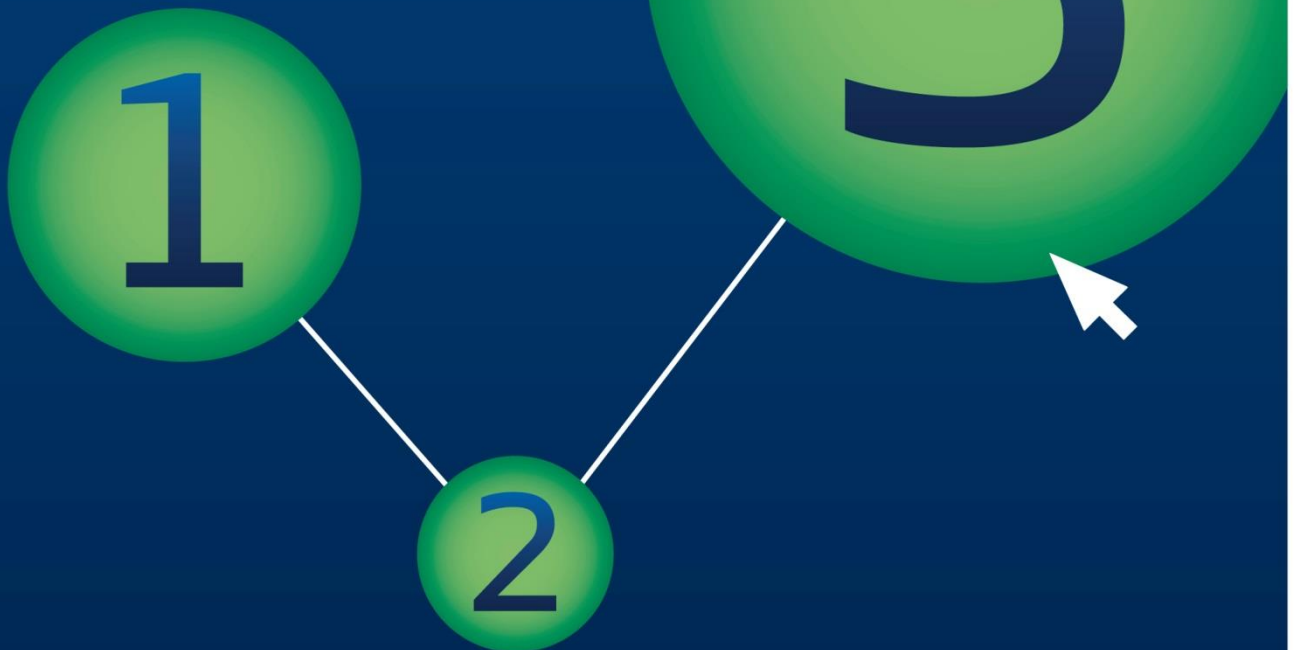


Biocides Submission Manual

Technical guide: using IUCLID



BSM Technical guide: using IUCLID**Reference:** ECHA-14-B-21-EN**Catalogue number:****ISBN:****DOI:****Publ. date:** February 2015**Language:** EN

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Version 1.0	First version	June 2013
Version 2.0	<p>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'.</p> <p>In addition, the following areas have been further elucidated in Chapter 2: description and use of supplementary datasets, and IUCLID help functions.</p>	November 2013
Version 2.1	Enhanced explanation of datasets and dossiers. Other changes include extra summary sheets added and previous summary sheets updated. A glossary section containing terms, definitions and identifiers applicable to the whole BSM series can now be found at the end of the manual.	April 2014
Version 2.2	Summary sheet information included in the body text.	June 2014
Version 3.0	<p>Update of title</p> <p>Reference to REACH-IT for LEO creation removed.</p> <p>IUCLID section 2.1, the role of the applicant clarified for formulators</p>	December 2014
Version 3.1	<p>New information available and included in the annex</p> <p>Annex I: 'How to include a mixture containing an active substance to a biocidal product dossier in IUCLID'</p> <p>Annex II: 'How to report active substance(s) generated in situ in IUCLID'</p>	February 2015

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1. Introduction

1.1 Objective

This manual gives guidance on how to create a IUCLID¹ dossier concerning biocidal active substances² (AS) and biocidal products³ (BP) for applications made under the Biocidal Products Regulation⁴ (BPR). The various chapters in this manual aim to explain the different functionalities in IUCLID, and how to use those functionalities to create a valid dossier that can be submitted through the Register for Biocidal Products (R4BP 3).

1.2 Biocides Submission Manuals

This manual is part of the Biocides Submission Manual (BSM) series concerning technical guides, application instructions and process manuals and also includes:

Technical guides:

Using R4BP 3, which describes how to create user accounts in R4BP 3 via ECHA Accounts and gives a detailed description of the various functionalities of the system.

Using the SPC Editor, which describes how to prepare a Summary of the Product Characteristics (SPC) required for certain application types.

Application instructions:

Application instruction manual give guidance on how to submit applications concerning various process concerning active substance approvals and biocidal product authorisations.

- **Active substances**
- **National authorisations**
- **Simplified authorisations**
- **Union authorisations**
- **Technical equivalence and chemical similarity**

Process manuals:

Invoicing in R4BP 3, which describes the general information related to invoices and credit notes issued by ECHA following the submission of an application.

Confidentiality requests for biocide applications, which describes how to make confidentiality claims in IUCLID 5 and which dossier information can be claimed confidential.



A link to all of the Biocides Submission Manuals, including the technical guides, application instructions and related processes can be found from the '[ECHA website](#)'.

¹ International Uniform Chemical Information Database

² An AS may refer to a substance, a substance in a mixture, or a micro-organism

³ A BP may refer to a single biocidal product, a biocidal product family or a representative biocidal product in the case of an application for approval of active substance

⁴ [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

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, mixtures and micro-organisms; including biocidal active substances and biocidal products. This data is entered and stored in editable 'datasets' and can be exported from a IUCLID dataset in a non-editable file called a 'dossier' (.i5z file). A dossier can then be uploaded as part of an application and submitted through R4BP 3 to the Authorities⁵. 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](#) and create a Legal Entity Object (LEO). A LEO contains administrative information on the legal entity (i.e. a company), such as the name, address and contact details of the company. In addition, a LEO is also used to clearly identify a company in R4BP 3. When a company creates a LEO, a numeric identifier called a Universal Unique Identifier (UUID) is generated and assigned to that company, acting as an unequivocal identifier.






The latest version of IUCLID, version 5, can be downloaded 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 website's [Support](#) tab.

2.1 What is a dataset and dossier?

A dataset is the editable central core of information in IUCLID 5, containing information on the intrinsic properties of a specific substance or mixture, and its constituents. It is thus the repository of technical and scientific data related to an active substance, all components of a biocidal product and the biocidal product itself, and is used to create a non-editable 'dossier'. A dossier is a non-editable snapshot file of the dataset, containing the information to be submitted as part of an application in the correct format, when required.

IUCLID 5 provides two different dataset types:

- i) a 'Substance' dataset (), and
- ii) a 'Mixture/Product' dataset ().

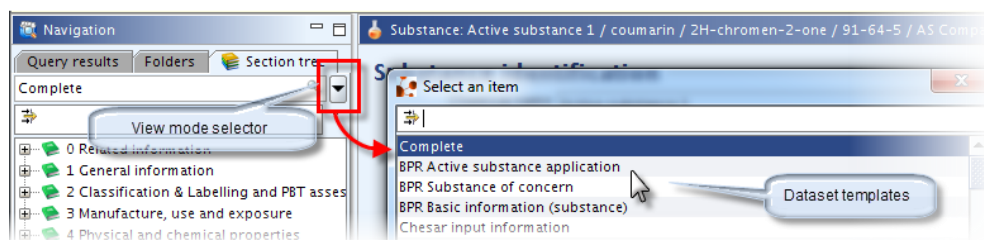
Separate IUCLID datasets should be created for each component of the biocidal product, along with one for the product itself. All these individual datasets should then be linked to each other in order to create a valid dossier ([Section 2.1.2](#)). These individual datasets are then linked to each other in order to create a valid dossier. To assist you with data entry, you can customise the sections in a dataset via the 'view mode' (i.e. dataset template) selector. By default, the dataset template is set to 'Complete'. However, you should change this by using the black arrow () to open a drop-down list (Figure 1). Note that this list contains numerous dataset templates accommodating various chemical regulations e.g. BPR, REACH⁶, CLP⁷ etc.

⁵ Meaning ECHA, member state competent Authorities, or the Commission.

⁶ [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.

Customising the dataset template will ensure that only the sections that are relevant to your dossier type are shown.

Figure 1: Changing the dataset template via the 'view mode' selector



2.1.1 Main dataset templates

To create a valid dossier, at least two 'main' dataset templates must be completed (Figure 2):

- i) a 'BPR Active substance application' dataset - containing information concerning an AS, and
- ii) a 'BPR Biocidal product authorisation' dataset - containing information concerning a BP. This dataset must **always** be used to create the dossier, see [chapter 7](#).



All dossiers must contain at least the two 'main' datasets. Even in cases where there is no relevant biocidal product, e.g. in the case of technical equivalence assessment and Article 95 dossiers.

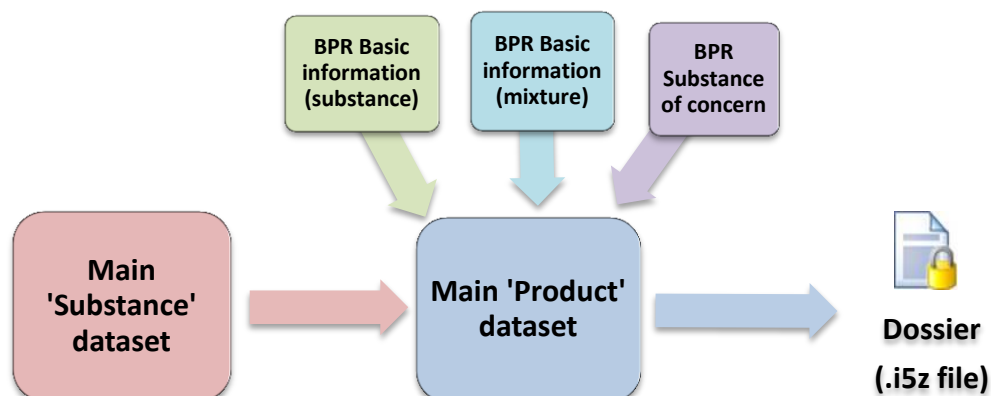
2.1.2 Supplementary dataset templates

The supplementary dataset templates should be used to include information concerning the other components (not the active substance) of a biocidal product, for example the solvents, emulsifiers, attractants, etc. The supplementary dataset templates are (Figure 2):

- i) 'BPR Basic information (substance)' dataset - containing information about each additional substance component
- ii) 'BPR Basic information (mixture)' dataset - containing information about each additional mixture component
- iii) 'BPR Substance of concern' dataset - containing information on substances of concern, according to Article 3(1)(f) of the BPR.

Ensure you complete individual datasets for all the components of a biocidal product. These datasets must then be linked to the biocidal product dataset in [IUCLID section 2.3 'Biocidal product composition'](#).

⁷ [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.

Figure 2: Link all datasets to the main 'Mixture/Product' dataset

For full details on how to prepare a dataset for an active substance and biocidal product, please refer to Chapter 3 and 4 of this manual. To report a mixture containing an active substance or for details on how to include active substances generated in situ, please refer to [Annex I](#) and [Annex II](#) to this manual.

2.2 Types of dossier

A IUCLID dossier is a non-editable snapshot file of any datasets, containing the information to be submitted as part of an application, when relevant. There are currently two types of dossiers that may be created and submitted through R4BP 3, as part of an application under the BPR:

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



All dossiers (for the active substance or biocidal product) must be created from a biocidal product dataset.

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

Figure 3 shows a 'BPR Active substance application' dossier that includes both a 'Substance' dataset for an AS and one for a solvent, along with a 'Mixture/Product' dataset for the BP. It was correctly created from the 'Mixture/Product' dataset. Please note that the number of datasets contained within a dossier may vary.

Figure 3: Valid active substance dossier

Navigation

Query results Folders Components

Dossier type

Dataset used to create the dossier; this should always be 'Mixture'

Datasets contained in the dossier

BIOC_ACTIVE_SUBSTANCE / Mixture Test / New Chemicals / Helsinki / Finland 2013-10-15 / Example

ECHA substance / methanol / methanol / 67-56-1 / ECHA CSR Example / Helsinki / Finland

Test / New Chemicals / Helsinki / Finland

Test / New Chemicals / Helsinki / Finland

ECHA Substance / ECHA Substance / ECHA Substance / 11111-11-1

Impurity 1 / Impurity 1

Figure 4 shows a 'BPR Biocidal product authorisation' dossier that includes both a 'Substance' dataset for an AS and one for an emulsifier, along with a 'Mixture/Product' dataset for the BP. It was correctly created from the 'Mixture/Product' dataset.

Figure 4: Valid biocidal product dossier

Navigation

Query results Folders Components

Dossier type

BIOC_BIOCIDAL_PRODUCT / Mixture Test / New Chemicals / Helsinki / Finland 2013-10-15 / Example

ECHA substance / methanol / methanol / 67-56-1 / ECHA CSR Example / Helsinki / Finland

Test / New Chemicals / Helsinki / Finland

Test / New Chemicals / Helsinki / Finland

ECHA Substance / ECHA Substance / ECHA Substance / 11111-11-1

Impurity 1 / Impurity 1



A dossier is **only valid** if it contains at least one 'BPR Active substance application' dataset and at least one 'BPR Biocidal product authorisation' dataset, and is created from the BP dataset.

2.3 What is a 'Reference substance'?

One of the elements characterising the IUCLID 5 dataset is its relationship to a 'Reference substance'. A 'Reference substance' (🔍) is a IUCLID 5 feature for storing information on the identity of specific substances and their constituents. It is used to store identification information of substances, allowing this information to be defined once, saved and reused easily.

Identification information stored in a 'Reference substance' includes the chemical's common name, EC number, CAS number or IUPAC name, molecular and structural information. 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.

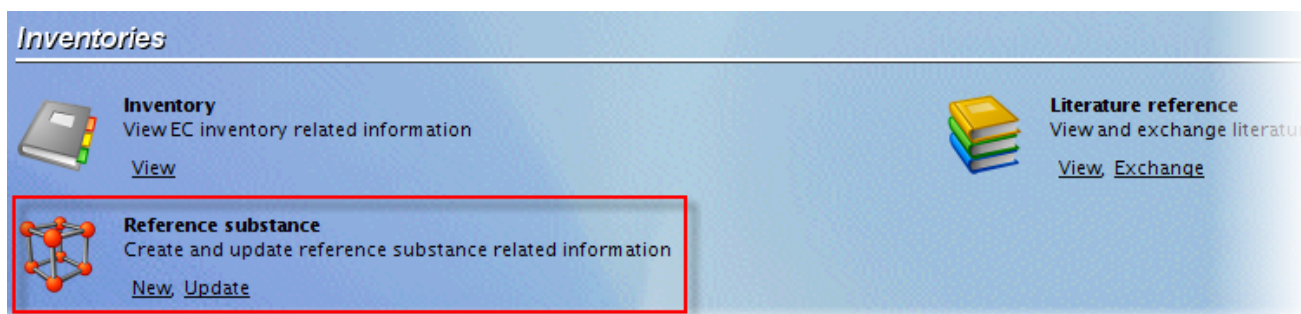
The 'Reference substance' is used in a 'Substance' dataset to specify the identification of the main substance that the dataset has been created for, along with its constituents, impurities and additives, if any.

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 5).



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 5).

Figure 5: Accessing the 'Reference substance' information

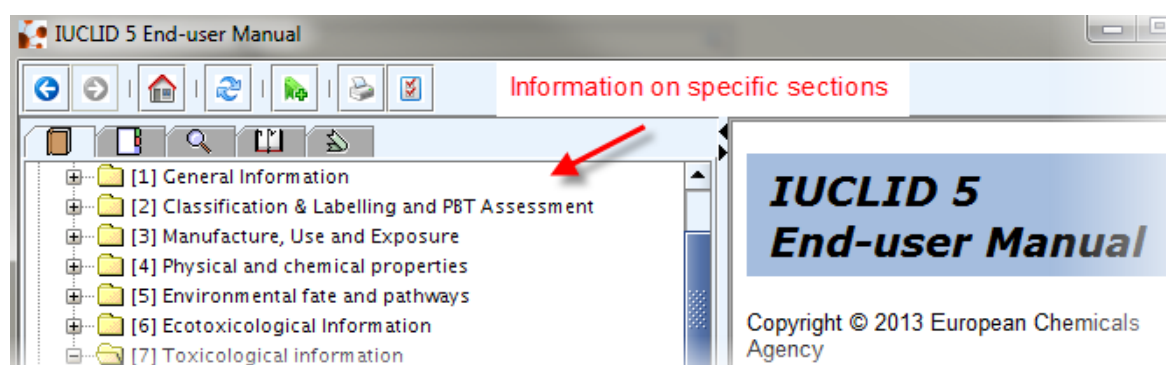


2.4 General functions in IUCLID 5


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.

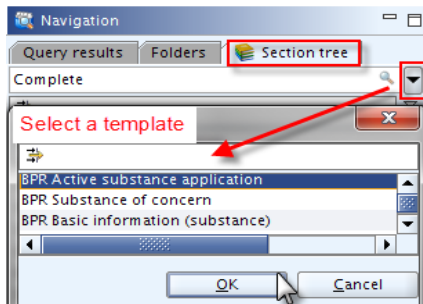
1. Help in IUCLID

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.




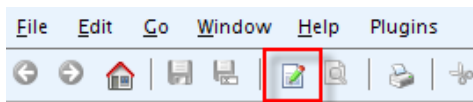
2. Using the 'view mode' to select a dataset template

Select the appropriate dataset template, e.g. 'BPR active substance application', from the drop-down menu using the view mode selector () under the 'Section tree' tab.




3. Edit function


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



4. Back button

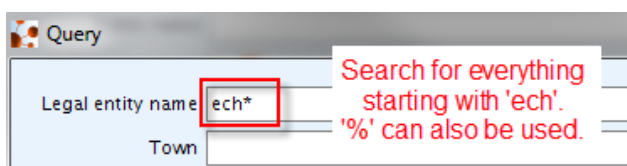
To get back to the original section press the back button () in the IUCLID 5 taskbar.

