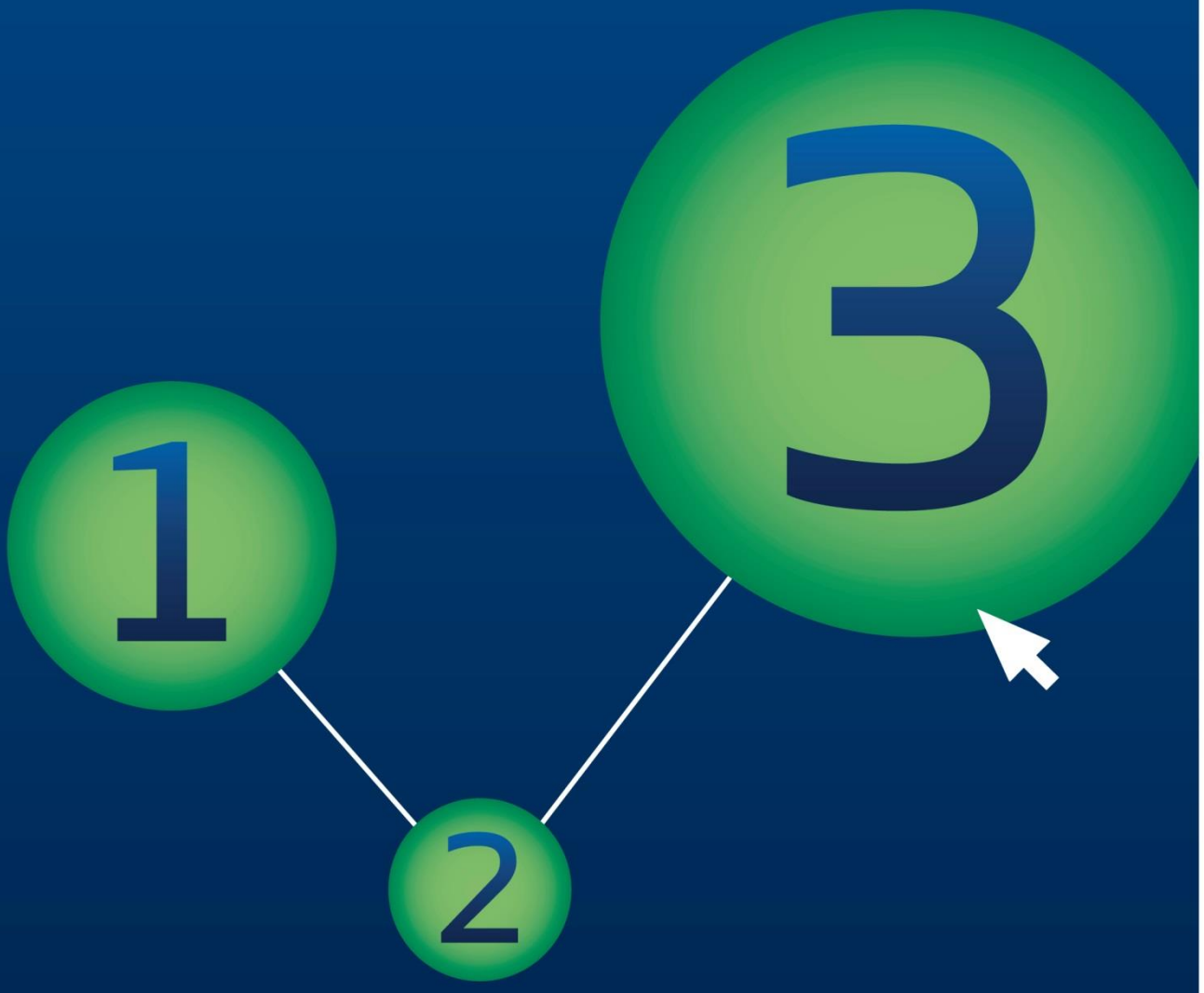
ECHA
EUROPEAN CHEMICALS AGENCY

MANUAL

How to prepare a biocides dossier



Changes to this document

Version	Changes
1.0	First version
2.0	Updated to reflect the release of IUCLID 5.5.1, in particular, the inclusion of the 'PBT assessment' in section 13 'Summary and evaluation', and section 12.4 'Packaging' has now changed to section 12.3 'Packaging'.
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.
2.2	Summary sheet information included in the body text.
3.0	Update of title Reference to REACH-IT for LEO creation removed. IUCLID section 2.1, the role of the applicant clarified for formulators
3.1	New information available and included in the annex Annex I: 'How to include a mixture containing an active substance to a biocidal product dossier in IUCLID' Annex II: 'How to report active substance(s) generated in situ in IUCLID'
3.2	Update of Annex II. Information on how to create datasets for precursor(s) of an in situ active substance was corrected: reference to IUCLID section 2.3 'Mixture composition' was deleted.
4.0	Update to reflect transition from IUCLID 5 to IUCLID 6
4.1	Conversion to new template to facilitate the manual integration with the IUCLID help system.

Legal notice

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This is a working translation of a document originally produced in English. Please note that only the English version, also available on the ECHA website, is the original version.

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Table of Contents

Table of Figures

1. Introduction

Objective

This manual gives guidance on how to create a IUCLID[1] dossier concerning biocidal active substances[2] (AS) and biocidal products[3] (BP) for applications made under the Biocidal Products Regulation[4] (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).

Biocides Submission Manuals

This manual is part of the Biocides Submission Manual (BSM) series concerning technical guides, application instructions and process manuals. The series 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 6 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 (https://echa.europa.eu/regulations/biocidal-products-regulation/legislation)

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' (.i6z file). A dossier can then be uploaded as part of an application and submitted through R4BP 3 to the Authorities[5]. 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 IUCLID, you must first 'sign-up' on the IUCLID website and download the application. When having installed IUCLID, you will be able to create and manage Legal Entity Objects (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 6, can be downloaded free of charge from the IUCLID website at the following address: https://iuclid6.echa.europa.eu/home. For more details about the installation and use of IUCLID 6 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 6, 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 6 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).

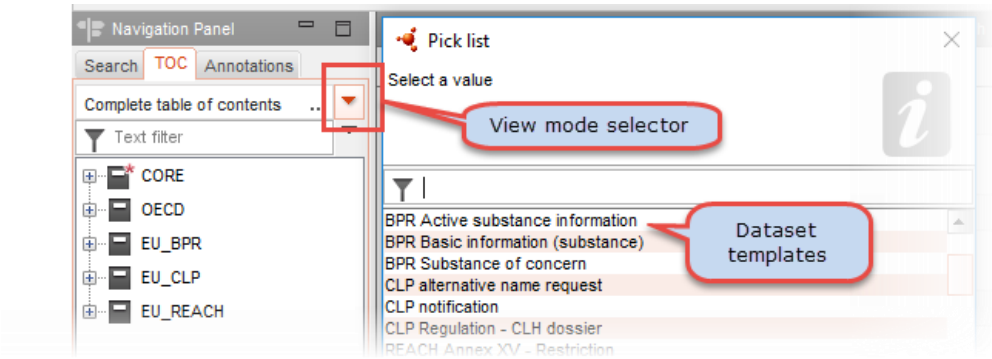
To assist you with data entry, you can customise the sections in a dataset via the 'view mode' (i.e. dataset template) selector. By default, the dataset template is set to 'REACH Complete table of contents'. However, you should change this by using the black arrow ( ) to open a drop-down list (Figure 1). Note that this list contains numerous dataset templates accommodating various chemical regulations e.g. BPR, REACH[6], CLP[7] etc. Customising the dataset template will ensure that only the sections that are relevant to your dossier type are shown.

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

6 Regulation (EC) No 1907/2006 (https://echa.europa.eu/regulations/reach) 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.

7 Regulation (EC) No 1272/2008 (https://echa.europa.eu/regulations/reach) 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 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 information' dataset - containing information concerning the AS, and

ii. either a 'BPR Biocidal product authorisation' dataset - containing information concerning the BP to be authorised

iii. or 'BPR Active substance application (representative product)' – used'used for the representative biocidal product needed to the active substance approval.

The dossier creation must be always initiated from the Mixture/Product dataset, 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. In these cases you can use the dataset for the representative product.

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):

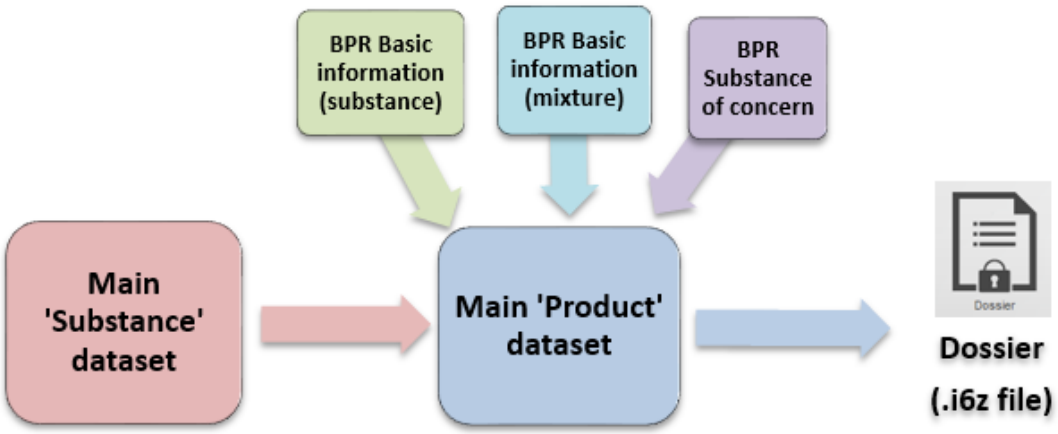
i. 'BPR Basic information (substance)' dataset – containing information about each additional substance component which is not substance of concern according to Article 3(1)(f) of the BPR

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 that 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' or 'Representative biocidal product composition'.

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. Dossier types

A IUCLID dossier is a non-editable snapshot file of any dataset, 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 (representative product)' dossier, and

ii. a 'BPR Biocidal product authorisation' dossier.

All dossiers (for the active substance or biocidal product) must be created from a **Mixture/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 (representative product)' 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

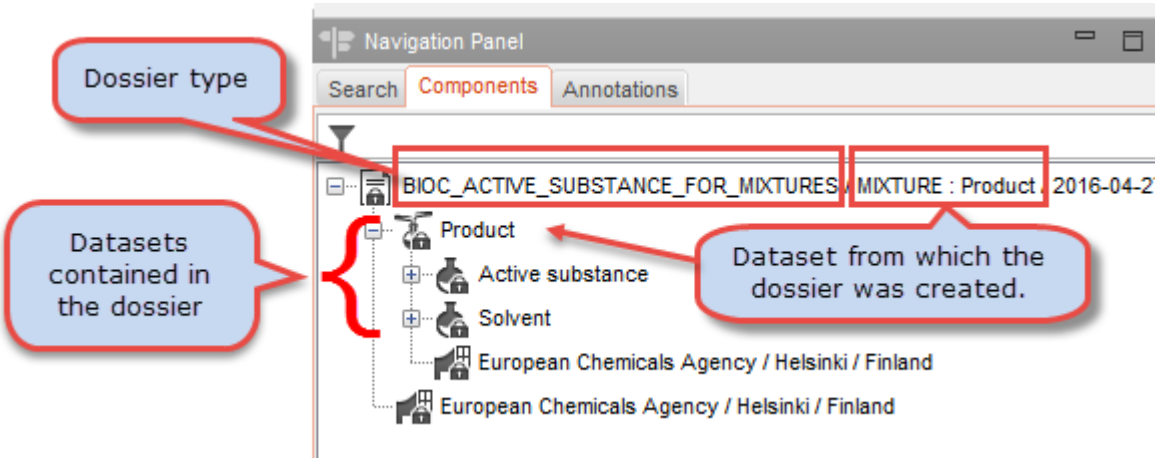
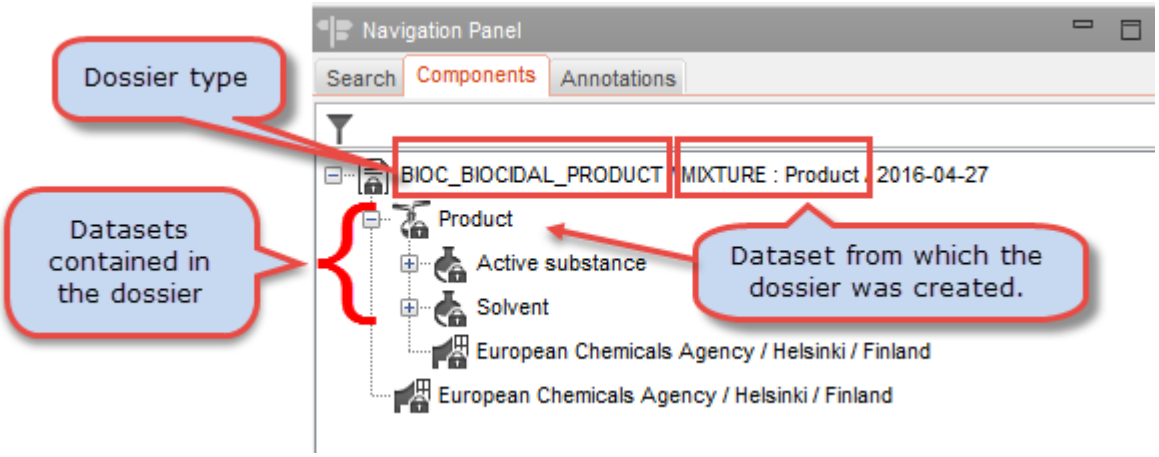


Figure 4 shows a 'BPR Biocidal product authorisation' dossier that includes both a 'Substance' dataset for an AS and one for a solvent, along with a 'Mixture/Product' dataset for the BP. It was correctly created from the 'Mixture/Product' dataset.

