic properties of a specific substance or mixture, and its constituents. One of the elements characterising the IUCLID 5 dataset is its relationship to a 'Reference substance'. The 'Reference substance' is a IUCLID 5 feature for storing identification information of substances and their constituents (see section 2.3).

The dataset is thus the repository of technical and scientific data and is used to create a dossier. A dossier is a non-editable snapshot file of the dataset, containing the information to be submitted as part of an application, when required.

IUCLID 5 provides two different dataset types:

i) A 'Substance' dataset ( ) and

ii) A 'Mixture/Product'[1] dataset ( )

Both dataset types contain various templates (see Step 2: Select the dataset template) enabling appropriate data entry.

[1] In IUCLID terminology, a 'Mixture/Product' dataset refers to a biocidal product dataset.

### 2.1.1 Main dataset templates

To create a valid dossier, at least two main dataset templates must be completed (Figure 1):

i) 'BPR Active substance application' template - containing information concerning an active substance

ii) 'BPR Biocidal product authorisation' template - containing information concerning a biocidal product, biocidal product family, or representative biocidal product. This dataset must also be used to create the dossier, see chapter 7.

⚠ Both of the above datasets must be created and then linked to each other to create a valid dossier, see IUCLID section 2.3 'Biocidal product composition'.

### 2.1.2 Supplementary dataset templates

The supplementary dataset templates should be used to include information concerning the other components of a biocidal product, biocidal product family, or representative biocidal product (e.g. solvents, emulsifiers, attractants, etc.). The supplementary dataset templates are (Figure 1):

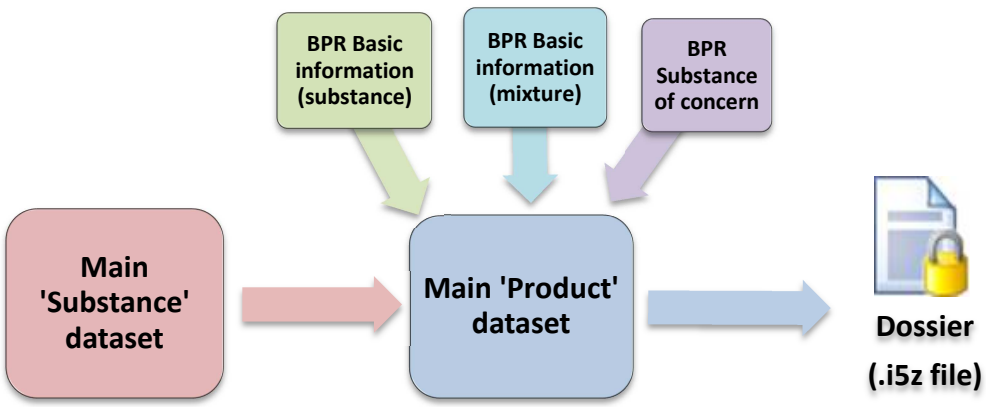
i) 'BPR Basic information (substance)' template – containing information about each additional substance component

ii) 'BPR Basic information (mixture)' template – containing information about each additional mixture component

iii) 'BPR Substance of concern' template – containing information on substances of high concern, according to Article 3(1)(f) of the BPR

Ensure you complete individual datasets for all the components of a biocidal product, biocidal product family, or representative biocidal product. These datasets must then be linked to the 'Mixture/Product' dataset with the template 'BPR Biocidal product authorisation' in IUCLID section 2.3 'Biocidal product composition'.

**Figure 1: Link all datasets to the main 'Mixture/Product' dataset**



## 2.2 Dossier types

A IUCLID 5 dossier is a non-editable snapshot file of the datasets, containing the information to be submitted as part of the application. There are currently two types of dossiers that may be created and submitted as part of an application under the BPR:

i) a 'BPR Active substance application' dossier, and
ii) a 'BPR Biocidal product authorisation' dossier.

⚠ Both dossier types must be created from a 'BPR Biocidal product authorisation' 'Mixture/Product' dataset.

For information on whether a dossier is required for your application and, if so, which type of dossier is required, please refer to the relevant Biocides Submission Manual. Chapter 7 of this manual explains how to create a specific dossier type. The screenshots below explain how you can tell what type of dossier you are looking at from the title in the 'Navigation' panel.

Figure 2 shows a 'BPR Active substance application' dossier that includes both a 'Substance' dataset for an active substance and one for a solvent, along with a 'Mixture/Product' dataset for the biocidal product. It was correctly created from the 'Mixture/Product' dataset. Please note that the number of datasets contained within a dossier may vary.

**Figure 2: Valid active substance dossier**

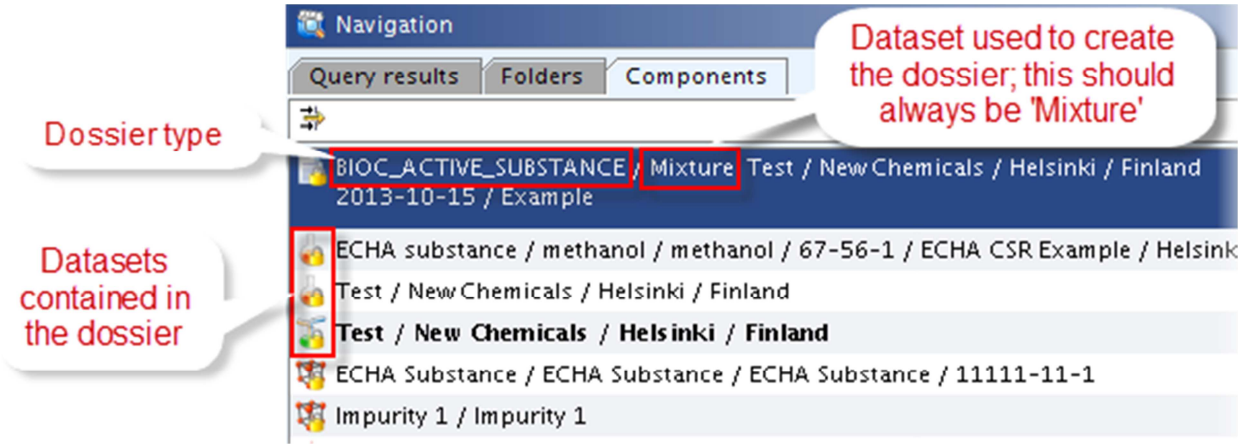
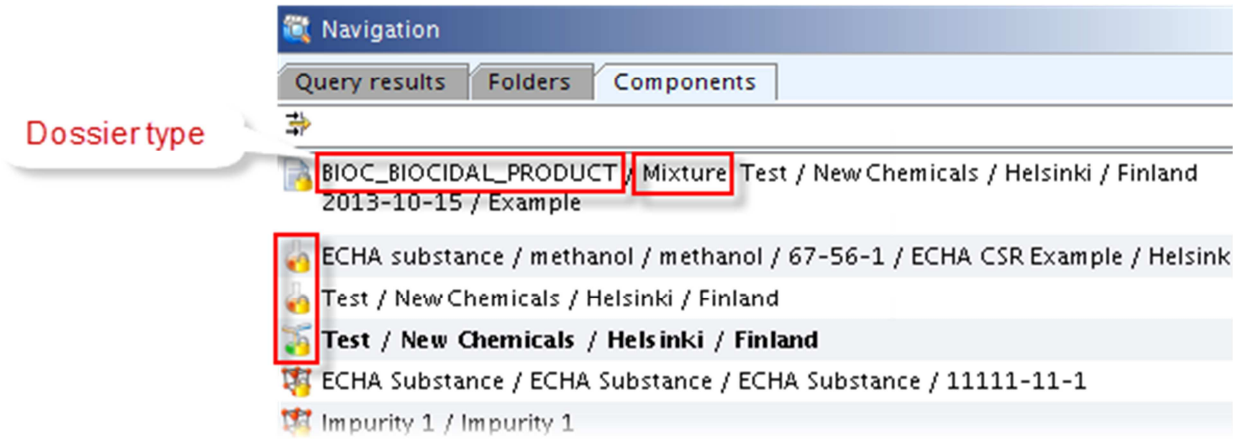



Figure 3 shows a 'BPR Biocidal product authorisation' dossier that includes both a 'Substance' dataset for an active substance and one for an emulsifier, along with a 'Mixture/Product' dataset for the biocidal product. It was correctly created from the 'Mixture/Product' dataset.

**Figure 3: Valid biocidal product dossier**




A dossier is **only valid** if it contains at least one 'Substance' dataset using the template 'BPR Active substance application' and at least one 'Mixture/Product' dataset using the template 'BPR Biocidal product authorisation', and is created from the 'Mixture/Product' dataset.

## 2.3 What is a 'Reference substance'?

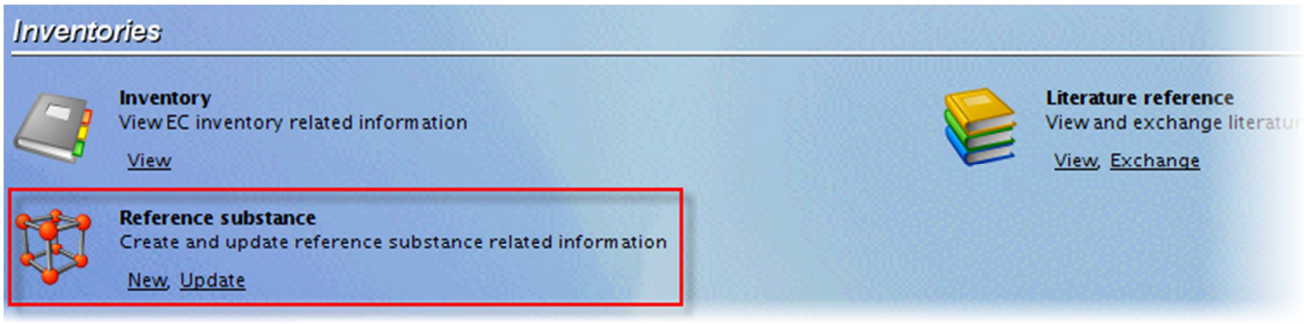
A 'Reference substance' ( ) is a function in IUCLID 5 that holds information on the identity of specific substances and their constituents. It is used to store identification information such as chemical names, EC and CAS numbers or other identity codes, molecular and structural information, etc. This concept was developed to avoid re-typing or manual copy and pasting, and, in general, to make sure that re-useable key data is entered only once, and then centrally managed and updated.

The 'Reference substance' is used in a 'Substance' dataset to specify the identification of the main substance that the dataset has been created for, along with its constituents, impurities and additives, if any.

From the IUCLID website, you can download 'Reference substance' data for tens of thousands of substances as well as an EC inventory containing a list of substance identities, and import them into your IUCLID 5 software program. You can also create a new 'Reference substance' or update information on a 'Reference substance' from the IUCLID 5 homepage (Figure 4).

You should maintain 'Reference substance' information relevant for you, in your local IUCLID 5 program. You can create a new 'Reference substance' or update substance information from the IUCLID 5 homepage (Figure 4).

**Figure 4: Accessing the 'Reference substance' information**

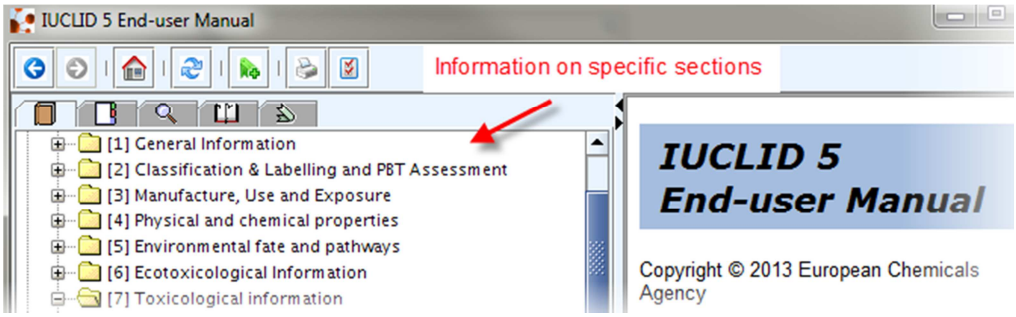



## 2.4 General functions in IUCLID 5

This sub-chapter contains instructions on some general functions that are frequently used throughout IUCLID 5. For further information on how to fill in specific sections of IUCLID 5, please see the corresponding chapter in this manual.

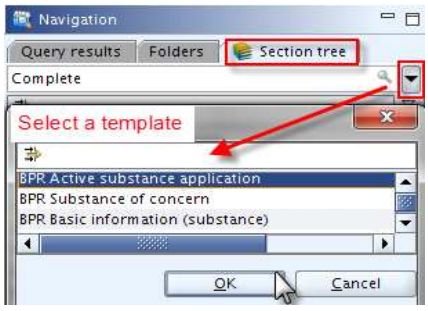
### 1. Help in IUCLID

Pressing 'F1' when you have a IUCLID section open will direct you to the relevant section of the IUCLID 5 End User Manual, for further assistance.




### 2. Selecting a template

Select the appropriate template for the dataset, e.g. 'BPR active substance application', from the drop-down menu using the black arrow ( ▾ ) under the 'Section tree' tab.




### 3. Edit function

Enable the 'edit' button ( ) in the IUCLID 5 taskbar or press Ctrl + E, to allow data input. You will have to do this every time you move to a new section in the dataset.

## 4. Back button

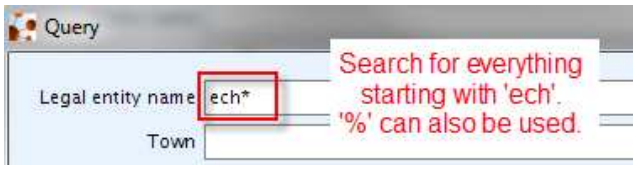
To get back to the original section press the back button ( ) in the IUCLID 5 taskbar.

## 5. Go to button

Clicking on the 'Go to' button ( ) will direct you to a new screen to fill in related information.

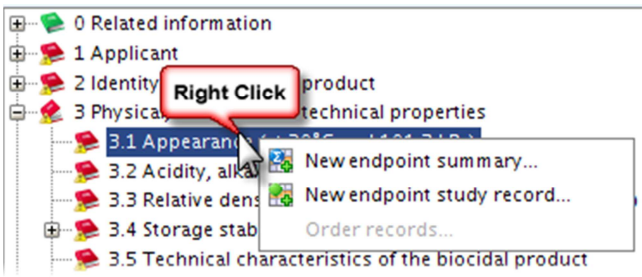
## 6. Wildcard symbols

When you are filling in search criteria, inserting '*' or '%' allows you to widen your search. You can use '*' on its own, or type in some letters and then add the symbols at the end/start. The search criteria text is not case sensitive.



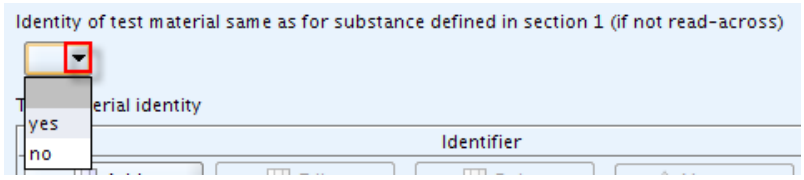

## 7. Creating an endpoint study record or endpoint study summary

An endpoint study record should contain all the data available on a particular endpoint study. An endpoint summary should be a summary of the evaluation made on all the data entered in the endpoint section. Right-click on the section you wish to create an endpoint study record/summary in and click on the correct option.




## 8. Drop-down menu

Access a drop-down menu using the black arrow ( ). Then select the correct option from the predefined options.

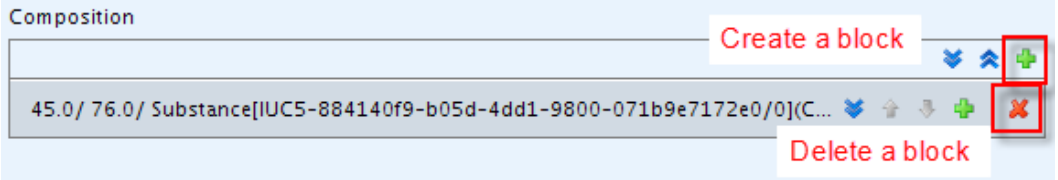



When there is a unit field related to a value field, then ensure a unit is always selected from the drop-down menu.


If 'other:' is selected from the drop-down menu, then the adjacent field must be filled in.

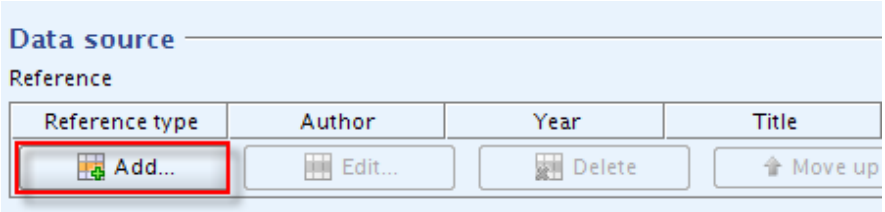
### 9. Plus function

Create a block with the 'plus' button ( ). Certain sections will require that you first create a block to proceed in inputting the relevant data. Delete any unwanted or empty blocks with the cross button ( ).



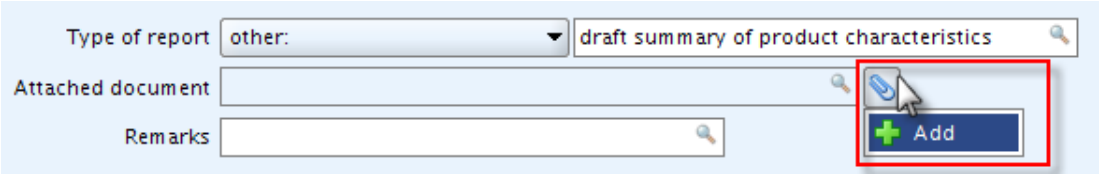

### 10. Add function

Add lines to an existing table by using the 'Add' button ( ). Certain sections will require you to first create a line in an existing table so that you can proceed to input the relevant data.




### 11. Attach function

Attach relevant documents to IUCLID section 13 'Summary and evaluation' using the attachment button ( ), and then click 'Add'.



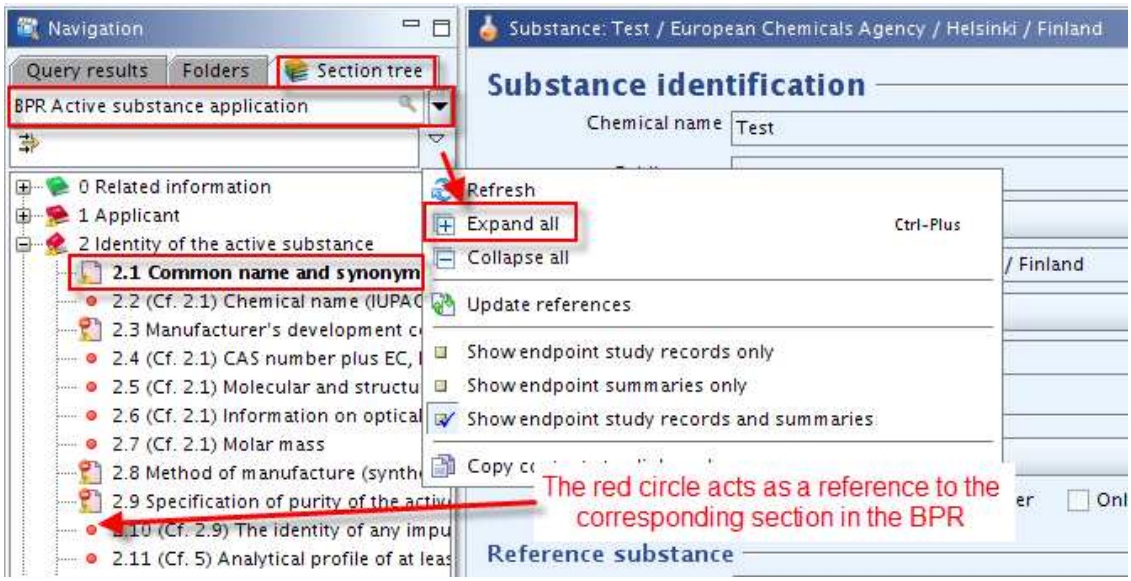

## 2.5 Using the 'Section tree' of a dataset

When a dataset is opened, you can select a specific template from the drop-down menu using the black arrow ( ) under the 'Section tree' tab (Figure 5). Ensure that you have selected the correct dataset template for your purpose e.g. 'BPR Active substance application' (Figure 5), 'BPR Biocidal product authorisation'. By selecting 'Expand all', you will see all the sections contained in the dataset (Figure 5). The book, leaf or circle symbols preceding the IUCLID sections are coloured in red ( , or ) for core sections, or green ( , or ) for additional sections.

The sections depicted by a red ( ) or green ( ) circle are not editable and serve only as a guide. They correspond to the BPR section and refer you to the editable section in IUCLID 5 in which you can input the appropriate data, e.g. ' 2.7 (Cf. 2.1) Molar mass' indicates that 'Annex II Title 1 2.7' of the BPR can be entered in IUCLID section 2.1 'Common name and synonyms' (Figure 5).

You can always tell which section is open in the main window, as it will appear in bold lettering. Figure 5 shows section '2.1 Common name and synonym' open in the main window.

**Figure 5: Navigation window**




Enable the 'edit' button ( ) in the toolbar to enter information into the dataset.

Pressing 'F1' when you are in a particular section will direct you to the relevant section of the IUCLID 5 End User Manual for additional assistance.