5. Go to button

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

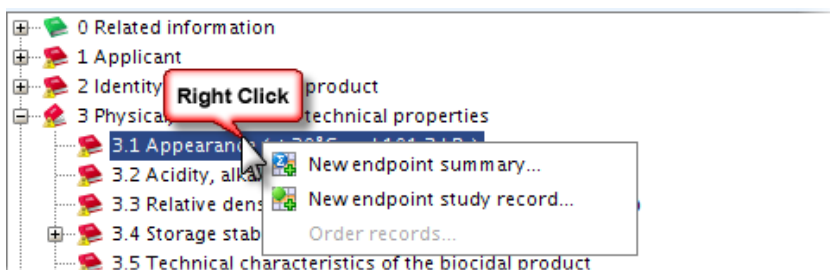
6. Wildcard symbols

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.



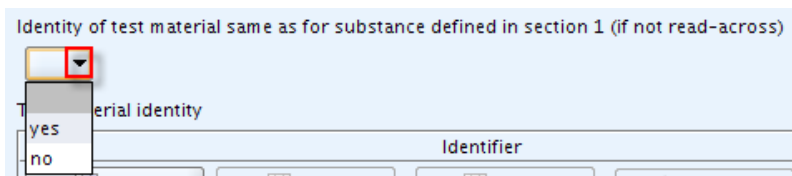
7. Creating an endpoint study record or endpoint study summary

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

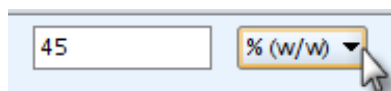
Access a drop-down menu using the black arrow (▾). Then select the correct option from the predefined options.



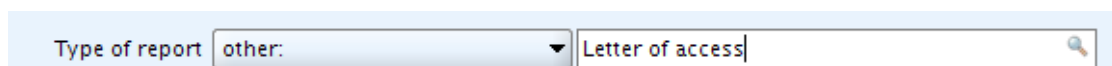
When there is a unit field related to a value field, then ensure a unit is always selected from the drop-down menu.



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

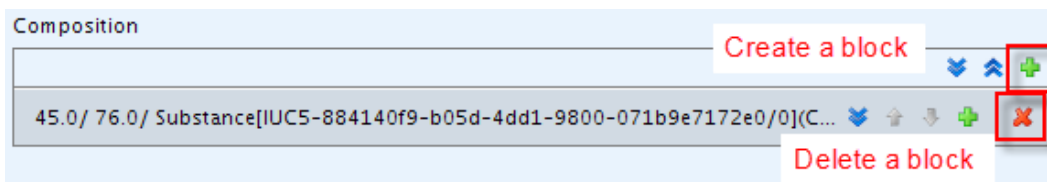


Please note: If 'other:' is selected from the drop-down menu, then the adjacent field must be filled in.



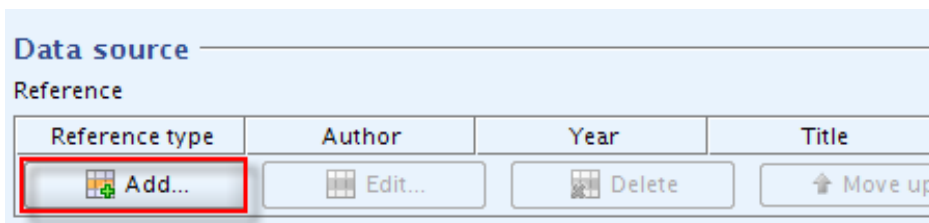
9. Add and delete function

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




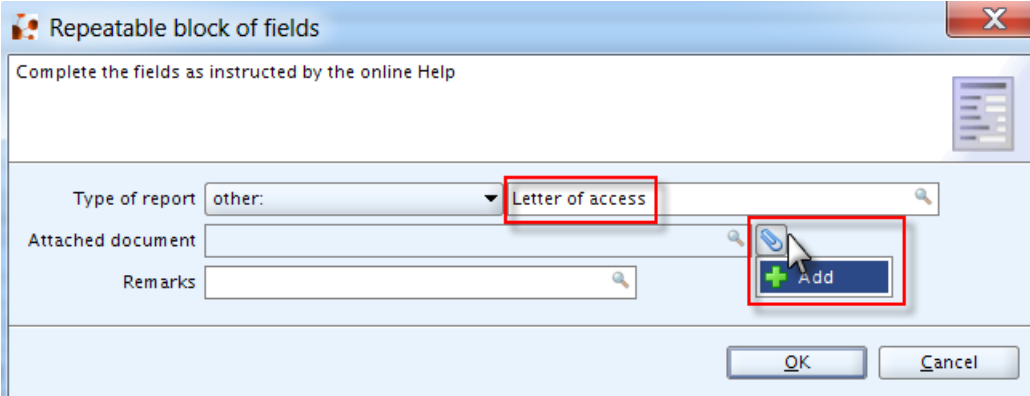
10. Add function

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













11. Attach function

Attach relevant documents to IUCLID section 13 'Summary and evaluation' using the attachment button (, and then click 'Add'. Refer to [chapter 6.4.1](#) for full instructions.




2.5 Using the 'Section tree' of a dataset

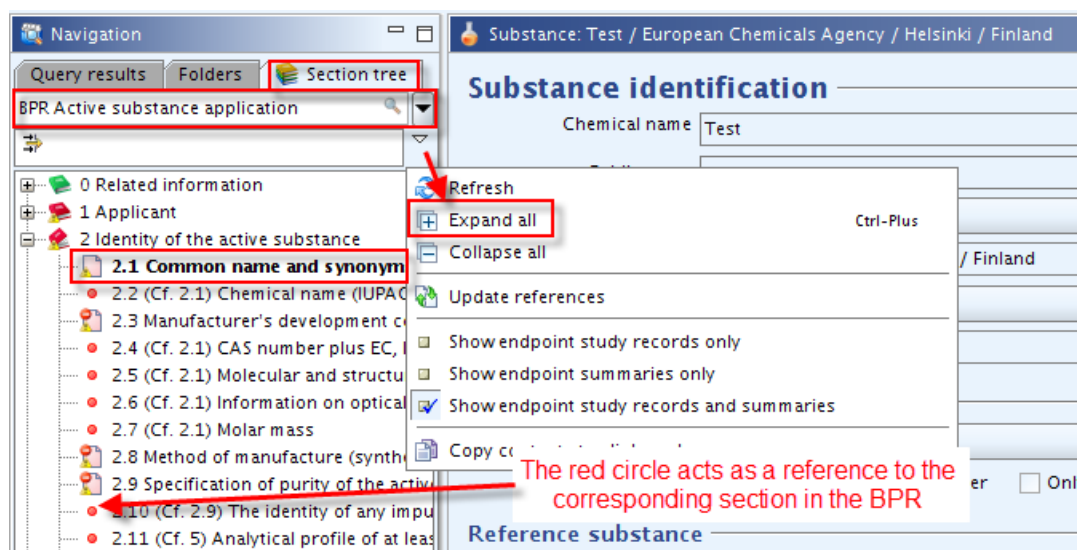
When a dataset is opened, you can select a specific dataset template from the view mode selector using the black arrow () under the 'Section tree' tab (Figure 6). Ensure that you have selected the correct dataset template for your purpose e.g. 'BPR Active substance application' (Figure 6), 'BPR Biocidal product authorisation'. By selecting 'Expand all', you will see all the relevant sections contained in this dataset template (Figure 6). 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 enter 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 6).



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

You can always tell which section is open in the main window, as it will appear in bold lettering. Figure 6 shows section '2.1 Common name and synonym' open in the main window.

Figure 6: Navigation window

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 Process of confidentiality requests for biocide applications](#).

3. Preparing a dataset for an active substance

This chapter outlines how to prepare a 'BPR Active substance application' dataset, containing information about an AS. Supplementary datasets such as 'BPR Basic information (substance)' and 'BPR Substance of concern' can be created in a similar manner but may contain different sections. Supplementary datasets contain information about additional components of a BP (e.g. solvent, emulsifier, etc.).






For full details on how to report a mixture containing an active substance or for details on how to include active substances generated in situ, please refer to [Annex I](#) and [Annex II](#) to this manual.



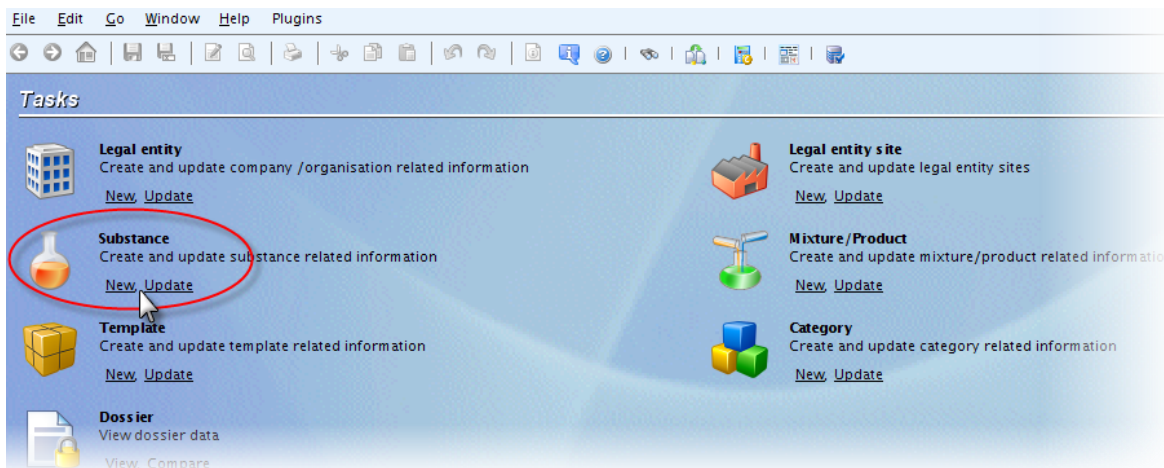
Information requirements will vary depending on the application type you are submitting, e.g. approval of an active substance, inclusion of an active substance in Annex I to the BPR, introduction of an active substance to the Review Programme implementing Regulation etc. To assist you in fulfilling the specific information requirements for your application type, ECHA has [guidance documents](#) and [practical guides](#) available on the ECHA website. In addition to this, 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 registered 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 7). Follow the prompts to i) enter the name of the chemical, ii) assign a 'Legal entity'⁸ 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 8).

If you have not created an official Legal entity to assign to the dataset, you can create one from the [IUCLID website](#).

Figure 7: 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 8). 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 8). Full details related to the Legal entity can be viewed by clicking on the 'Go to' button () (Figure 8).


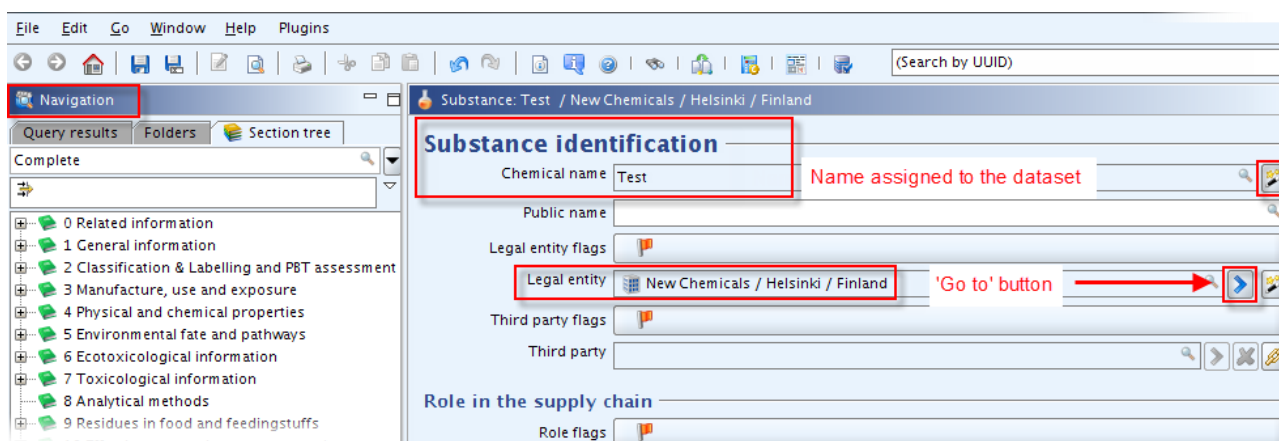
⁸ A Legal entity () is either a company/organisation or a natural person capable of and having the right to engage into contracts or commercial transactions e.g. authorisation holder, manufacturer. In IUCLID 5, a Legal entity is an element used to store and manage Legal entity information i.e. the name, contact details, any Legal entity specific identification numbers, etc.

Figure 8: 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 7). 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 9).

Figure 9: Updating a 'Substance' dataset



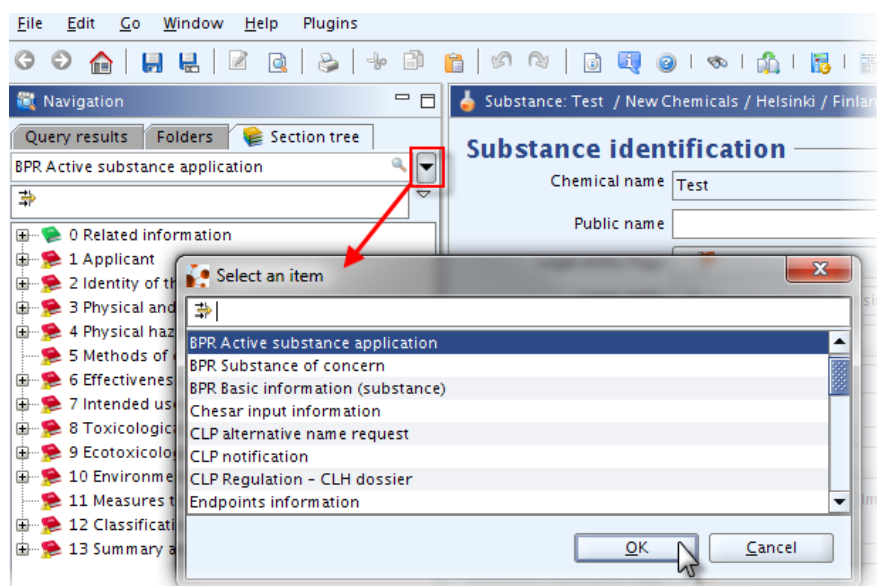
Step 2: Select the dataset template

Select the 'main' dataset template ([chapter 2.1](#)), i.e. 'BPR active substance application', from the drop-down menu using the black arrow (▼) under the 'Section tree' tab (Figure 10). By selecting 'Expand all', you will see all of the sections contained in the template (Figure 6).

If you are creating a 'Substance' dataset for additional components of a BP (e.g. a solvent, emulsifier, etc.), select the supplementary dataset template 'BPR Basic information (substance)', or 'BPR Substance of concern'.



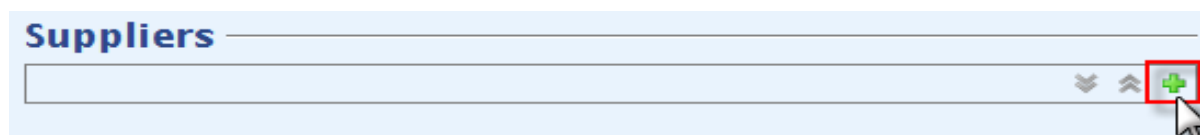
Please use the designated IUCLID fields whenever possible to enter data.

Figure 10: 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 11).

Figure 11: 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 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 12). 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 12), to launch the Legal Entity assistant (Figure 13).

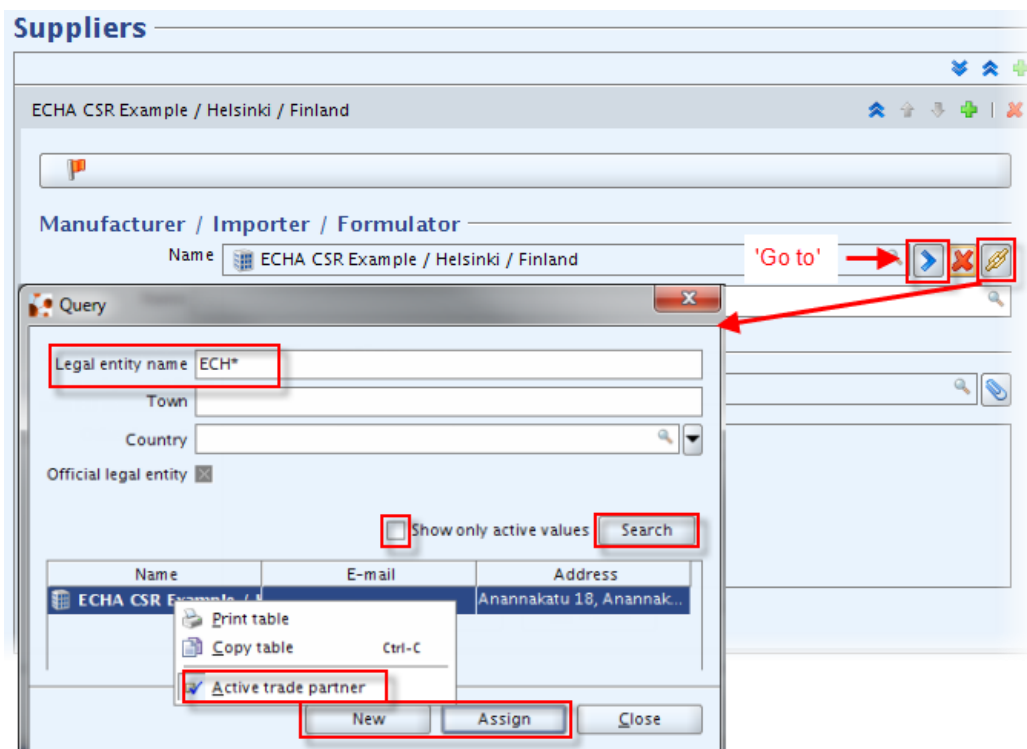


The legal entity of the manufacturer has to be 'active' before it can be assigned. A legal entity can be activated by right-clicking on it in the search result list and selecting 'Active trade partner' (Figure 12).



Make sure that the 'Show only active values' checkbox is **not** ticked when performing the search (Figure 12).