Figure 4: Valid biocidal product dossier



A dossier is valid if it contains at least one 'Substance' dataset for an AS and one 'Mixture/Product' dataset for the BP, and is created from the 'Mixture/Product' dataset.

2.3. What is a 'Reference substance'?

One of the elements characterising the IUCLID 6 dataset is its relationship to a 'Reference substance'. A 'Reference substance' ( ) is a IUCLID 6 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.

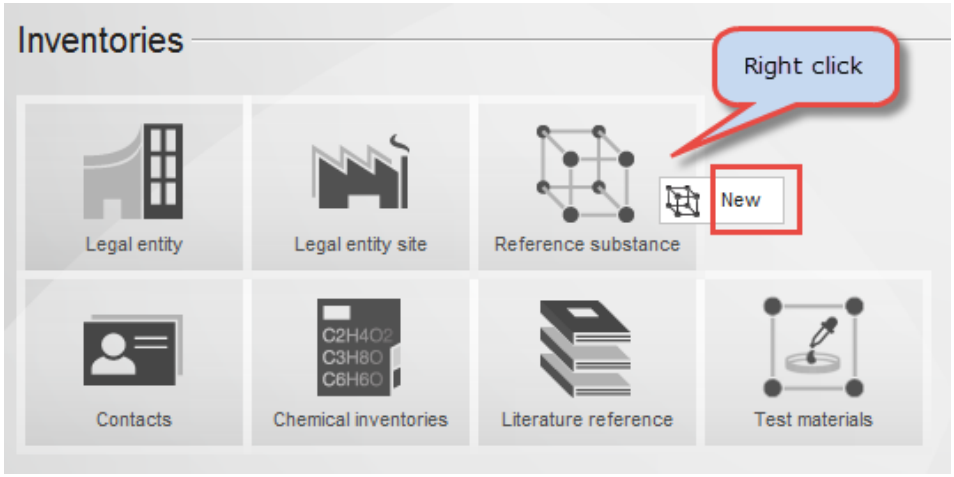
The 'Reference substance' is used in a 'Substance' dataset to specify the identification of the main substance that the dataset has been created for. In addition, the constituents, impurities

and additives of the main substance, if any, will have reference substances of their own, linked to the same dataset as the main substance.

From the IUCLID website, you can download 'Reference substance' data and import it into your IUCLID 6 software program. You can also create a new 'Reference substance' yourself (Figure 5) or update an existing 'Reference substance'.

You should maintain 'Reference substance' information relevant for you, in your local IUCLID 6 program. You can create a new 'Reference substance' or update substance information from the IUCLID 6 homepage (Figure 5).

Figure 5: Accessing the 'Reference substance' information

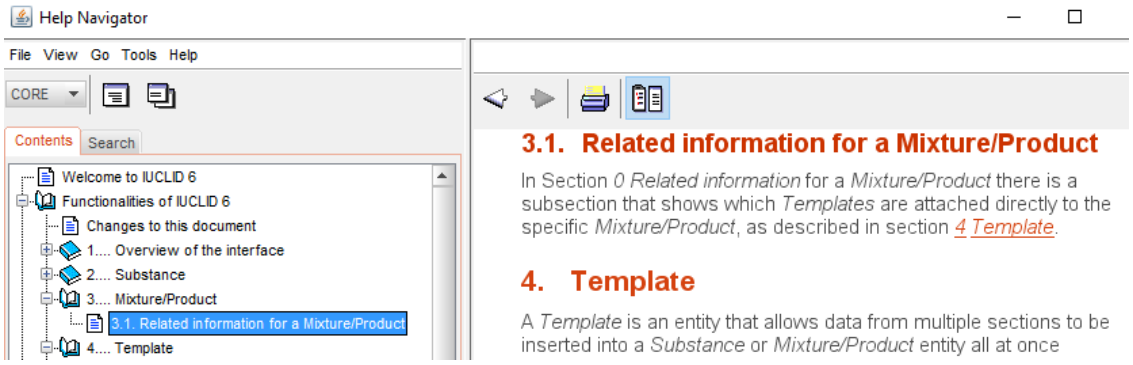


2.4. General functions in IUCLID 6

This sub-chapter contains instructions on some general functions that are frequently used throughout IUCLID 6. For further information on how to fill in specific sections of IUCLID 6, please see the corresponding chapter in this manual.

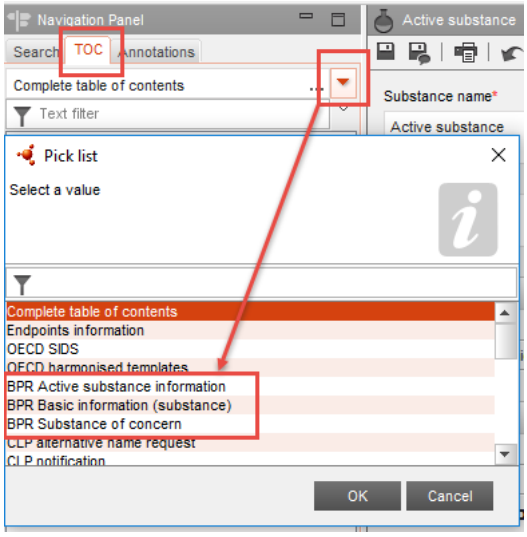
Help in IUCLID

Pressing 'F1' when you have a IUCLID section open will direct you to the IUCLID 6 Help system, for further assistance.



Using the 'view mode' to select a dataset template

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



Back button

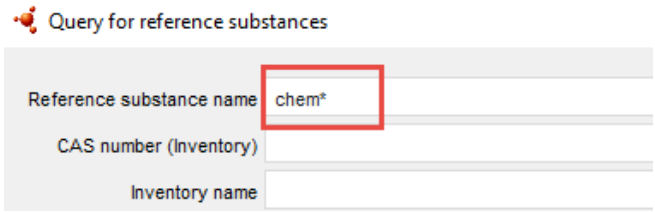
To get back to the original section press the back button ( ) in the IUCLID 6 taskbar.

Go to button

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

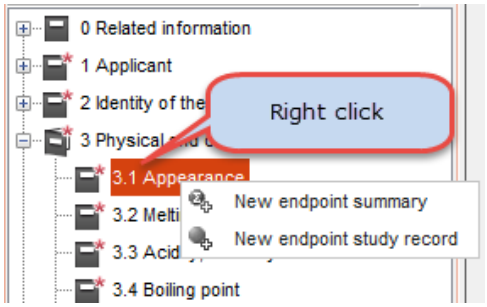
Wildcard symbols

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.



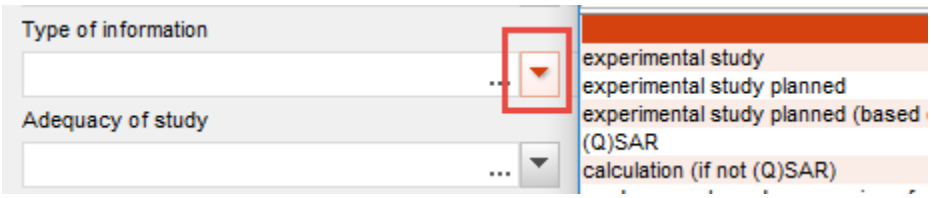
Creating an endpoint study record or endpoint summary

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.

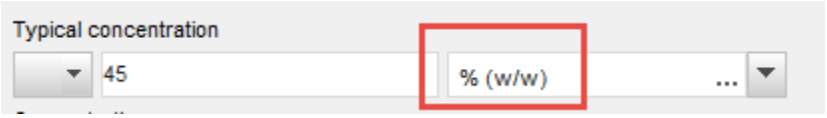


Drop-down menu

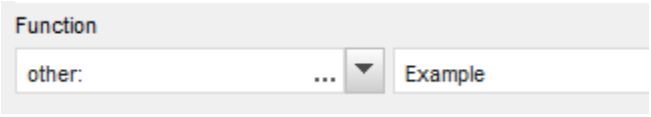
Access a drop-down menu using the black arrow ( ). Then select the correct option from the predefined options.



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

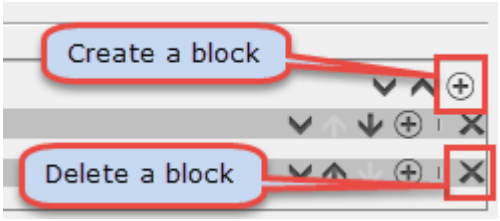


Note: If 'other:' is selected from the drop-down menu, then the adjacent field must be filled in.



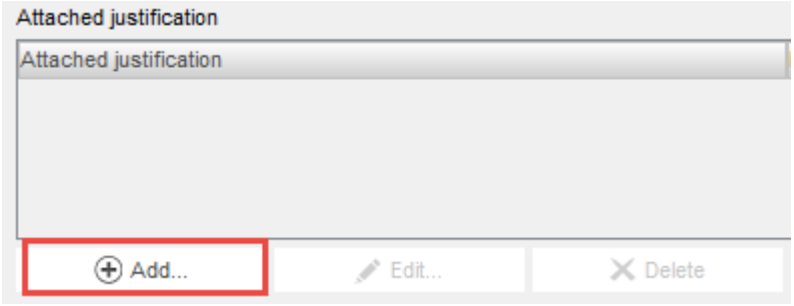
Add and delete function

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 (✕).