## 2.6 Confidentiality requests

Confidentiality requests may be made in accordance with Article 66(4) of the BPR. Applicants can submit confidentiality requests by 'flagging' a field in the IUCLID 5 dataset as confidential. Any time a confidentiality flag is set, the justification as to why publishing the information could be harmful for their commercial interests or those of any other party concerned must be provided in the adjacent field. These confidentiality requests will then be assessed.

For further details on what can be claimed confidential, how to make a confidentiality request, and which requests may incur a fee, please consult BSM 6: Confidentiality requests for biocide applications. Alternatively, consult Summary sheet 1 at the end of this manual.

# 3. Preparing a dataset for an active substance

This chapter outlines how to prepare a 'Substance' dataset using the template 'BPR Active substance application', containing information about an active substance. Additional 'Substance' datasets, using the supplementary templates 'BPR Basic information (substance)' and 'BPR Substance of concern' can be created in a similar manner but may contain different sections. Use the supplementary templates to create datasets containing information about additional components of a biocidal product or a biocidal product family (e.g. solvent, emulsifier, etc.).

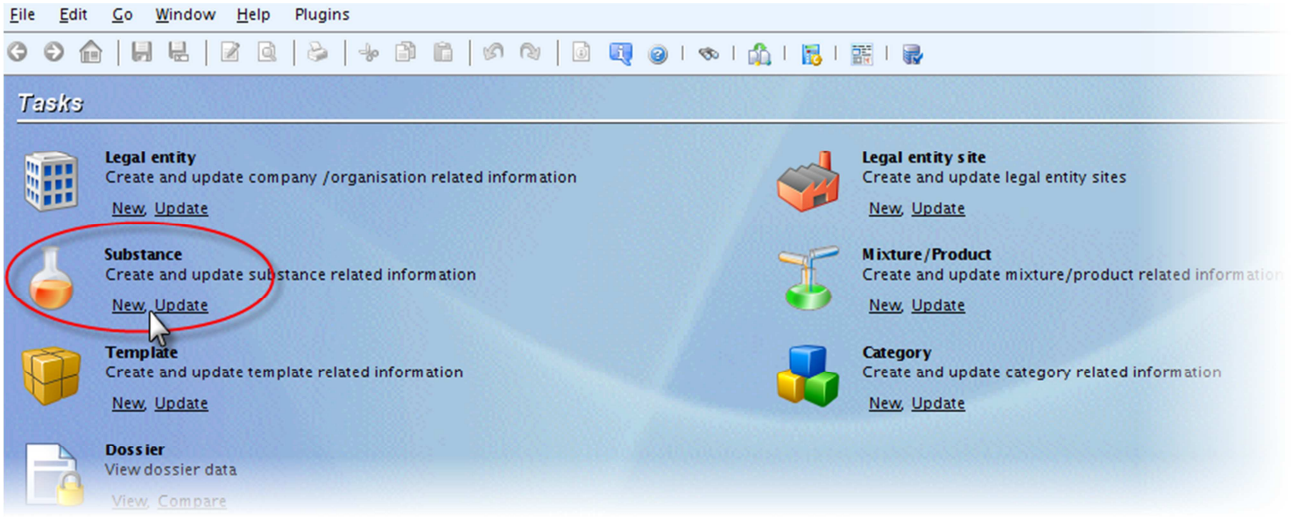
Information requirements will vary depending on the application type you are submitting, e.g. approval of an active substance, inclusion of an active substance in Annex I of the BPR, etc. To assist you in fulfilling the specific information requirements for your application type, ECHA has provided several guidance documents. In addition, please consult the appropriate Biocides Submission Manual for more information on how to submit a specific application.

## Step 1: Create a 'Substance' dataset and link it to a Legal entity

In the 'Tasks' pane of the IUCLID 5 homepage ( ), create a 'Substance' dataset by clicking on 'New' next to the Substance ( ) icon (Figure 6), and follow the prompts to i) enter the name of the chemical, ii) assign a 'Legal entity[2]' using the black arrow ( ), and iii) click 'Finish'. Once you click 'Finish', you will be directed to the Navigation window and the 'Substance identification' page of the newly created 'Substance' dataset (Figure 7).

If you have not created an official Legal entity to assign to the dataset, you can create one either at the IUCLID website: http://iuclid.eu, or via REACH-IT which is accessible from the ECHA website (http://echa.europa.eu). For more information on how to create an official Legal entity, please refer to BSM 2: Using R4BP 3 for biocide applications.

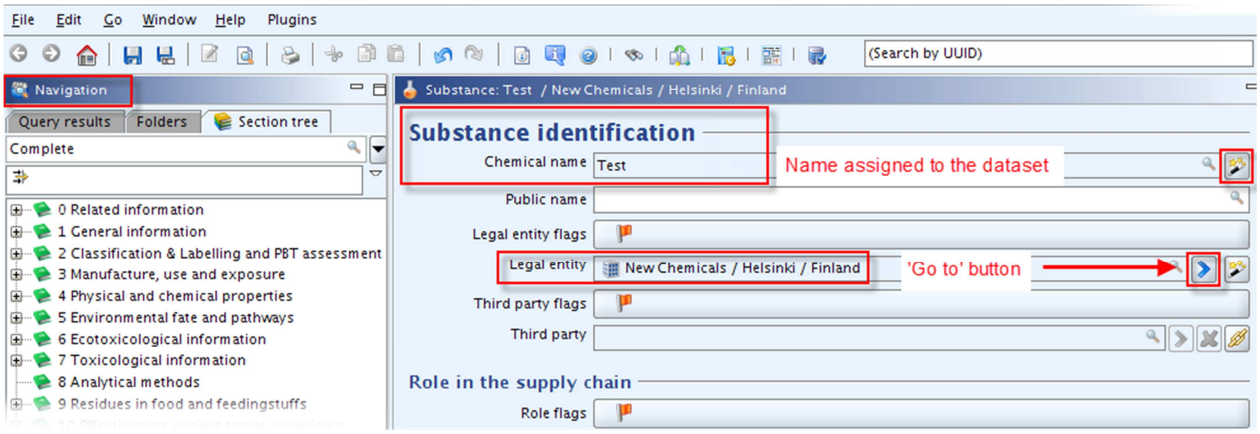
**Figure 6: Creating a 'Substance' dataset**




Upon creating a new 'Substance' dataset, the 'Substance identification' page will automatically open. On this page, you can see the name given to the 'Substance' dataset (Figure 7). You can change the name, if necessary, by clicking the Wizard button ( ). The 'Substance identification' page also allows you to confirm whether the correct Legal entity is linked or not (Figure 7). Full details related to the Legal entity can be viewed by clicking on the 'Go to' button ( ) (Figure 7).

[2] A Legal entity ( ) is either a company/organisation or a natural person capable of and having the right to engage into contracts or commercial transactions e.g. authorisation holder, manufacturer. In IUCLID 5, a Legal entity is an element used to store and manage Legal entity information i.e. the name, contact details, any Legal entity specific identification numbers, etc.

**Figure 7: Identifying the Legal entity assigned to the 'Substance' dataset**




If you have already created a 'Substance' dataset and you wish to update the information within it at any stage, click 'Update' next to the Substance ( ) icon (Figure 6). You will then need to search for the correct dataset, double click on the dataset title, and click the 'Section tree' tab to view all of the sections (Figure 8).

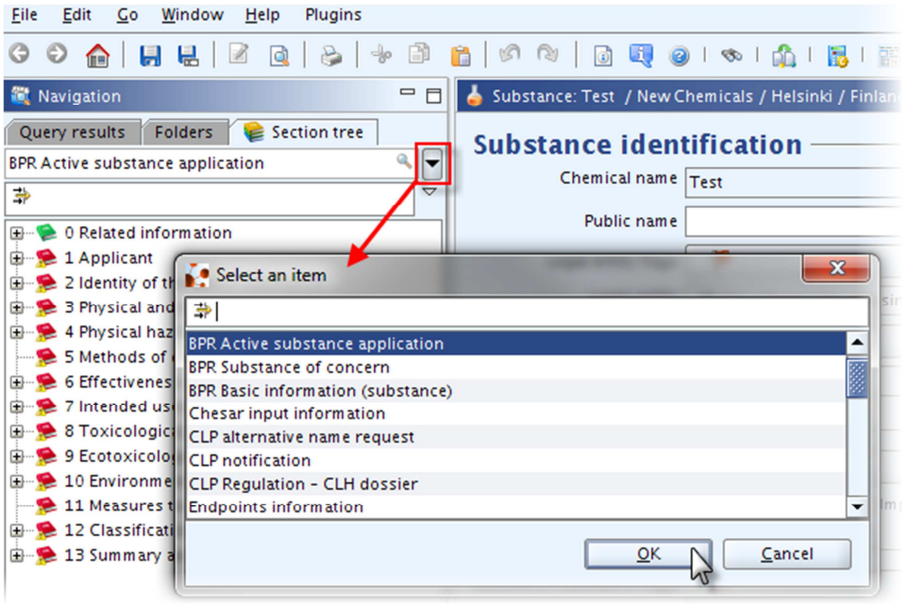
**Figure 8: Updating a 'Substance' dataset**


## Step 2: Select the dataset template

Select the main dataset template (section 2.1), i.e. 'BPR active substance application', from the drop-down menu using the black arrow ( ) under the 'Section tree' tab (Figure 9). By selecting 'Expand all', you will see all of the sections contained in the template (Figure 5).

If you are creating a 'Substance' dataset for additional components of a biocidal product/family or representative biocidal product (e.g. a solvent) select the supplementary template 'BPR Basic information (substance)', or 'BPR Substance of concern'.

**Figure 9: Selecting the dataset template**

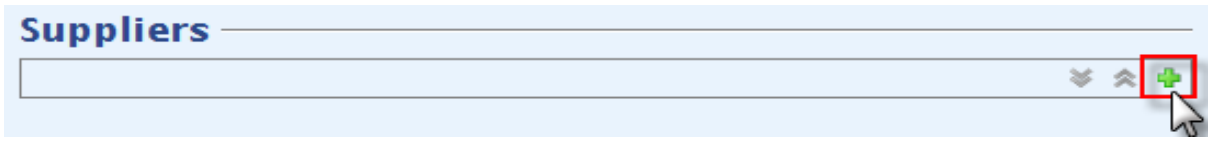



## Step 3: Enter the 'Applicant' details

### IUCLID section 1.3 'Active substance manufacturer'

IUCLID section 1.3 contains the identity of the active substance manufacturer, importer and/or formulator. It is recommended that you include the name of the active substance manufacturer, importer and/or formulator in IUCLID section 1.3 even if it is the same as the applicant, i.e. the Legal entity that will submit the dossier via R4BP 3. To indicate the name of the manufacturer, importer and/or formulator, start by creating a 'Suppliers' block with the 'plus' function ( ) (Figure 10).

**Figure 10: Creating a 'Suppliers' block**



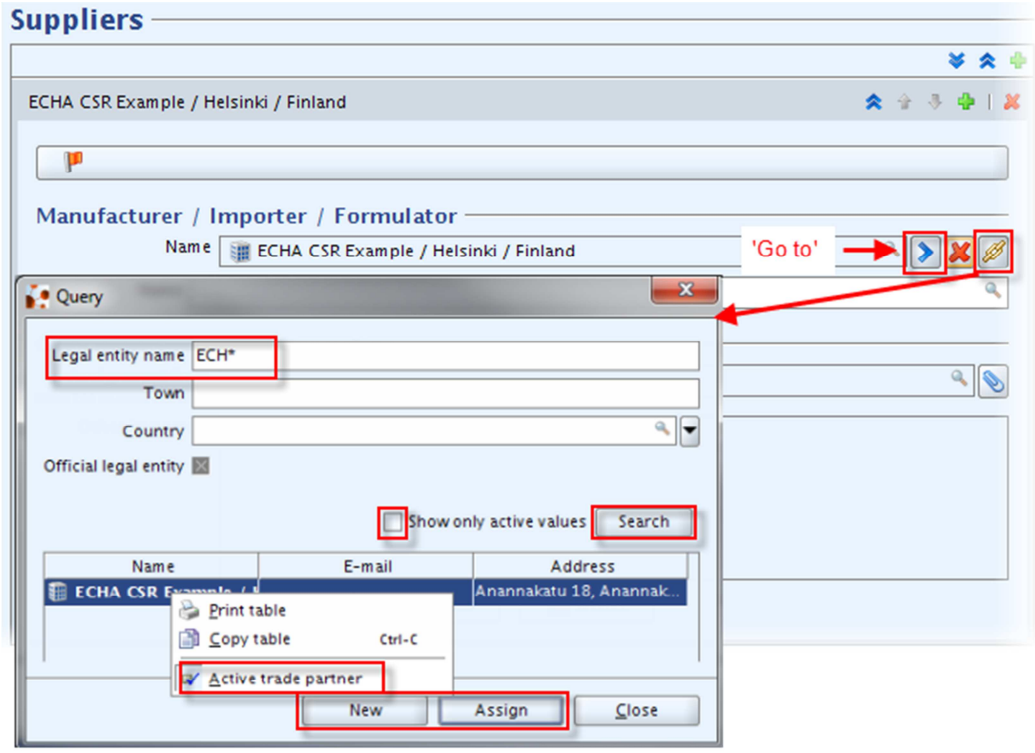

When the active substance is included in a biocidal product, as of the date of the authorisation of the biocidal product, information on the biocidal product will be disseminated on the ECHA website. This includes the manufacturers of the active substances, as part of the Summary of product characteristics.

Once you have created a suppliers block in IUCLID section 1.3, click the link button ( ) next to the 'Name' field, enter some search criteria (e.g. Legal entity name) in the appearing 'Query' window and then click 'Search' (Figure 11). It may be the case that the manufacturer has not been entered into your database. In this case, click the 'New' button in the 'Query' window (Figure 11), to launch the Legal Entity assistant (Figure 12).

Make sure that the 'Show only active values' checkbox is **not** ticked when performing the search (Figure 11).

The legal entity of the manufacturer has to be 'active' before it can be assigned. A legal entity can be activated by right-clicking on it in the search result list and selecting 'Active trade partner' (Figure 11).

**Figure 11: Specifying a manufacturer**




The Legal entity assistant will prompt you to enter the name of the Legal entity, then click 'Finish' (Figure 12). Next, click on the 'Go to' button ( ) in IUCLID section 1.3 (Figure 11) and enter the details of the ‚anufacturer's Legal entity in the 'Contact information' tab, i.e. the contact address and contact persons details (Figure 13).

**Figure 12: Legal entity assistant**

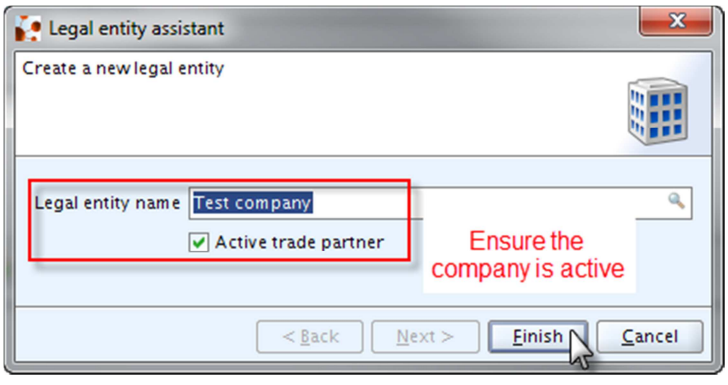
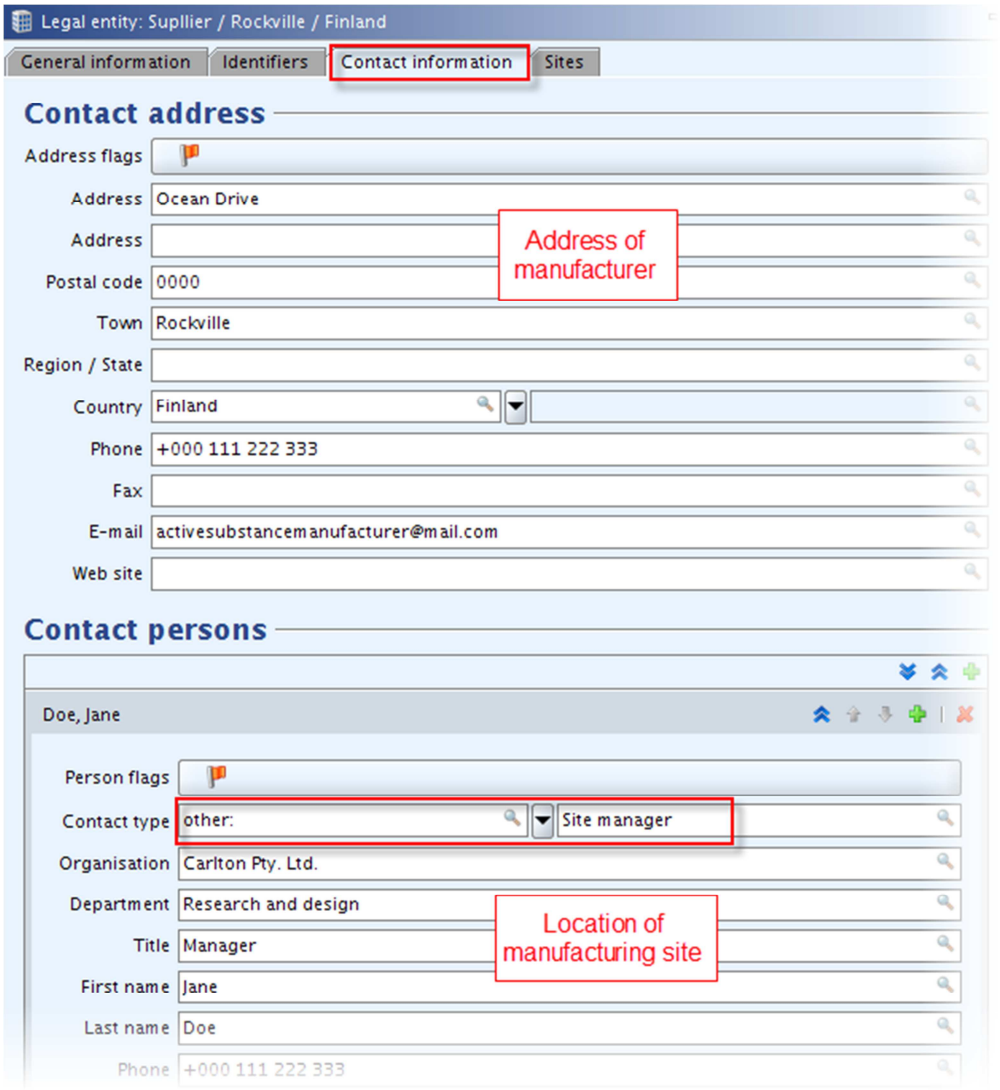


**Figure 13: Updating Legal entity details**

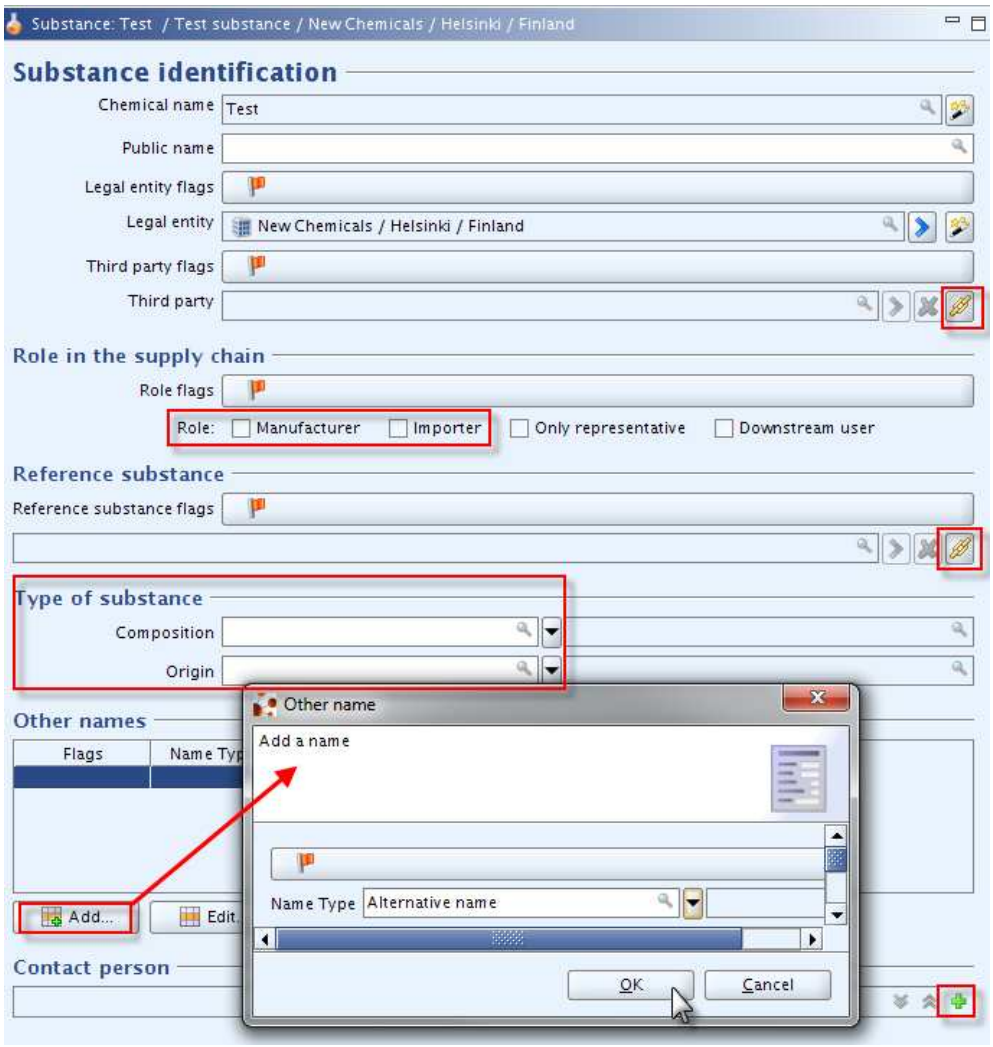



## Step 4: Identify the active substance

### IUCLID section 2.1 'Common name and synonyms'

This section allows the identification of the active substance, by filling in pre-defined fields. The fields indicate the name of the active substance, the Legal entity assigned to the dataset (e.g. the prospective authorisation holder, i.e. asset owner), the role they play in the supply chain, i.e. either manufacturer or importer (or both), along with contact details of the applicant. The name of the active substance and the Legal entity, are defined during Step 1 but they can be changed by clicking on the Wizard button ( ). Fields of prime importance are indicated in red in Figure 14 and are explained below the figure.