Figure 12: Specifying a manufacturer



The Legal entity assistant will prompt you to enter the name of the Legal entity, then click 'Finish' (Figure 13). Next, click on the 'Go to' button (🔍) in IUCLID section 1.3 (Figure 12) and enter the details of the manufacturer's Legal entity in the 'Contact information' tab, i.e. the contact address and contact persons details (Figure 14).

Figure 13: Legal entity assistant

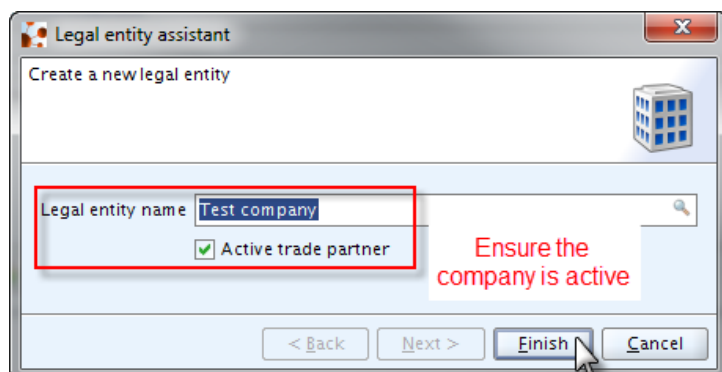


Figure 14: Updating Legal entity details

Legal entity: Supplier / Rockville / Finland

General information Identifiers **Contact information** Sites

Contact address

Address flags

Address Ocean Drive

Address **Address of manufacturer**

Postal code 0000

Town Rockville

Region / State

Country Finland

Phone +000 111 222 333

Fax

E-mail activesubstancemanufacturer@mail.com

Web site

Contact persons

Doe, Jane

Person flags

Contact type other: Site manager

Organisation Carlton Pty. Ltd.

Department Research and design

Title Manager **Location of manufacturing site**

First name Jane

Last name Doe

Phone +000 111 222 333

Step 4: Identify the active substance

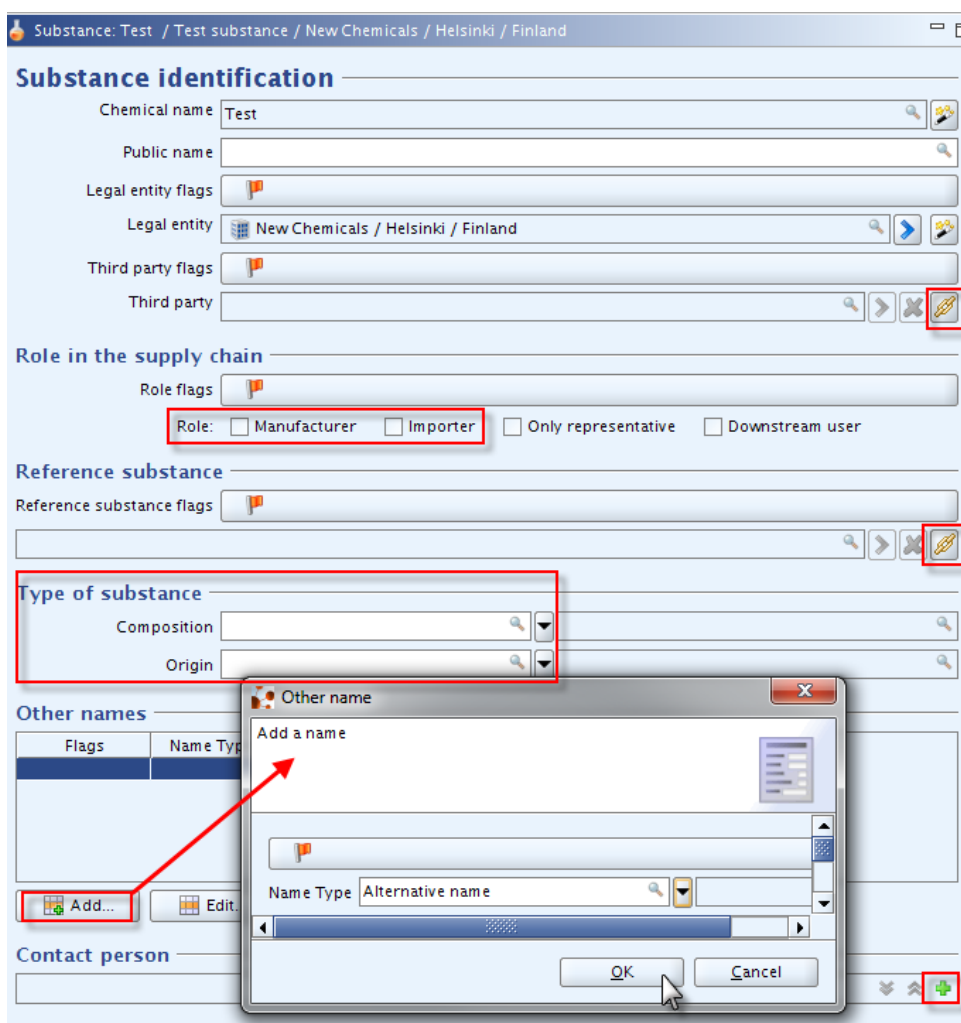
IUCLID section 2.1 'Common name and synonyms'

This section allows the identification of the AS, by filling in pre-defined fields. The fields indicate the name of the AS, 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 AS 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 15 and are explained below the figure.



Special note for formulators: In section 2.1 of the active substance dataset, you may either select 'Downstream user' or leave this section empty if none of the options apply to you.

Figure 15: 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 12). 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 12), to launch the Legal Entity assistant (Figure 13).

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 in the 'Substance' dataset identifies the AS this dataset has been created for; the AS may be a substance or a micro-organism. Establish the reference substance by using the link button (🔗) in the 'Reference substance' section (Figure 15). 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 16). 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 17).

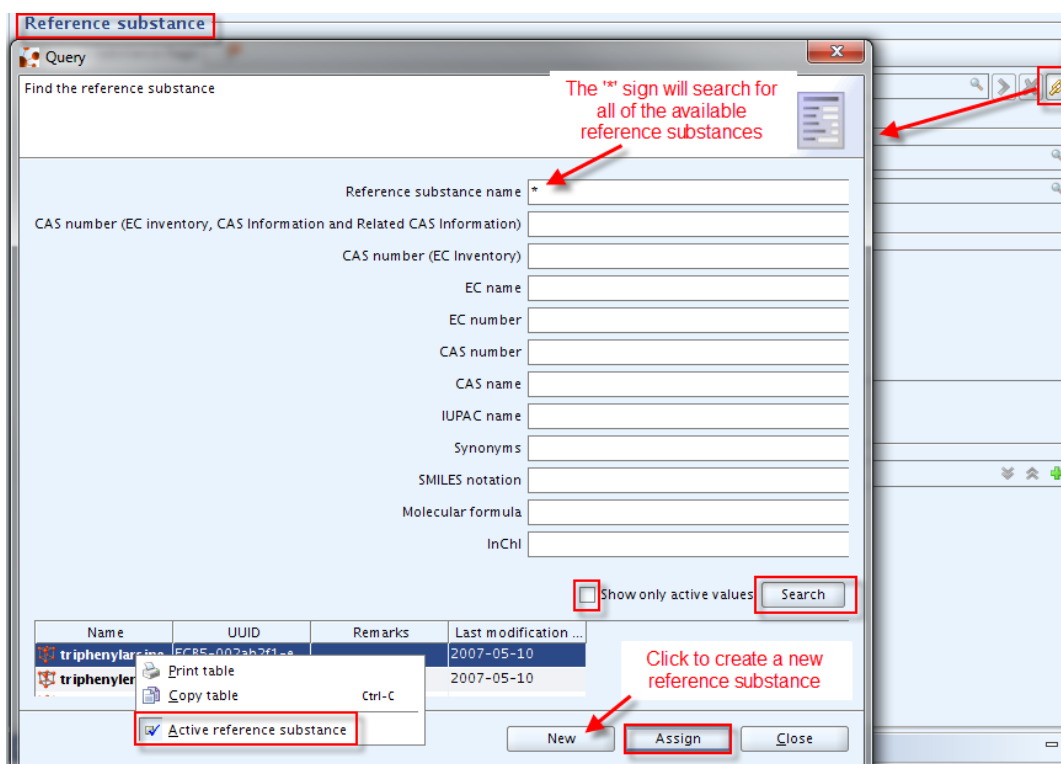


Make sure that the 'Show only active values' checkbox is **not** ticked when performing the search (Figure 16).



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 16).

Figure 16: 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 17). Then, click on the 'Go to' button (🔍) in IUCLID section 2.1 and manually enter the details of the reference substance (Figure 18). If you are creating a dataset for a micro-organism, then enter the scientific name of the micro-organism into the 'IUPAC name' field.

Figure 17: Reference substance assistant

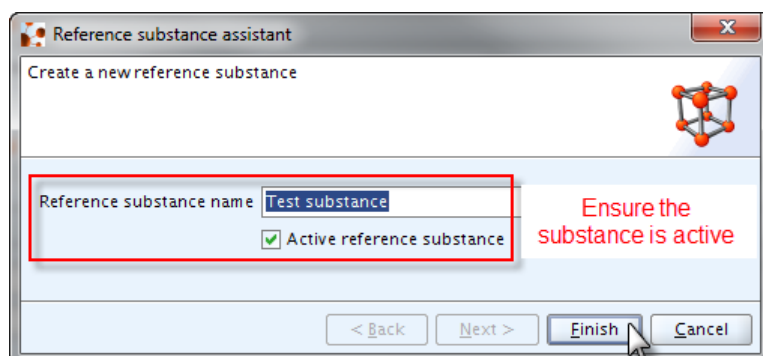



Figure 18: Updating the details of the 'Reference substance'

The screenshot displays the IUCLID software interface for updating reference substance details. At the top, there is a 'Reference substance' section with a 'Reference substance flags' field and a 'Go to' button. Below this, a 'Test substance' entry is shown with a red box around the 'Go to' button and a red arrow pointing to it. The main content area is divided into several sections: 'General information' (with fields for EC number, EC name, CAS number, CAS name, Reference substance name, and IUPAC name), 'EC inventory' (with fields for EC number, CAS number, EC name, Molecular formula, and Description), 'No EC information available' (with a Justification field), 'Reference substance information' (with a flag field), and 'CAS information' (with fields for CAS number and CAS name). A red box highlights the 'EC name' field in the 'EC inventory' section with the text 'Fill in the reference substance details'.


Type of substance

Select the composition type (e.g. mono constituent, multi constituent, etc.) of the reference substance. If you are creating a dataset for a micro-organism, then select 'other: and type 'micro-organism' into the adjacent field. Then, select the origin (e.g. element, inorganic, etc.) of the reference substance from the pre-defined picklist options using the drop-down menu button (▼).

Other names

Enter all the trade (commercial) names and alternative names by which the AS 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 (▼,); 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 AS, and then select the country in which the name is associated with the AS. 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 15). 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 AS or article production. Start by creating blocks with the 'plus' function () and then type in the appropriate information in the free text fields (Figure 19).

Figure 19: Entering information on the technological processes

The screenshot displays a software interface for entering technological process information. It is divided into two main sections: 'Methods of manufacture of substance' and 'Methods of article production'. Each section has a header bar with navigation icons (back, forward, home, add, delete). The 'Methods of manufacture of substance' section contains a large text area with a 'Free text field...' placeholder. A red box highlights this text area. Below it is a 'Related manufactures' section with a smaller text area and navigation icons. The 'Methods of article production' section is currently empty.



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

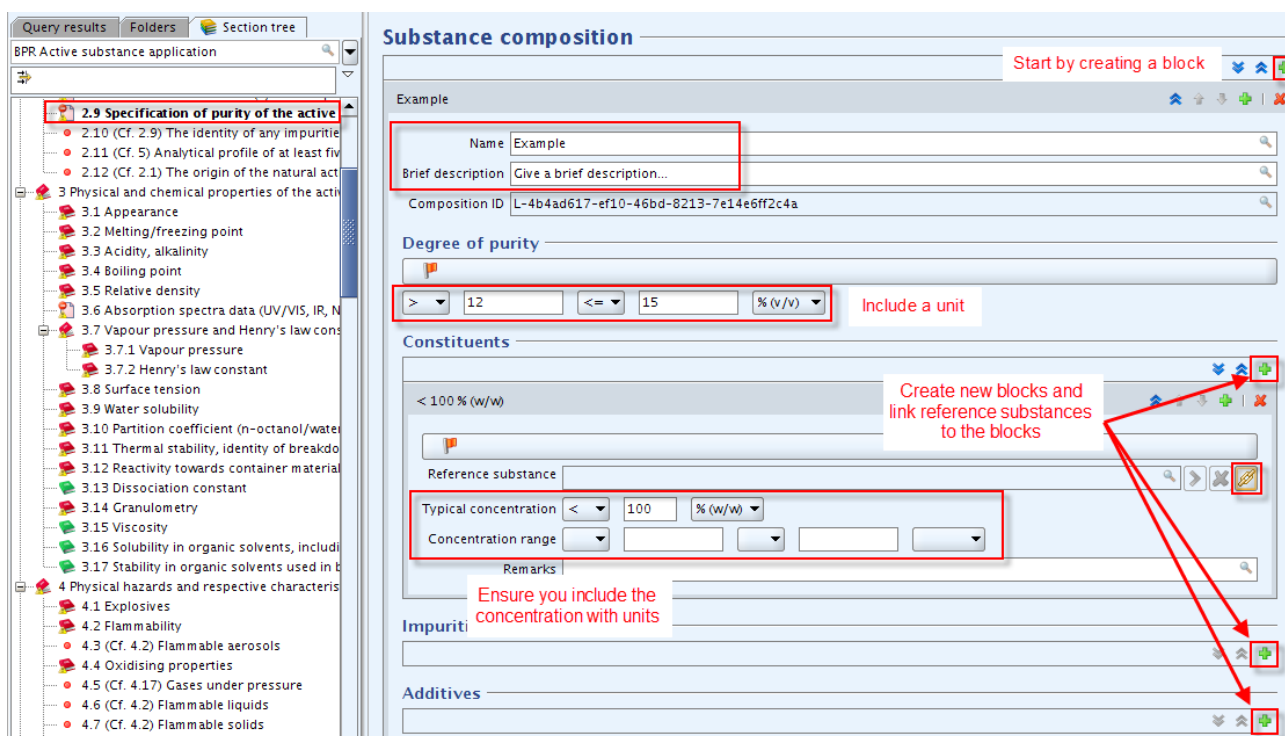
IUCLID section 2.9 'Specification of purity'

The composition, constituents, impurities and additives of a substance define it. This section allows the entry of multiple compositions of the substance, for example, 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 20). Enter the name, a brief description and the degree of purity of the AS in the fields provided. Create a block under the constituents section and link (🔗) all the constituents of your AS to reference substances (Figure 20). If you have any impurities or additives, create a block for each and fill in relevant 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 20: 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' dataset, you must also create a dataset for the BP, using the dataset 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 of a BP. Note that a 'Mixture/Product' dataset using the dataset 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 'Mixture/Product' dataset is used to contain the information of the representative BP, see [IUCLID section 2.3 'Biocidal product composition'](#).




To create a valid dossier, the 'Mixture/Product' dataset must always be linked to a 'BPR Active substance application' dataset (Figure 2).

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



Information requirements will vary depending on the application type you are submitting. To assist you in fulfilling the specific information requirements for your application type, ECHA has [guidance documents](#) and practical guides available on the ECHA website. In addition to this, 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 21), and follow the prompt to i) enter the BP name in the field 'Mixture/product name', ii) assign a 'Legal entity'⁹ 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 22).


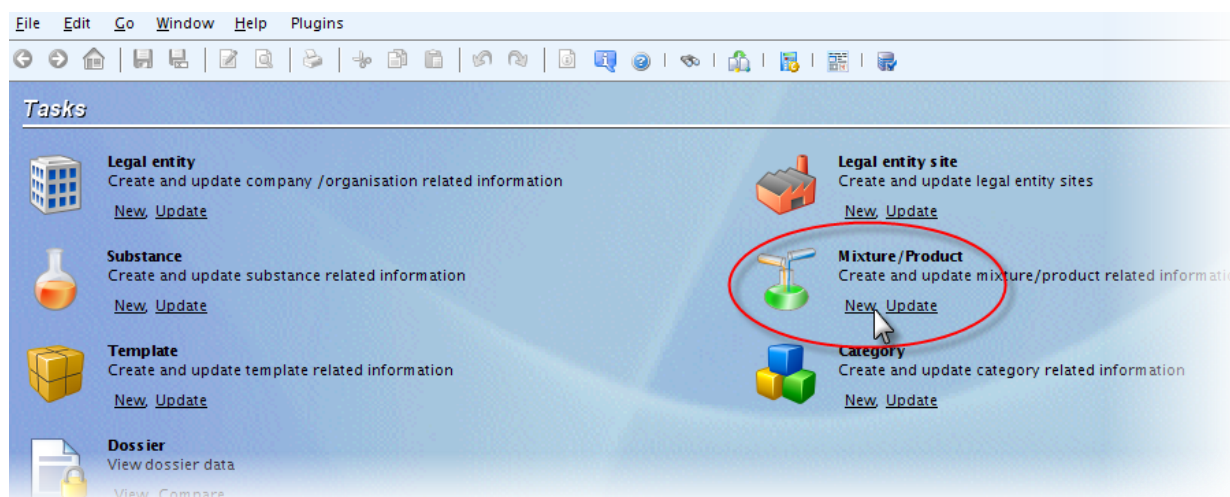
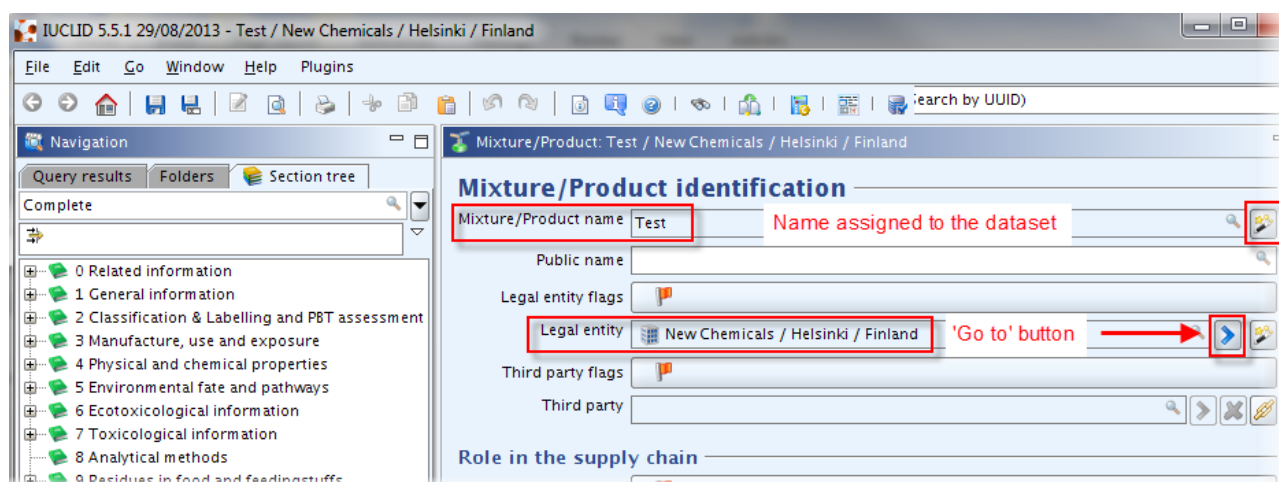
⁹ A Legal entity () is either a company/organisation or a natural person capable of and having the right to engage into contracts or commercial transactions e.g. authorisation holder, manufacturer. In IUCLID 5, a Legal entity is an element used to store and manage Legal entity information i.e. the name, contact details, any Legal entity specific identification numbers, etc.