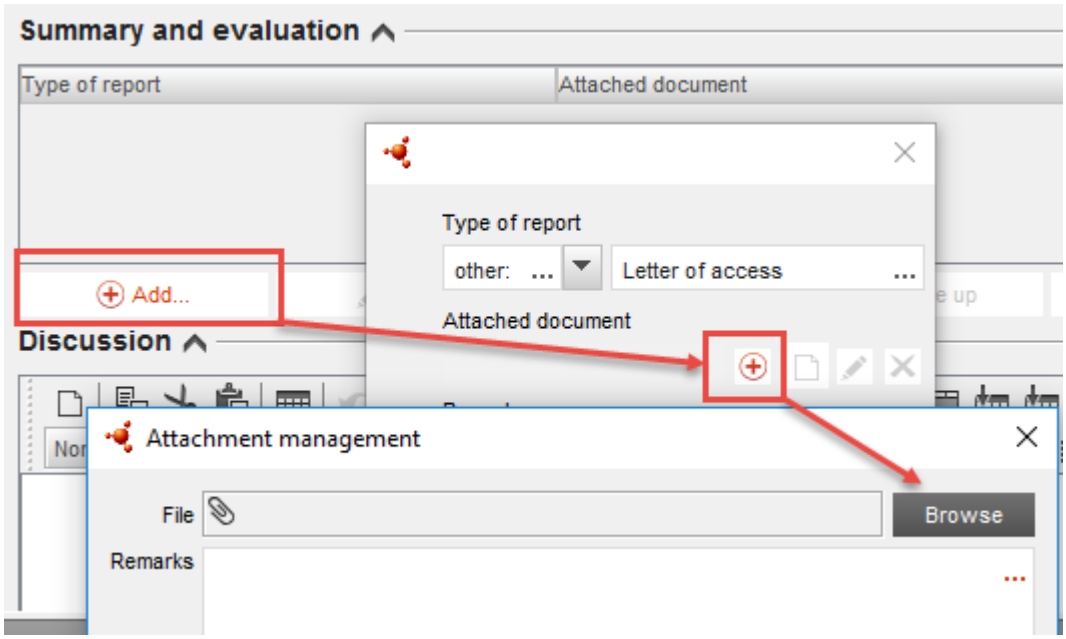
Add function

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



Attach function

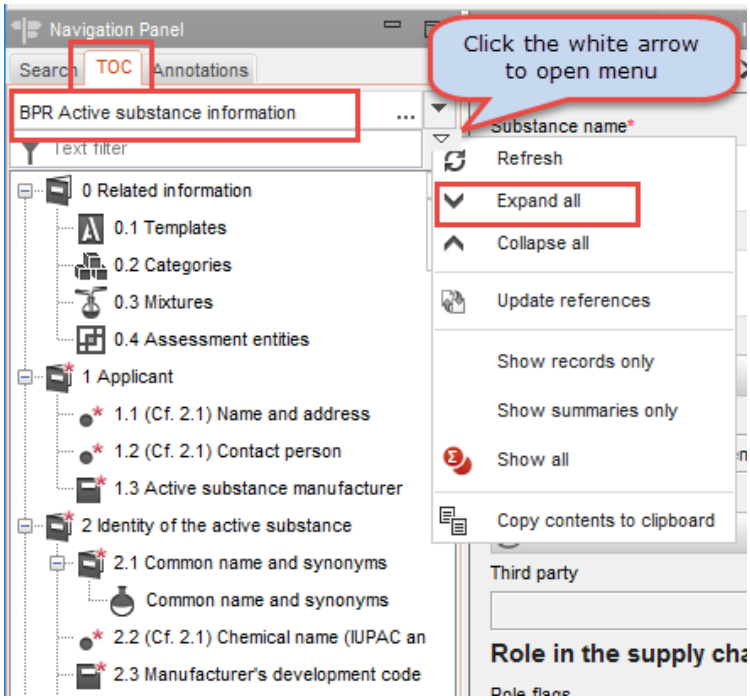
Attach relevant documents to IUCLID section 13 'Summary and evaluation' by first clicking 'Add', then using the 'plus' button (⊕), and then click 'Browse'. Refer to chapter 6.4.1 for full instructions.



2.5. Using the table of contents ('TOC') of a dataset

When you open a dataset, select a specific dataset template, e.g. 'BPR Active substance information', using the view mode selector ( ) under the tab 'TOC' (table of contents). By selecting 'Expand all', you will see all the relevant sections contained in this dataset template (Figure 6).

Figure 6: Navigation window



The core sections of IUCLID are marked with book and circle symbols with red asterisk (,).

The sections depicted by a small 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 6 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'.

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 6 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 information' 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

In the 'Main tasks' pane of the IUCLID 6 homepage ( ), create a 'Substance' dataset by right clicking on the Substance ( ) icon, and then clicking 'New' (Figure 7).

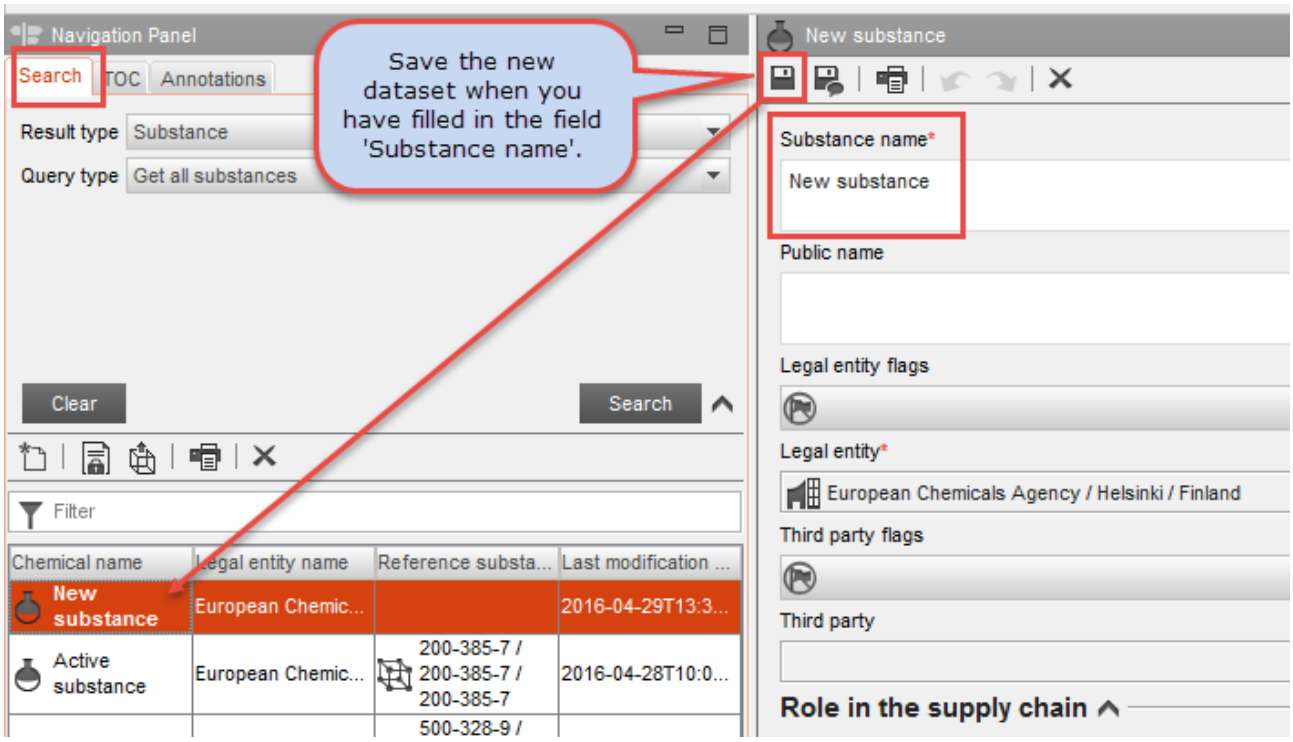
Figure 7: Creating a 'Substance' dataset

An empty 'Substance' dataset will open. Enter a name for your dataset in the field 'Substance name', and click the Save ( ) icon. The new dataset will appear in the list of datasets in the 'Search' tab (Figure 8).

Once you have saved the dataset you can start filling in the information within it. Click the 'TOC' tab (table of contents) to view all of the sections.

If you have already created a 'Substance' dataset and you wish to update information in this dataset, click the Substance ( ) icon on the IUCLID 6 homepage (Figure 7). A list of datasets will open in the 'Search' tab. Search for the correct dataset, double click on the dataset title, and click the 'TOC' tab to view all of the sections.

Figure 8: Naming the 'Substance' dataset

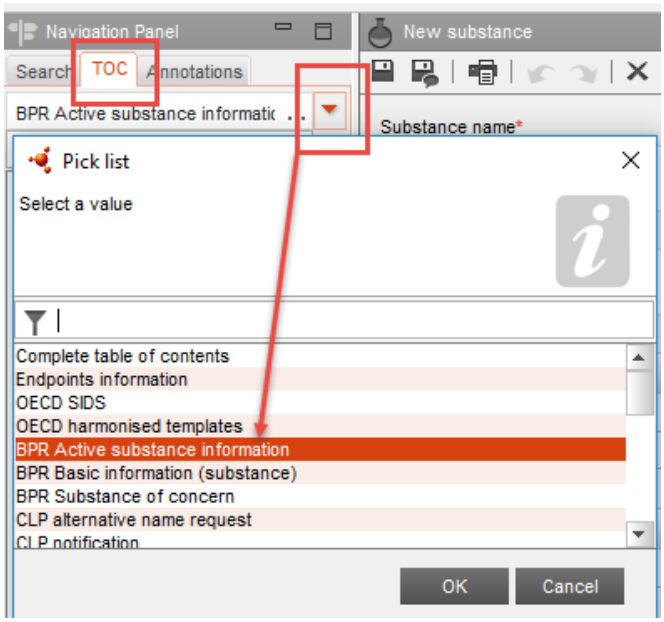


Step 2. Select the dataset template

Open the 'TOC' tab in the 'Navigation panel'. Click the black arrow ( ) to open the drop-down menu and select the 'main' dataset template (chapter 2.1), i.e. 'BPR active substance

information' (Figure 9). By selecting 'Expand all', you will see all of the sections contained in the template (Figure 6).

Figure 9: Selecting the dataset template



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.

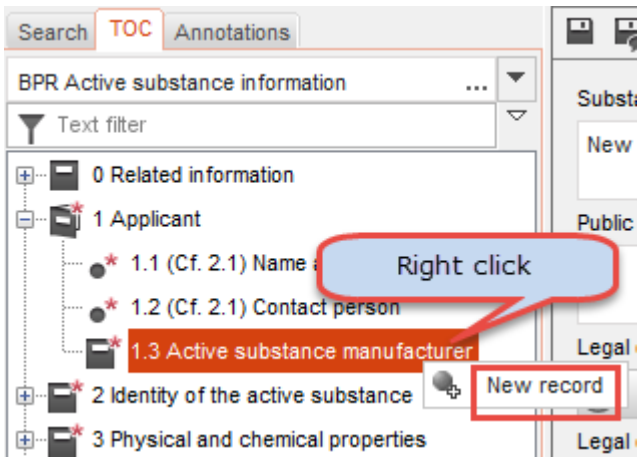
Step 3. Enter the 'Applicant' details

IUCLID section 1.3 'Active substance manufacturer'

IUCLID section 1.3 contains the name and details of the active substance manufacturer, importer and/or formulator. It is recommended that you indicate the name and details in IUCLID section 1.3 even if they are the same as the one of the applicant.

Start by creating a 'record' by right clicking on top of the section name and clicking 'New record' (Figure 10).

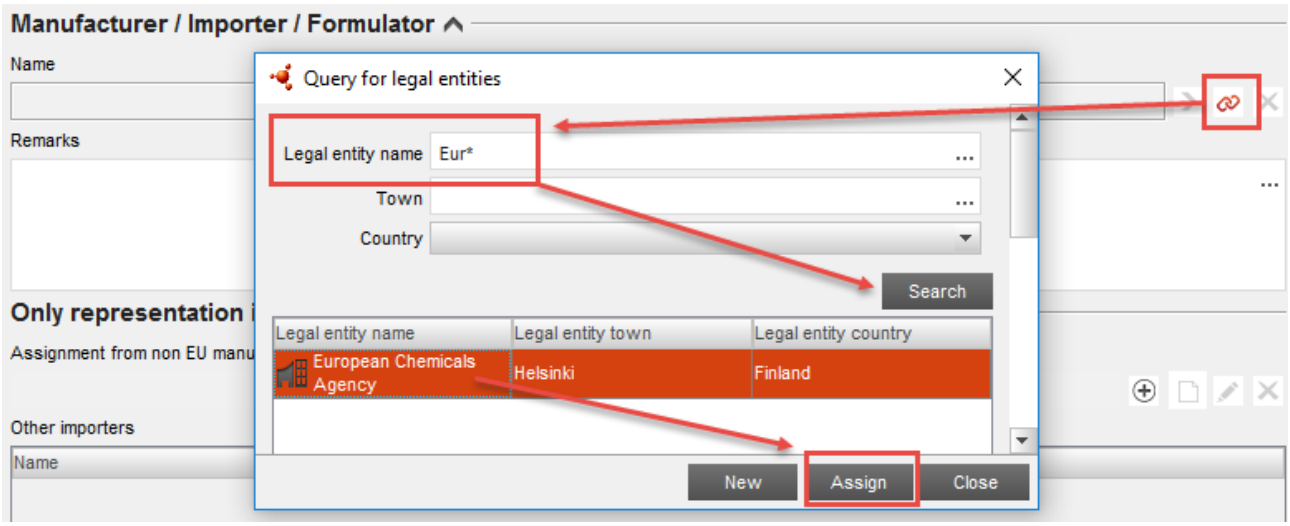
Figure 10: Creating a record



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 record 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 for legal entities' window and then click 'Search'. Select the correct legal entity from the search results, and click the button 'Assign' (Figure 11).