**Figure 14: Section 2.1 'Common name and synonyms'**




### Third party (representative)

If relevant, indicate the name of a representative, e.g. a consultancy company working on behalf of the prospective authorisation holder. Achieve this by clicking the link button ( ), enter some search criteria (e.g. Legal entity name) in the appearing 'Query' window and then click 'Search' (Figure 11). It may be the case that the representative has not been entered into your database. In this case, click 'New' button in the 'Query' window (Figure 11), to launch the Legal Entity assistant (Figure 12).

### Role in the supply chain

Select the role you play in the supply chain, i.e. manufacturer or importer (or both). Note that 'Only representative' and 'Downstream user' are REACH terms and are not relevant for BPR dossiers or applications.

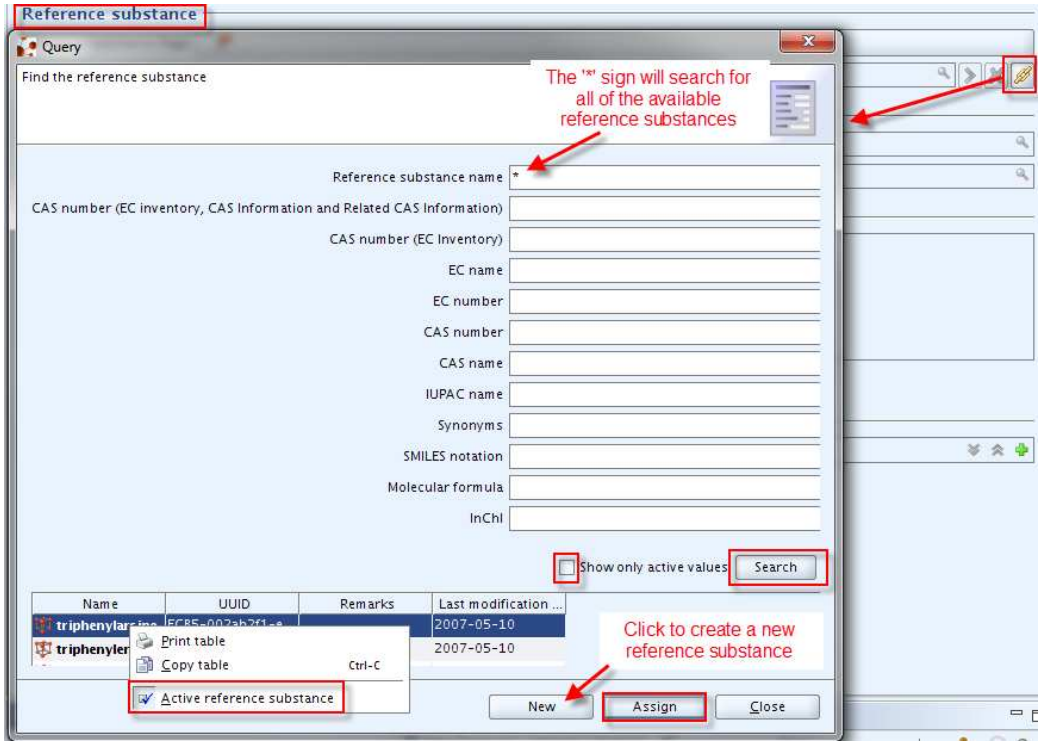
### Reference substance

The reference substance for the 'Substance' dataset must be established by using the link button ( ) in the 'Reference substance' section (Figure 14). In the appearing 'Query' window, enter some search criteria and then click 'Search'. From the search results, you can 'Assign' a reference substance to the 'Substance' dataset (Figure 15). It may be that the reference substance has not been entered into your database. In this case, click 'New' to launch the 'Reference substance assistant' (Figure 16).

Make sure that the 'Show only active values' checkbox is **not** ticked when performing the search (Figure 15).

The reference substance has to be 'active' before it can be assigned. A reference substance can be activated by right clicking it in the search result list and selecting 'Active reference substance' (Figure 15).

**Figure 15: Linking a 'Reference substance' to the 'Substance' dataset**




The 'Reference substance assistant' will prompt you to enter the name of the reference substance, and click 'Finish' (Figure 16). Then, click on the 'Go to' button ( ) in IUCLID section 2.1 and manually enter the details of the reference substance (Figure 17).

**Figure 16: Reference substance assistant**

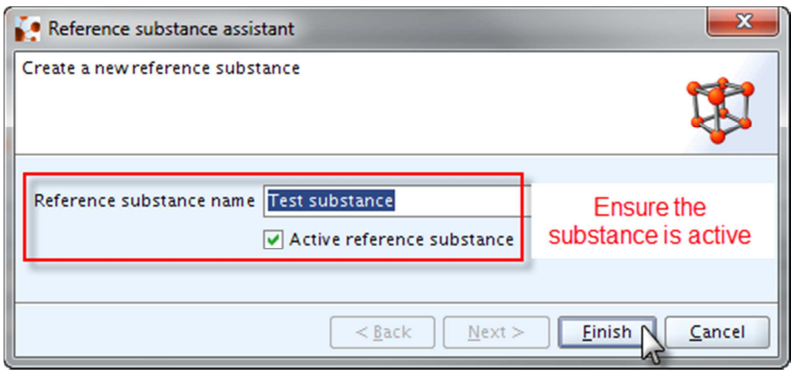
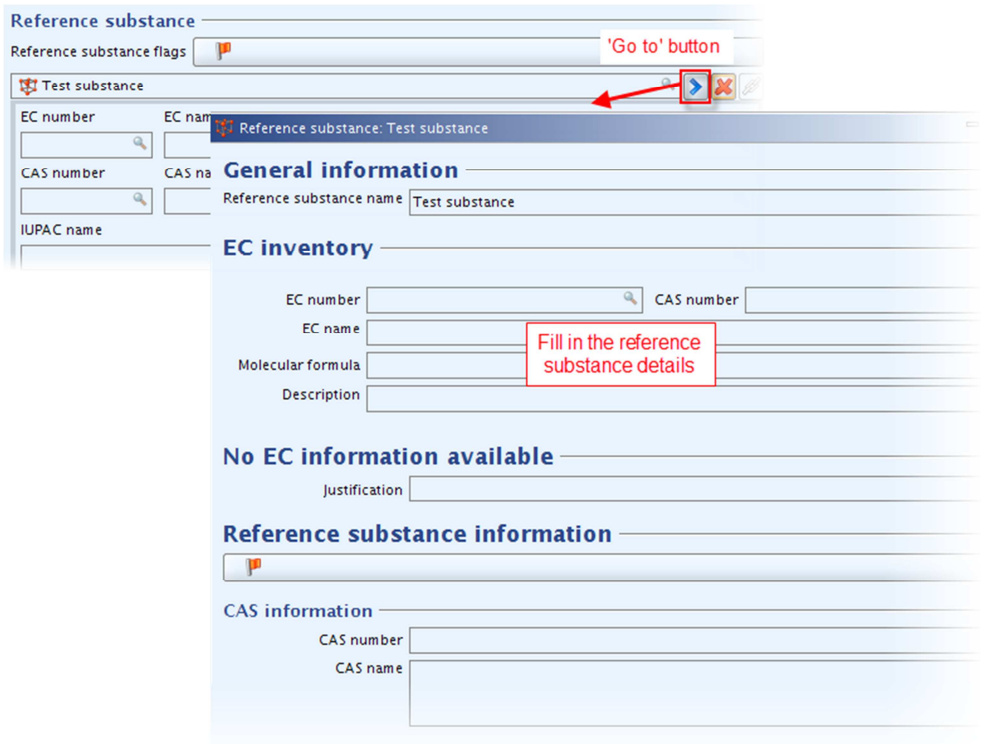


**Figure 17: Updating the details of the 'Reference substance'**




### Type of substance

Select the composition type (e.g. mono constituent, multi constituent, etc.) and origin (e.g. element, inorganic, etc.) of the substance from the pre-defined picklist options using the drop-down menu button ( , Figure 14).

### Other names

Enter all the trade (commercial) names and alternative names by which the active substance is known. For each entry, add a new row in the table by clicking on the Add button ( ). Select the type of name using the drop-down menu button ( , Figure 14); alternative name, trade name, or, if none of the pre-defined items apply, select 'other:' and fill in the type of name in the adjacent free text field. Enter the name of the active substance, and then select the country in which the name is associated with the active substance. You can also add any remark about the name that might be required.

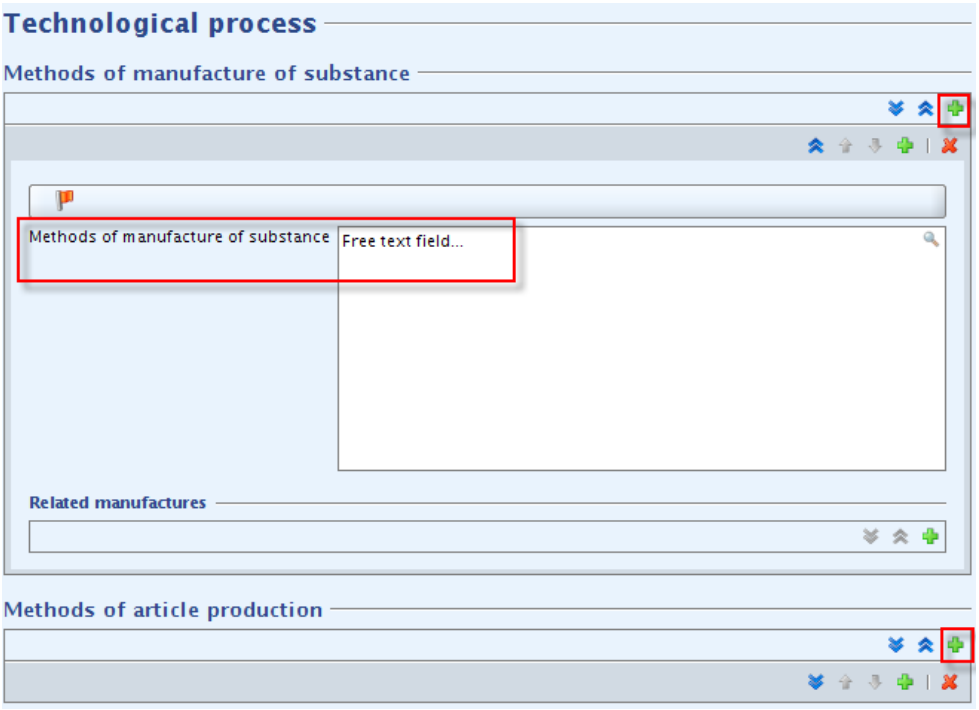
### Contact person

Create a block using the 'plus' function ( ) to add the details of the contact person (Figure 14). This person may be contacted e.g. to provide assistance or ask about the information submitted.

## IUCLID section 2.8 'Method of manufacture'

This section allows you to enter information on the technological processes involved in the manufacture of the active substance or article production. Start by creating blocks with the 'plus' function ( ) and then type in the appropriate information in the free text fields (Figure 18).

**Figure 18: Entering information on the technological processes**




Where multiple blocks are created, ensure that every block is fully completed. Delete any unwanted blocks using the red cross ( ).

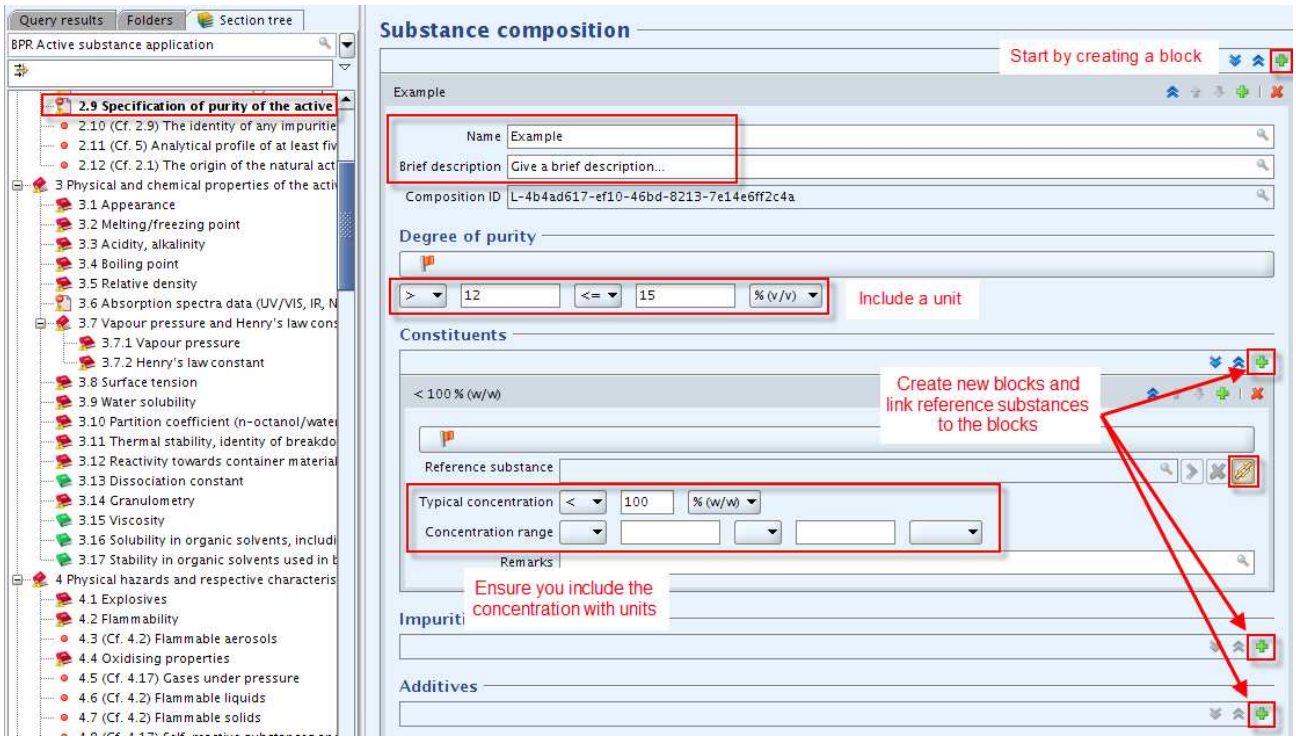
## IUCLID section 2.9 'Specification of purity'

Its composition, constituents, impurities and additives define a substance. This section allows the input of multiple compositions of the substance, e.g. to allow different profiles of impurities provided this does not change the identification of the substance.

Start by creating a new 'Substance composition' block with the 'plus' function ( ) (you can create more than one if required) in section 2.9 'Specification of purity of the active substance as manufactured' (Figure 19). Enter the name, a brief description and the degree of purity of the active substance in the fields provided. Create a block under the constituents section and link ( ) all the constituents of your active substance to reference substances (Figure 19). If you have any impurities or additives, create a block for each and fill in the information, and then link reference substances to the impurities and/or additives by using the link button ( ).

The steps to follow when linking a reference substance are the same as those outlined in IUCLID section 2.1, Reference substance.

**Figure 19: Entering the substance composition**




## Step 5: Complete the dataset information requirements

You are now ready to enter the remaining relevant data, to fulfil the specific information requirements for your application type. As the endpoint sections are common to both 'Substance' datasets and 'Mixture/Product' datasets, how to complete endpoint sections (IUCLID sections 3-13) is described in chapters 5 and 6.

For further assistance on entering information into your IUCLID 5 dataset, please refer to chapter 5 ('General IUCLID endpoint sections').

ECHA has provided guidance documents to assist you in fulfilling the information requirements - Guidance documents.

## Step 6: Create a dossier

Once you have filled in all of the required 'Substance' dataset sections in the 'BPR Active substance application' template, you must also create a dataset for the biocidal product/family or representative biocidal product, using the template 'BPR Biocidal product authorisation' (chapter 4). Once both datasets are complete refer to chapter 7 ('How to create a dossier').

# 4. Preparing a dataset for a biocidal product

This chapter outlines how to prepare a dataset containing information for a either a single biocidal product or a biocidal product family. Note that a biocidal product dataset using the template 'BPR Biocidal product authorisation' must always be created, regardless of the application type, e.g. if you are going to create an 'BPR Active substance application' dossier,

the biocidal product dataset is used to contain the information for the representative biocidal product, see IUCLID section 2.3 'Biocidal product composition'.

To create a valid dossier, the 'Mixture/Product' dataset must always be linked to a 'Substance' dataset with the 'BPR Active substance application' template (Figure 1).

Additional 'Mixture/Product' datasets, using the supplementary template 'BPR Basic information (mixture)' can be created in a similar manner but may contain different sections. Use this supplementary template to create datasets containing information about additional components of a biocidal product/family or representative biocidal product (e.g. solvent, emulsifier, etc.).

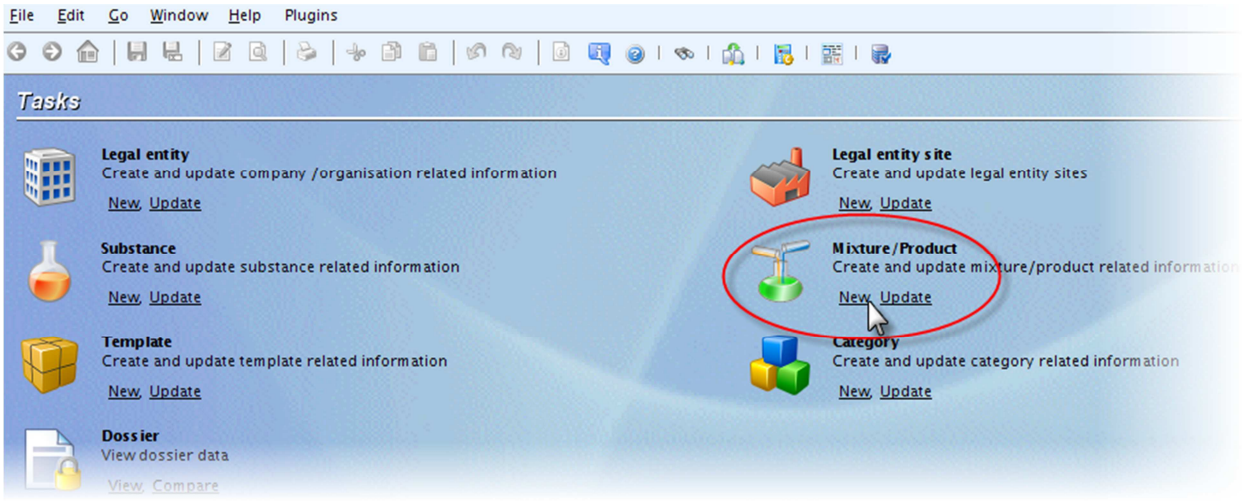
Information requirements will vary depending on the application type you are submitting, e.g. applications for national authorisation, simplified authorisation, etc. To assist you in fulfilling the specific information requirements for your application type, ECHA has provided several guidance documents. In addition, please consult the appropriate Biocides Submission Manual for more information on how to submit a specific application.

## Step 1: Create a dataset for a biocidal product and link it to a Legal entity

In the 'Tasks' pane of the IUCLID 5 homepage ( ), create a 'Mixture/Product' dataset by clicking 'New' next to the Mixture/Product ( ) icon (Figure 20), and follow the prompt to i) enter the biocidal product name in the field 'Mixture/product name', ii) assign a 'Legal entity[3]' using the black arrow ( ), and iii) click 'Finish'. Once you click 'Finish', you will be directed to the Navigation window and the 'Mixture/Product identification' page of the newly created 'Mixture/Product' dataset (Figure 21).

If you have not created an official Legal entity to assign to the dataset, you can create one either at the IUCLID website: http://iuclid.eu, or via REACH-IT, accessible from the ECHA website (http://echa.europa.eu). For more information on how to create an official Legal entity, please refer to BSM 2: Using R4BP 3 for biocide applications.