Figure 21: Creating a dataset for a biocidal product



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 22). Full details related to the Legal entity can be viewed by clicking on the 'Go to' button () (Figure 22).

Figure 22: 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 21). 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 9).

Step 2: Select the dataset template

Select the main dataset template (chapter 2.1), i.e. 'BPR Biocidal product authorisation application', from the drop-down menu using the black arrow () under the 'Section tree' tab (Figure 23). By selecting 'Expand all', you will see all of the sections contained in the dataset template (Figure 6).

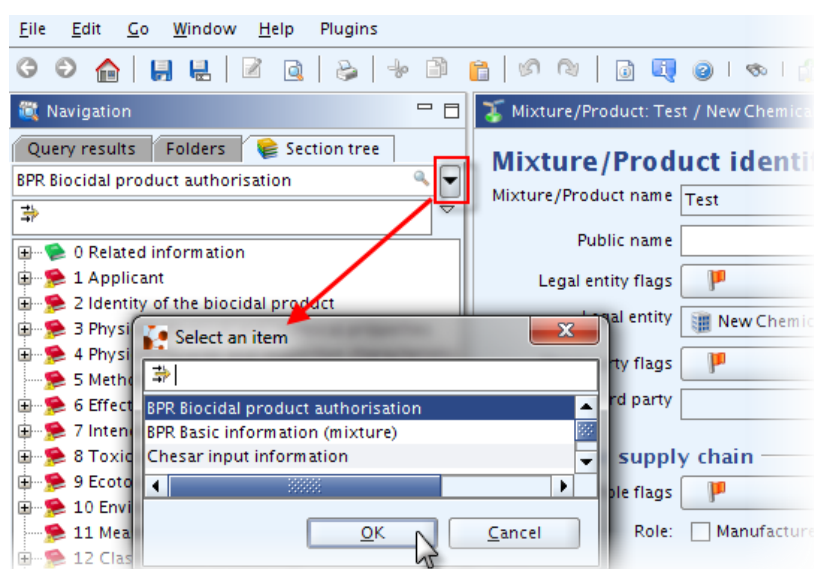
If you are creating a 'Mixture/Product' dataset for additional components of the BP (e.g. a

solvent) select the supplementary dataset template 'BPR Basic information (mixture)'.



Please use the designated IUCLID fields whenever possible to enter data.

Figure 23: 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 BP manufacturer, importer and/or formulator. It is recommended that you include the name of the BP 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 11).



As of the date of the authorisation of the BP, information on the BP 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.

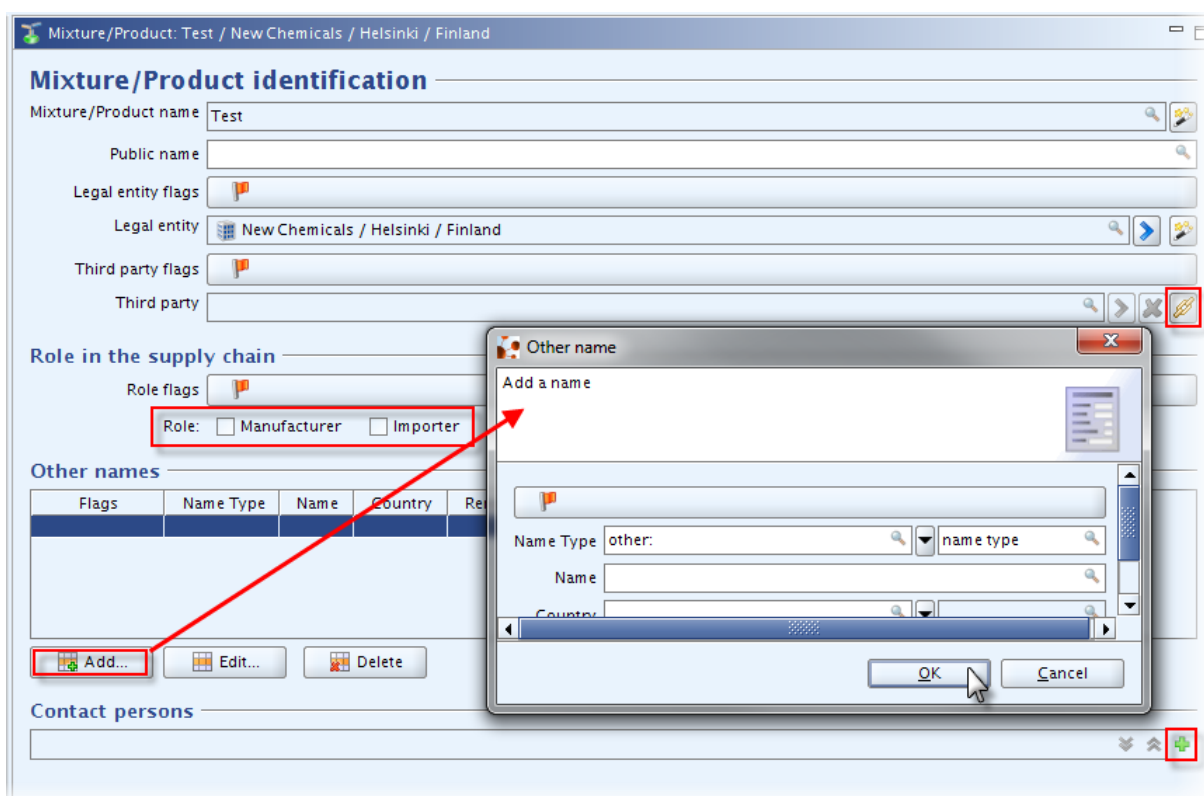
Once you have created a suppliers block in IUCLID section 1.3, click the link button (🔗) next to the 'Name' field, enter some search criteria (e.g. Legal entity name) in the appearing 'Query' window and then click 'Search' (Figure 12). It may be the case that the manufacturer has not been entered into your database. In this case, click 'New' button in the 'Query' window (Figure 12), to launch the Legal Entity assistant (Figure 13). 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 BP, by filling in the pre-defined fields. The fields indicate the name of the BP, 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 BP 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 24 and are explained below the figure.

Figure 24: 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 12). 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 12), to launch the Legal Entity assistant (Figure 13).

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 BP 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 24); 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 BP, and then select the country in which the name is associated with the BP. 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 24). This person may be contacted e.g. to provide assistance or ask about the information submitted.

IUCLID section 2.3 'Biocidal product composition'

A BP is defined by its name, formulation type and its exact composition percentage. A BP 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 BP or multiple compositions for a BP family.



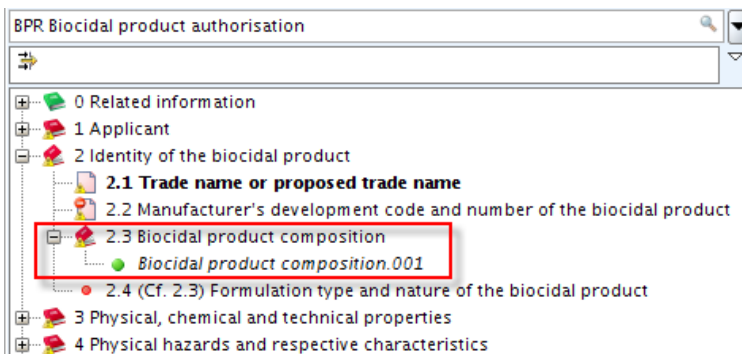

For a single biocidal product: Start by right-clicking on IUCLID section 2.3 'Biocidal product composition', and select 'New endpoint study record' () (Figure 25). Only one endpoint study record () should be created and completed.

Figure 25: 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 BP family.


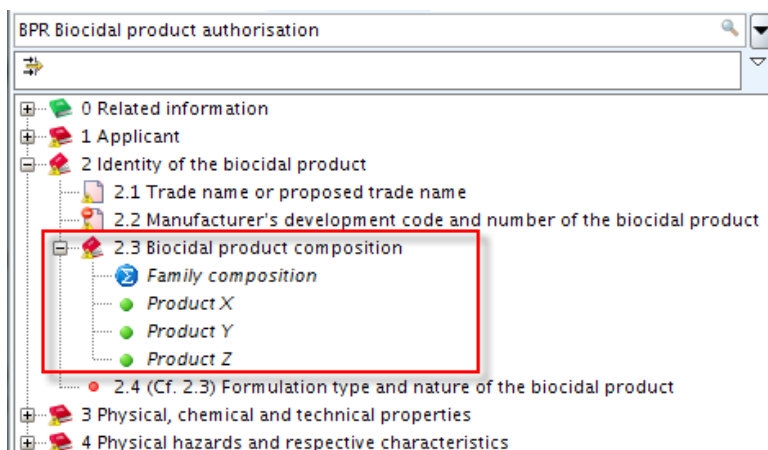
You will then need to create and complete an endpoint study record () for each product within the family. Figure 26 shows an example of how section 2.3 should look for a BP family containing three products.

Figure 26: Endpoint study summary with multiple records for a BP 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'](#)).

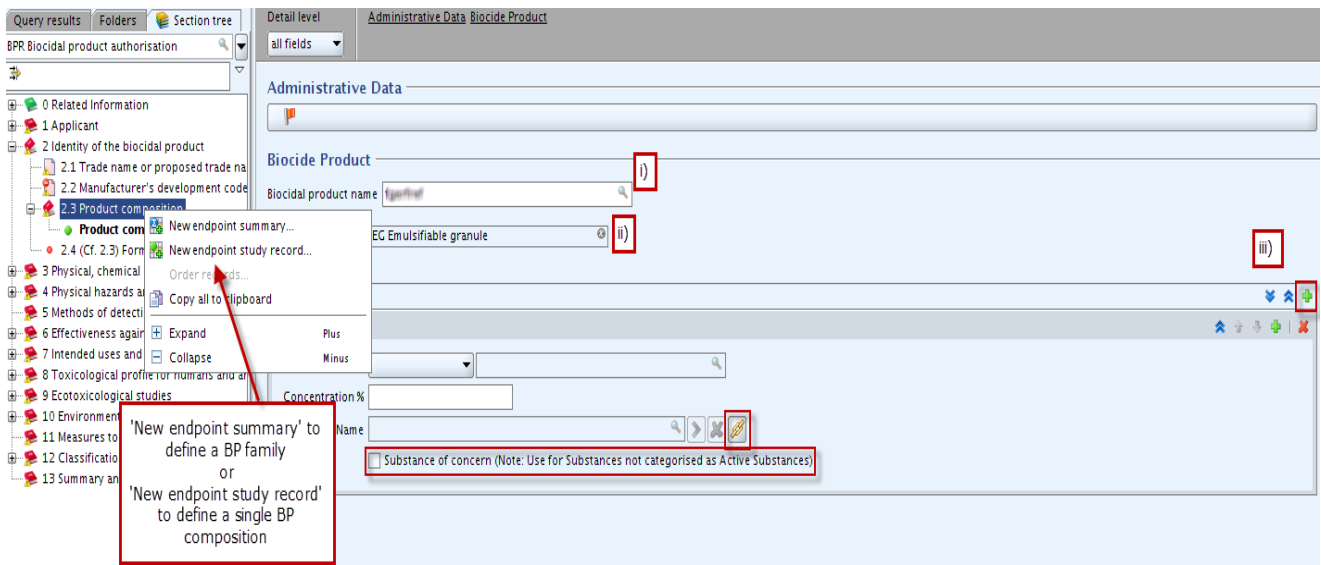


Section 2.3 'Product composition': If you create an 'Endpoint summary' or you include more than one AS in the BP composition, e.g. include more than one 'Endpoint Study record' each with an AS, you will be unable to make a 'BPR Active substance application' dossier.

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 27):

- i) the BP 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 27). You will need to create an individual block for each component of your BP. Within the block, indicate the BP function (e.g. AS, 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 27).

Figure 27: 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 BP 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 27). Be sure to identify all of the components of your BP 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 dataset

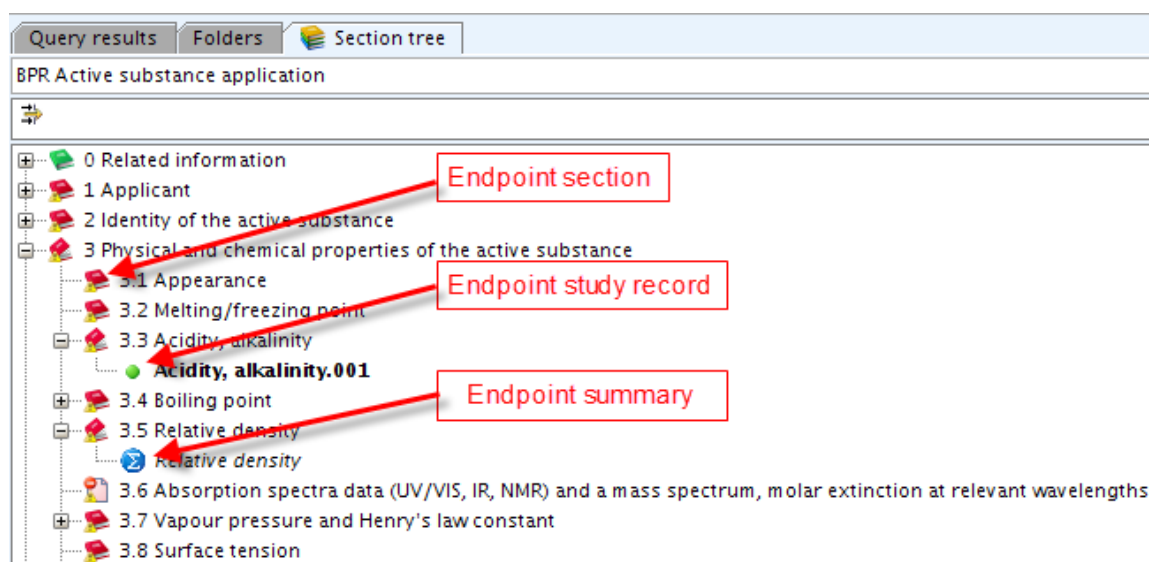
template 'BPR Biocidal product application', and linked a fully completed 'Substance' dataset using the dataset template 'BPR Active substance application' ([chapter 3](#)) in [section 2.3 'Product composition'](#), you can create a valid dossier. For detailed instructions on how to create a dossier 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 28). 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 28: 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 29).



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 29: Administrative data fields

'Data Source' block

Complete the 'Reference' table as much as possible (Figure 30) by adding lines to the existing table using the 'Add' button (). 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 30). More information on how to complete the above data fields is provided in the [IUCLID 5 End User Manual](#).

Figure 30: 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 31). Achieve this by firstly adding lines to the existing tables using the 'Add' button (). 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 29), 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 31).



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 30).

Figure 31: '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 [chapter 2.4](#)).

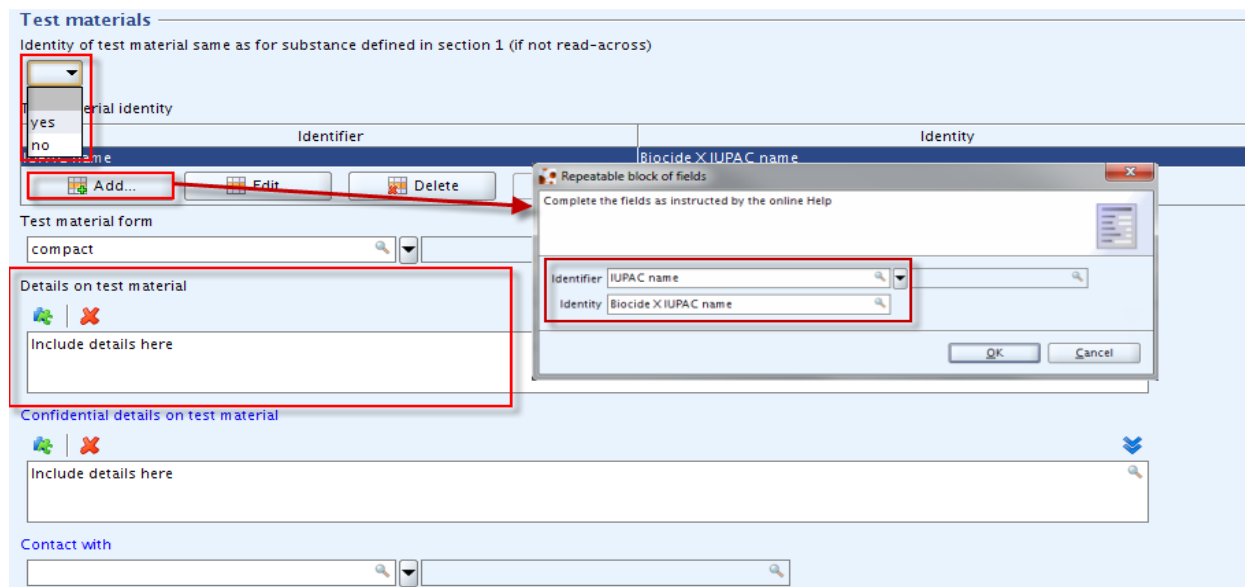
'Test Materials' block

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 32). 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 32). 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 enter 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 32: 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. CO₂, 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'.