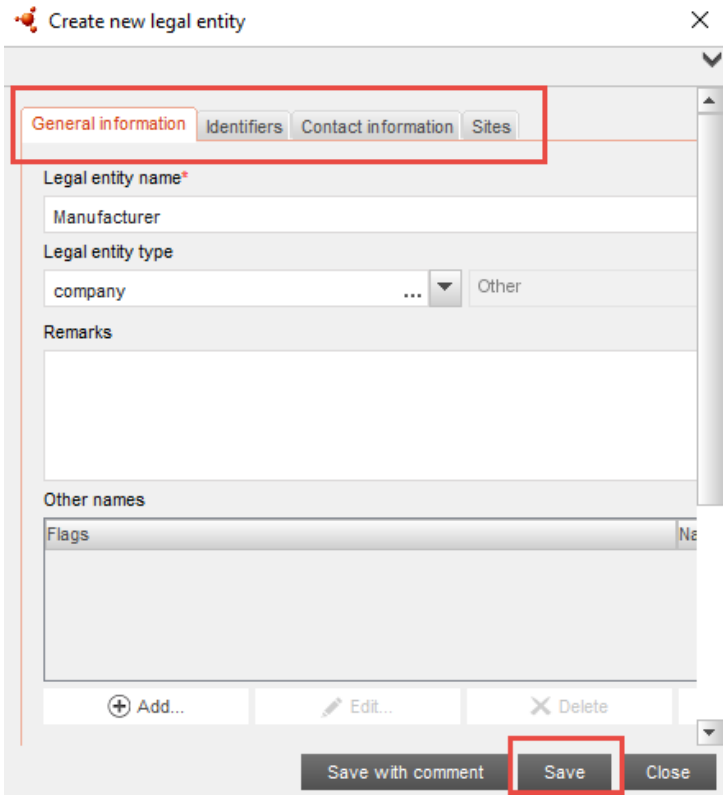
Figure 11: Assigning a legal entity in section 1.3



It may be the case that the manufacturer has not yet been entered into your database. In this case, click the button 'New' in the 'Query for legal entities' window, to open the 'Create new legal entity' window (Figure 12).

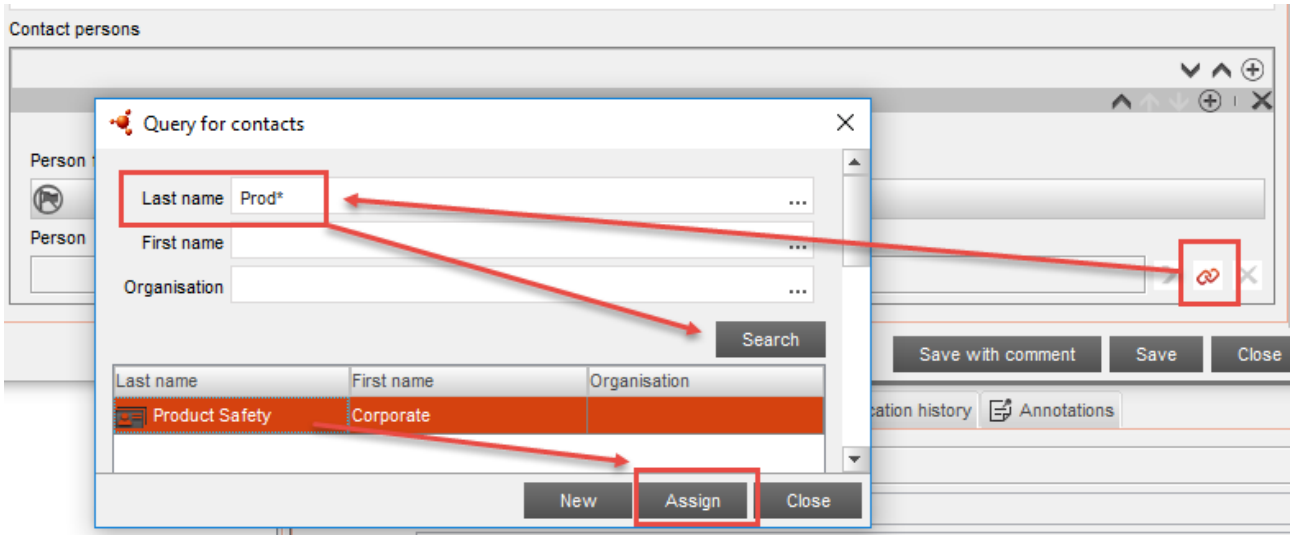
In the 'Create new legal entity' window, enter the Legal entity name, and the applicable details of the manufacturer's Legal entity under the tabs 'General information', 'Identifiers' and 'Contact information' (Figure 12).

Figure 12: Create new legal entity



Under the 'Contact information' tab (last entry on the tab) you can assign a contact person for the manufacturer's legal entity. Click the link button (🔗) next to the 'Person' field. Enter some search criteria (e.g. Last name) in the appearing 'Query for contacts' window and then click 'Search'. Select the correct contact person from the search results, and click the button 'Assign' (Figure 13).

Figure 13: Assign a contact person for legal entity



It may be the case that the contact person has not yet been entered into your database. In this case, click the button 'New' in the 'Query for contacts' window, to open the 'Create new

contact' window. Define the contact type as 'other: Site'. Enter the rest of the contact person details and when you are ready, click 'Save'.

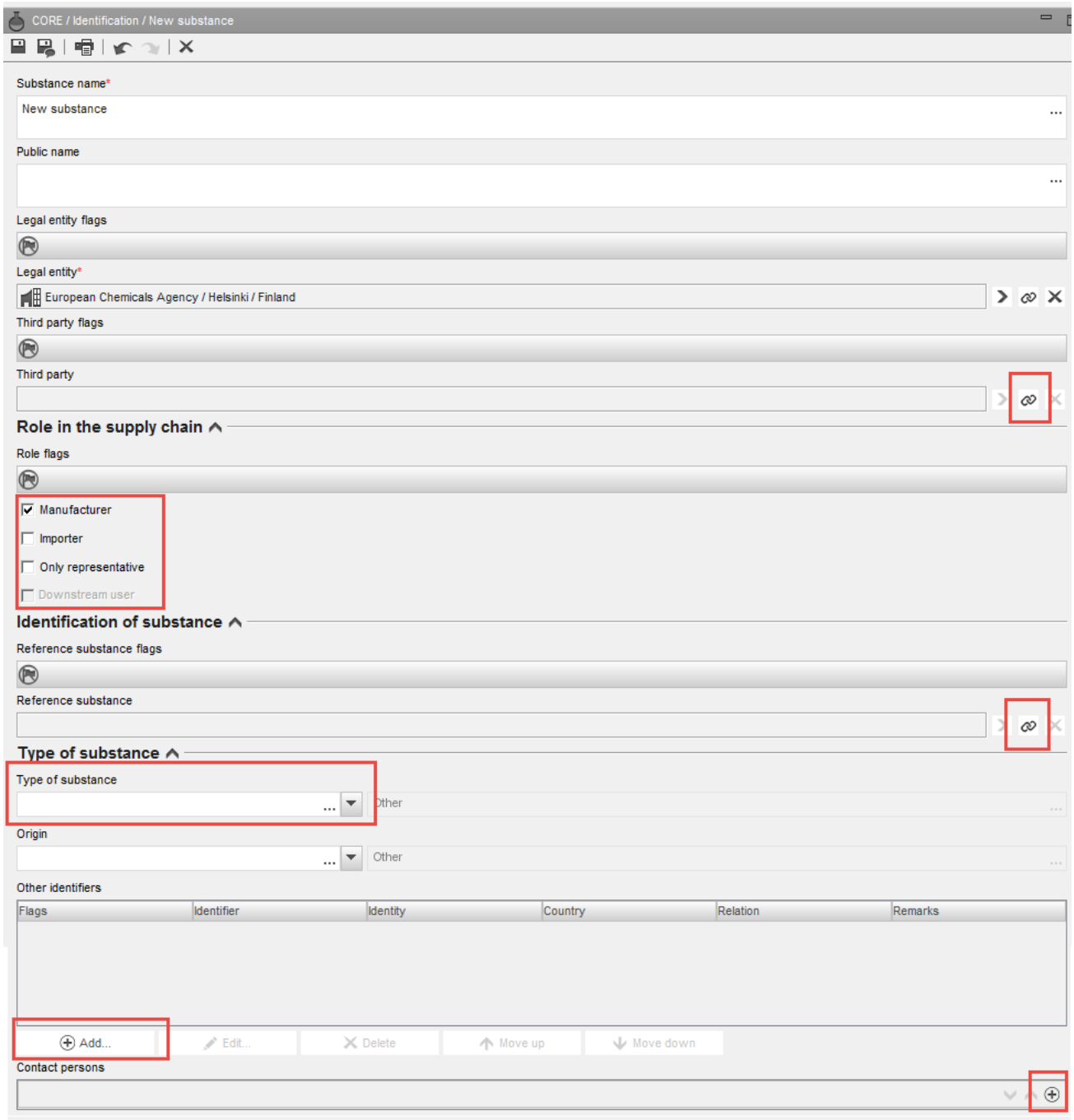
Step 4. Identify the active substance

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 is defined during Step 1 but it can be changed at any point when editing the dataset. Fields of prime importance are indicated in red in Figure 14 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 14: Section 2.1 'Common name and synonyms'



Third party (representative)

If relevant, indicate the name of a representative, e.g. a consultancy company working on behalf of the prospective authorisation holder. Achieve this by clicking the link button (🔗), enter some search criteria (e.g. Legal entity name) in the appearing 'Query for legal entities' window and then click 'Search'. Select the correct legal entity from the search results, and click the button 'Assign' (Figure 11).

It may be the case that the representative has not yet been entered into your database. In this case, click the button 'New' in the 'Query for legal entities' window (Figure 11), to open the 'Create new legal entity' window (Figure 12).

Role in the supply chain

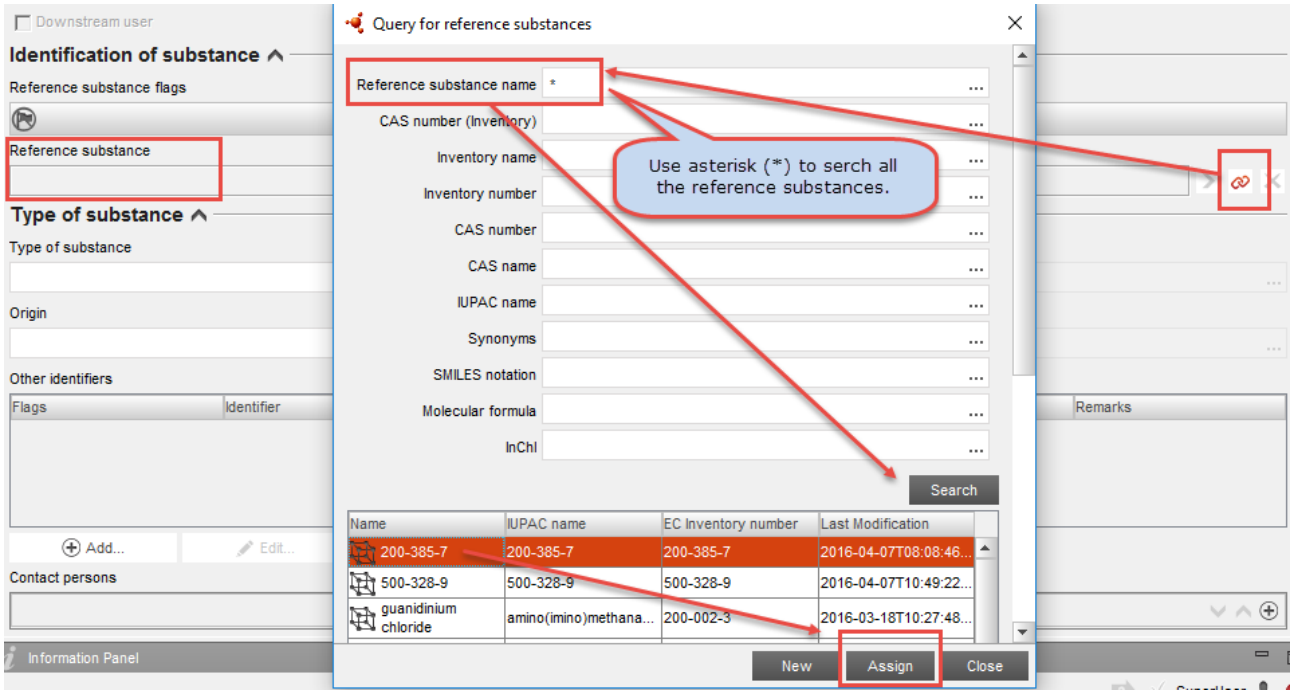
Select the role you play in the supply chain, i.e. manufacturer or importer (or both). Note that 'Only representative' and 'Downstream user' are REACH terms and are not relevant for BPR dossiers or applications.

Reference substance

The reference substance in the 'Substance' dataset identifies the AS for which this dataset has been created; the AS may be a substance or a micro-organism.