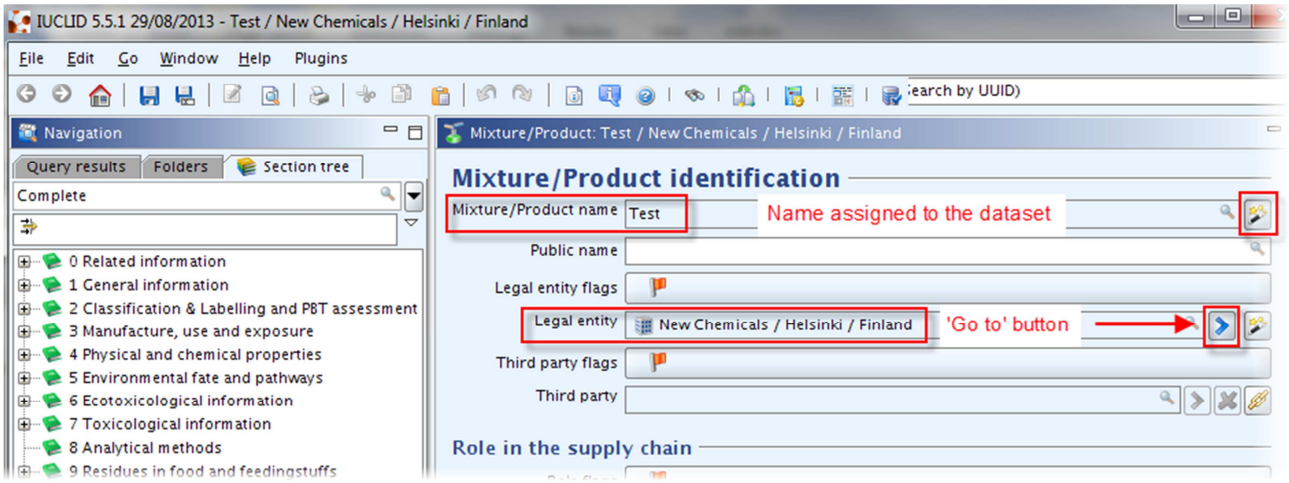
**Figure 20: Creating a dataset for a biocidal product**




[3] A Legal entity ( ) is either a company/organisation or a natural person capable of and having the right to engage into contracts or commercial transactions e.g. authorisation holder, manufacturer. In IUCLID 5, a Legal entity is an element used to store and manage Legal entity information i.e. the name, contact details, any Legal entity specific identification numbers, etc.

Similar to the creation of your 'Substance' dataset, from the automatically opened 'Mixture/Product identification' page you can see the name given to the 'Mixture/Product' dataset. You can change the name, if necessary, by clicking the Wizard button ( ). The 'Mixture/Product identification' page also allows you to confirm the correct Legal entity is linked (Figure 21). Full details related to the Legal entity can be viewed by clicking on the 'Go to' button ( ) (Figure 21).

**Figure 21: Identifying the Legal entity assigned to the 'Mixture/Product' dataset**



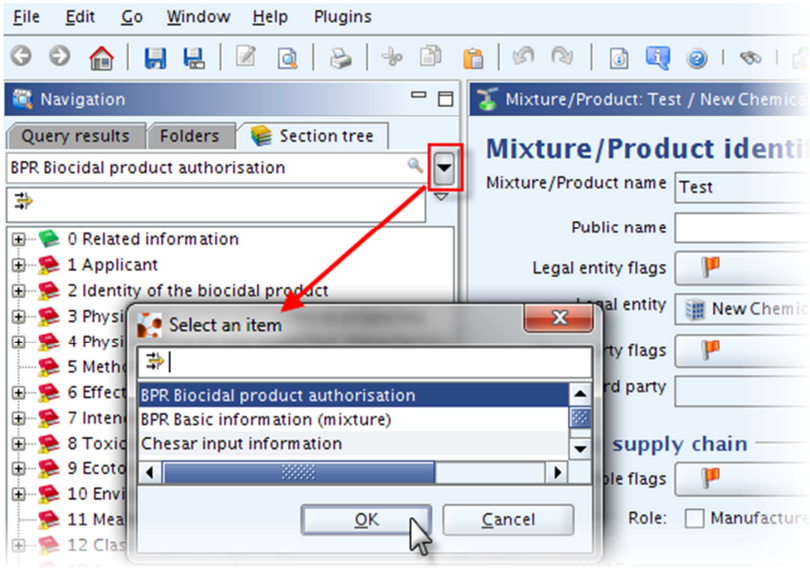

If you have already created a 'Mixture/Product' dataset and you wish to update the information within it at any stage, click 'Update' next to the Mixture/Product ( ) icon (Figure 20). You will then need to search for the correct dataset, double click on the dataset title, and click the 'Section tree' tab to view all of the sections (Figure 8).

## Step 2: Select the dataset template

Select the main dataset template (section 2.1), i.e. 'BPR Biocidal product authorisation application', from the drop-down menu using the black arrow ( ) under the 'Section tree' tab (Figure 22). By selecting 'Expand all', you will see all of the sections contained in the template (Figure 5).

If you are creating a 'Mixture/Product' dataset for additional components of the biocidal product/family or representative biocidal product (e.g. a solvent) select the supplementary template 'BPR Basic information (mixture)'.

**Figure 22: Selecting the dataset template**




## Step 3: Enter 'Applicant' details

### IUCLID section 1.3 'Biocidal product manufacturer'

IUCLID section 1.3 contains the identity of the biocidal product manufacturer, importer and/or formulator. It is recommended that you include the name of the biocidal product manufacturer, importer and/or formulator in IUCLID section 1.3 even if it is the same as the applicant, i.e. the Legal entity that will submit the dossier via R4BP 3. To indicate the name of the manufacturer, importer and/or formulator, start by creating a 'Suppliers' block with the 'plus' function ( ) (Figure 10).

As of the date of the authorisation of the biocidal product, information on the biocidal product will be disseminated on the ECHA website. This includes the manufacturers of the active substances and biocidal products, as part of the Summary of Product Characteristics.

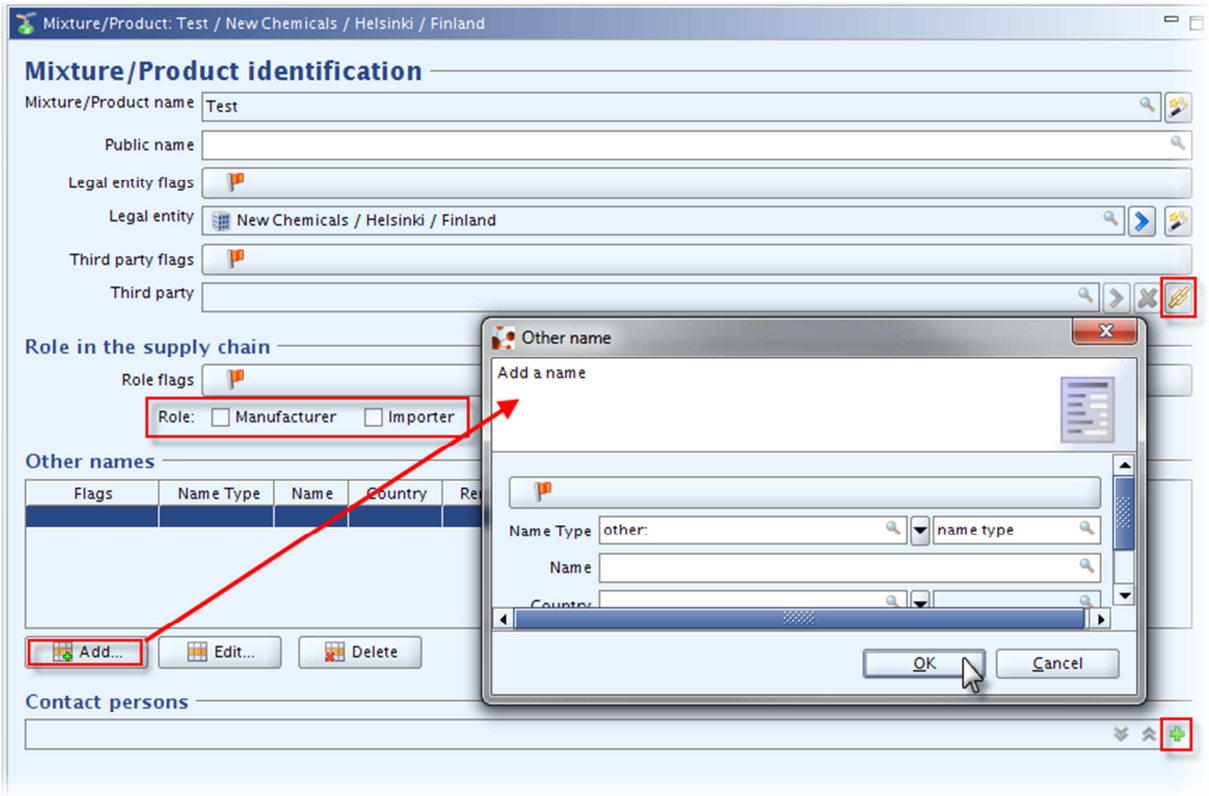
Once you have created a suppliers block in IUCLID section 1.3, click the link button ( ) next to the 'Name' field, enter some search criteria (e.g. Legal entity name) in the appearing 'Query' window and then click 'Search' (Figure 11). It may be the case that the manufacturer has not been entered into your database. In this case, click 'New' button in the 'Query' window (Figure 11), to launch the Legal Entity assistant (Figure 12). How to use the Legal entity assistant is explained in chapter 3, step 3 ('Enter the 'Applicants' details').

## Step 4: Identify the biocidal product

### IUCLID section 2.1 'Trade name or proposed trade name'

This section allows the identification of the biocidal product, by filling in the pre-defined fields. The fields indicate the name of the biocidal product, the Legal entity assigned to the dataset (e.g. the prospective authorisation holder, i.e. asset owner), the role they play in the supply chain, i.e. manufacturer or importer (or both), along with contact details for the applicant. The name of the biocidal product and the Legal entity, are defined during Step 1 but they can be changed by clicking on the Wizard button ( ). Fields of prime importance are indicated in red in Figure 23 and are explained below the figure.

**Figure 23: Section 2.1 'Trade name or proposed trade name'**




## Third party (representative)

If relevant, indicate the name of a representative, e.g. a consultancy company working on behalf of the prospective authorisation holder. Achieve this by clicking the link button ( ), enter some search criteria (e.g. Legal entity name) in the appearing 'Query' window and then click 'Search' (Figure 11). It may be the case that the representative has not been entered into your database. In this case, click the 'New' button in the 'Query' window (Figure 11), to launch the Legal Entity assistant (Figure 12).

## Role in the supply chain

Select the role you play in the supply chain, i.e. manufacturer or importer (or both). Note that 'Only representative' and 'Downstream user' are REACH terms and are not relevant for BPR dossiers or applications.

## Other names

Enter all the trade (commercial) names and alternative names by which the biocidal product is known. For each entry, add a new row in the table by clicking on the Add button ( Add... ). Select the type of name using the drop-down menu button ( , Figure 23); alternative name, trade name, or, if none of the pre-defined items apply, select 'other:' and fill in the type of name in the adjacent free text field. Enter the name of the biocidal product, and then select the country in which the name is associated with the biocidal product. You can also add any remark about the name that might be required.

## Contact person

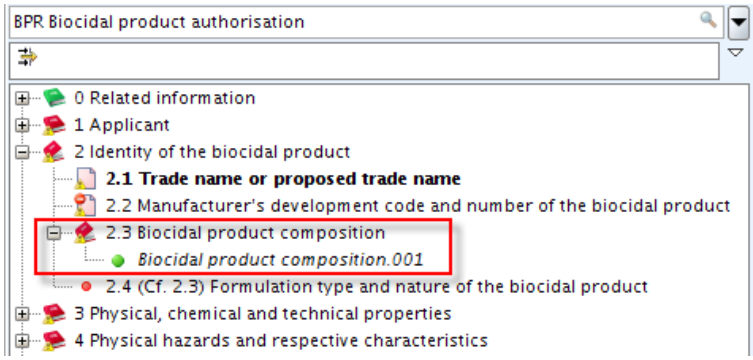
Create a block using the 'plus' function ( ) to add details of a contact person (Figure 23). This person may be contacted e.g. to provide assistance or ask about the information submitted.

## IUCLID section 2.3 'Biocidal product composition'

A biocidal product is defined by its name, formulation type and its exact composition percentage. A biocidal product family is similarly defined to include the individual products within it and the range of concentration percentages. This section details how to enter product composition data for a single biocidal product or multiple compositions for a biocidal product family.

**For a single biocidal product:** Start by right-clicking on IUCLID section 2.3 'Biocidal product composition', and select 'New endpoint study record' ( ) (Figure 24). Only one endpoint study record ( ) should be created and completed.

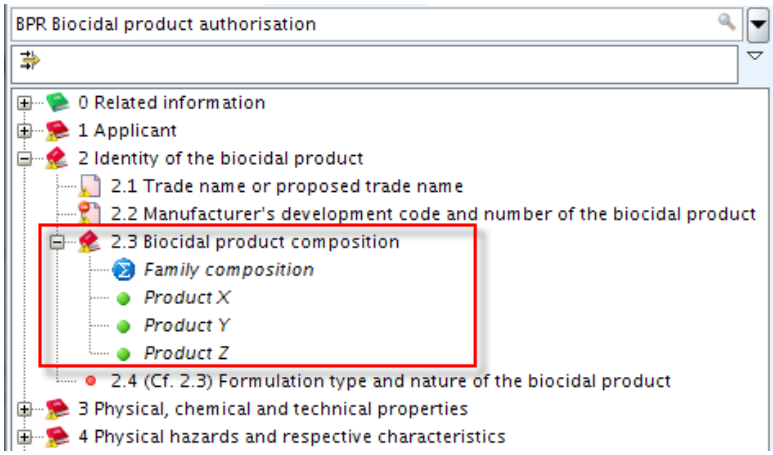
**Figure 24: Endpoint study record for a biocidal product**




**For a biocidal product family:** Start by right clicking on IUCLID section 2.3 'Biocidal product composition', and select 'New endpoint study summary' ( ). Only one study summary can be created and it is used to enter the generic composition data for the biocidal product family.

You will then need to create and complete an endpoint study record ( ) for each product within the family. Figure 25 shows an example of how section 2.3 should look for a biocidal product family containing three products.

**Figure 25: Endpoint study summary with multiple records for a biocidal product family**




Provide suitable labels for your study records/summary as this will assist in the completion of other sections, for example, if you have different uses for the biocidal products (IUCLID section 7.1 'Fields of use…') or different packaging types for the

biocidal products (IUCLID section 12.3 'Packaging').

Section 2.3 'Product composition': If you create an 'Endpoint summary' or you include more than one active substance in the biocidal product composition, e.g. include more than one 'Endpoint Study record' each with an active substance, you will be unable to make a 'BPR Active substance application' dossier.

Once you have created a 'study summary' or 'study record', you will be able to enter information in the fields provided for the following (Figure 26):

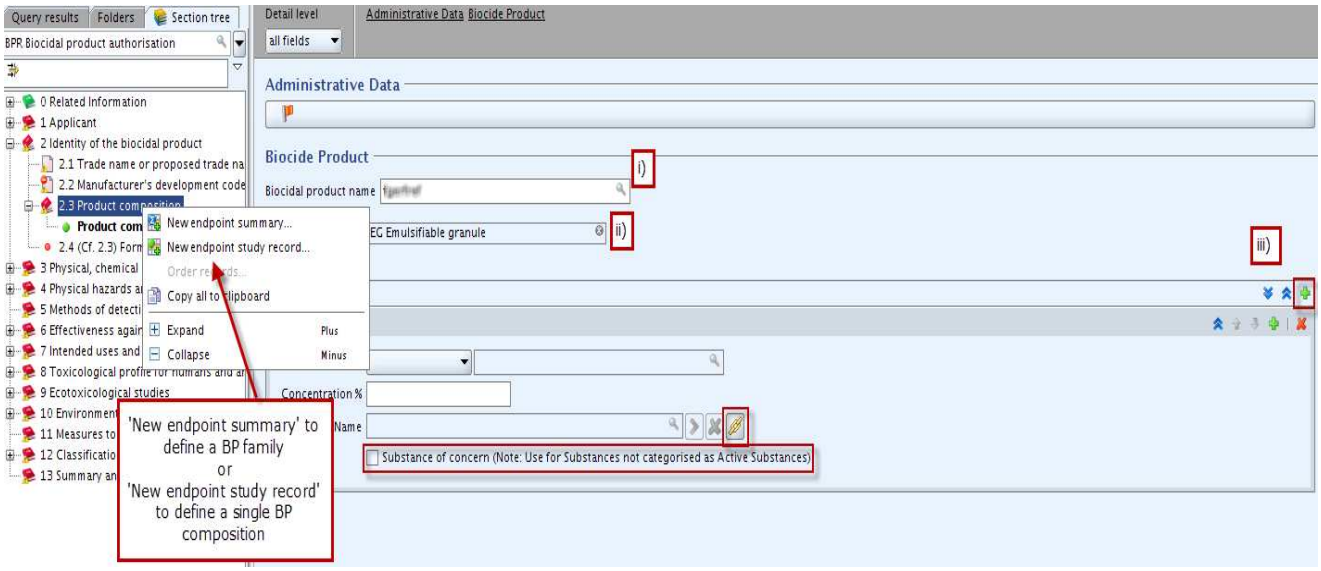
i) the biocidal product name/BP family name,

ii) the formulation types from the drop-down menu ( ) and click 'OK', and

iii) all of the 'Composition' components in composition blocks.

Create composition blocks by clicking the green plus sign ( ) (Figure 26). You will need to create an individual block for each component of your biocidal product. Within the block, indicate the biocidal product function (e.g. active substance, solvent, emulsifier, etc.) using the drop-down menu ( ), enter the exact concentration % (study record) or concentration % range (study summary), and then link ( ) the block to a Substance or 'Mixture/Product' dataset (Figure 26).

**Figure 26: Defining a biocidal product composition**




Clicking the link button ( ) opens a 'Query' window, in which you can specify the query result type from the drop-down menu ( ). Then, specify some search criteria and click 'Search'. From the search results, you can 'Assign' or link a dataset to the 'Mixture/Product' dataset. By linking the datasets together, a dossier can be created from the 'Mixture/Product' dataset and include both datasets.

Lastly, indicate if any of the substances in the biocidal product is a 'substance of concern' (in accordance with Article 3(1)(f) of the BPR) by ticking the box below the name of the substance (Figure 26). Be sure to identify all of the components of your biocidal product in individual blocks.

If you do not have a 'Substance' dataset prepared, refer to chapter 3 ('Preparing a dataset for an active substance').

### Step 5: Complete the dataset information requirements

You are now ready to enter the remaining relevant data, to fulfil the specific information requirements for your application type. As the endpoint sections are common to both 'Substance' datasets and 'Mixture/Product' datasets, how to complete endpoint sections (IUCLID sections 3-13) is described in chapters 5 and 6.

For further assistance on entering information into your IUCLID 5 dataset, please refer to chapter 5 ('General IUCLID endpoint sections').

ECHA has provided guidance documents to assist you in fulfilling the information requirements - Guidance documents.

### Step 6: Create a dossier

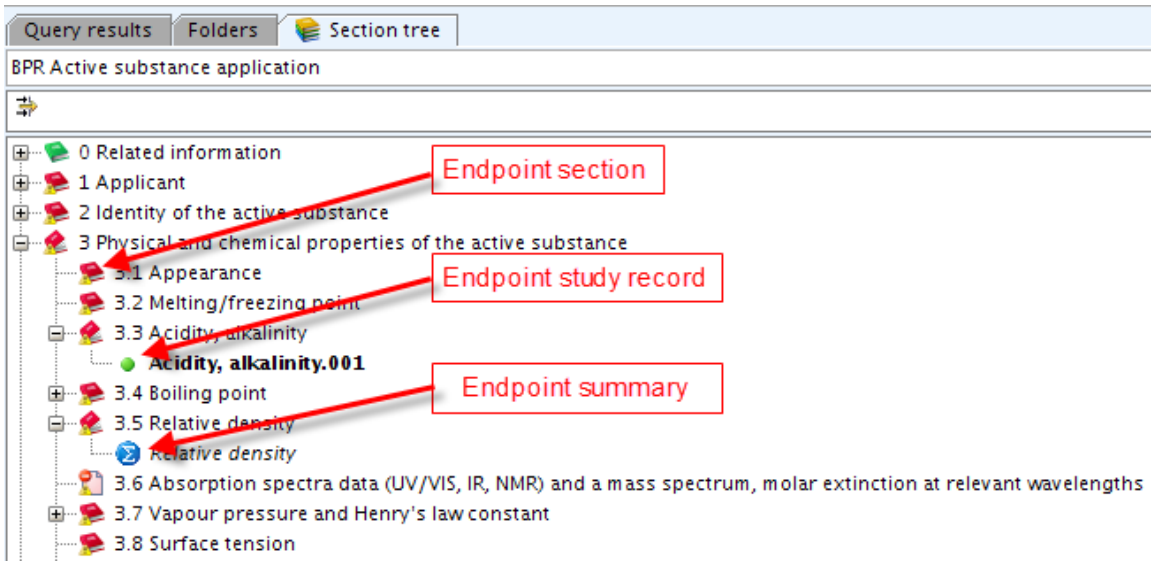
Once you have filled in all of the required 'Mixture/Product' dataset sections using the template 'BPR Biocidal product application', and linked a fully completed 'Substance' dataset using the template 'BPR Active substance application' (chapter 3) in section 2.3 'Product composition', you can create a valid dossier. For detailed instructions on how to create a dossier from the 'Mixture/Product' dataset, please refer to chapter 7 ('How to create a dossier').

## 5. General IUCLID endpoint sections

Endpoint sections (IUCLID sections 3–13) comprise of either an endpoint study record ( ) or endpoint study summary ( ) (Figure 27). The endpoint sections are used to include data on endpoint studies. However, some endpoint sections (IUCLID section 7 and sections 11-13) are used to include additional information i.e. non-endpoint study related information (e.g. intended uses, classification and labelling, and protective measures).

This chapter deals with the general input of endpoint related information (including administrative data, data source, materials and methods, and results and discussion) into the endpoint sections, to fulfil the information requirements laid out in the BPR.

**Figure 27: IUCLID section tree components**




To enter the scientific data for these sections, right-click on the specific endpoint section to create a new 'endpoint summary' or 'endpoint study record'.