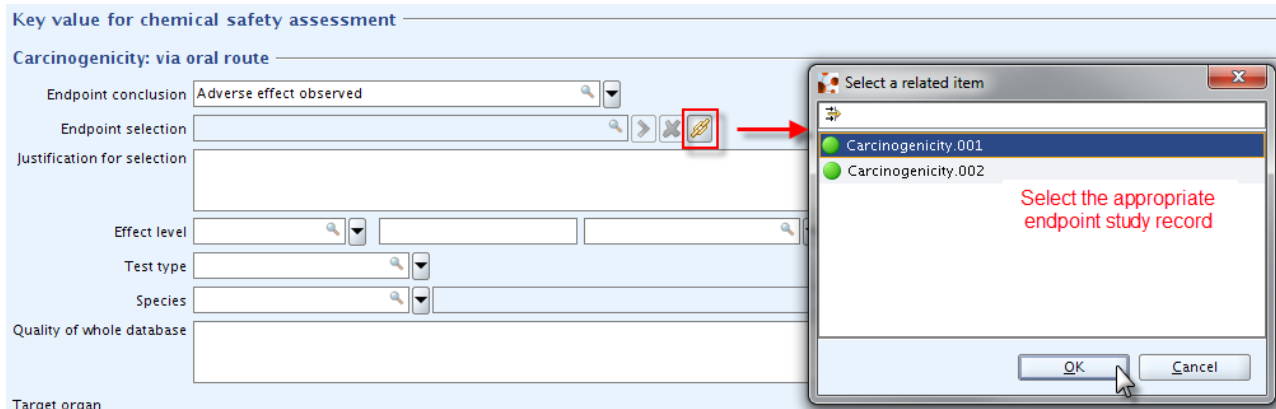
5.2 Endpoint study summaries

An endpoint study summary (🔗) should be a summary of the evaluation made on all the data entered in the endpoint study records (see [chapter 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 33).

Figure 33: 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](#)

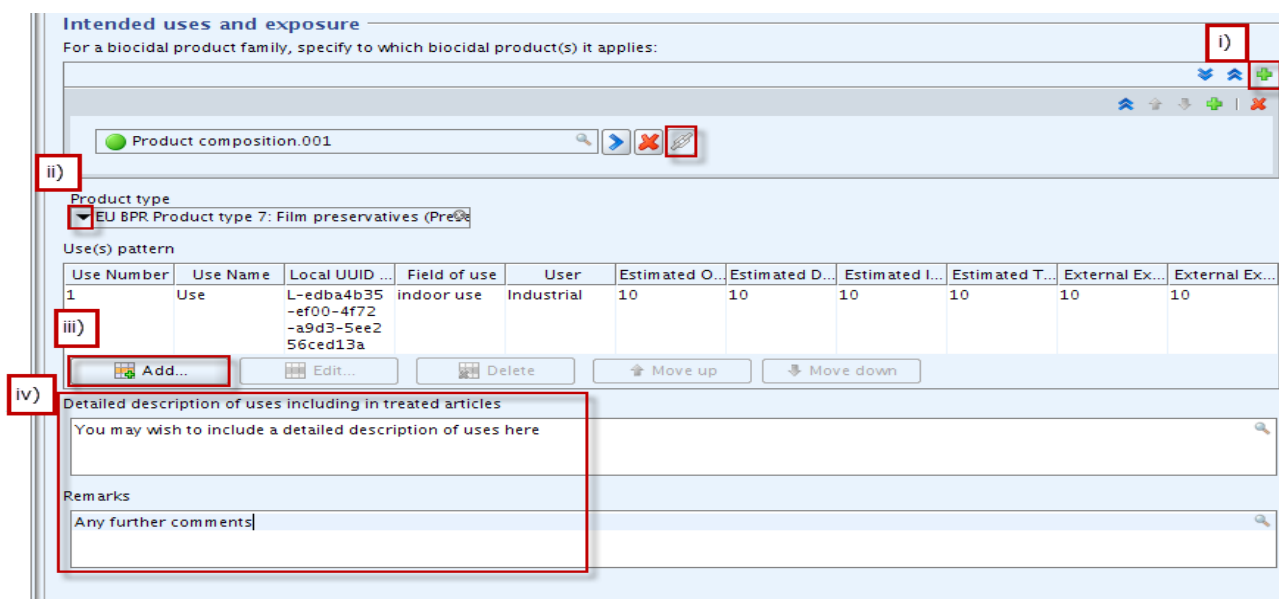
6.1 IUCLID section 7 'Intended uses and exposure'

IUCLID section 7.1 'Fields of use...'

This endpoint section enables the generation of a systemic overview of the intended uses of the representative BP in the BP dataset i.e. there is no need to fill this section for the active substance. 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 34):

- 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'](#). Note that this step **only applies if the dataset concerns a product family**.
- 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 34: 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 enter 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 BP type and/or year (Figure 35).

Figure 35: Entering the 'Likely tonnage to be placed on the market'

Likely tonnage to be placed on the market

Likely tonnage to be put on the market (tonnes / year)

Product type	Year	Tonnage placed on the market (t)	Remarks
EU BPR Product type 4: Food and feed area (Disinfectants)	2013	100	

Repeatable block of fields

Complete the fields as instructed by the online Help

Product type

Year

Tonnage placed on the market (t)

Remarks

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...'](#) for the representative BP.

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 36):

- 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...' () 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 36: Entering the method of application

Directions for use

Reference use

Method of application

Detailed description of method of application

Include a detailed description of the method of application here

Application dose and final concentration of active substance and biocidal product in treated article or system

Dilution (%)	Application dose	Final concentration of active...	Final concentration of biocid...	Remarks
50	> 200 – 250 % (w/w)	300 % (w/w)	900 % (w/w)	Any further information

Add... Edit... Delete Move up Move down

Application aim

Number and timing of applications

Include the number and timing of applications here

Proposed instruction for use

Include the proposed instruction for use here

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 AS or BP, 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 AS or a BP;

- 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 from the [Regulation's > CLP](#) page from ECHA's website.

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 37).

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 37).

Figure 37: How to specify the 'Classification' labels

Classification and Labelling according to GHS

General information

Name

Not classified

Implementation

State / form of the mixture

Remarks

Related compositions

Classification

Physical hazards

	Hazard category	Hazard statement	Reason for no classification
<input type="radio"/> Classified	Explosives	Expl. Div. 1.2	H203: Explosive; fi
<input type="radio"/> No classification	Flammable gases		inconclusive

An AS may have multiple C&L records, for instance in the case where the AS contains an impurity with specific hazard properties having an impact on the classification. A BP can also have multiple C&L records, for instance in the case where there are different compositions of the BP. You can include multiple C&L blocks, allowing the entry 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 37). Further information on CLP is available from the [Regulation's > CLP](#) page from ECHA's website at.

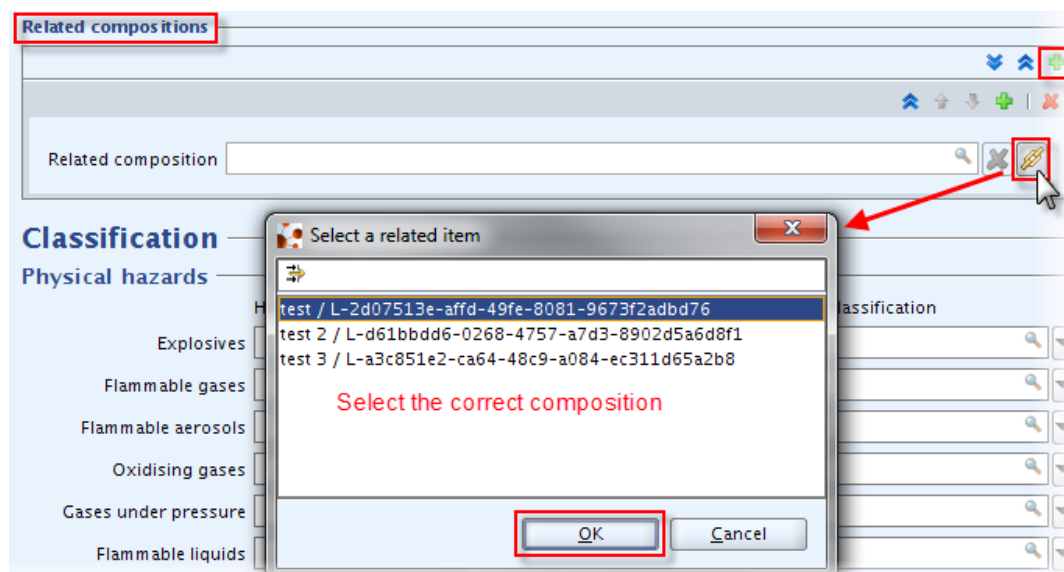


Select 'conclusive but not sufficient for classification' for no classification if a hazard category does not apply to your substance (e.g. 'Flammable gases' for a solid substance).

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 38).

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 38). Several compositions can be linked to the same C&L block.

Figure 38: 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 BP (type, materials, size, compatibility of the BP 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 39):

- 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'](#). Note that this step **only applies if the dataset concerns a product family**.


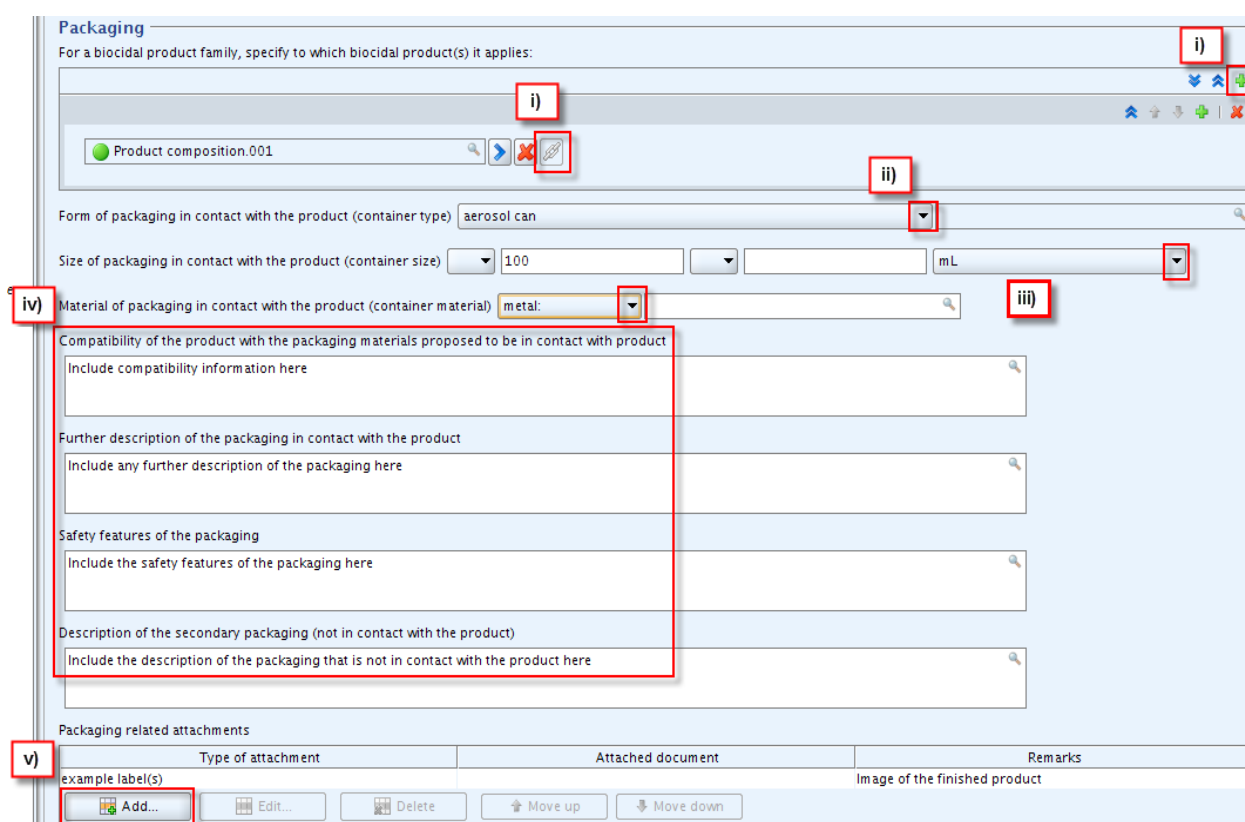
- ii) Select a form of packaging from the available drop-down menu (▼).
- iii) Enter the size and material of packaging (use the drop-down menus (▼) to include the unit).
- iv) Enter the compatibility of the BP, and further description of the packaging, safety features and secondary packaging in the 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 ().

Figure 39: Entering packaging information



The screenshot shows the 'Packaging' form in IUCLID. It includes a search bar for product families, a dropdown for 'Form of packaging in contact with the product (container type)', and input fields for 'Size of packaging in contact with the product (container size)' and 'Material of packaging in contact with the product (container material)'. Below these are four text areas for compatibility, further description, safety features, and secondary packaging. At the bottom is a table for 'Packaging related attachments' with an 'Add...' button.

Annotations:

- i)** Search bar for product family.
- ii)** Form of packaging dropdown menu.
- iii)** Material of packaging dropdown menu.
- iv)** Text area for compatibility information.
- v)** 'Add...' button for attachments.

Type of attachment	Attached document	Remarks
example label(s)		Image of the finished product


6.4 IUCLID Section 13 'Summary and Evaluation'

In accordance with the BPR, additional documentation may be required for certain applications. The different types of additional information files may include primary supporting documents and additional supporting documents. The required file types are dependent on the application being submitted. Such additional documentation may include a draft risk assessment report, a decision on technical equivalence, and/or a letter of access. 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)' dataset(s). Please refer to Annex III, 2.3 of the BPR.

6.4.1 Summary and evaluation

To attach relevant documents and include some important information concerning your AS and BP, right-click on IUCLID section 13 and select 'New endpoint summary' (). This endpoint summary is divided into three sections: 'Summary and evaluation', 'Active substance related information' and 'Biocidal product related information'.




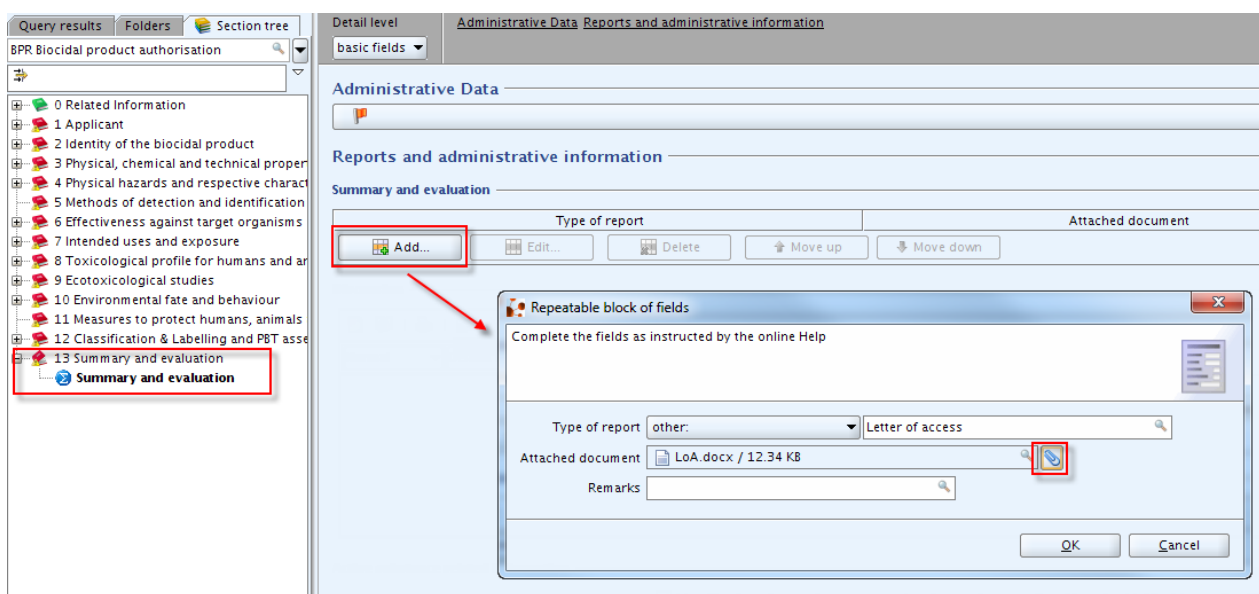
The 'Summary and evaluation' section should be used to attach relevant supporting documentation (including but limited to, a letter of access, a decision on technical equivalence, a risk assessment report, etc.). Attach the appropriate documents by adding () as many lines as needed in the tables provided (Figure 40). Select the applicable option from the drop-down menu () and attach the documents ( , Figure 40). 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 40: Attaching documents in IUCLID section 13



The 'Active substance related information' section contains some checkboxes and drop-down menus. Click on the checkboxes that concern you, for example if you have a decision on technical equivalence, click the appropriate box and ensure you include the decision number (Figure 41). Use the drop-down menus to indicate if your substance is a 'candidate for substitution' or has 'endocrine disrupting properties', i.e. yes or no (Figure 41).


The 'Biocidal product related information' free text field should be used to include information concerning the Summary of Product Characteristics if relevant (Figure 41). If you have authorisation numbers related to authorised biocidal products then enter these into the table using the add button () and typing in the numbers and any remarks you have (Figure 41).

Figure 41: Including a decision on technical equivalence

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.