Establish the reference substance by using the link button (🔗) next to the 'Reference substance' field. In the appearing 'Query for reference substances' window, enter some search criteria and then click 'Search'. From the search results, select the correct reference substance and click 'Assign' (Figure 15).

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

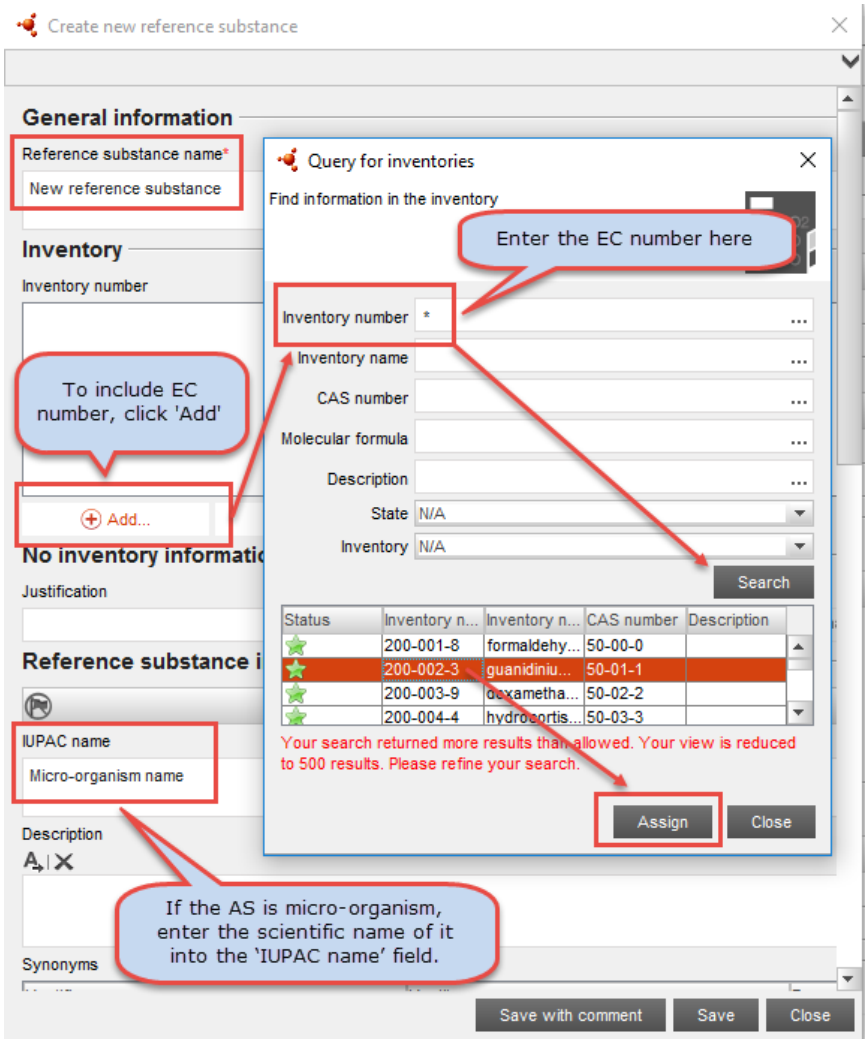


It may be that the reference substance has not yet been entered into your database. In this case, click 'New' to open the 'Create new reference substance' window. In this window, enter the Reference substance name, and the details of the reference substance (Figure 16).

In order to indicate the EC number of your reference substance, click 'Add' under the 'Inventory number'. Enter some search criteria (e.g. EC number in the 'Inventory number' field) in the appearing 'Query for inventories' window and then click 'Search'. Select the correct EC entry from the search results, and click the button 'Assign'.

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 16: Entering the details of the 'Reference substance'



Type of substance

Select the type of substance (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. Select also the origin (e.g. element, inorganic, etc.) of the reference substance.

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 from the list 'Identifier'; e.g. common 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 trade name of the AS in the field 'Identity', 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 assign the contact person (Figure 14).

Use the link button (🔗) next to the 'Person' field. In the appearing 'Query for contacts' window, enter some search criteria and then click 'Search'. From the search results, select the correct contact and click 'Assign'.

This person may be contacted e.g. to provide assistance or ask about the information submitted.

IUCLID section 2.9 'Specification of purity'

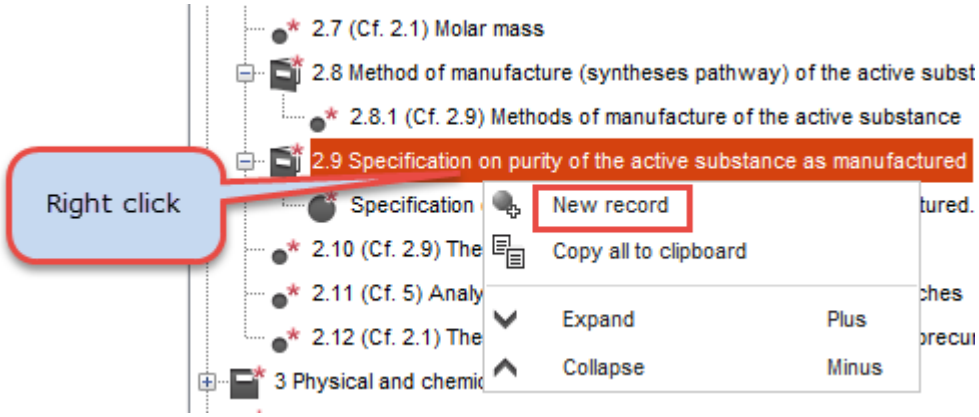
The composition, constituents, impurities and additives define the substance. This section allows the entry of multiple compositions of the substance, for example, to allow different profiles of impurities, provided this does not change the identification of the substance.

Start by creating a 'record' by right clicking on top of the section name and selecting 'New record'. You can create multiple records if needed (Figure 17).

Enter the name, and other relevant information of the composition in the fields provided. Create a block under the constituents section and assign (🔗) reference substances to all the constituents of your AS. If you have any impurities or additives, create a block for each and fill in relevant information, and then assign 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 17: Entering the substance composition



In IUCLID 6 the section 2.8 'Method of manufacture' is no longer editable, however the method of manufacture should be entered in the field 'Description of composition'. If needed, additional details for the method can be included as an attachment under 'Attached description'.

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 6 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 information' dataset, you must also create a dataset for the BP, using the dataset template 'BPR Biocidal product authorisation' or 'BPR Active substance application

(representative product)' (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 must always be created, regardless of the application type, e.g. if you are going to create a 'BPR Active substance application (representative product)' 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 information' dataset (Figure 2).

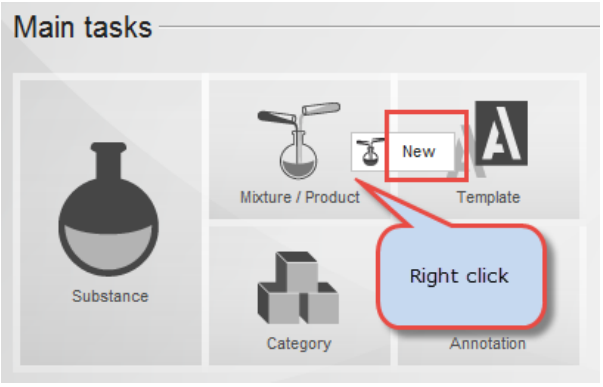
Additional 'Mixture/Product' datasets, using the supplementary dataset template 'BPR Basic information (mixture)' can be created in a similar manner but may contain different sections. Use this supplementary dataset template to create datasets containing information about additional components of a BP (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 'Main tasks' pane of the IUCLID 6 homepage ( ), create a 'Mixture/Product' dataset by right clicking on the Mixture/Product ( ) icon (Figure 18), and then clicking 'New'.

Figure 18: Creating a 'Mixture/Product' dataset



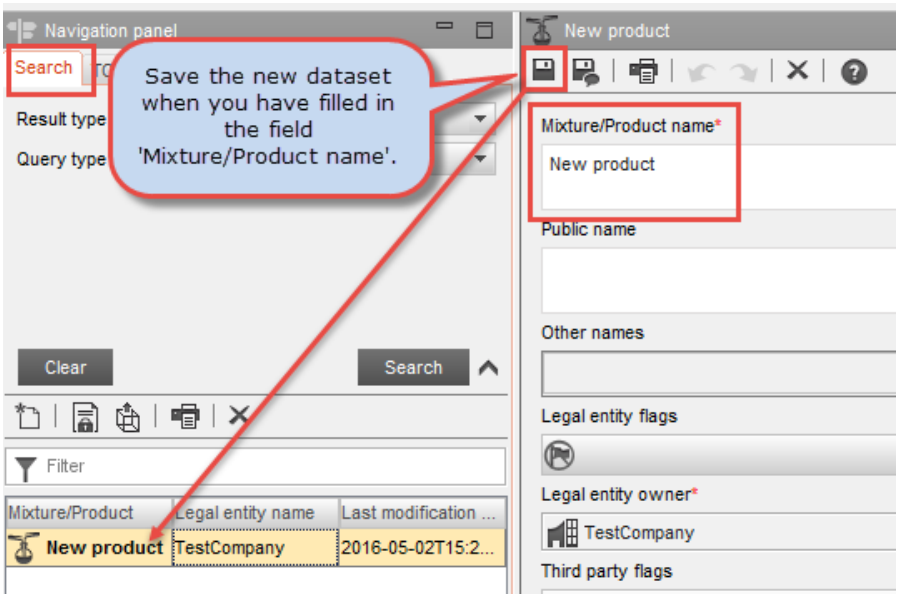
Similar to the creation of your 'Substance' dataset, an empty 'Mixture/Product' dataset will open. Enter a name for your dataset in the field 'Mixture/Product name', and click the Save ( ) icon. The new dataset will appear in the list of datasets in the 'Search' tab (Figure 19)

Once you have saved the dataset you can start filling in the information within it. Click the 'TOC' tab (table of contents) to view all of the sections.

If you have already created a 'Mixture/Product' dataset and you wish to update information in this dataset, click the Mixture/Product ( ) icon on the IUCLID 6 homepage (Figure 18). A list

of datasets will open in the 'Search' tab. Search for the correct dataset, double click on the dataset title, and click the 'TOC' tab to view all of the sections.

Figure 19: Naming the 'Mixture/Product' dataset



Step 2. Select the dataset template

Open the 'TOC' tab in the 'Navigation Panel'. Click the black arrow ( ) to open the drop-down menu.

Depending on the application type, you have two options for the dataset template.

i. 'BPR Biocidal product authorisation' - to be used with BP applications.

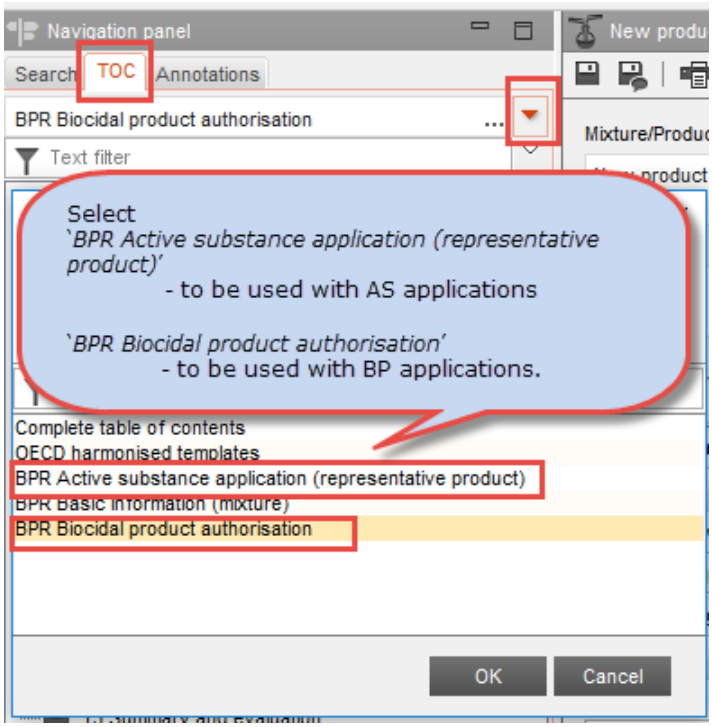
ii. 'BPR Active substance application (representative product)' – to be used with AS applications

Select the appropriate dataset template for your application (Figure 20). By selecting 'Expand all', you will see all of the sections contained in the 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 20: Selecting the dataset template



Step 3. Enter 'Applicant' details

IUCLID section 1.3 'Biocidal product manufacturer'

IUCLID section 1.3 contains the name and details of the BP manufacturer, importer and/or formulator. It is recommended that you indicate the name and details in IUCLID section 1.3 even if they are the same as the one of the applicant. Start by creating a 'record' by right clicking on top of the section name and clicking 'New record' (Figure 10).