Endpoint summaries/study records contain numerous fields in which you need to provide data. Each field can be filled in using the drop-down menus ( ) with pre-selected responses, adding lines ( Add... ) to the existing tables, or typing text into the free text fields.

## 5.1 Endpoint study records

An endpoint study record ( ) should contain all the data available on a particular endpoint study, entered into the pertinent fields. An endpoint study record provides a template with pre-defined fields and free text prompts, to help you include key information on a study. Endpoint study records usually consist of the data entry blocks: 'Administrative data', 'Data source', 'Materials and methods', 'Test materials', and 'Results and discussion'. There are also sections for any 'Overall remarks, attachments' and the 'Applicant's summary and conclusion'. This structure is maintained for the following endpoint study records:

- Section 3 'Physical and chemical properties of the active substance' in the 'Substance' dataset, or 'Physical, chemical and technical properties' in the 'Mixture/Product' dataset.
- Section 4 'Physical hazards and respective characteristics'.
- Section 5 'Methods of detection and identification'.
- Section 6 'Effectiveness against target organisms'.
- Section 8 'Toxicological profile for humans and animals'.
- Section 9 'Ecotoxicological studies'.
- Section 10 'Environmental fate and behaviour'.

The following sections include an example of how an endpoint study record could be filled. The sections will differ depending on the endpoint section being filled in.

### 'Administrative Data' block

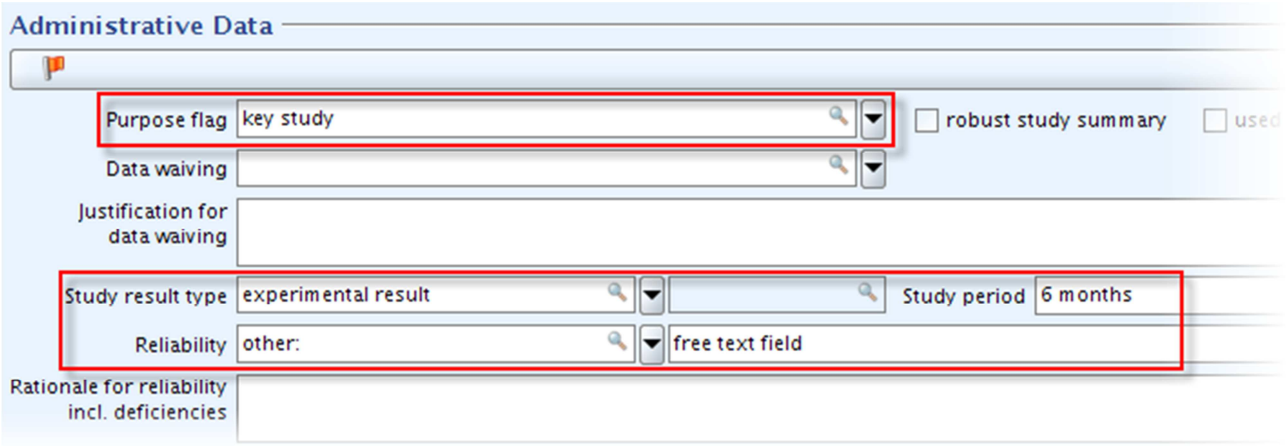
Make a selection in the field 'Purpose flag' using the drop-down menu ('key study', 'supporting study', 'weight of evidence', or 'disregarded study').

- A key study is one that has been identified as the most suitable to describe an endpoint from the perspective of quality and completeness of data.
- A supporting study provides information to support the conclusions from the key studies or the weight of evidence approach.
- A weight of evidence study record is one that comprises of several independent sources of information leading to a justification for the non-submission of a key study. A single source alone may be considered insufficient to describe an endpoint, but there may be sufficient information from the weight of evidence studies to describe the endpoint (further information in Annex IV 1.2 of the BPR).
- A disregarded study is a study that was available to the applicant, but was not taken into account in the draft risk assessment report of the substance because of lack of quality or reliability.

In addition, make a selection in the fields 'Study result type' and 'Reliability' using the drop-down menus ( ). If 'other:' is selected from any of the drop-down menus, then the adjacent field must be filled in (Figure 28).

Data waiving: if a study has been waived according to the specific rules for waiving of data requirements in Article 21 of the BPR, then this must be identified in an endpoint study record. A justification must be entered in the appropriate field. In this case, **no further information should be included** in the same endpoint study record.

**Figure 28: Administrative data fields**




### 'Data Source' block

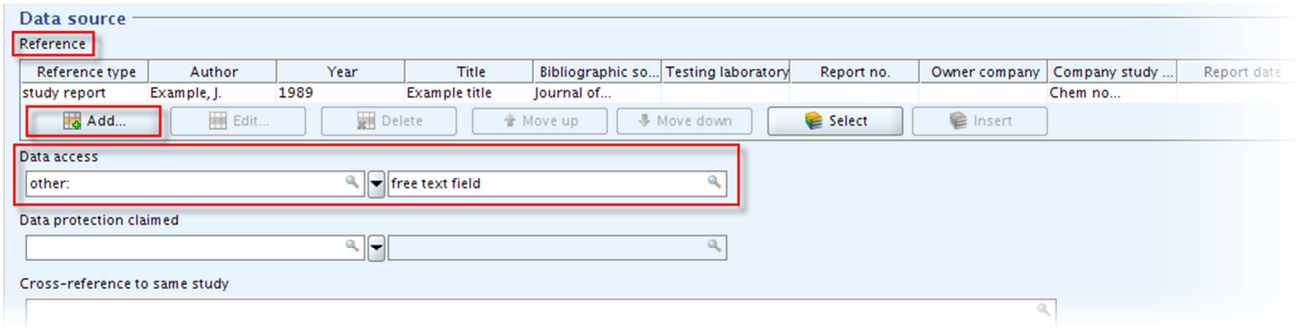
Complete the 'Reference' table as much as possible (Figure 29) by adding lines to the existing table using the 'Add' button ( Add... ). As a minimum, the following fields are required:

- Provide the 'Year' or the 'Report date'.
- If the data is from a literature source, fill in the field 'Bibliographic source'.

- If the data is from a testing laboratory, complete the field 'Testing laboratory'. Provide the full address of the testing laboratory including the city and country. In addition, provide either 'Report no.', 'Company study no.' and/or 'Title'.
- If the data is from a company, fill in either the field 'Report no.' or the field 'Company study no.'. In addition, provide information in the fields 'Author', 'Owner company' and/or 'Title'.

A selection must also be made from the drop-down menu ( ▾ ) 'Data access'. If 'other:' is selected, then the adjacent field must be filled in (Figure 29). More information on how to complete the above data fields is provided in the IUCLID 5 End User Manual (see section 2.4).

**Figure 29: Data source table**




## 'Materials and Methods' block

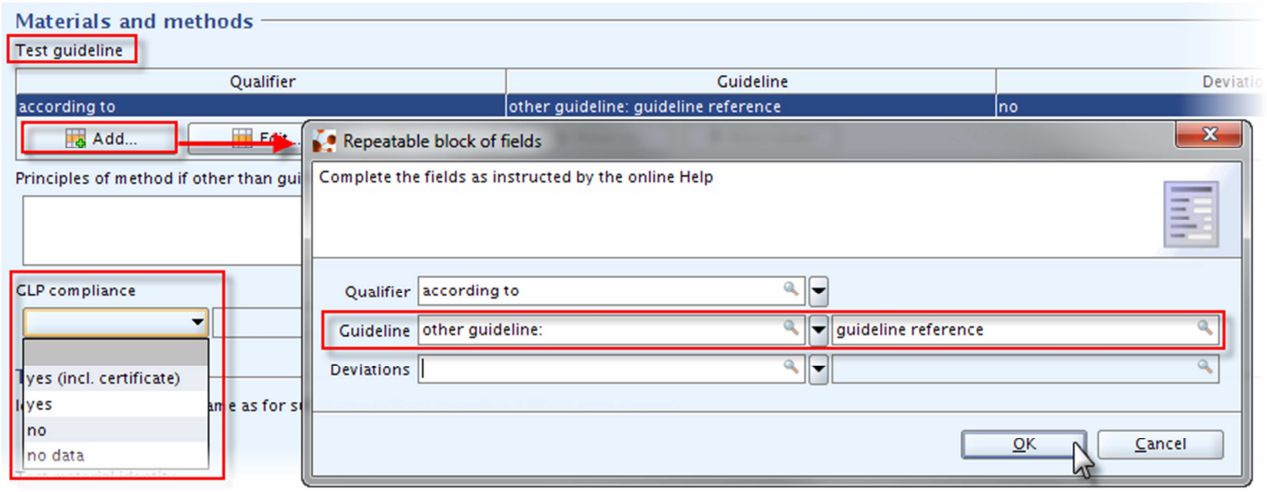
Fill in all the necessary fields, ensuring you supply information on the method of testing in the table 'Test guideline', in the field 'Guideline' (Figure 30). Achieve this by firstly adding lines to the existing tables using the 'Add' button ( Add... ). Alternatively, you may enter this information in the free text field 'Principles of method if other than guideline', since there may be cases where an alternative method has been developed, other than that in a guideline.

If 'other guideline:' is selected from the drop-down menu for the field 'Guideline', then the adjacent field must be filled in.

For endpoint study records that are indicated as 'experimental result', 'read-across based on grouping of substances (category approach)' or 'read-across from supporting substance (structural analogue or surrogate)' in the 'Study result type' field in the 'Administrative Data' block (Figure 28), indicate whether the study is GLP compliant or not. Select one of the options in the drop-down menu ( ▾ ) in the field 'GLP compliance' (Figure 30).

If 'yes (incl. certificate)' or 'yes' is selected in the field 'GLP compliance' then ensure the field 'Testing laboratory' in the 'Reference' table of the 'Data source' block is filled in (Figure 29).

**Figure 30: 'Material and Methods' block for information on testing methods**




There may be additional fields to be completed depending on the endpoint section being completed. For example, endpoint section 8.5, 'Mutagenicity', has the additional fields 'Type of genotoxicity' and 'Type of study'. Fill in the fields using the drop-down menus ( ) with pre-selected responses, or typing text into the free text fields. Note that if 'other:' is selected in any of the drop-down menus, then information must be provided in the adjacent free text field (see section 2.4).

### 'Test Materials' block

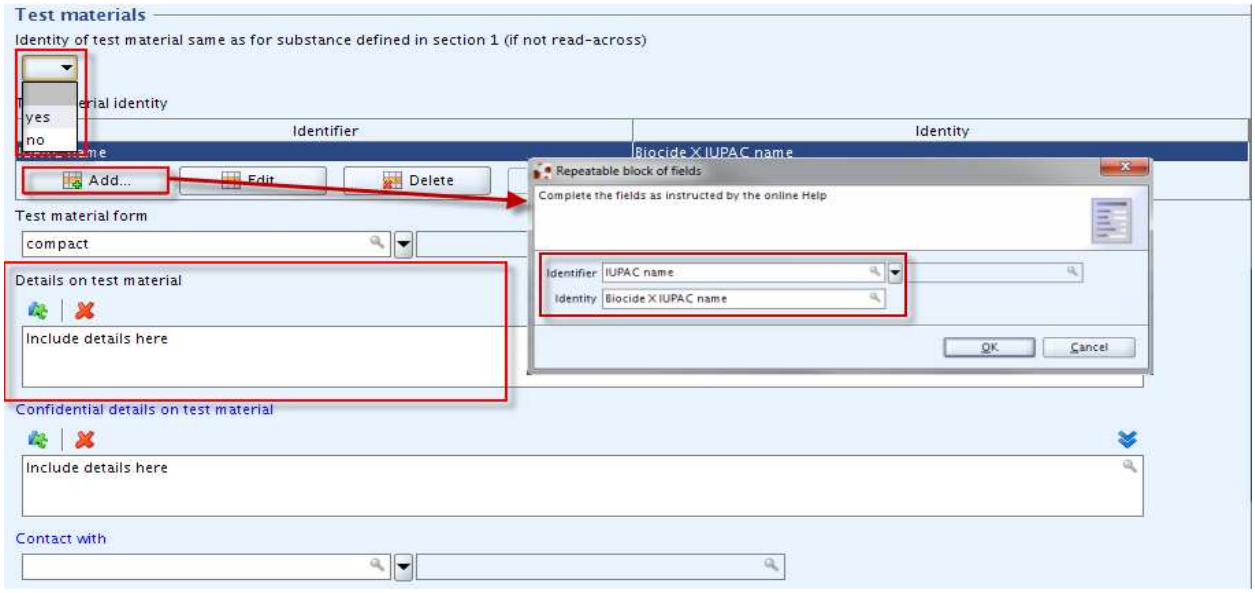
There are three alternatives to completing this section, depending on the option selected in the first field 'Identity of test material same as for substance defined in section 1 (if not read-across)' (Figure 31). The three options are:

- Select 'Yes', it is then optional to provide further information in the table 'Test material identity' and in the field 'Details on test material'.

- Select 'No', and fill in either the table 'Test material identity' (by inserting the identifier and the identity) or the field 'Details on test material' (Figure 31). To fill in the table 'Test material identity' add lines to the existing table using the 'Add' button ( Add... ), select an option from the drop-down menu ( ) in the 'Identifier' field, and then input the identity in the free text field 'Identity'.

- In rare cases where a selection would not be relevant, leave this field blank. In this case, fill in either the table 'Test material identity' ('Identifier' and 'Identity') or the field 'Details on test material'.

**Figure 31: Adding details on the test materials**




## 'Results and Discussion' block

For this block, the fields that must be filled in are specific for each endpoint. Consequently, depending on the endpoint section, the following information may have to be provided when relevant:

- specific endpoint, effect type/level, the value as well as the unit (e.g. EC50 (48h) = 0.20 mg/L),
- parameter measured (e.g. $CO_2$, DOC in the case of a screening biodegradability test) or the sex of the test animals (e.g. toxicity to reproduction),
- information on parameters applied during the testing phase (e.g. temperature, pH, concentration), and
- duration of testing.

The fields can be filled in by adding lines to the existing tables using the 'Add' button ( Add... ) and selecting the relevant option from the drop-down menu ( ), and by filling in the free text fields provided.

Information should primarily be reported in the fields defined for reporting that result. However, in rare cases where these basic fields cannot be completed, an explanatory text must be provided in the field 'Any other information on results incl. tables'. Alternatively, for the cases in which there is a 'Remarks' field at the end of the table for reporting the results, it is possible to provide the text in this field.

The field 'Any other information on results incl. tables' should be used only in exceptional cases when, for example, it is not possible to report a numerical value in the field due to difficulties during the testing.

If you add several lines to the table under 'Results and discussion' ensure you complete all of them.

Take care not to confuse the free text fields with the field named 'Overall remarks, attachments'.

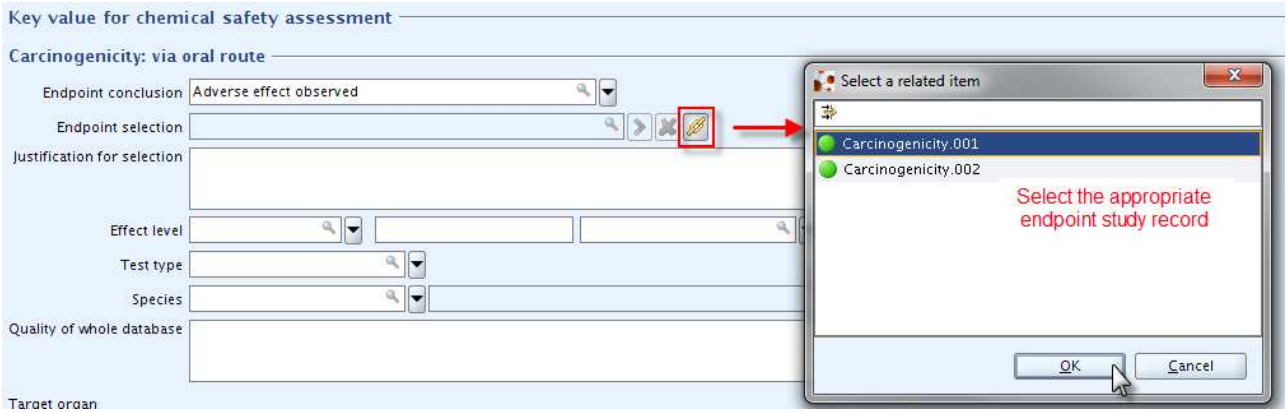
## 5.2 Endpoint study summaries

An endpoint study summary ( ) should be a summary of the evaluation made on all the data entered in the endpoint study records (see section 5.1). An endpoint summary should focus on the most important results and conclusions, and justify the use of certain studies.

Endpoint summaries usually consist of the data entry blocks: 'Administrative data', 'Short description of key information', 'Key value for chemical safety assessment', and 'Discussion'. There are also additional sections, e.g. 'Justification for classification or non-classification' or, in section 9 'Ecotoxicological studies' there is a 'Hazard for air' block.

The fields to be filled in vary greatly between endpoint summaries. However, each field can be filled in using the drop-down menus ( ) with pre-selected responses, adding lines ( Add... ) to the existing tables, or typing text into the free text fields. In some cases, you may wish to link the summarised data to a specific endpoint study record. Achieve this by clicking the link button ( ) and selecting the appropriate endpoint study record from the appearing pop-up menu (Figure 32).

**Figure 32: Linking an endpoint summary to an endpoint study record**




# 6. Additional IUCLID endpoint sections

Information on how to enter information into the additional endpoint sections, i.e. non-endpoint study related sections, is provided in subsequent chapters:

- Section 7 'Intended uses and exposure', section 6.1
- Section 11 'Measure to protect humans, animals and the environment', section 6.2
- Section 12 'Classification and Labelling', section 6.3
- Section 13 'Summary and evaluation', section 6.4

## 6.1 IUCLID section 7 'Intended uses and exposure'

### IUCLID section 7.1 'Fields of use...'

This endpoint section enables the generation of a systemic overview of the intended uses of the biocidal product in the dataset. Start by creating a 'New endpoint study record' (right-click) in section 7.1 'Field(s) of use envisaged for biocidal products…' and enter the information in the fields provided (Figure 33):

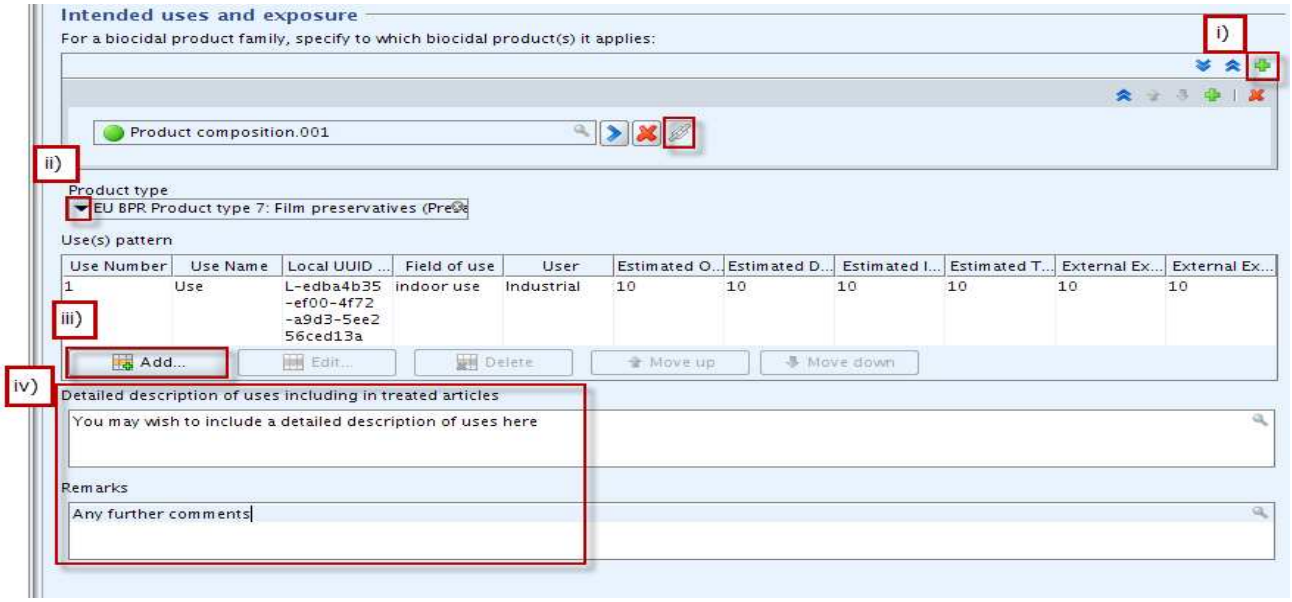
i) Create a new block under 'Intended uses and exposure' by clicking on the green plus ( ) and link ( ) the use to the endpoint study records containing the composition of the biocidal products the intended use applies. These endpoint study records were created in IUCLID section 2.3 'Biocidal product composition'.

ii) Select a 'Product type' from the available drop-down menu ( ).

iii) Add rows to the table 'Use(s) pattern' ( Add... ) and define the uses pattern.

iv) Enter the 'Detailed description of uses' and 'Remarks' (if any) in the free text fields provided.