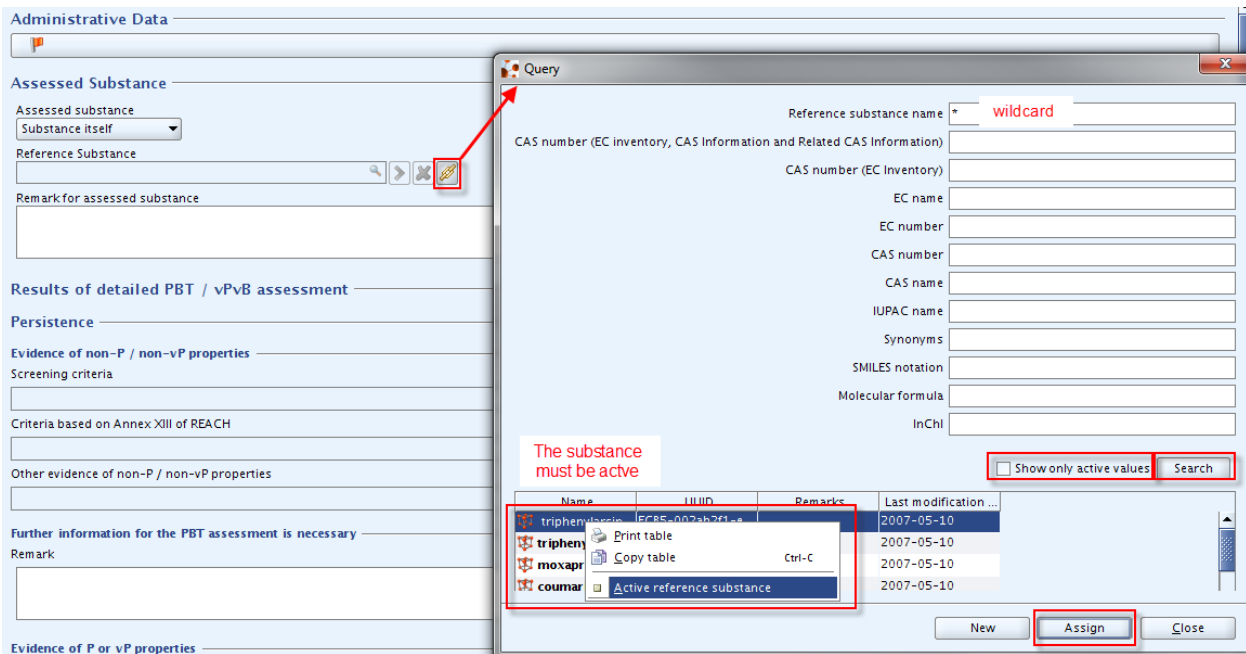
To enter the scientific data for this section, right-click on IUCLID section 13.1 'PBT assessment' and click 'New endpoint study record' or 'New endpoint summary'. An endpoint study record should contain information related to one given PBT assessment study. Whereas, an endpoint summary can be created 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 42).



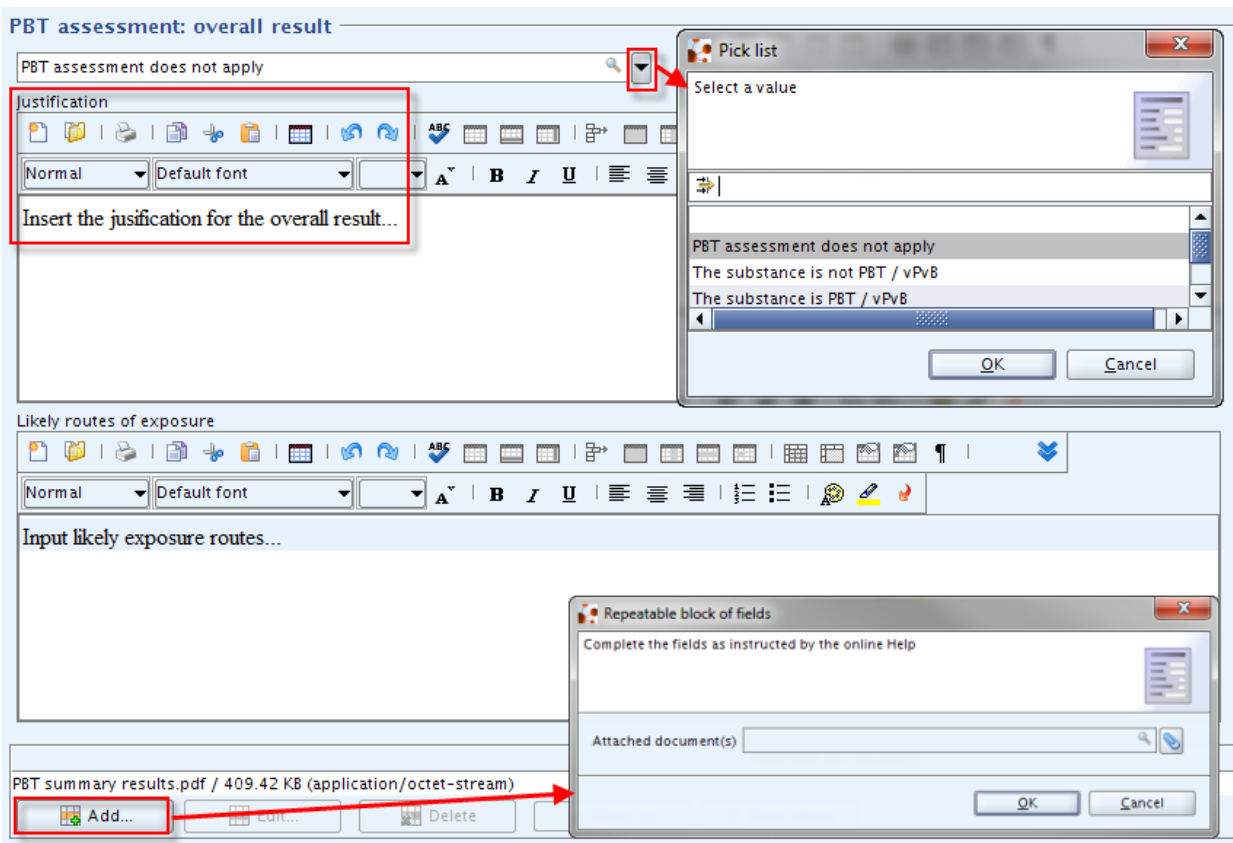
The reference substance has to be 'active' before it can be assigned. A reference substance can be activated by right-clicking it in the search result list and selecting 'Active reference substance'.

Figure 42: Linking a 'Reference substance' to a PBT endpoint study record



PBT endpoint summary: use the drop-down menu (▼) to give an overall result (Figure 43), and then enter 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 43: 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.




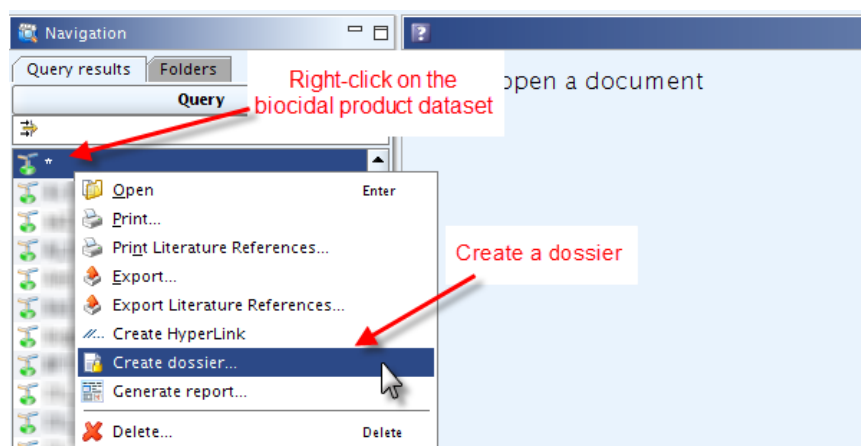
To create the dossier click 'Update' next to the Mixture/Product icon () on the IUCLID 5 homepage (). Then, right-click on the name of your chosen 'Mixture/Product' dataset ( ; contained in the 'Query results' tab) and click 'Create dossier' (Figure 44). This will launch the dossier creation wizard (Figure 45).

Figure 44: 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.

The steps below explain how to navigate through the dossier creation wizard. Click 'Next>' to move to the next step of the wizard (Figure 45).

Step 1 Select the correct dossier type for your application (Figure 45).

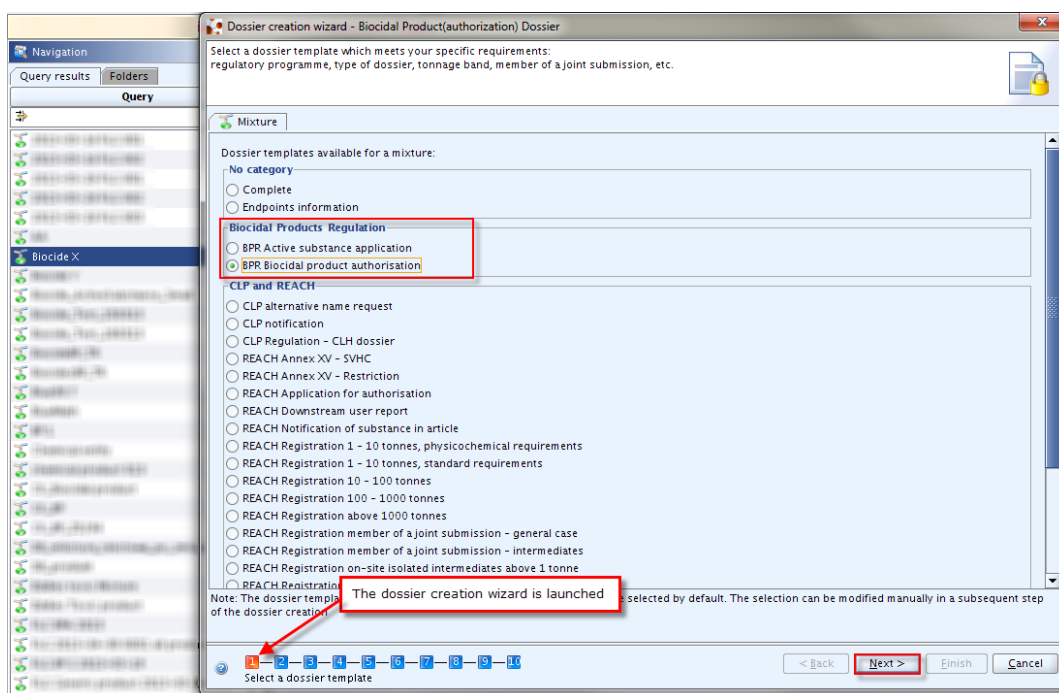


Section 2.3 'Product composition' of your 'Mixture/Product' dataset: If you create an 'Endpoint summary' or you include more than one AS in the BP composition, e.g. include more than one 'Endpoint Study record' each with an AS, you will not be able to make a 'BPR active substance application' dossier,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



For information on whether a dossier is required for your application type and, if so, which type of dossier is required, please refer to the relevant [Biocides Submission Manual](#).

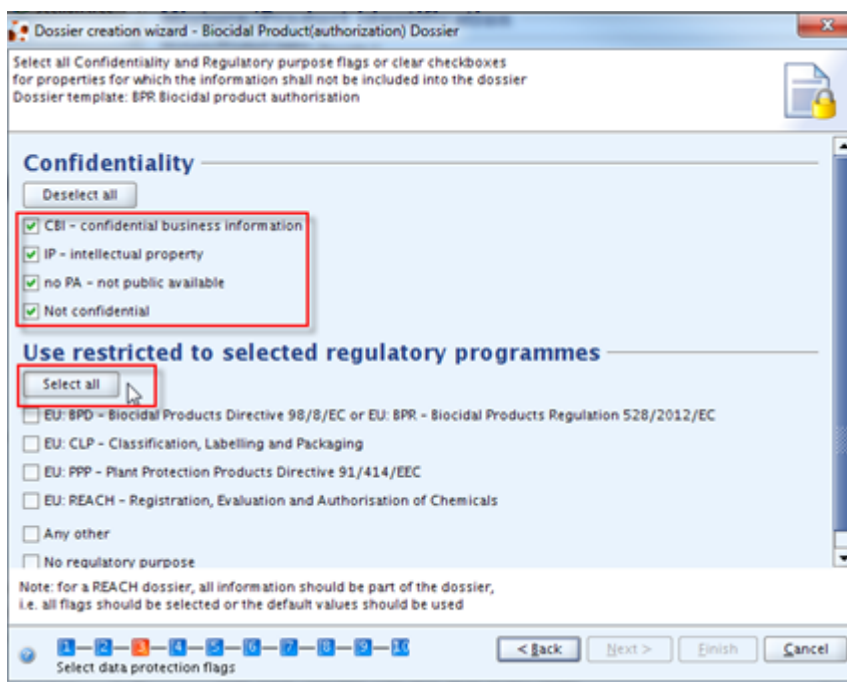
Figure 45: Step 1 of the dossier creation 'wizard'



Step 2 Review the related entities.

Step 3 Filter the information to be included in the dossier (Figure 46). 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.

Figure 46: Step 3 of the dossier creation 'wizard'

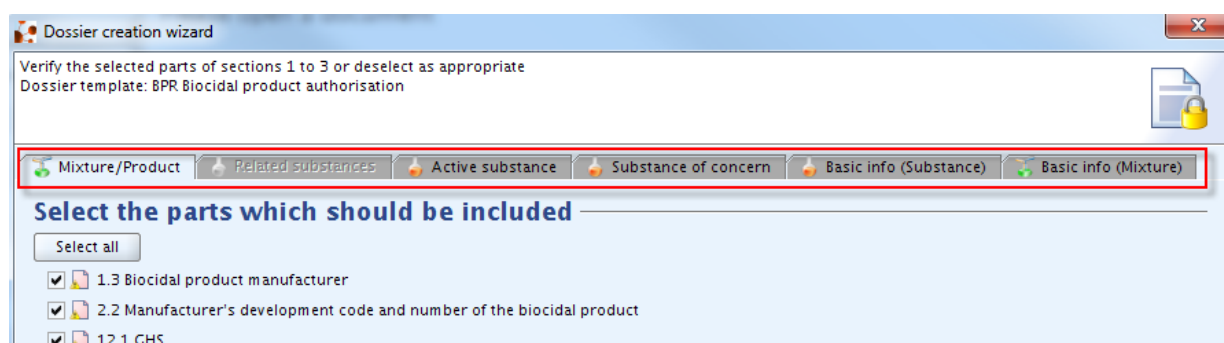




For most cases, ECHA recommends that you 'Select all' the checkboxes, making sure that all of the required elements of the 'Substance' or 'Mixture/Product' dataset are included in the dossier to be submitted.

- 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 47). By default, all the components selected in accordance with the dataset template are included in the dossier. To exclude a component, un-tick the pertinent box in the relevant dataset.

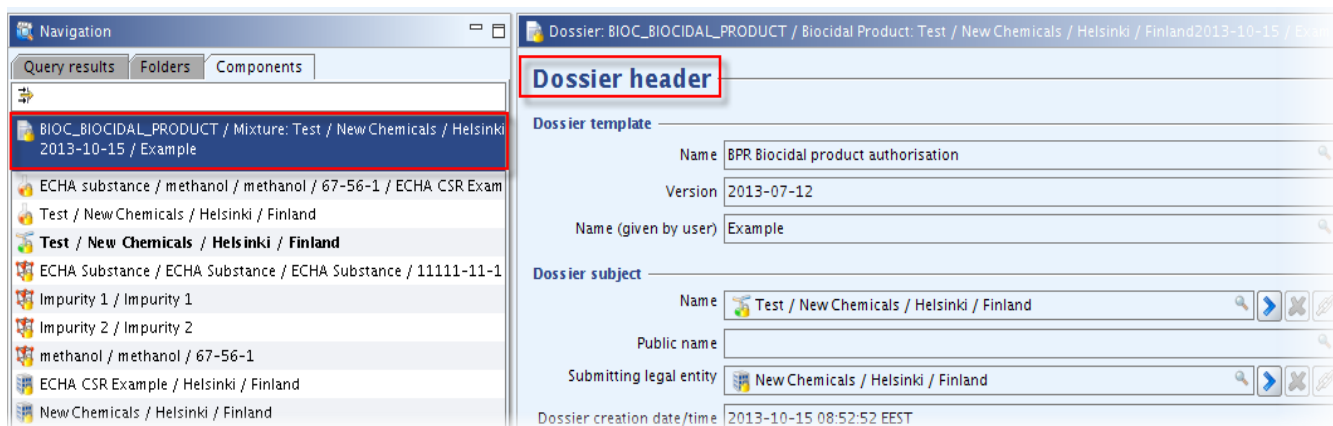
Figure 47: Verifying the sections to be included



- 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 ([chapter 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 48). To view the full dossier content see [chapter 7.2.2](#).