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 record 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 for legal entities' window and then click 'Search'. Select the correct legal entity from the search results, and click the button 'Assign' (Figure 11).

It may be the case that the manufacturer has not yet been entered into your database. In this case, click the button 'New' in the 'Query for legal entities' window, to open the 'Create new legal entity' window (Figure 12). How to use the Legal entity assistant is explained in chapter 3, step 3 ('Enter the 'Applicants' details').

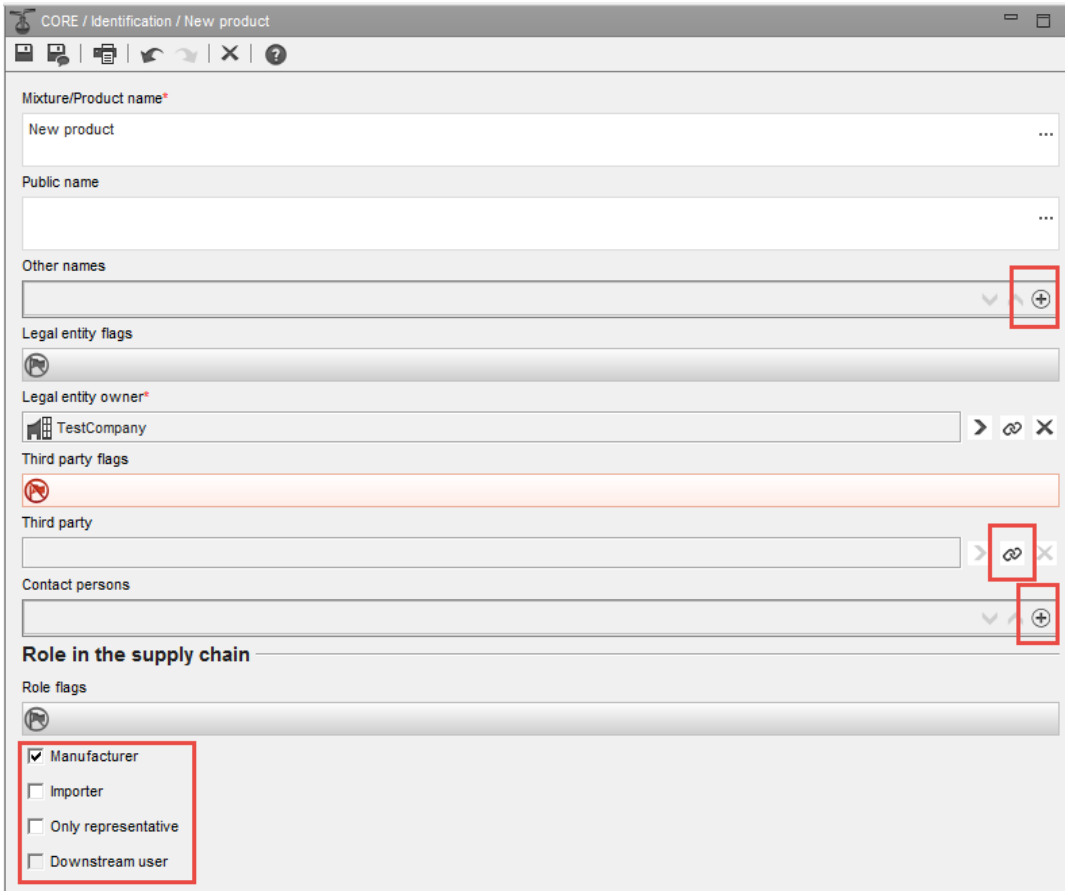
Step 4. Identify the biocidal product

IUCLID section 2.1 'Trade name or proposed trade name'

This section allows the identification of the 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 at any point when editing the dataset. Fields of prime importance are indicated in red in Figure 21 and are explained below the figure.

Figure 21: Section 2.1 'Trade name or proposed trade name'



Other names

Enter all the trade (commercial) names and alternative names by which the BP is known. For each entry, add a new block using the 'plus' function ( ). Select the name type; 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.

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 for legal entities' window and then click 'Search' (Figure 11). Select the correct legal entity from the search results, and click the button 'Assign' (Figure 11).

It may be the case that the representative has not yet been entered into your database. In this case, click the button 'New' in the 'Query for legal entities' window (Figure 11), to open the 'Create new legal entity' window (Figure 12).

Contact persons

Create a block using the 'plus' function ( ), and assign a contact person by clicking the **link** button ( ). This person may be contacted e.g. to provide assistance or ask about the information submitted.

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.

IUCLID section 2.3 'Biocidal product composition'

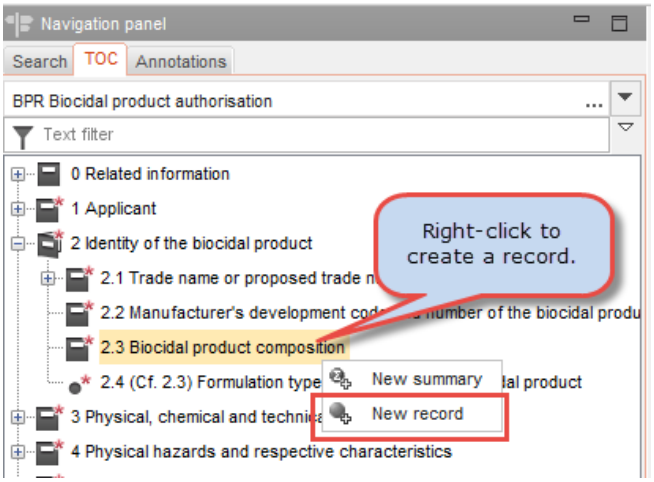
A BP is defined by its name, formulation type and its exact composition percentage. A BP family is similarly defined to include the individual products within it and the range of concentration percentages. This section details how to enter product composition data for a single BP or multiple compositions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

Provide suitable labels for your 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 'Biocidal product composition': If you create a summary or you include more than one AS in the BP composition, e.g. include more than one record each with an AS, you will be unable to make a 'BPR Active substance application (representative product)' dossier.

For a single biocidal product: Start by right-clicking on IUCLID section 2.3 'Biocidal product composition', and select 'New record' ( ). Only one record ( ) should be created and completed (Figure 22).

Figure 22: Record for a biocidal product



Once you have created a record, you will be able to enter information in the fields provided for the following:

i. the BP name,

ii. brief description of the BP,

iii. the formulation types from the drop-down menu, and

iv. all of the components, impurities and additives of the BP.

Create blocks for the components by clicking the plus sign ( ) (Figure 23). You will need to create an individual block for each component, impurity and additive of your BP.

- Within the 'Components' block, assign ( ) a 'Substance' or 'Mixture/Product' dataset to the component of the BP. In a similar manner, assign a 'Reference substance' for any potential 'Impurities' and 'Additives'.
  Clicking the link button ( ) inside the block opens a 'Query for reference substances, mixtures, substances' window, in which you can specify the 'Query type' (dataset or reference substance) from the drop-down menu ( ) (Figure 24). Then, specify some search criteria and click 'Search'. From the search results, select the dataset or reference substance, and click 'Assign'.
- For the BP components and additives, indicate the function using the drop-down menu ( ).
- Enter the concentration value(s) and unit.
- 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 related box (Figure 23). 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').

Figure 23: Defining a biocidal product composition

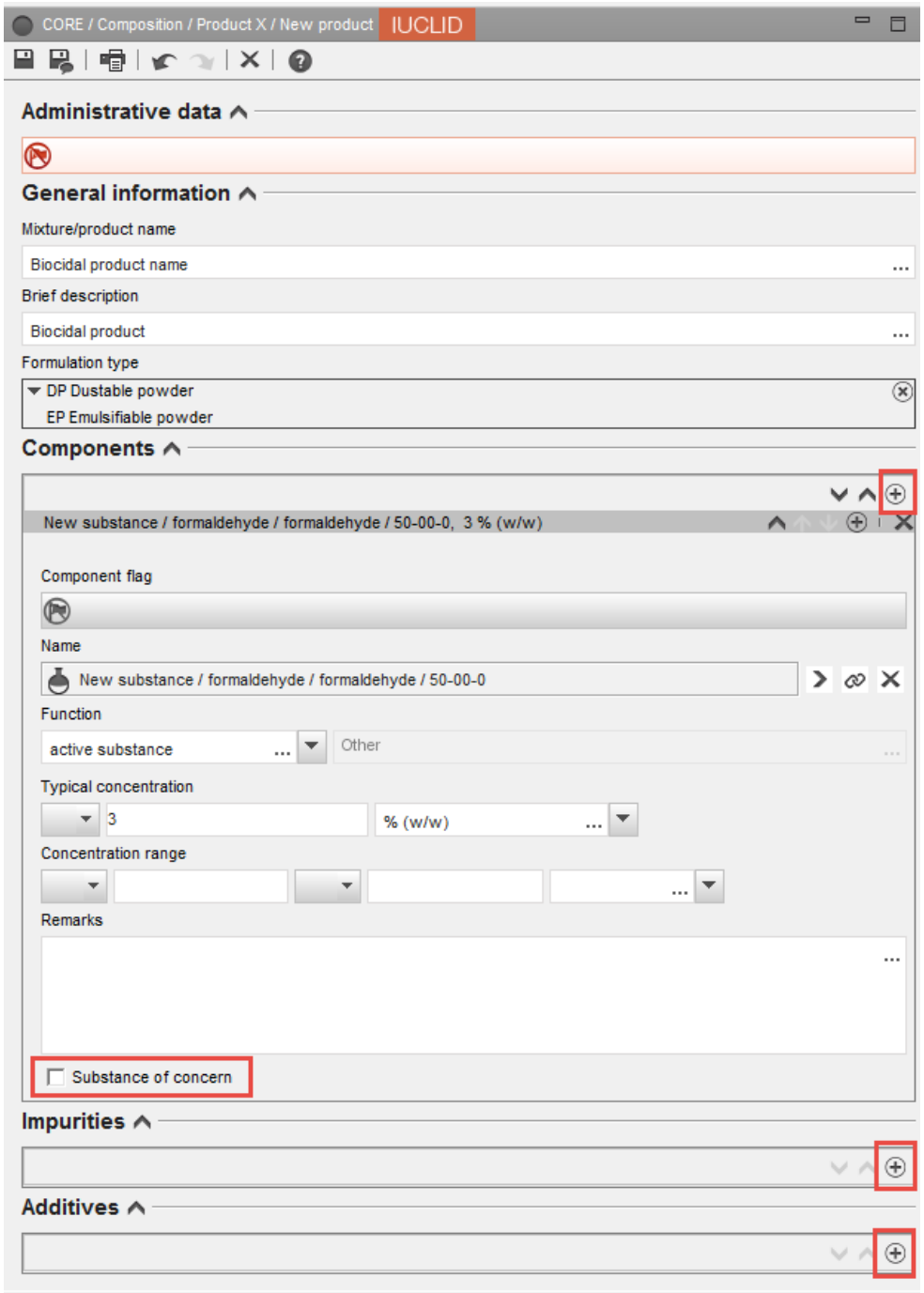
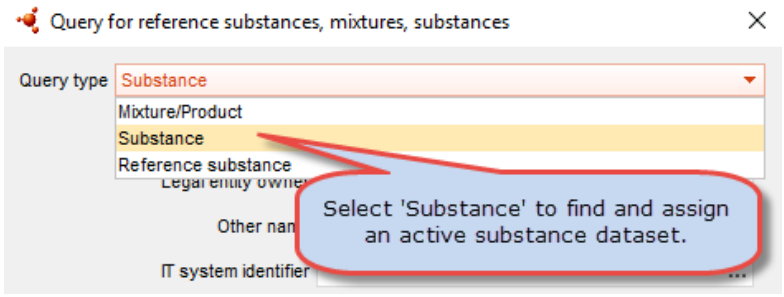


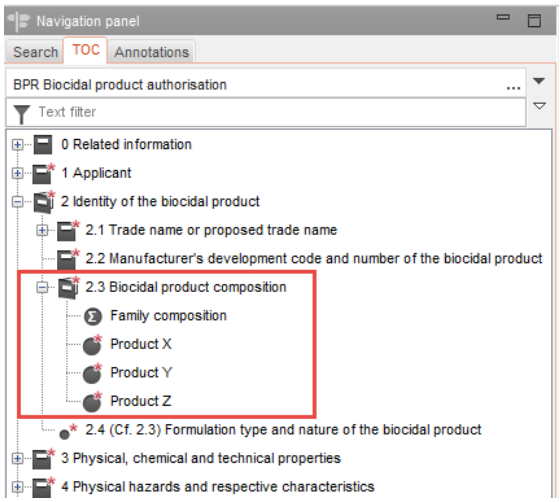
Figure 24: Select a dataset or a reference substance



For a biocidal product family: Start by right clicking on IUCLID section 2.3 'Biocidal product composition', and select 'New summary' ( ). Only one summary ( ) should be created and completed.