**Figure 33: Entering the intended uses**

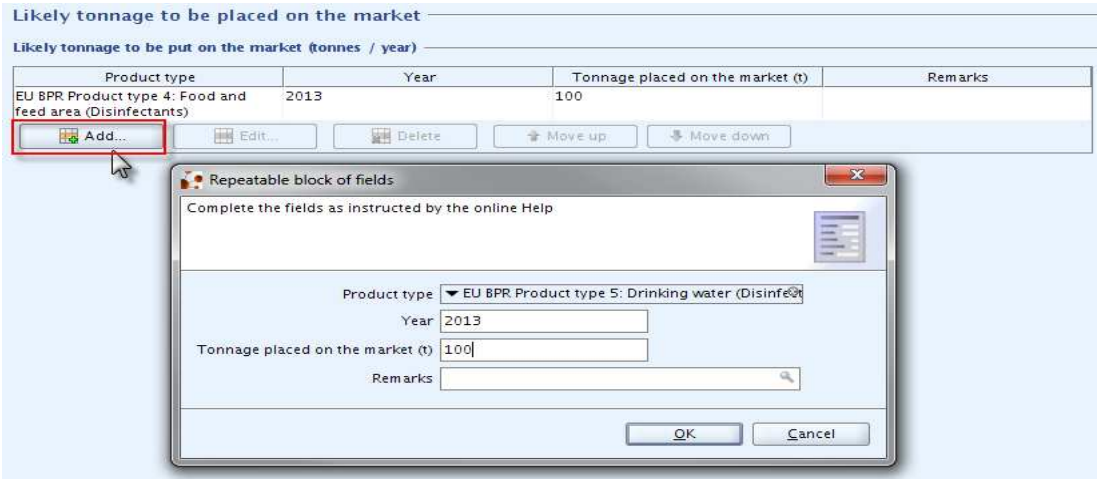



## IUCLID section 7.5 'Likely tonnage to be placed on the market'

The aim of this section is to report the likely tonnage to be placed on the market per calendar year, and if relevant, for different use categories, implied here as product types. You can include multiple rows, allowing the input of information for a number of years and for different product type combinations.

To provide this information, create a 'New endpoint summary' (right-click) in section 7.5 'Likely tonnage to be placed on the market' and fill in the table provided by pressing the 'Add' button ( Add... ) (for as many rows as you require) for each biocidal product type and/or year (Figure 34).

**Figure 34: Entering the 'Likely tonnage to be placed on the market'**




## IUCLID section 7.6 'Method of Application…'

This endpoint section enables the generation of a systemic overview of the directions of use for each of the uses described in IUCLID section 7.1 'Fields of use…'.

Start by creating a 'New endpoint study record' (right-click) in IUCLID section 7.6 'Method of application and a description of this method', and enter the directions for use in the fields provided (Figure 35):

i) The 'Reference use' field identifies the use defined in IUCLID section 7.1 'Fields of use…' that the directions of use apply to. You must have defined a use in IUCLID section 7.1 'Fields of use…' to make it available in the drop-down menu ( ).

ii) Select a 'Method of application' from the available drop-down menu ( ).

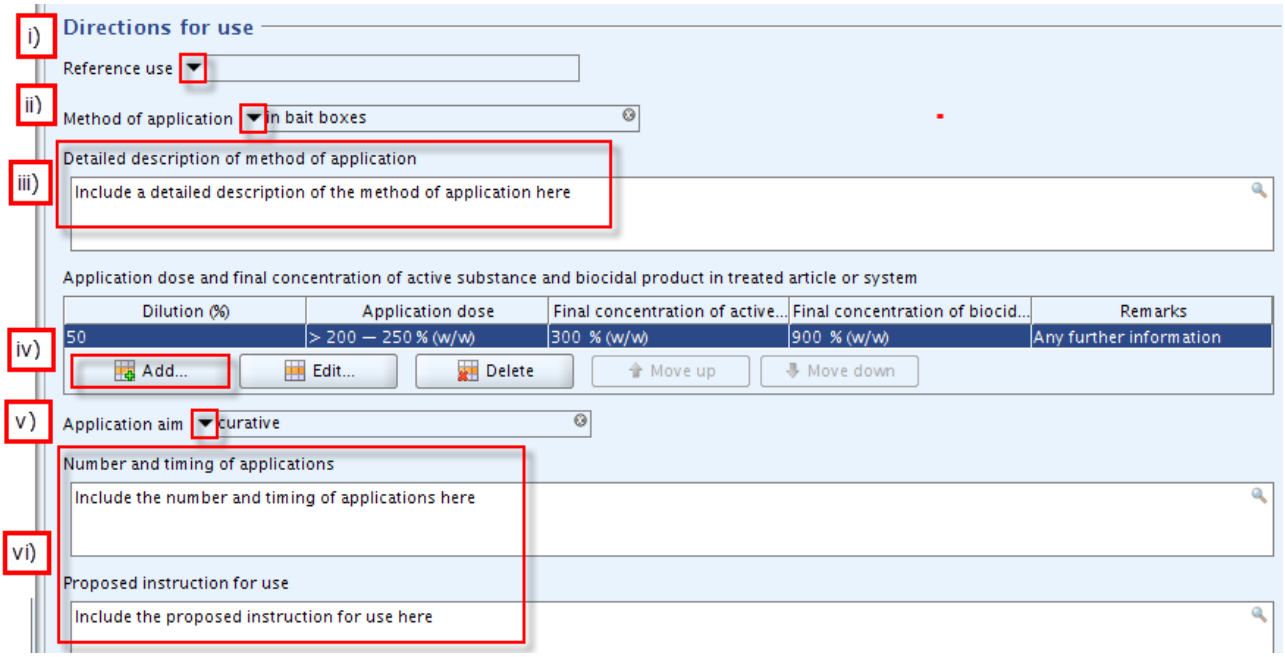
iii) Enter the 'Detailed description of method of application' in the free text field provided.

iv) Add rows to the table 'Application dose…' ( Add... ) and fill in the various parameters.

v) Select an 'Application aim' from the available drop-down menu ( ).

vi) Enter the 'Number and timing of applications' and 'Proposed instructions for use' in the free text fields provided.

**Figure 35: Entering the method of application**




## 6.2 IUCLID section 11 'Measures to protect humans, animals and the environment'

This endpoint section enables the generation of a systemic overview of measures that ensure the appropriate level of protection of humans, animals, and the environment. Start by creating a 'New endpoint study record' (right-click) in IUCLID section 11 'Measures to protect humans, animals and the environment'. The endpoint study record provides you with free text fields, e.g. 'First aid instructions, antidotes', into which you should type all the information concerning the protective measures for the active substance or biocidal product, depending on the dataset you are completing.

## 6.3 IUCLID section 12 Classification and Labelling

There are two sub-sections for entering information related to the classification and labelling (C&L) of an active substance or a biocidal product; section 12.1 'GHS' and section 12.2 'DSD – DPD'. Section 12.1 'GHS' contains the C&L information according to the Globally Harmonised System of C&L of chemicals (GHS) in accordance with the Regulation (EC) No 1272/2008.

Section 12.2 'DSD – DPD' contains the C&L information according to the Directive 67/548/EEC for C&L of substances and according to Directive 1999/45/EC of the European Parliament and of the Council for C&L of preparations.

The Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP) is replacing DSD and DPD in a stepwise approach. Further information on CLP is available on the ECHA website.

**DSD:** Dangerous Substances Directive (Directive 67/548/EEC).

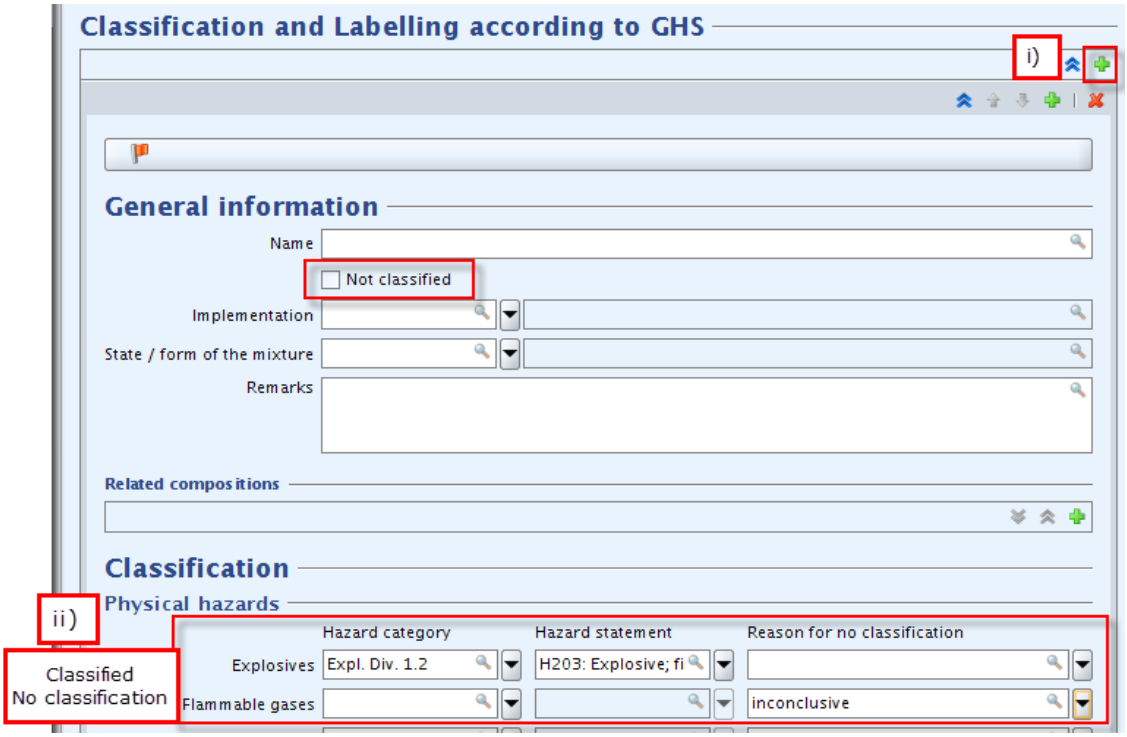
**DPD:** Dangerous Preparations Directive (Directive 1999/45/EC).

### IUCLID section 12.1 'GHS'

Include C&L data according to the GHS by creating a 'New endpoint study record' (right-click) in IUCLID section 12.1 'GHS'. Then, make a C&L block by clicking the green plus sign ( ) (Figure 36).

If the substance is not classified, tick the box 'Not classified' and justify why no classification is given for each endpoint, hazard class or differentiation. This is achieved by filling in the fields 'Reason for no classification'. In IUCLID 5, the fields 'Reason for no classification' indicate 'data lacking' as a default. Where applicable, change the default reason to the appropriate reason, for example 'inconclusive' or 'conclusive but not sufficient for classification' (Figure 36).

**Figure 36: How to specify the 'Classification' labels**




An active substance may have multiple C&L records, for instance in the case where the active substance contains an impurity with specific hazard properties having an impact on the classification. A biocidal product can also have multiple C&L records, for instance in the case where there are different compositions of the biocidal product. You can include multiple C&L blocks, allowing the input of multiple C&L records.

If multiple repeatable C&L blocks are created in section 12.1, please ensure all of the blocks are completed. Delete any unwanted blocks using the red cross ( ).

The reason for **no classification** should be selected according to the following principles:

- Select 'data lacking' if you do not have relevant data or other adequate and reliable information that can be compared with the classification criteria.
- Select 'inconclusive' if you have data that is not completely reliable (e.g. data of poor quality), or if you have several equivocal study results or information. Therefore, the available data cannot be regarded as a firm basis for classification.

- Select 'conclusive but not sufficient for classification' where a substance is tested with the appropriate high quality study or where other high quality information is available, and based on that, it is concluded that the classification criteria is not fulfilled.

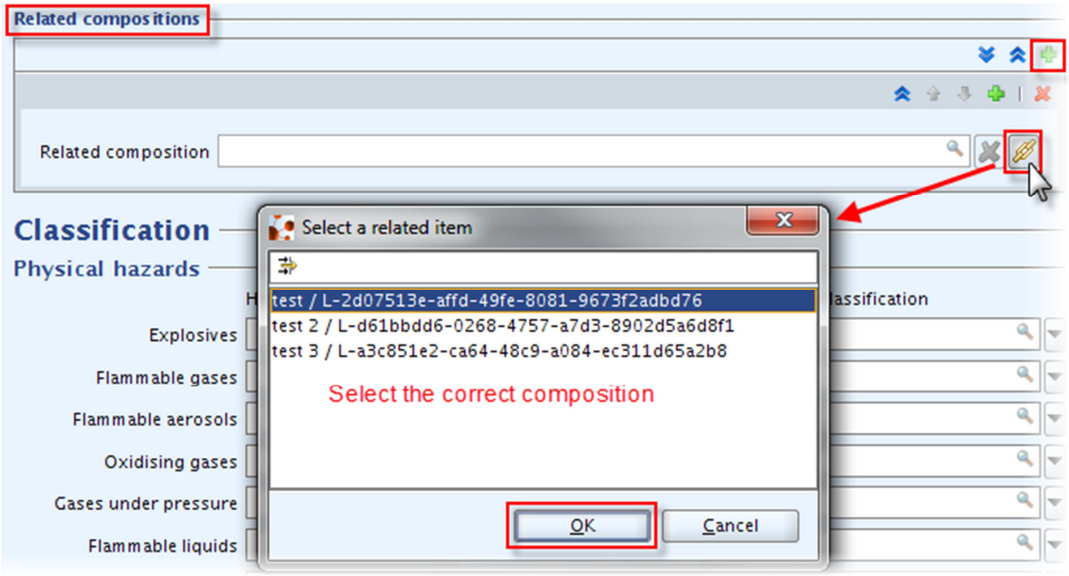
If the criteria for classification is met, you should specify a 'Hazard category' **and** a 'Hazard statement' (Figure 36). Further information on CLP is available on our website at: http://echa.europa.eu/regulations/clp.

Select 'conclusive but not sufficient for classification' for no classification if a hazard category does not apply to your substance (e.g. 'Flammable gases' for a solid substance).

If there are multiple compositions (i.e. several composition blocks in IUCLID section 2.9 'Specification of purity' in the 'Substance' dataset) and several C&L blocks in IUCLID section 12.1 'GHS' of the 'Substance' dataset, then each composition block must be linked to at least one C&L block using the field 'Related compositions' (Figure 37).

Link a related composition by clicking on the green plus ( ) and making a block, then add a link ( ) to the appropriate composition in IUCLID section 2.9 'Specification of purity' (Figure 37). Several compositions can be linked to the same C&L block.

**Figure 37: How to link to 'Related compositions'**




## IUCLID section 12.3 'Packaging'

In the 'Mixture/Product' dataset, there is the additional endpoint section 12.3 'Packaging'. This section should include all the information related to the packaging of a biocidal product (type, materials, size, compatibility of the biocidal product with proposed packaging materials etc.).

Start by creating a 'New endpoint study record' (right-click) in section 12.3 'Packaging', then enter the packaging information in the fields provided (Figure 38):

i) Create a new block under 'Packaging' by clicking on the green plus ( ) and link ( ) the packaging information to the endpoint study records containing the composition of the biocidal products the packaging applies. These endpoint study

records were created in IUCLID section 2.3 'Biocidal product composition'.

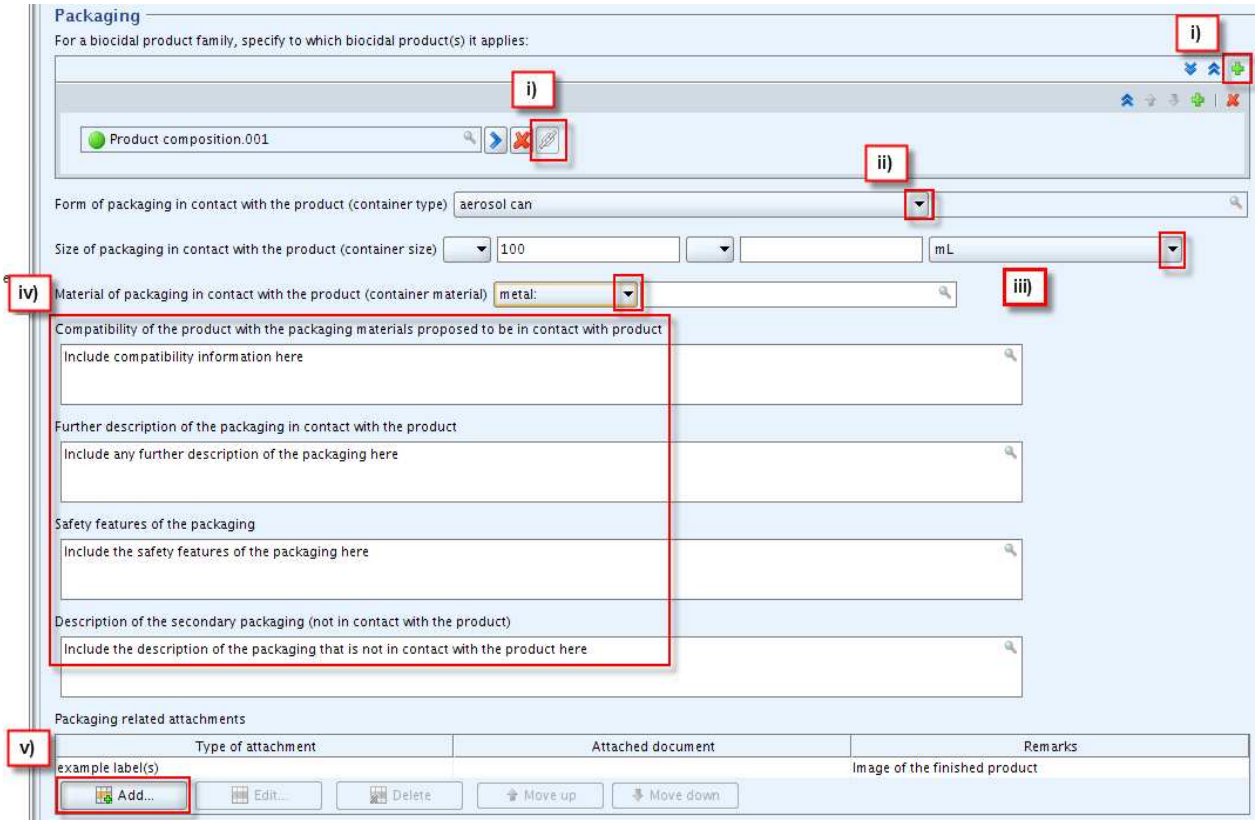
ii) Select a form of packaging from the available drop-down menu ( ▾ ).

iii) Enter the size and material of packaging (use the drop-down menus (▾) to include the unit).

iv) Enter the compatibility of the biocidal product, and further description of the packaging, safety features and secondary packaging in the free text fields provided.

v) Include any other packaging related attachments if available, e.g. a picture of the package, by clicking on the 'Add' button ( Add... ).

**Figure 38: Entering packaging information**




## 6.4 IUCLID Section 13 'Summary and Evaluation'

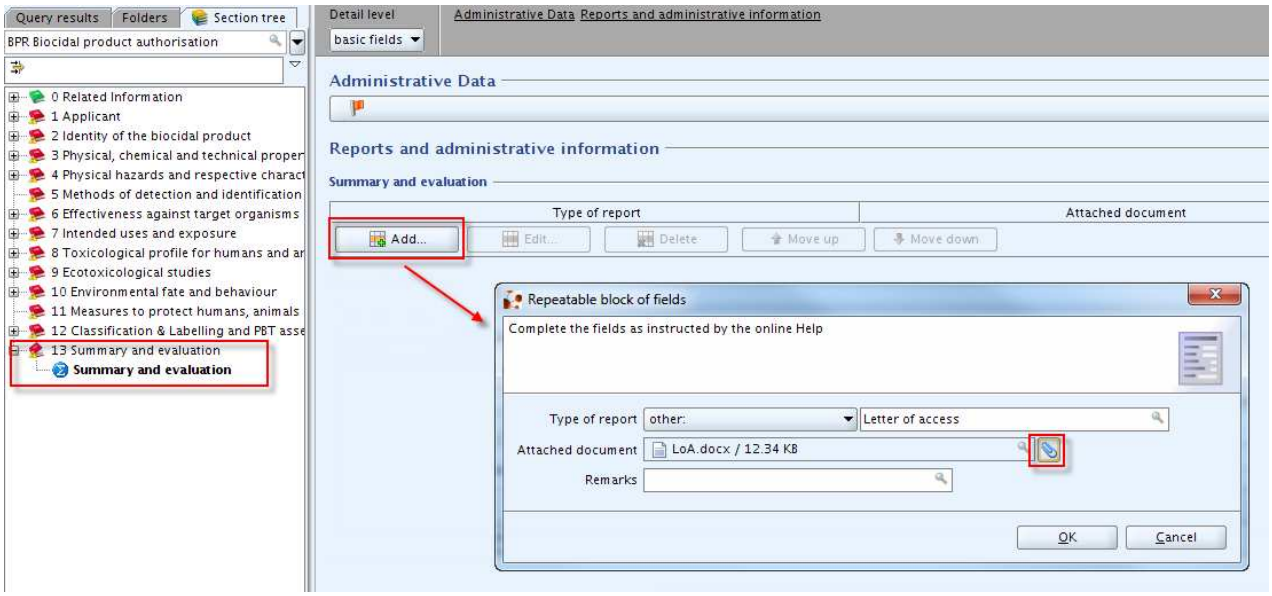
In accordance with the BPR, additional documentation may be required for certain applications. Such documentation may include a safety data sheet, a draft risk assessment report, a letter of access, and/or a summary of product characteristics. These and any other pertinent supporting documents can be attached in IUCLID section 13 of either of your IUCLID datasets. Please refer to the corresponding Biocides Submission Manual for more information on what additional documents should be attached in IUCLID section 13.

For non-active substances and substances that are not of concern, a safety data sheet according to the REACH Regulation must be provided in IUCLID Section 13 of the 'BPR Basic information (substance)/(mixture)' template. Please refer to Annex III, 2.3 of the BPR.