Figure 48: Dossier header

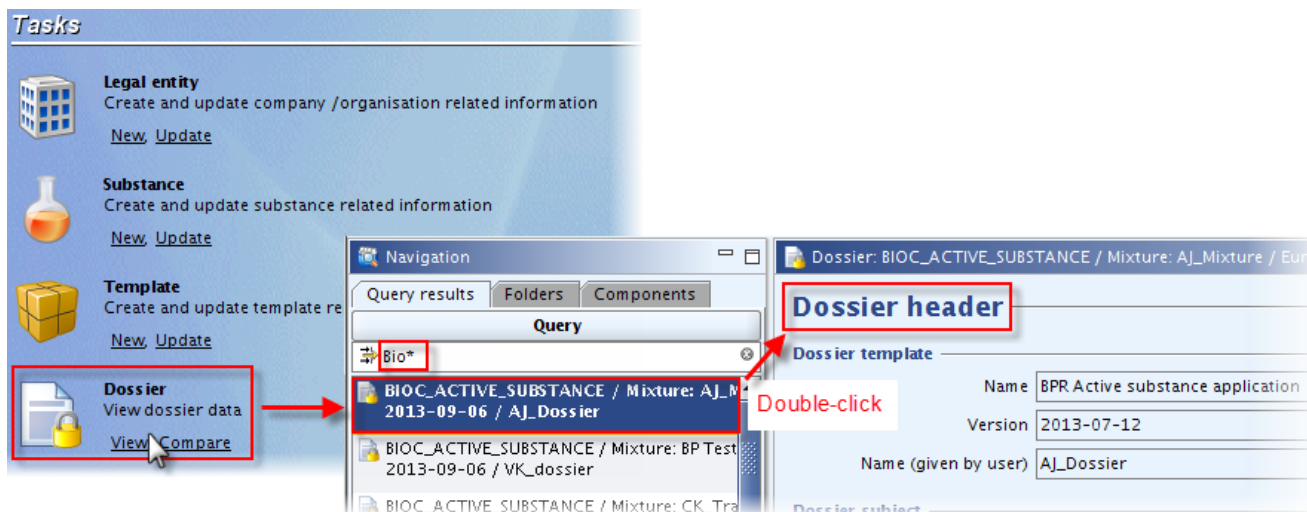


7.2 Viewing a dossier

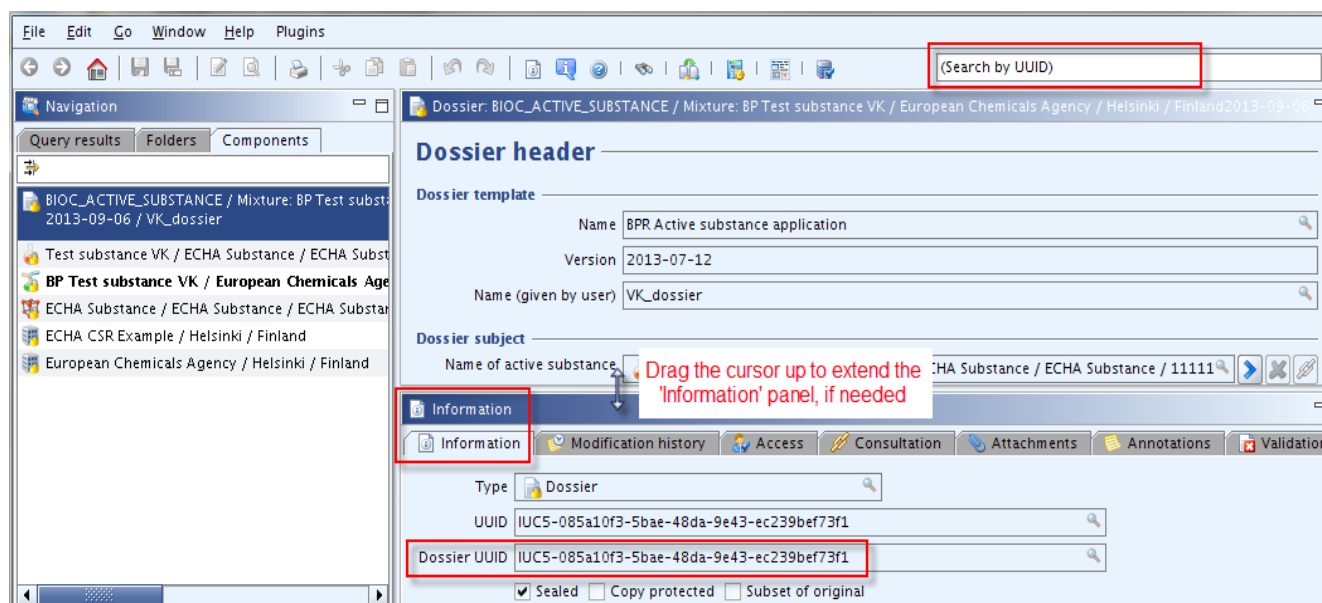
7.2.1 Searching for a dossier

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 49). This will open the 'Navigation' window (Figure 49). In the 'Query' tab, type in the dossier name (to broaden your search, you may use the wildcard *, Figure 48). When you have located the relevant dossier, double-click on the dossier title to open the 'Dossier header' section (Figure 49). 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 49: Searching for a dossier with the dossier name



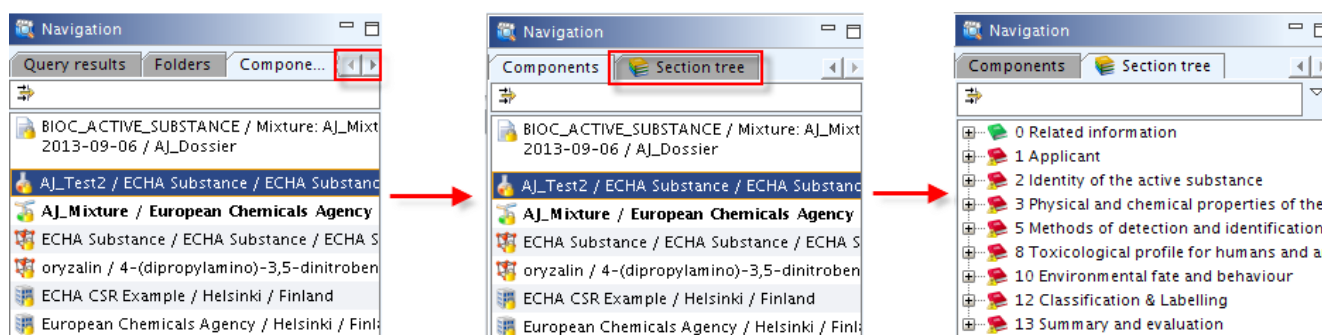
To search for a dossier with the unique dossier UUID, use the 'Search by UUID' field in the upper right corner of any IUCLID 5 screen (Figure 50). The dossier UUID can be obtained from the 'Information' tab in the 'Information' panel at the bottom of any section in the dossier. Figure 50 shows the 'Information' panel in the 'Dossier header' section.

Figure 50: Searching for a dossier with the dossier UUID

7.2.2 Viewing the full dossier content

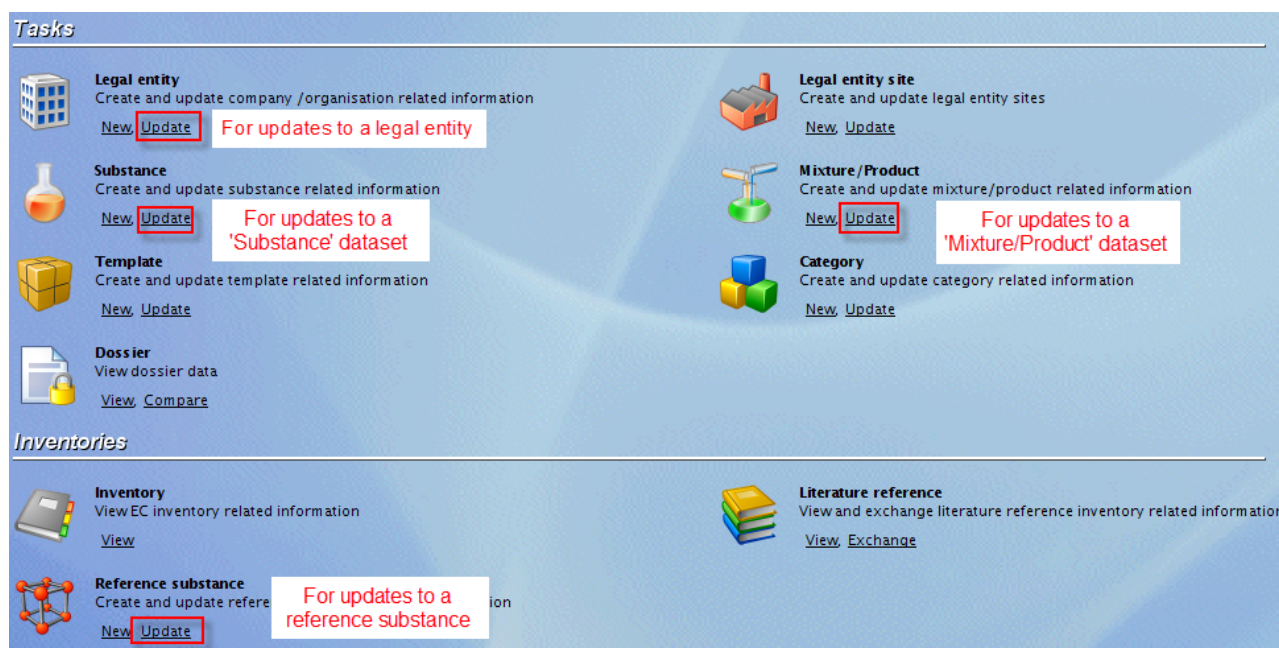
You can view the dataset content within the dossier by double-clicking on either the substance component (🧪) or the mixture/product component (🧴) under the 'Components' tab in the 'Navigation' panel. Clicking the substance component will open the substance identification section of the 'Substance' dataset, 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 51).

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 51: 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 52). Then, create a new dossier as outlined in [chapter 7.1](#).

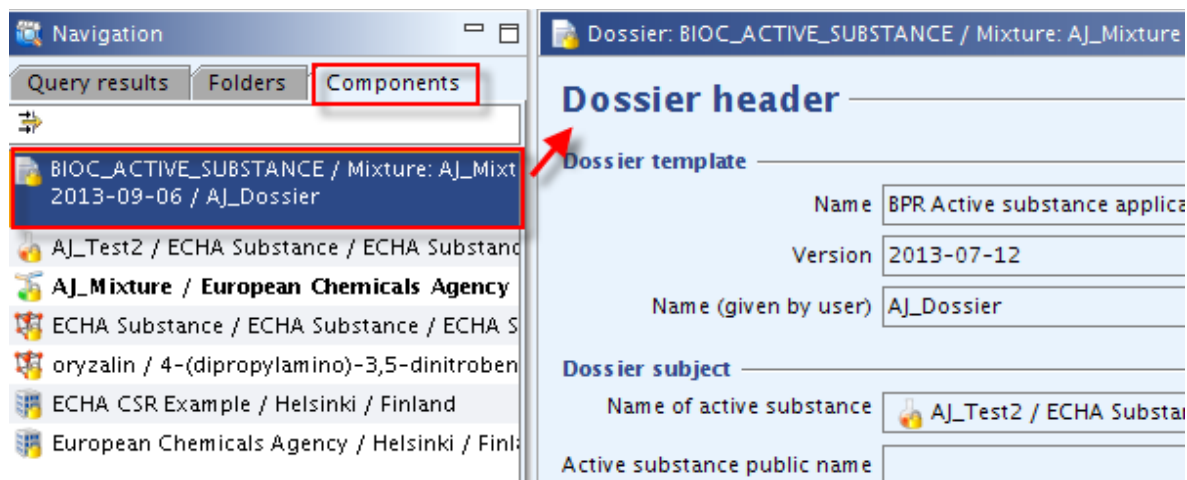
Figure 52: Updating data



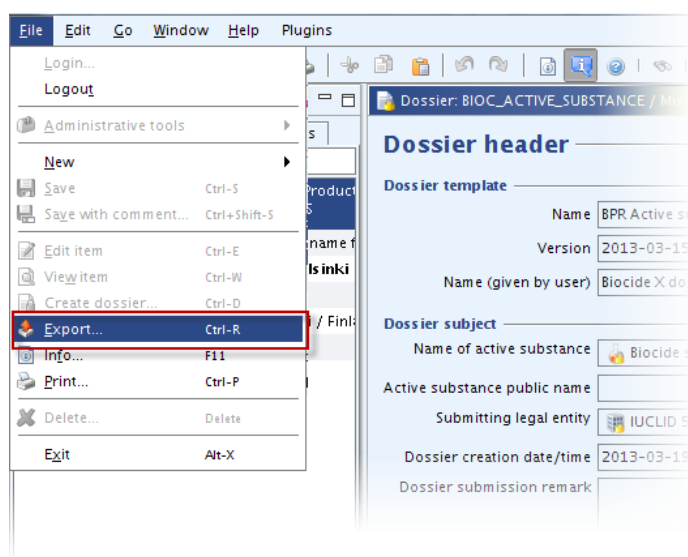
7.3 Dossier export

When you are satisfied with a dossier, export the final dossier from IUCLID 5 and save it on your local IT environment. Exporting the dossier file (.i5z) allows you to upload it in an R4BP 3 application 'wizard' as part of an application. To export a dossier open the 'Dossier header' section by double-clicking the dossier component under the 'Components' tab (Figure 53).

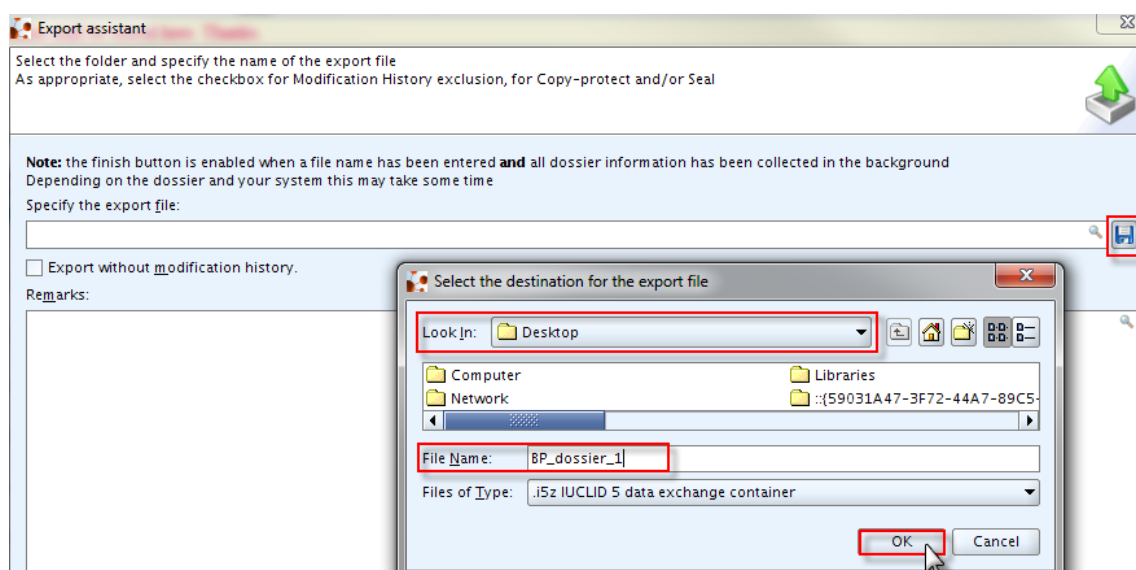
Figure 53: Opening the 'Dossier header' section



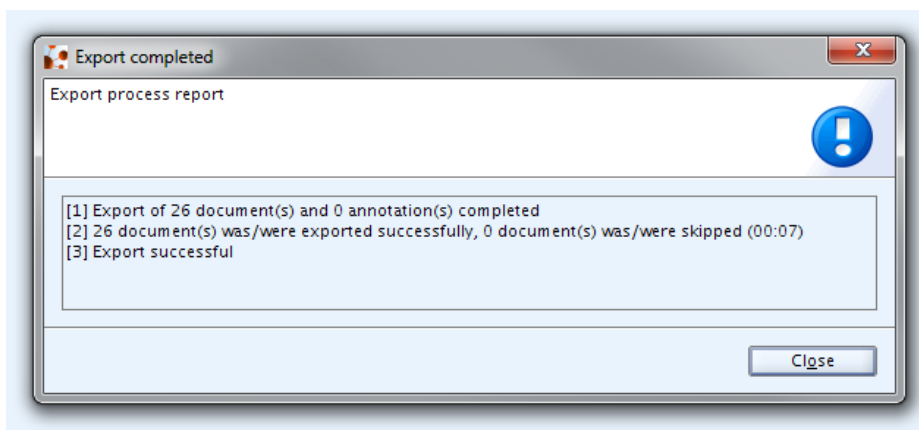
Then select File >> Export... from the menu bar (Figure 54). This will launch the Export assistant (Figure 55).

Figure 54: 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 55).

Figure 55: Saving the dossier

Click 'Finish' and wait until IUCLID 5 displays the export process report (Figure 56), 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 56: Export complete

Once you have exported your dossier and saved it on your local IT environment, you can upload it in an R4BP 3 application 'wizard' and submit it as part of an application.



Once an application is submitted via R4BP 3, it is subsequently processed in a series of steps. For more information on how your application is processed by ECHA, please consult [BSM Technical guide: using R4BP 3](#).

ANNEX I - How to include a mixture containing an active substance in a biocidal product dossier

ACTIVE SUBSTANCE(S) IN A MIXTURE IN A BIOCIDAL PRODUCT

According to Article 20 (a) of the BPR, an application for authorisation of a biocidal product shall contain the information satisfying the requirements set out in Annex II for each active substance in the biocidal product. This is done by including the active substance dataset in the IUCLID dossier submitted for the application. Alternatively, the letter of access may be provided.

If an active substance is part of a mixture, and this mixture is a component of a biocidal product, the requirements of Article 20(a) still apply to this active substance. A complete active substance dataset needs to be provided together with a biocidal product authorisation dossier in IUCLID.

In the next sections we will propose an approach to include a mixture containing an active substance to a biocidal product dossier.

Creation of the active substance and biocidal product datasets

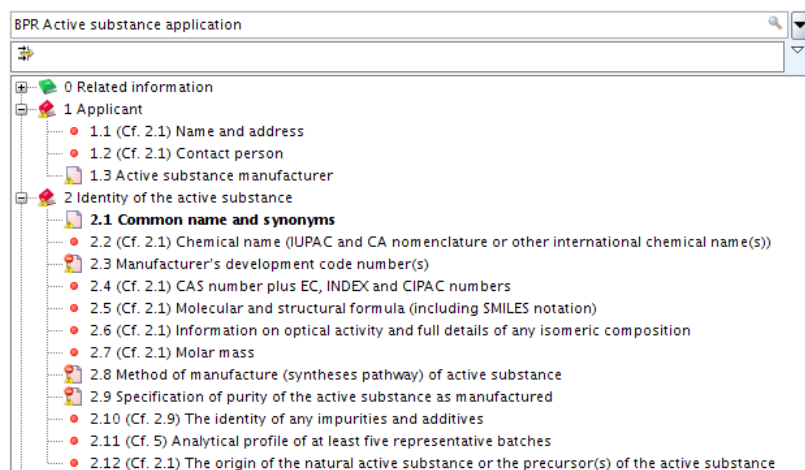
STEP 1. CREATE AN ACTIVE SUBSTANCE DATASET

A new substance dataset should be created for the active substance (using the main 'substance' dataset template 'BPR Active substance application'). This is done exactly in the same way as all other active substances datasets included in a biocidal product (Refer to chapter 2.1.1 '[Main dataset templates](#)' of this manual).

Where there is no letter of access: All mandatory sections shall be filled-in if there is no letter of access provided for this active substance. The mandatory sections are marked in red.

Where there is a letter of access: IUCLID sections 1 and 2 of the 'Substance dataset' shall be filled-in if there is a letter of access for this active substance (See figure below). This letter of access should be attached to the section 13 Summary and evaluation of the active substance dataset (Refer to chapter 6.4.1 '[Summary and evaluation](#)' for instructions).