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

Figure 25: Summary with multiple records for a BP family



Once you have created a summary, you will be able to enter information in the fields provided for the following:

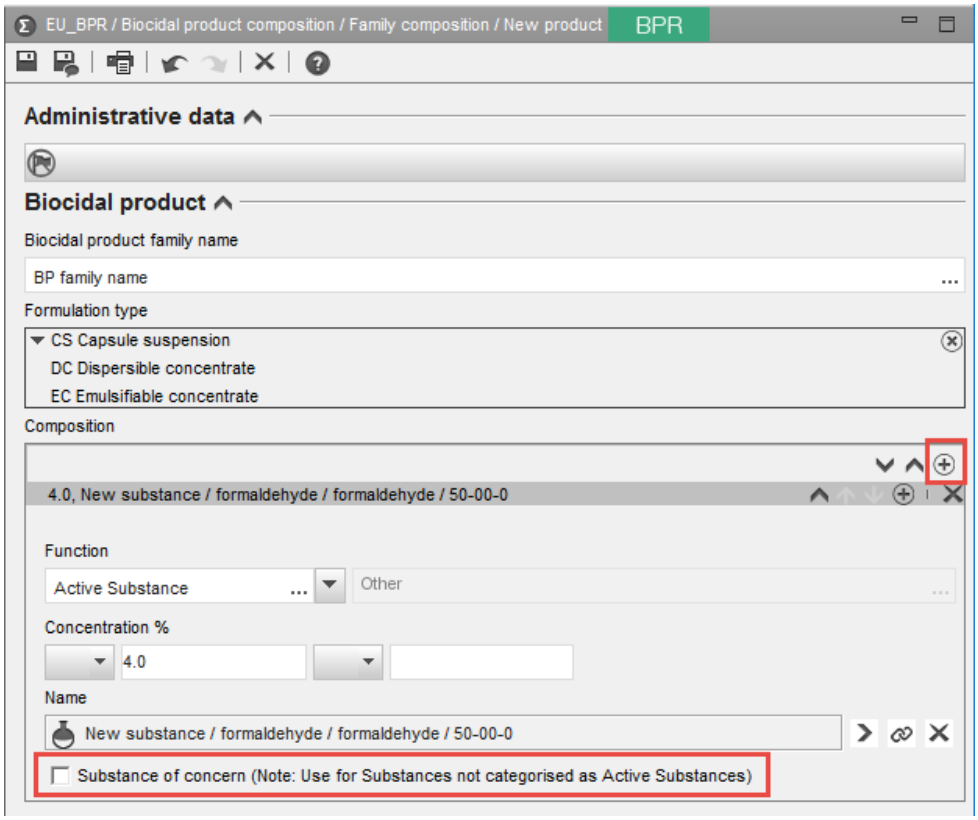
i. the BP family name,

ii. the formulation types from the drop-down menu, and

iii. all of the components.

Create blocks for the components by clicking the plus sign ( ) (Figure 26). You will need to create an individual block for each component of your BP.

Figure 26: Defining a biocidal product family composition



- Within the 'Composition' block, indicate the BP function (e.g. AS, solvent, emulsifier, etc.) using the drop-down menu ( ).
- Enter the concentration % range.
- Assign ( ) a 'Substance' or 'Mixture/Product' dataset to the component of the BP family. Clicking the link button ( ) inside the block opens a 'Query for reference substances, mixtures, substances' window, in which you can specify the 'Query type' (dataset or reference substance) from the drop-down menu ( ) (Figure 24). Then, specify some search criteria and click 'Search'. From the search results, select the dataset or reference substance, and click 'Assign'.
- 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 related box (Figure 26). Be sure to identify all of the components of your BP in individual blocks.

When you have completed the summary, create a record for each product within the family. For how to fill in the information in each record, follow the instructions in the section '**For a single biocidal product'** in the beginning of this chapter.

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 6 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

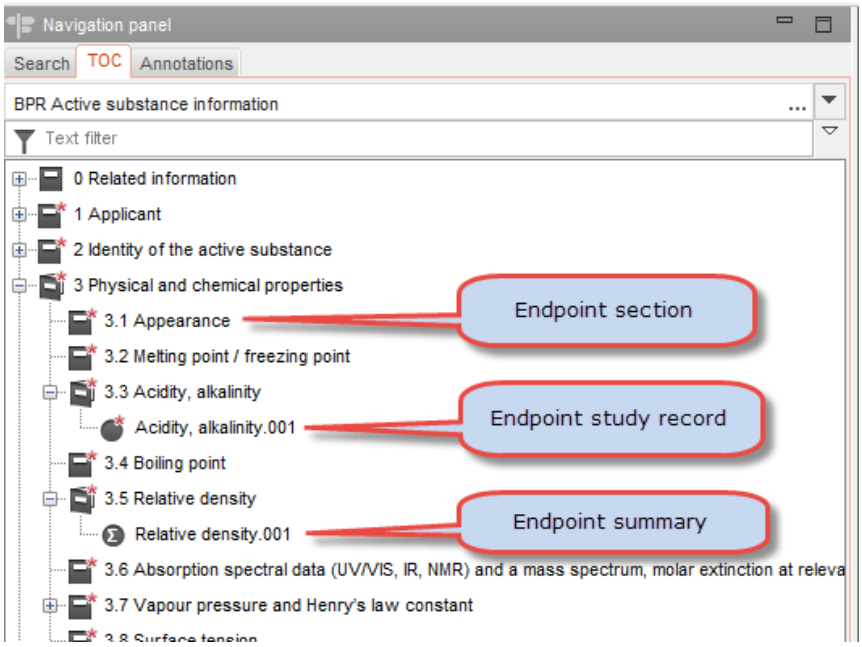
Once you have filled in all of the required 'Mixture/Product' dataset sections, and linked a fully completed 'Substance' dataset using the dataset template 'BPR Active substance information' (chapter 3) in section 2.3 'Product composition', you can create a valid dossier. For detailed instructions on 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 an endpoint summary ( ) (Figure 27). The endpoint sections are used to include data on endpoint studies. However, some endpoint sections (IUCLID section 7 and sections 11-13) are used to include additional information i.e. non-endpoint study related information (e.g. intended uses, classification and labelling, and protective measures).

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

Figure 27: IUCLID section tree components



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

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

5.1. Endpoint study records

An endpoint study record ( ) should contain all the data available on a particular endpoint study, entered into the pertinent fields. An endpoint study record provides a template with pre-defined fields and free text prompts, to help you include key information on a study. Endpoint study records usually consist of the data entry blocks: 'Administrative data', 'Data source', 'Materials and methods', 'Test material', 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' 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

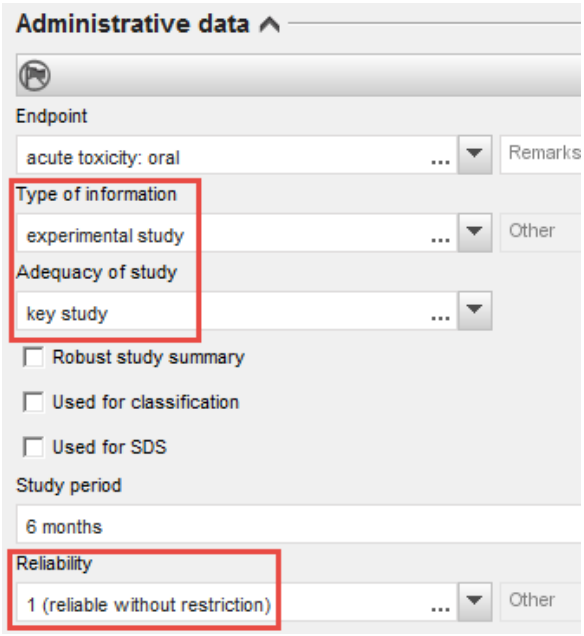
Make a selection (e.g. 'key study') in the field 'Adequacy of study' using the drop-down menu.

- 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).
- Disregarded due to major methodological deficiencies 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 'Type of information' and 'Reliability' using the drop-down menus ( ). If 'other:' is selected from any of the drop-down menus, then the adjacent field must be filled in (Figure 28).

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

Figure 28: Administrative data fields



'Data Source' block

In order to indicate literature reference in the 'Reference' table (Figure 29) click the 'Add' button (Add...). Enter some search criteria in the appearing 'Query for literature' window and then click 'Search'. Select the correct literature reference from the search results, and click the button 'Assign'.

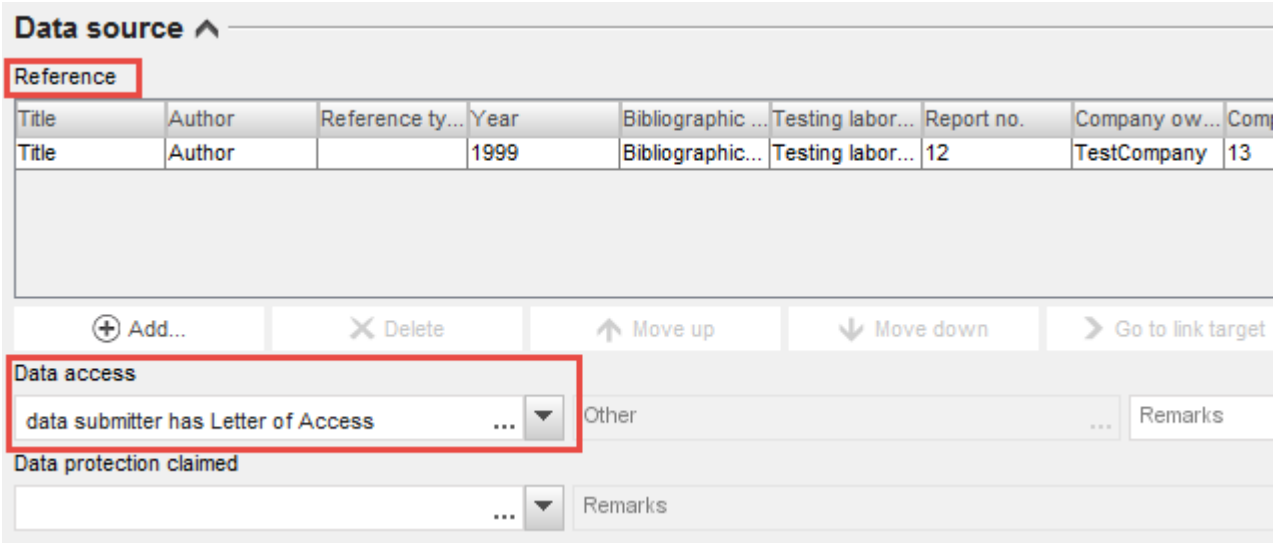
It may be that the literature reference has not yet been entered into your database. In this case, click 'New' to open the 'Create new literature' window. In this window, enter the Title, and the other details of the literature reference.

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', 'Company owner' and/or 'Title'.

A selection must also be made from the drop-down menu ( ) 'Data access'. If 'other:' is selected, then the adjacent field must be filled in (Figure 29).

Figure 29: Data source table



'Materials and Methods' block

Fill in all the necessary fields, ensuring you supply information on the method of testing in the table 'Test guideline', in the field 'Guideline'. Achieve this by firstly adding lines to the existing tables using the 'Add' button (Add...) (Figure 30). 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:' is selected from the drop-down menu for the field 'Guideline', then the adjacent field must be filled in.