### 6.4.1 Summary and evaluation

To include the appropriate documents, right-click on IUCLID section 13 and select 'New endpoint summary' ( ). Fill in the relevant fields by adding ( Add... ) as many lines as needed in the tables provided (Figure 39). Select the applicable option from the drop-down menu ( ) and attach all the additional documents ( ) (Figure 39). If no applicable option is available in the drop-down menu, then select 'other:' and enter the type of document you are attaching in the adjacent field.

**Figure 39: Attaching additional information**




### 6.4.2 IUCLID section 13.1 'PBT assessment'

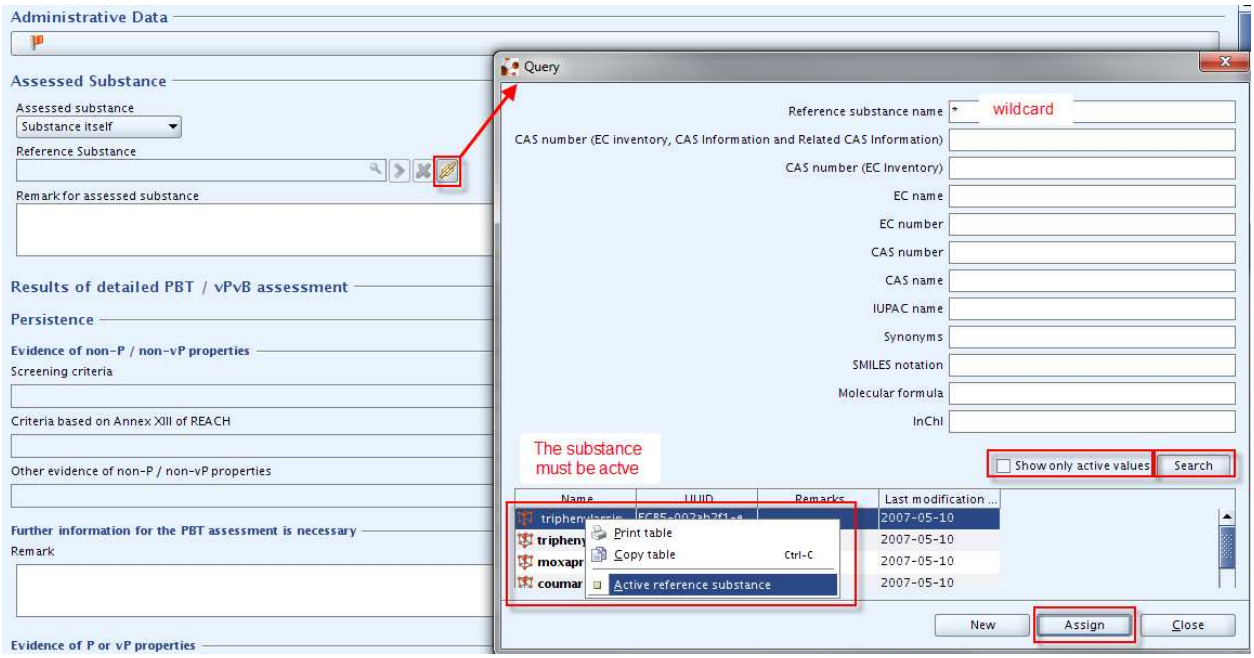
In the 'Substance' dataset only, there is an additional endpoint in section 13.1 'PBT assessment'. A persistent, bioaccumulative and toxic (PBT) assessment of your substance (i.e. the substance itself, its constituents or transformation products) can be included in this section of the 'Substance' dataset.

To enter the scientific data for this section, right-click on IUCLID section 13.1 'PBT assessment' and click 'New endpoint study record' or 'New endpoint summary'. An endpoint study record should contain information related to one given PBT assessment study. Whereas, an endpoint summary can be created to give the overall conclusions of the PBT assessment of the substance, based on all the data in the PBT endpoint study records.

**PBT endpoint study record:** fill in the relevant fields by either selecting the appropriate option from the drop-down menu ( ) or adding boxes to the existing blocks by clicking on the green plus ( ). Ensure you link the PBT assessment to a 'Reference substance'. Achieve this by clicking on the link button ( ) that will open a 'Query' window. Use the 'Query' window to specify the search criteria (to widen your search you can use the wildcard *) and click 'Search'. From the search results, 'Assign' a reference substance (Figure 40).

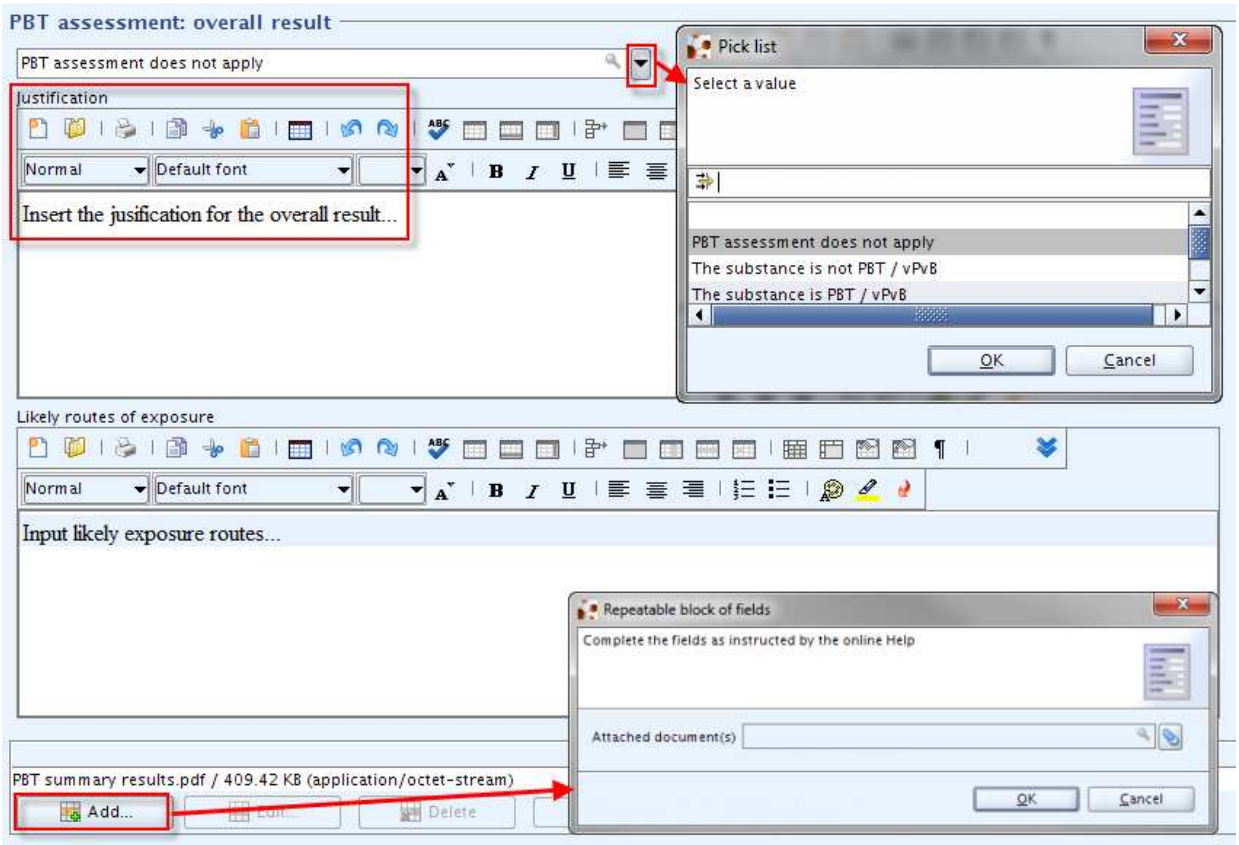
The reference substance has to be 'active' before it can be assigned. A reference substance can be activated by right-clicking it in the search result list and selecting 'Active reference substance'.

**Figure 40: Linking a 'Reference substance' to a PBT endpoint study record**




**PBT endpoint summary:** use the drop-down menu ( ▾ ) to give an overall result (Figure 41), and then input a justification for the overall result in the free text field provided. Ensure you include all of the appropriate documents in the 'Attached document(s)' table, by first adding lines to the table and then using the attach button ( 📎 ).

**Figure 41: PBT endpoint summary**

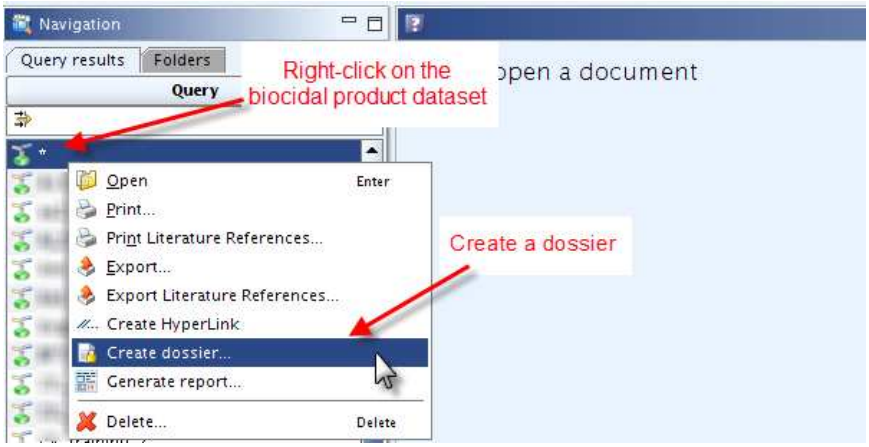


# 7. How to create a dossier

Ensure all of the appropriate information is included in the 'Mixture/Product' dataset, including a link to a 'Substance' dataset in IUCLID section 2.3 'Biocidal product composition', before creating your dossier.

To create the dossier click 'Update' next to the Mixture/Product icon ( ) on the IUCLID 5 homepage ( ). Then, right-click on the name of your chosen 'Mixture/Product' dataset ( ; contained in the 'Query results' tab) and click 'Create dossier' (Figure 42). This will launch the dossier creation wizard (Figure 43).

**Figure 42: Launching the creation wizard**




## 7.1 The dossier creation wizard

The dossier creation wizard will guide you through a set of steps in order to create the relevant dossier type, either a 'BPR Active substance application' dossier or a 'BPR Biocidal product authorisation' dossier. The type of dossier will vary depending on the process you are applying for. For information on whether a dossier is required for your application and, if so, which type of dossier is required, please refer to the relevant Biocides Submission Manual.

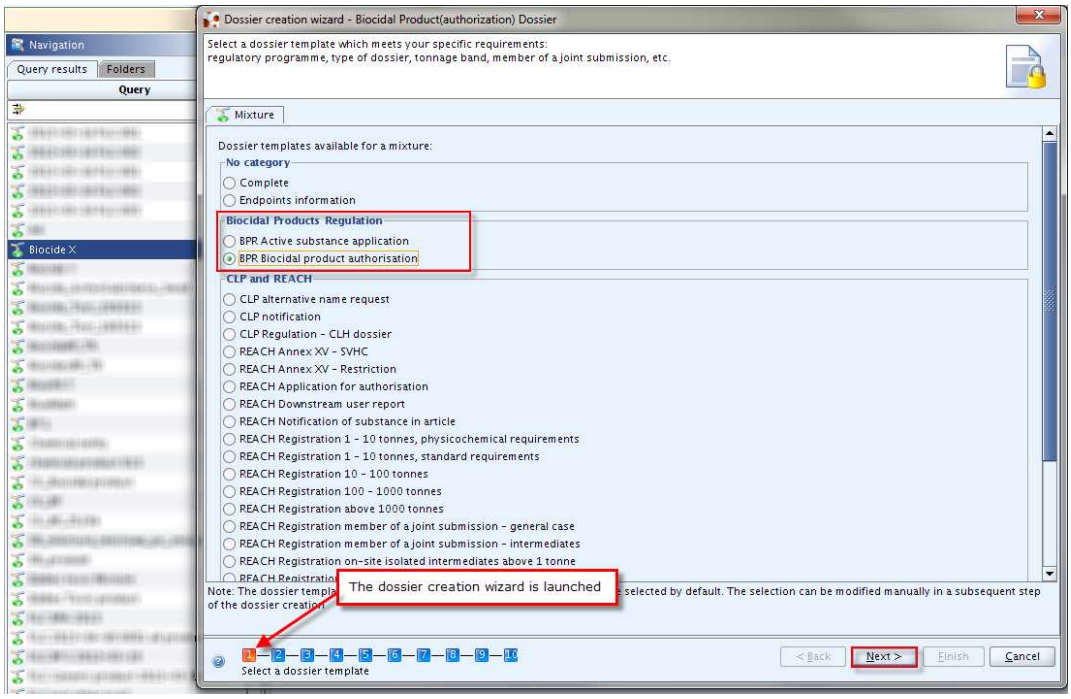
The steps below explain how to navigate through the dossier creation wizard. Click 'Next>' to move to the next step of the wizard (Figure 43).

**Step 1** Select the correct dossier type for your application (Figure 43).

Section 2.3 'Product composition' of your 'Mixture/Product' dataset: If you create an 'Endpoint summary' or you include more than one active substance in the biocidal product composition, e.g. include more than one 'Endpoint Study record' each with an active substance, you will not be able to make a 'BPR active substance application' dossier, see IUCLID section 2.3 'Biocidal product composition'.

For more information on the type of dossier required, please refer to the guidance documents and relevant Biocide Submission Manual for the specific process.

**Figure 43: Step 1 of the dossier creation 'wizard'**

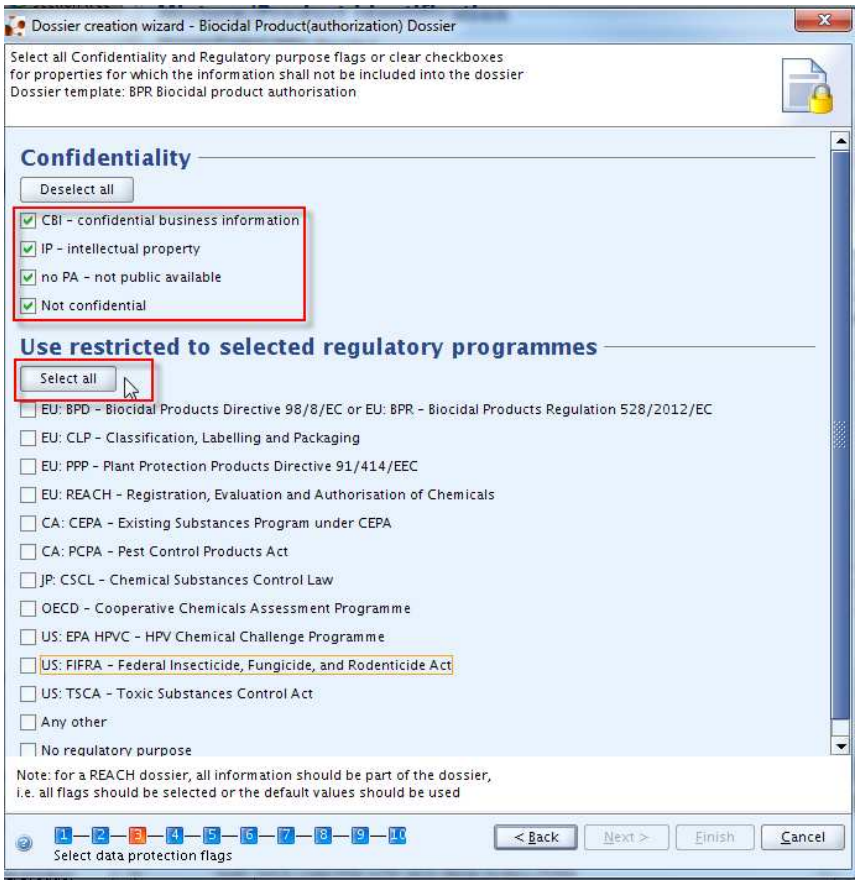



**Step 2** Review the related entities.

**Step 3** Filter the information to be included in the dossier (Figure 44). Most fields in a IUCLID 5 dataset can be flagged as confidential and/or specifically for the purpose of certain regulatory programmes. To include all records in a dossier, no matter how their confidentiality and/or regulatory purpose flags are set, click both 'Select all' buttons. To exclude records that have a particular type of flag set, un-tick the box for that flag type.

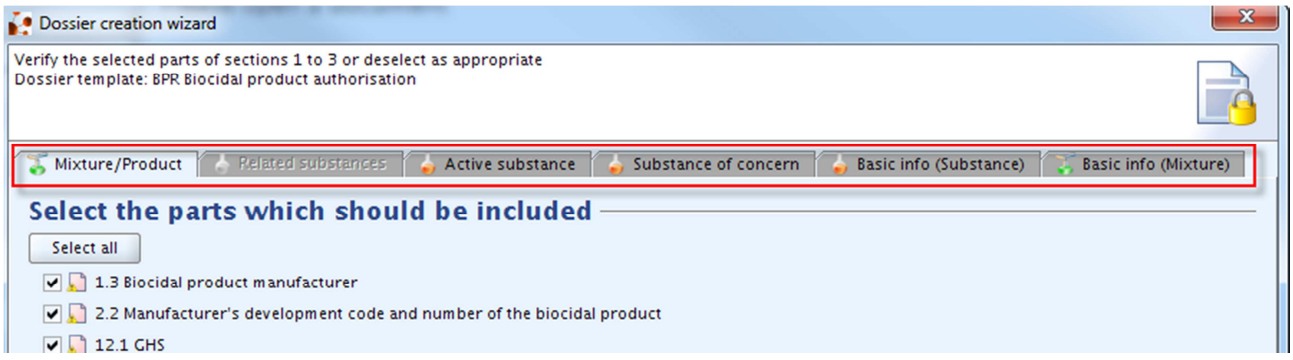
For most cases, ECHA recommends that you 'Select all' the checkboxes, making sure that all of the required elements of the Substance or 'Mixture/Product' dataset are included in the dossier to be submitted.

**Figure 44: Step 3 of the dossier creation 'wizard'**




**Step 4** Verify the selected sections for inclusion. There are default tabs displayed, one for each of the 'Substance' dataset templates and the 'Mixture/Product' dataset templates available in IUCLID 5 (Figure 45). By default, all the components selected in accordance with the template are included in the dossier. To exclude a component, un-tick the pertinent box in the relevant dataset.

**Figure 45: Verifying the sections to be included**




**Step 5** Verify the selected endpoint summaries/study records. Deselect sections as appropriate.

**Step 6** Verify the sections of your dataset that shall be included in the dossier.

**Step 7** Verify the inclusion or exclusion of annotations.

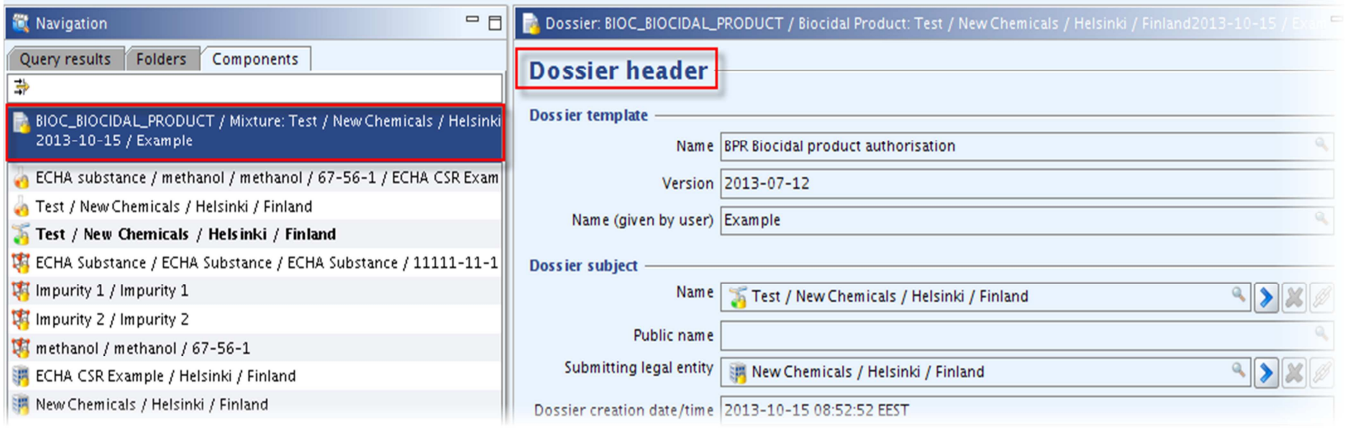
**Step 8** Specify the dossier name in the free text field and include any additional remarks if relevant. Please record the dossier name as this can be used to view the dossier later (section 7.2).

**Step 9** Note that the dossier creation 'wizard' skips step 9 for the creation of biocides dossiers as this step is only relevant to REACH-related dossiers.

**Step 10** Copy-protect study records as appropriate and click 'Finish'. If you tick this box, the ownership of the dossier data will be protected in such a way that copying the endpoint summaries/study records using the IUCLID 5 clipboard manager will be prevented.

Clicking 'View dossier' in the prompt window will direct you to the 'Components' tab which contains the 'Dossier header' section of your newly created dossier (Figure 46). To view the full dossier content see section 7.2.2.