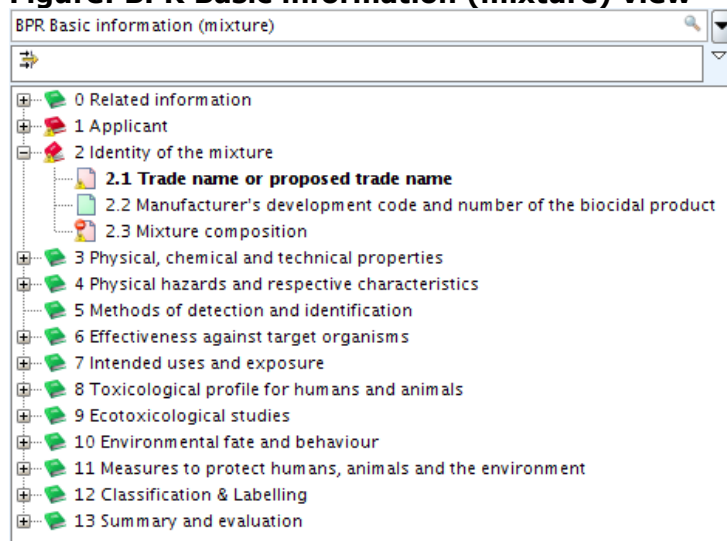
Figure: Sections 1 and 2 of the active substance dataset template 'BPR Active substance application'



STEP 2. CREATE A MIXTURE DATASET

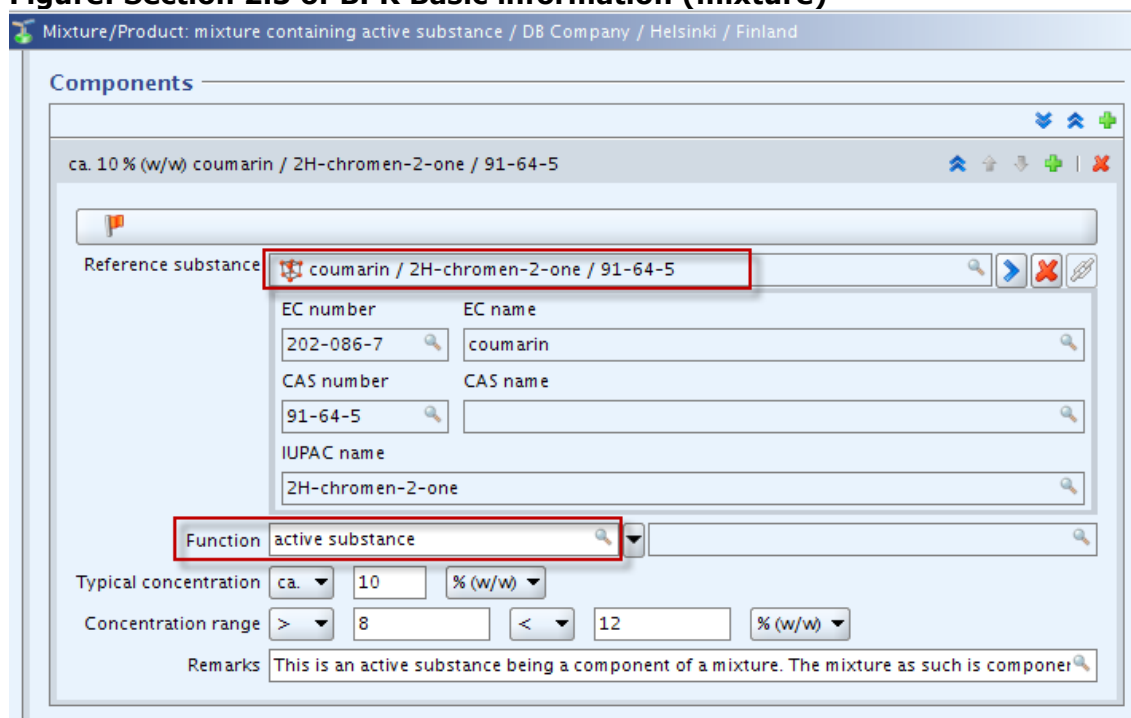
A new mixture/product dataset should be created for the mixture using the dataset template 'BPR Basic information (mixture)' (Refer to chapter 2.1.2 '[Supplementary dataset templates](#)' for more details). All mandatory sections, marked in red, shall be filled-in (See figure below).

Figure: BPR Basic information (mixture) view



In IUCLID section 2.3 'Mixture composition', the full composition of the mixture shall be indicated. The reference substance shall be linked and its function 'active substance' shall be selected (See figure below).

Figure: Section 2.3 of BPR Basic information (mixture)



STEP 3. SPECIFY THE BIOCIDAL PRODUCT COMPOSITION

For a mixture that contains an active substance, two entries should be created in IUCLID section 2.3 'Biocidal product composition' (both in the same endpoint, see figure below). Additional instructions can be found in chapter 4 step 4 '[Preparing a dataset for a biocidal product; IUCLID section 2.3 Biocidal product composition](#)'.

The first composition block should have:

- Function 'active substance'
- Concentration of a mixture in a biocidal product
- Linked mixture dataset (created in step 2)

The second composition block should have:

- Function 'active substance'
- Concentration 0 (the concentration of the active substance can be retrieved from the mixture dataset linked in the first record)
- Linked active substance dataset (created in step 2)

Figure: Two records in section 2.3 Biocidal product composition, related to a mixture that contains an active substance

The screenshot shows the 'Composition' window with two records. The first record is for a mixture with a concentration of 5% and is linked to a dataset named 'mixture containing active substance / DB Company / He...'. The second record is for a substance (coumarin) with a concentration of 0% and is linked to a dataset named 'coumarin being part of a mixture / DB Company / Helsir...'. Both records have 'Active Substance' selected in the 'Function' dropdown and a checkbox for 'Substance of concern'.

Information displayed in a biocidal product authorisation dossier

Based on the biocidal product dataset (created in step 3), the biocidal product authorisation dossier shall be created (Refer to chapter 7 '[How to create a dossier](#)' for more details). Once the dossier is ready, its components are displayed in the Navigation window (see figure below).

Figure: Biocidal product dossier components in the navigation window in IUCLID



The following sections explain where the different components of the biocidal product can be found in the final biocidal dossier i.e. the:

- i) active substance component of the mixture,
- ii) mixture itself,
- iii) biocidal product containing this mixture

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 (See chapter 7.2.2 '[Viewing the full dossier content](#)' for more details).

I) ACTIVE SUBSTANCE COMPONENT

The active substance composition contains all information that was inserted in IUCLID section 2.9 of the active substance dataset template 'BPR Active substance application' (See figure below).

Figure: Active substance inside of a mixture – dossier view

The screenshot displays the IUCLID 5.6 interface for a dossier titled 'coumarin being part of a mixture / DB Company / Helsinki / Finland'. The left-hand 'Navigation' panel shows a tree structure under 'Components', with '2.9 Specification of purity of the active substance' highlighted. The main window is titled 'Substance composition' and contains the following fields and sections:

- substance inside of a mixture** (Section header)
- Name:** substance inside of a mixture
- Brief description:** (Empty field)
- Composition ID:** L-b45bcd1b-96f3-4a71-9e5a-f0f9361ffdd5
- Degree of purity:** (Empty field)
- Constituents:**
 - ca. 100 % (w/w) coumarin / 2H-chromen-2-one / 91-64-5
 - Reference substance:** coumarin / 2H-chromen-2-one / 91-64-5
 - EC number:** 202-086-7
 - EC name:** coumarin
 - CAS number:** 91-64-5
 - CAS name:** (Empty field)
 - IUPAC name:** 2H-chromen-2-one
 - Typical concentration:** ca. 100 % (w/w)
 - Concentration range:** (Empty fields)
 - Remarks:** (Empty field)

II) MIXTURE COMPONENT

The mixture composition contains all information that was inserted in IUCLID section 2.3 of the dataset template 'BPR Basic information (mixture)' (See figure below).

Figure: Mixture in a biocidal product – dossier view

IUCLID 5.6 - mixture containing active substance / DB Company / Helsinki / Finland

File Edit Go Window Help Plugins

Navigation

Components Section tree

- 0 Related information
- 1 Applicant
- 2 Identity of the mixture
 - 2.1 Trade name or proposed trade name
 - 2.2 Manufacturer's development code
 - 2.3 Mixture composition**
- 12 Classification & Labelling

Mixture/Product: mixture containing active substance / DB Company / Helsinki / Finland

Mixture composition

Name

Brief description

Composition ID L-ec3c566b-fcdf-4b1a-b9a1-4a41738c4ca7

Components

ca. 10 % (w/w) coumarin / 2H-chromen-2-one / 91-64-5

Reference substance

EC number	EC name
<input type="text" value="202-086-7"/>	<input type="text" value="coumarin"/>
CAS number	CAS name
<input type="text" value="91-64-5"/>	<input type="text"/>
IUPAC name	
<input type="text" value="2H-chromen-2-one"/>	

Function

Typical concentration

Concentration range

Remarks

Impurities

III) BIOCIDAL PRODUCT COMPONENT

The biocidal product component contains all information that was inserted in IUCLID section 2.3 of the dataset template 'BPR Biocidal product authorisation' (See figure below).

Figure: Biocidal product component – dossier view

IUCLID 5.6 - product containing AS in a mixture / DB Company / Helsinki / Finland

File Edit Go Window Help Plugins

(Search by UUID)

Navigation

Components Section tree

- 0 Related information
- 1 Applicant
- 2 Identity of the biocidal product
 - 2.1 Trade name or proposed trade name
 - 2.2 Manufacturer's development code
 - 2.3 Biocidal product composition
 - Biocidal product composition.001**
- 12 Classification & Labelling

Additional information: Biocidal product composition.001

Detail level Administrative Data Biocidal product

all fields

Administrative Data

Biocidal product

Biocidal product name product containing AS in a mixture

Formulation type

Composition

Function	Concentration %	Name	Substance of concern
Active Substance	5	mixture containing active substance / DB Company / Helsinki / Finland	<input type="checkbox"/>
Active Substance	0	coumarin being part of a mixture / DB Company / Helsinki / Finland	<input type="checkbox"/>

ANNEX II - How to report active substance(s) generated in-situ in IUCLID

ACTIVE SUBSTANCE(S) IN A BIOCIDAL PRODUCT

According to Article 20 (a) of the BPR, an application for authorisation of a biocidal product shall contain the information satisfying the requirements set out in Annex II for each active substance in the biocidal product. This is done by including the active substance dataset in the IUCLID dossier submitted for the application.

According to Article 6(b) of the BPR, an active substance application dossier shall contain the information satisfying the requirements set out in Annex III for at least one representative biocidal product that contains the active substance. Therefore each active substance application has to include a dataset for a representative product with an active substance indicated as its component.

IN-SITU GENERATED ACTIVE SUBSTANCES

The definition of an in situ generated substance is understood to be an active substance that is generated at the place of use from one or more precursors.

All precursors and the active substance generated in situ shall be reported in the IUCLID technical dossier. For an active substance application dossier it shall be done in a presentative biocidal product and for a biocidal product authorisation dossier inside the biocidal product itself. In both cases, the active substance generated in situ is reported in the way which is described below, in step 3.

Creation of the active substance and biocidal product datasets

STEP 1. CREATE AN ACTIVE SUBSTANCE (IN SITU) DATASET

A new substance dataset should be created for the active substance that is supposed to be generated in a biocidal product (using the 'main' substance dataset template 'BPR Active substance application'). This is done exactly in the same way as for all other active substances datasets included in a biocidal product or linked to a representative biocidal product in an active substance application (Refer to chapter 2.1.1 '[Main dataset templates](#)' of this manual).

STEP 2. CREATE DATASETS FOR PRECURSOR(S) OF AN IN SITU ACTIVE SUBSTANCE

For each precursor of an in situ active substance, and for each substance that would be an impurity of an active substance generated in situ, a separate substance dataset shall be created. Depending on the properties of a substance, the corresponding dataset template, i.e. BPR Active substance application, BPR Substance of concern, or, BPR Basic information (substance), should be used to insert the required data. The selection of the correct template has to be done based on the substance's properties and function. The active substance and the substance of concern are defined in the Biocidal Products Regulation. The template 'BPR Basic information (substance)' should be used for all other substances.

The reaction pathways describing how the active substance is generated should be inserted in IUCLID section 2.8 'Method of manufacture (syntheses pathway)' of the active substance dataset. In IUCLID section 2.3 'Mixture composition', the full composition of the mixture shall be indicated. The reference substance shall be linked; its function 'active substance' shall be selected (See figure below).

Figure: Section 2.3 of BPR Basic information (mixture)

Mixture/Product: mixture containing active substance / DB Company / Helsinki / Finland

Components

ca. 10 % (w/w) coumarin / 2H-chromen-2-one / 91-64-5

Reference substance: coumarin / 2H-chromen-2-one / 91-64-5

EC number	EC name
202-086-7	coumarin
CAS number	CAS name
91-64-5	
IUPAC name	
	2H-chromen-2-one

Function: active substance

Typical concentration: ca. 10 % (w/w)

Concentration range: > 8 < 12 % (w/w)

Remarks: This is an active substance being a component of a mixture. The mixture as such is component

STEP 3. SPECIFY THE BIOCIDAL PRODUCT COMPOSITION

For a biocidal product that contains an in situ generated active substance, both the active substance and the precursors should be inserted as 'components' in the defined composition in IUCLID section 2.3 'Biocidal product composition'. Represented in the figure below, this is done in the following way:

- Entries identifying precursor(s) of in situ generated active substance should have the following data provided:
 - o Function 'other: precursor'
 - o Concentration of the substance in the biocidal product
 - o Linked substance dataset (created in step 2 above)
- Entry identifying the in situ generated active substance should have:
 - o Function 'active substance'
 - o Concentration 0
 - o Linked active substance dataset (created in step 1)

Figure: Records in section 2.3 Biocidal product composition, related to precursors of an active substance and an active substance generated in situ

The screenshot shows a 'Composition' window with three records. Each record has a header with a unique ID and a path, followed by input fields for 'Function', 'Concentration %', and 'Name', and a checkbox for 'Substance of concern'.

ID	Path	Function	Concentration %	Name	Substance of concern
10.0/	Substance[IUC5-c1b9c4a2-f112-466d-b36f-5c7a8ecb0b1c/0](substancja / DB Company / Helsinki / Finland)	other: precursor of in situ generated active substance	10	substancja / DB Company / Helsinki / Finland	<input checked="" type="checkbox"/>
5.0/	Substance[IUC5-482fe795-8833-4b9b-9cec-50529c04d22d/0](substancja 2 / DB Company / Helsinki / Finland)	other: precursor of in situ generated active substance	5	substancja 2 / DB Company / Helsinki / Finland	<input type="checkbox"/>
0.0/	Substance[IUC5-ae90ae5e-d085-473b-ac98-f55cccd9767f/0](generated in situ active substance / DB Company / Helsinki / Finland)	Active Substance	0	generated in situ active substance / DB Company / Helsinki / Finland	<input type="checkbox"/>

A Special Case: Precursor in a mixture

The detailed procedure of including a mixture containing an active substance in a biocidal product IUCLID dossier is described in [Annex I](#) to this manual. The example composition of a biocidal product containing a precursor being a part of a mixture is presented in the figure below.

- 1** - concentration of the first precursor in the biocidal product; this precursor is a substance;
- 2** - first block: concentration of the mixture containing the second precursor; second block: link to the substance being the second precursor;
- 3** - link to the active substance generated in situ based on the first precursor (substance) and the second precursor (substance in a mixture).

Figure: Records in IUCLID section 2.3 'Biocidal product composition', related to precursors of an active substance being a part of a mixture.

The screenshot displays the 'Composition' section of IUCLID, showing four records related to precursors of an active substance being a part of a mixture. Each record is highlighted with a red box and a red number (1, 2, or 3).

- Record 1:** Substance [IUC5-c1b9c4a2-f112-466d-b36f-5c7a8ecb0b1c/0] (susbstancja / DB Company / Helsinki / Finland). Function: other: precursor of in situ generated active substance. Concentration %: 10. Name: susbstancja / DB Company / Helsinki / Finland. Substance of concern (Note: Use for Substances not categorised as Active Substances).
- Record 2:** Mixture [IUC5-b3871abe-63f3-4073-bd29-a8e5d44b34a2/0] (mixture containing a precursor / DB Company / Helsinki / Finland). Function: other: precursor of in situ generated active substance. Concentration %: 15. Name: mixture containing a precursor / DB Company / Helsinki / Finland. Substance of concern (Note: Use for Substances not categorised as Active Substances).
- Record 3:** Substance [IUC5-04ef830b-7834-4bd4-93fb-3e1545b65aab/0] (precursor in a mixture substance / DB Company / Helsinki / Finland). Function: other: precursor of in situ generated active substance. Concentration %: 0. Name: precursor in a mixture substance / DB Company / Helsinki / Finland. Substance of concern (Note: Use for Substances not categorised as Active Substances).
- Record 4:** Substance [IUC5-ae90ae5e-d085-473b-ac98-f55cccd9767f/0] (generated in situ active substance / DB Company / Helsinki / Finland). Function: Active Substance. Concentration %: 0. Name: generated in situ active substance / DB Company / Helsinki / Finland. Substance of concern (Note: Use for Substances not categorised as Active Substances).

Information displayed in a biocidal product authorisation dossier

Based on the biocidal product dataset (created in step 3), the biocidal product authorisation dossier shall be created (Refer to chapter 7 '[How to create a dossier](#)' for more details). Once the dossier is ready, its components are displayed in the Navigation window (See figure below). All precursors and the in situ generated active substance are among the components of the biocidal product authorisation dossier.

Figure: Biocidal product dossier components in the navigation window in IUCLID

The screenshot shows the navigation window in IUCLID, displaying the components of a biocidal product authorisation dossier. The 'Components' tab is active, showing a list of components. The main window displays the 'Dossier header' with the following information:

- Dossier header:** Name: BPR Biocidal product authorisation; Version: 2014-02-19; Name (given by user): dossier_containing_in_situ_generated_active_susban
- Dossier subject:** Name: product containing in situ generated active substan; Public name: ; Submitting legal entity: DB Company / Helsinki / Finland; Dossier creation date/time: 2014-08-25 14:12:13 EEST

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