**Figure 46: Dossier header**

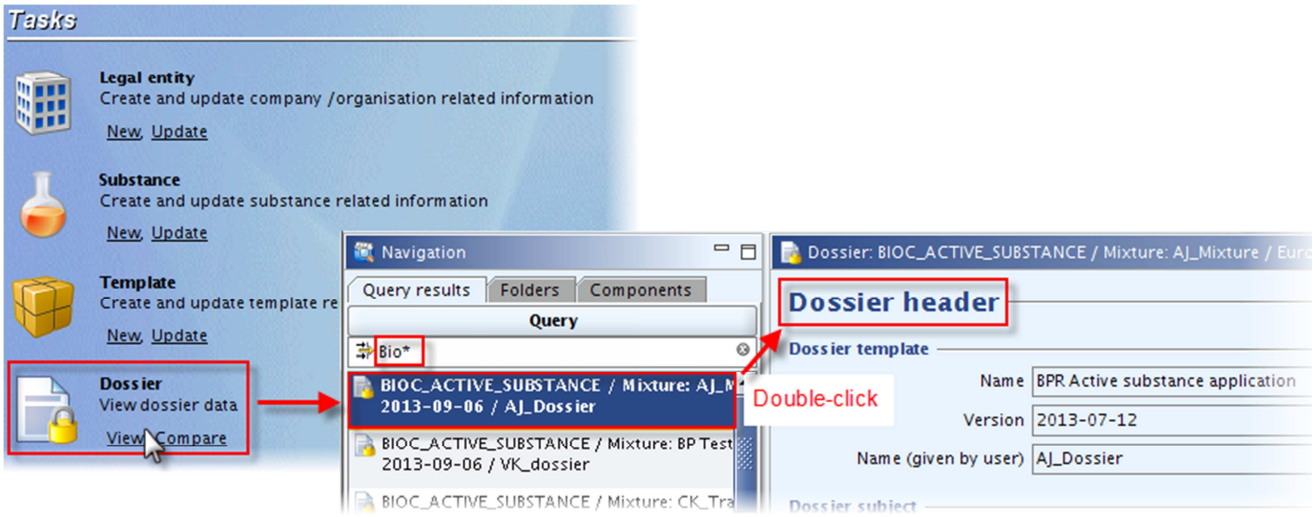



## 7.2 Viewing a dossier

### 7.2.1 Searching for a dossier

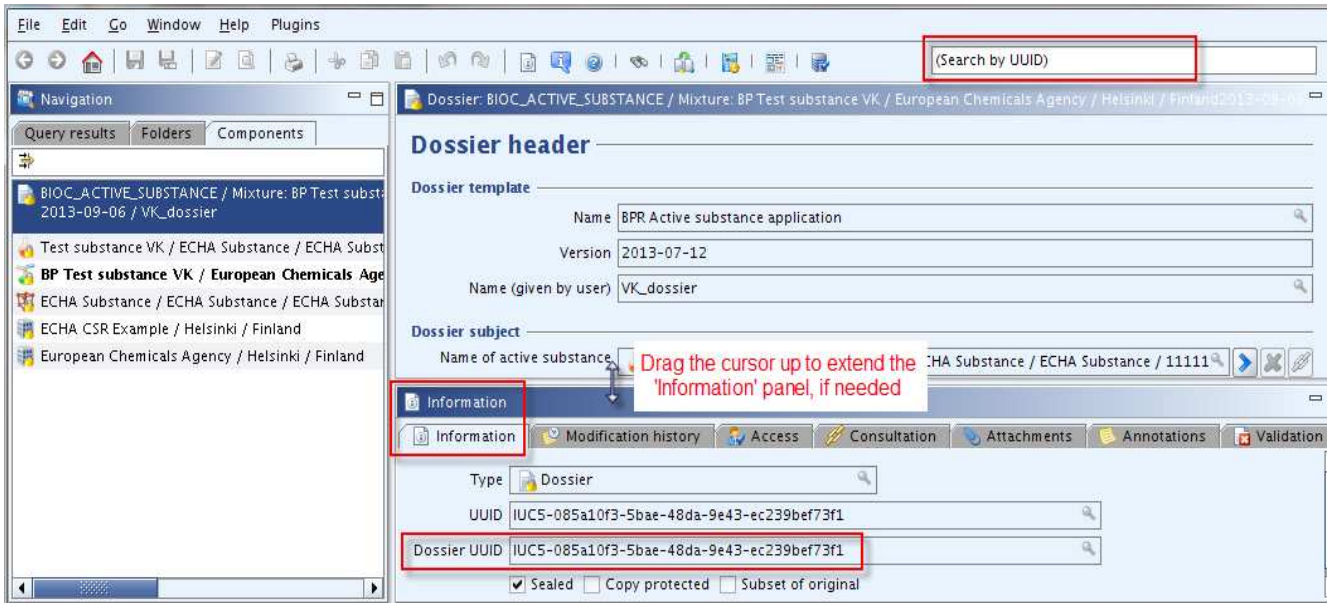
You can view a dossier at any time, for example to verify that all of the information is correct, using the dossier name or the dossier UUID number. To search by dossier name, go to the IUCLID 5 homepage and select 'View' next to the dossier icon (Figure 47). This will open the 'Navigation' window (Figure 47). In the 'Query' tab, type in the dossier name (to broaden your search, you may use the wildcard *, Figure 47). When you have located the relevant dossier, double-click on the dossier title to open the 'Dossier header' section (Figure 47). You can then click on the 'Components' tab to see all of the components (e.g. the datasets, legal entity) of the selected dossier.

**Figure 47: Searching for a dossier with the dossier name**




To search for a dossier with the unique dossier UUID, use the 'Search by UUID' field in the upper right corner of any IUCLID 5 screen (Figure 48). The dossier UUID can be obtained from the 'Information' tab in the 'Information' panel at the bottom of any section in the dossier. Figure 48 shows the 'Information' panel in the 'Dossier header' section.

**Figure 48: Searching for a dossier with the dossier UUID**



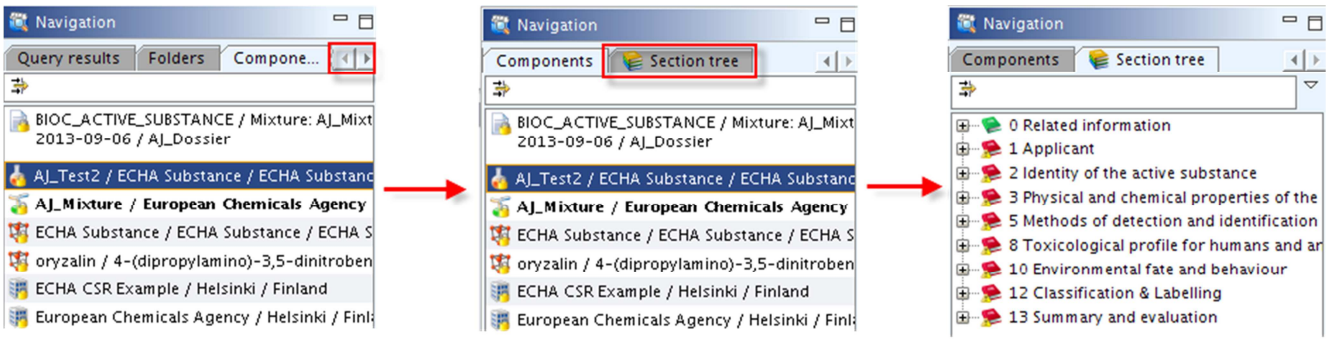

## 7.2.2 Viewing the full dossier content

You can view the dataset content within the dossier by double-clicking on either the substance component ( ) or the mixture/product component ( ) under the 'Components' tab in the 'Navigation' panel. Clicking the substance component will open the substance identification section of the 'Substance' dataset, whilst clicking on the mixture/product component will open the mixture/product identification section of the 'Mixture/Product' dataset. The 'Section tree' tab will also appear as the last tab in the 'Navigation' panel. The 'Section tree' tab allows you to open all the other sections contained in the dataset. Use the arrows ( ) to view the 'Section tree' tab (Figure 49).

Double-clicking on the reference substance icon ( ) will take you to the reference substance

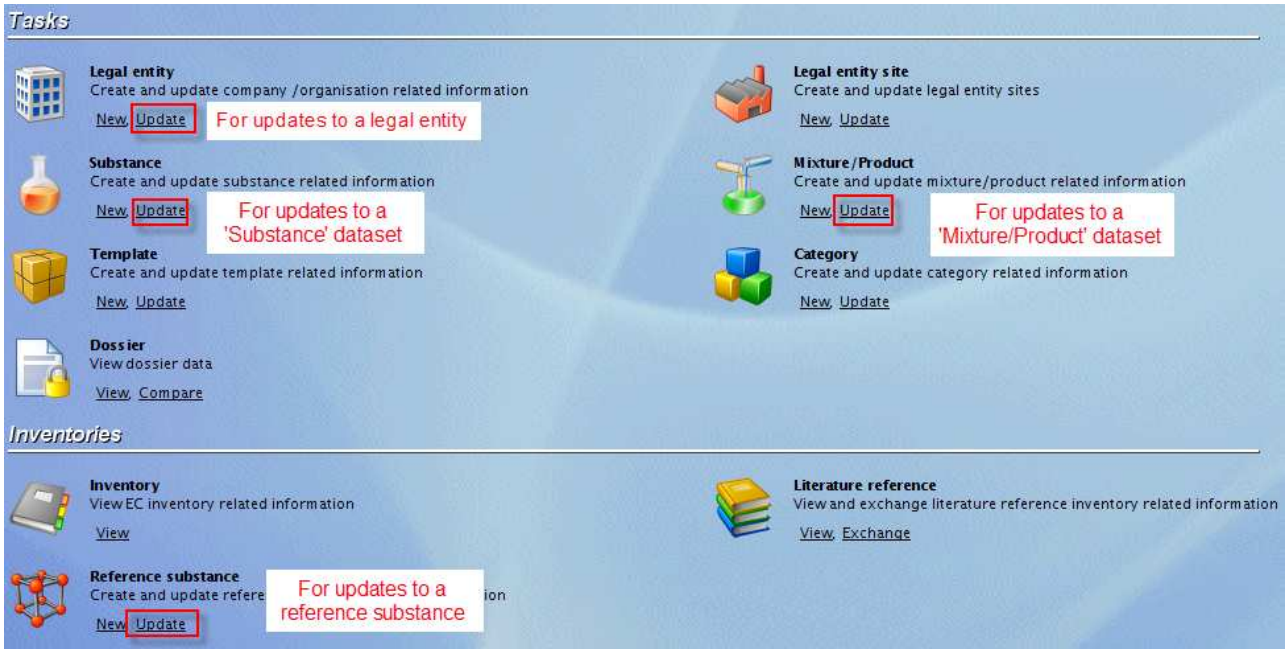
general information page. Double-clicking on the legal entity icon ( ) will open the legal entity information.

**Figure 49: Viewing the 'Section tree'**




Remember that a dossier is a non-editable snapshot of the datasets. If you find mistakes in the dossier, go to the IUCLID 5 homepage and update the relevant dataset/reference substance/legal entity by clicking 'Update' next to the appropriate icon (Figure 50). Then, create a new dossier as outlined in chapter 7.1.

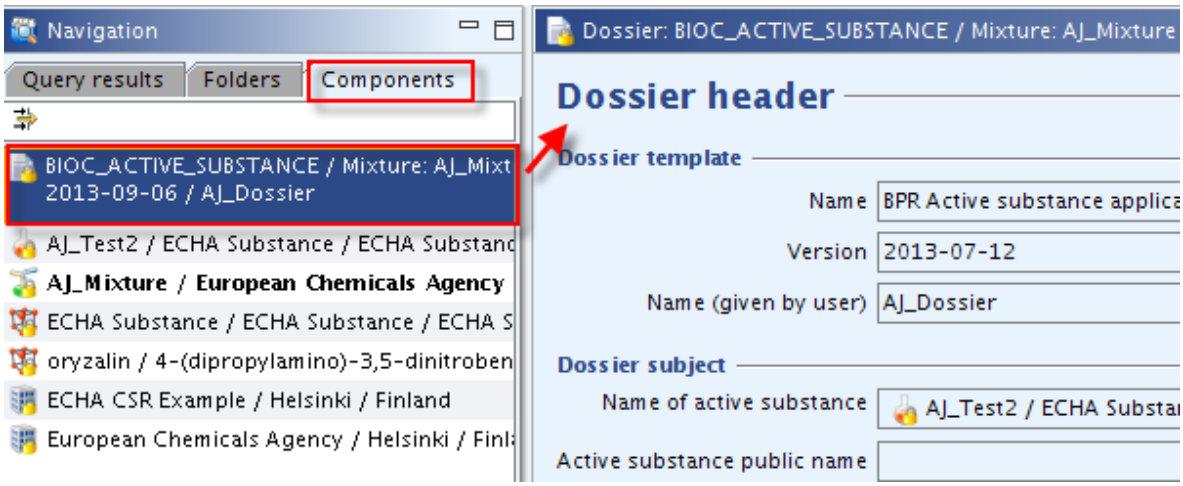
**Figure 50: Updating data**




## 7.3 Dossier export

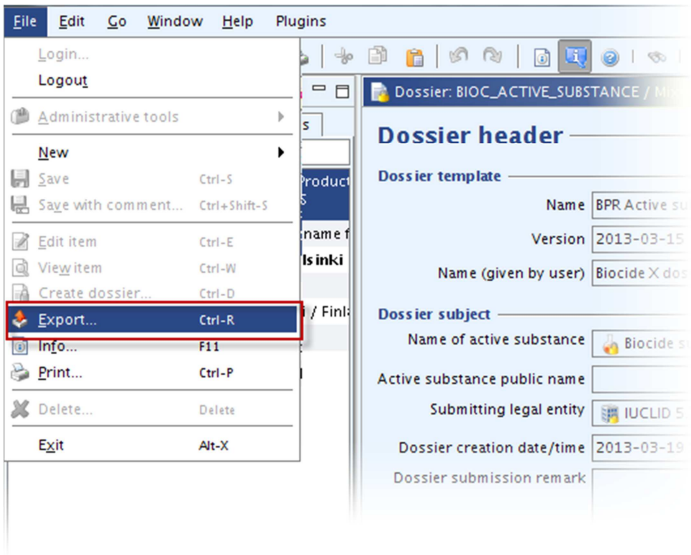
When you are satisfied with a dossier, export it from IUCLID 5 to submit it via R4BP 3. To export a dossier open the 'Dossier header' section by double-clicking the dossier component under the 'Components' tab (Figure 51).

**Figure 51: Opening the 'Dossier header' section**



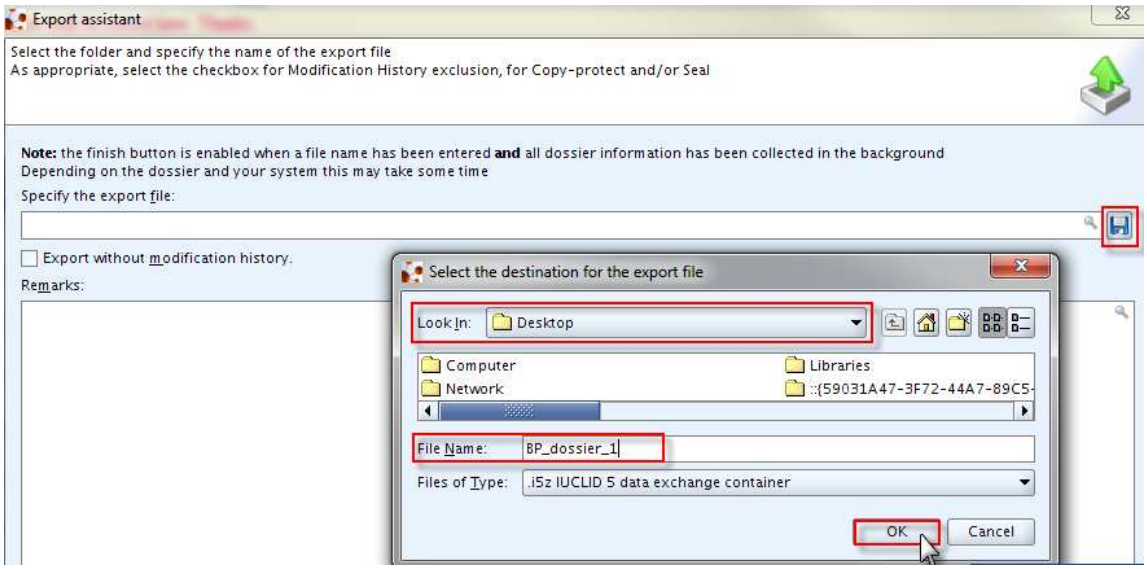

Then select File >> Export… from the menu bar (Figure 52). This will launch the Export assistant (Figure 53).

**Figure 52: Exporting the dossier**



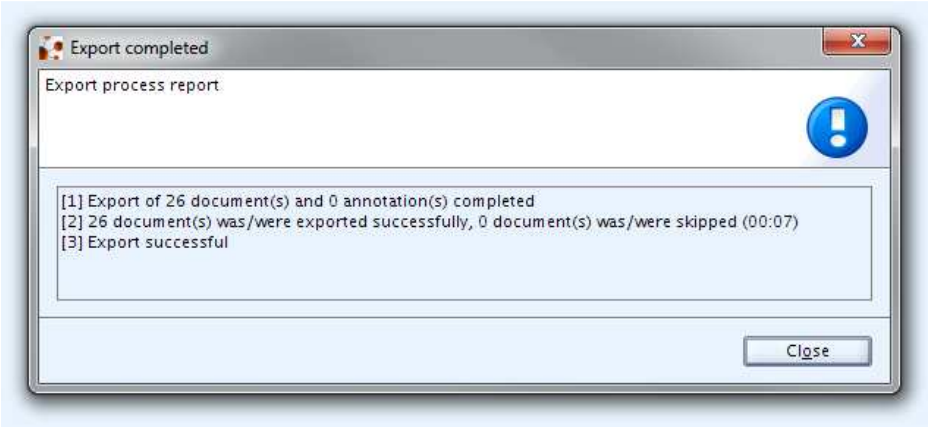

Follow the steps in the Export assistant to i) select the appropriate option for annotation export and click 'Next', then ii) click the 'Save' button ( ) to define where you wish to save the dossier. Select your desired location from the 'Look In' field and specify the name of the dossier in the 'File Name' field, then click 'OK' (Figure 53).

**Figure 53: Saving the dossier**




Click 'Finish' and wait until IUCLID 5 displays the export process report (Figure 54), informing you that the export has been successfully completed. The dossier can now be located in an .i5z file format in the location specified in step ii) of the Export assistant.

**Figure 54: Export complete**



# Summary sheet 1:

# How to make a confidentiality claim in IUCLID 5

In accordance with Article 67 of the BPR, ECHA is required to make publicly and easily available free of charge certain information it holds on active substances and biocidal products. In some cases, certain information can be claimed confidential, according to Article 66(4) of the BPR, if the person submitting the information also submits a justification as to why publishing the information could be harmful for their commercial interests or those of any other party concerned. For further and more detailed information, please consult the Biocides Submission Manual 6: Confidentiality requests for biocide applications.

To 'flag' a IUCLID 5 field as confidential:

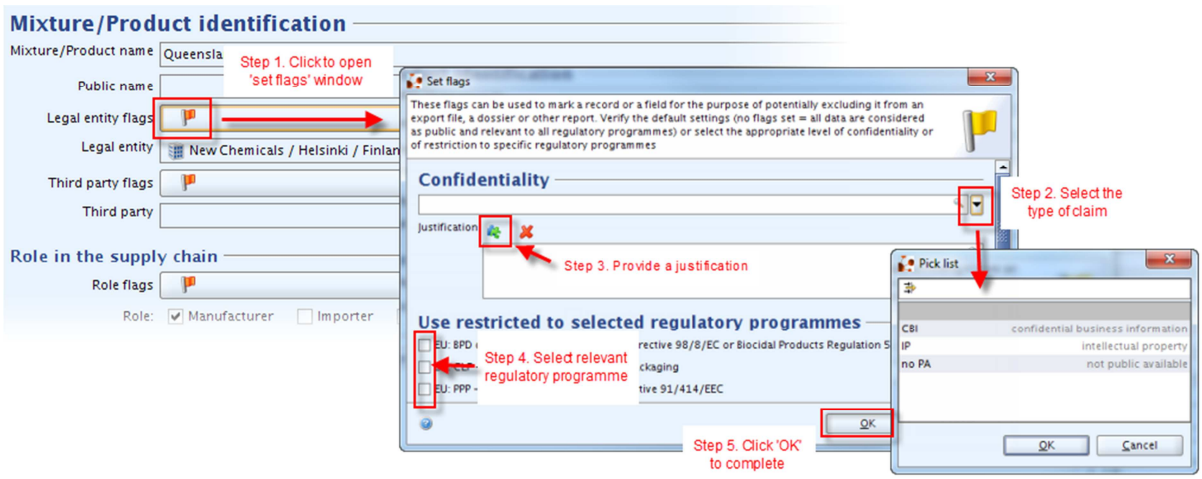
**Step 1:** Click the confidentiality claim flag ( ) to open the 'Set flags' window.

**Step 2:** Select the type of confidential claim from the picklist: 'CBI', 'IP', or 'no PA'.

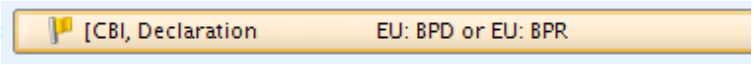
**Step 3:** Include an appropriate justification ( ) in the justification text box for every confidentiality claim flagged. It is strongly recommended that the template provided should be completed (edit as appropriate) for each confidentiality claim.

**Step 4:** Select the relevant regulatory programmes from the list provided (optional). If you select 'other:' from the list, then you must input the relevant regulatory programme in the adjacent free text field.

**Step 5:** Click on 'OK' to complete




A yellow flag indicates that the field has been 'flagged' as confidential.



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