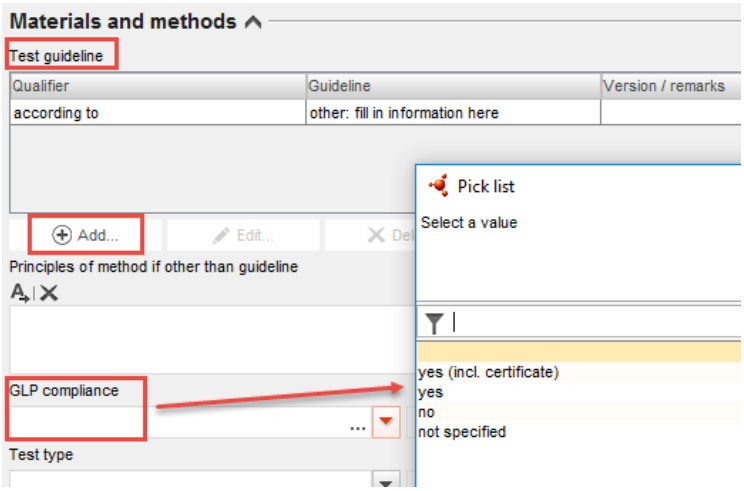
For endpoint study records that are indicated in the 'Administrative data' block 'Type of information' field as

- experimental study,
- read-across based on grouping of substances (category approach), or
- read-across from supporting substance (structural analogue or surrogate),

indicate whether the study is GLP compliant or not. Select one of the options in the drop-down menu ( ) in the field 'GLP compliance' (Figure 30).

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

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



There may be additional fields to be completed depending on the endpoint section being completed. For example, endpoint section 8.5.4, 'Genetic toxicity in vitro', has the additional field 'Type of assay'. 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).

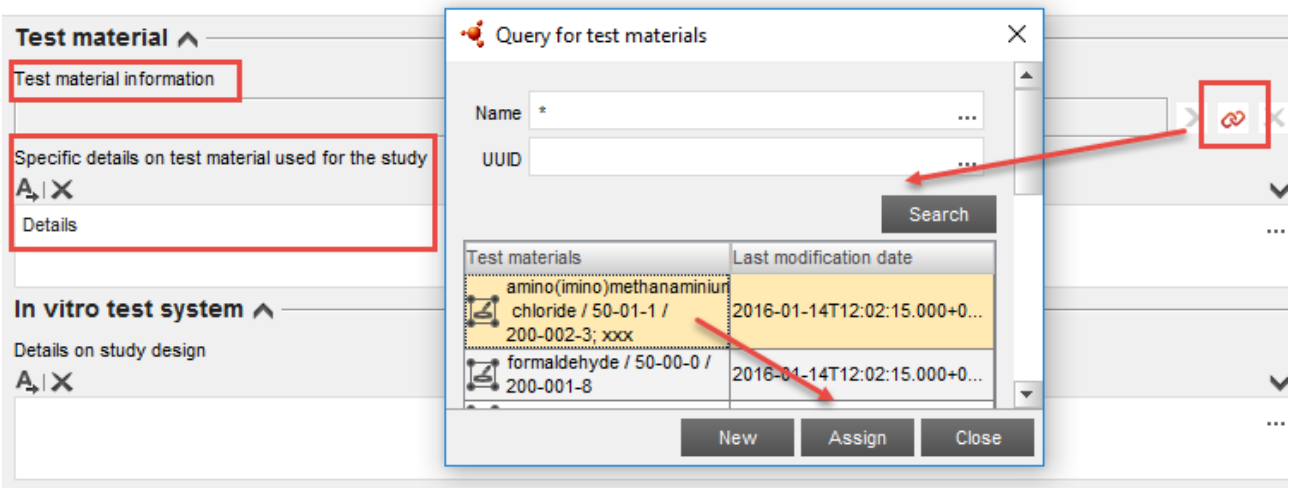
'Test Material' block

If the test material identity is same as for the substance defined in section 2.1, then it is optional to provide further information about the test material. If the test material is different, then assign test material under 'Test material information' or fill in the field 'Specific details on test material used for the study' (Figure 31).

In order to indicate test material under 'Test material information', click the link button ( ). Enter some search criteria in the appearing 'Query for test materials' window and then click 'Search'. Select the correct test material from the search results, and click the button 'Assign'.

It may be that the test material has not yet been entered into your database. In this case, click 'New' to open the 'Create new test material' window. In this window, enter the name and other details of the test material.

Figure 31: Adding details on the test materials



'Results and Discussion' block

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

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

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

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

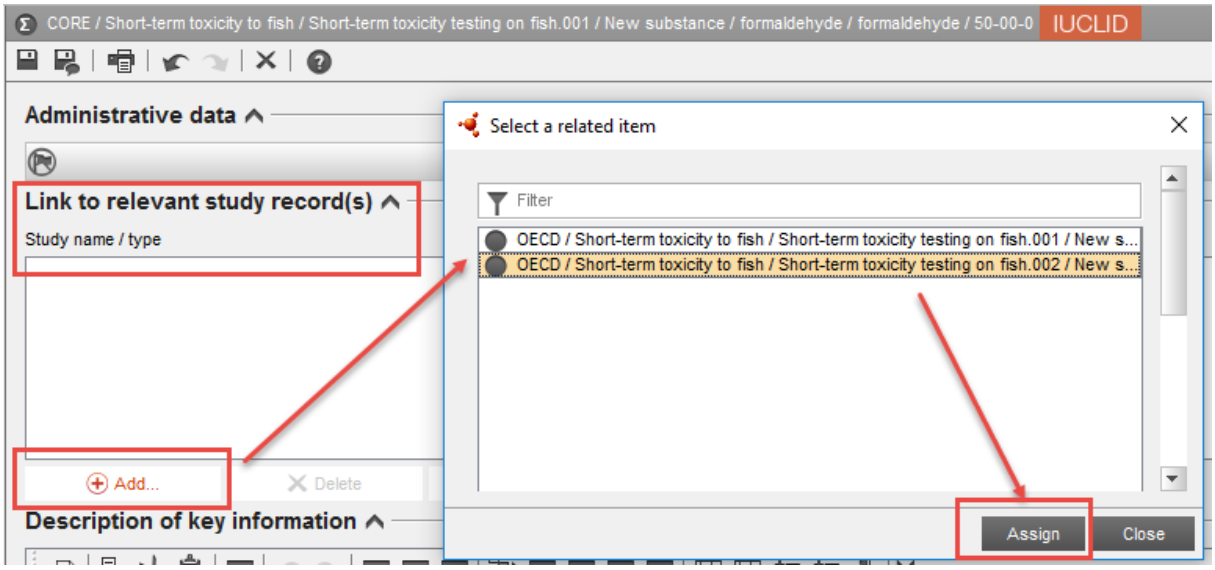
5.2. Endpoint study summaries

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', 'Description of key information', 'Key value for chemical safety assessment', and 'Additional information'. 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 'Add' button (Add...) and selecting the appropriate endpoint study record from the appearing pop-up menu (Figure 32).

Figure 32: Assigning an endpoint study record to an endpoint summary



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 'Measures 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**.

Step 1. Create a 'New record' (right-click) in section 7.1 'Field(s) of use envisaged for biocidal products…' and enter the information in the fields provided (Figure 33).

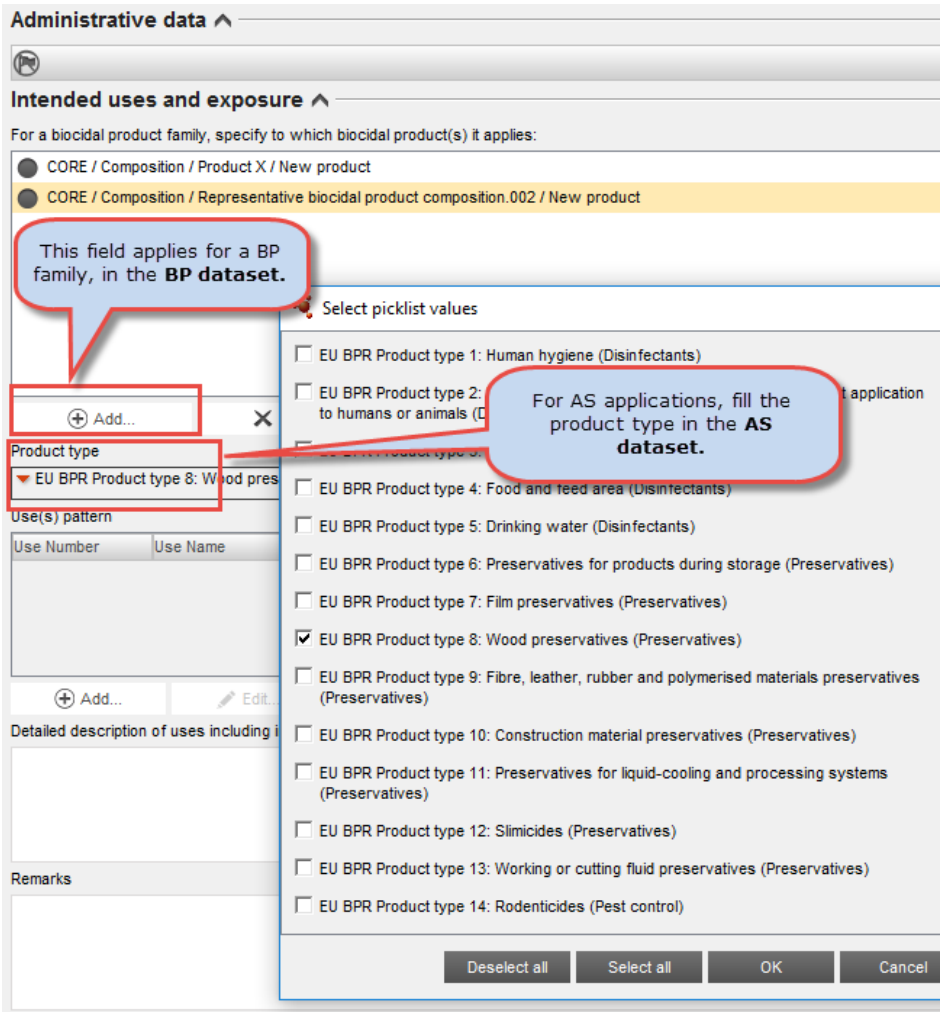
Step 2. Add a line in the field 'Intended uses and exposure' by clicking the 'Add' button (Add...) and assign records containing the composition of the biocidal products to the intended use. These records were created in IUCLID section 2.3 'Biocidal product composition'. Note that this step **only applies if the dataset concerns a product family**.

Step 3. Select a 'Product type' from the available drop-down menu ( ). Note that for AS applications, you must indicate the product type in section 7.1 of the **AS dataset**.

Step 4. Add rows to the table 'Use(s) pattern' (Add...) and define the uses pattern.

Step 5. Enter the 'Detailed description of uses including in treated articles' and 'Remarks' (if any) in the free text fields provided.

Figure 33: Entering the intended uses

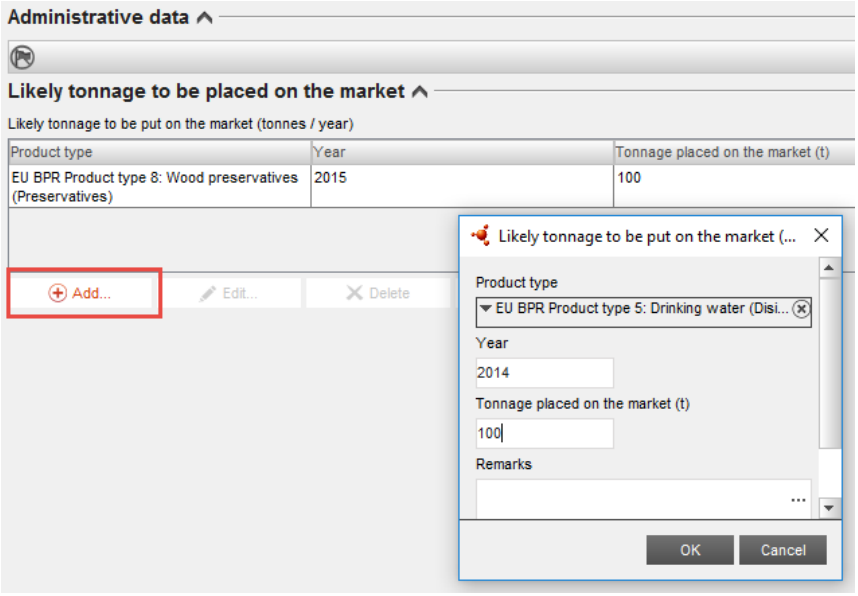


IUCLID section 7.5 'Likely tonnage to be placed on the market'

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

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

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



IUCLID section 7.6 'Method of Application…'

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

Step 1. Create a 'New record' (right-click) in IUCLID section 7.6 'Method of application and a description of this method', and enter the directions for use in the fields provided (Figure 35).

Step 2. The 'Reference use' field identifies the use for which the directions of use apply to. Add a line in this field by clicking the 'Add' button (Add...) and assign use records as appropriate. You must have defined a use in IUCLID section 7.1 'Fields of use…' in order for a use to be available for assignment.

Step 3. Select a 'Method of application' from the available drop-down menu ( ).

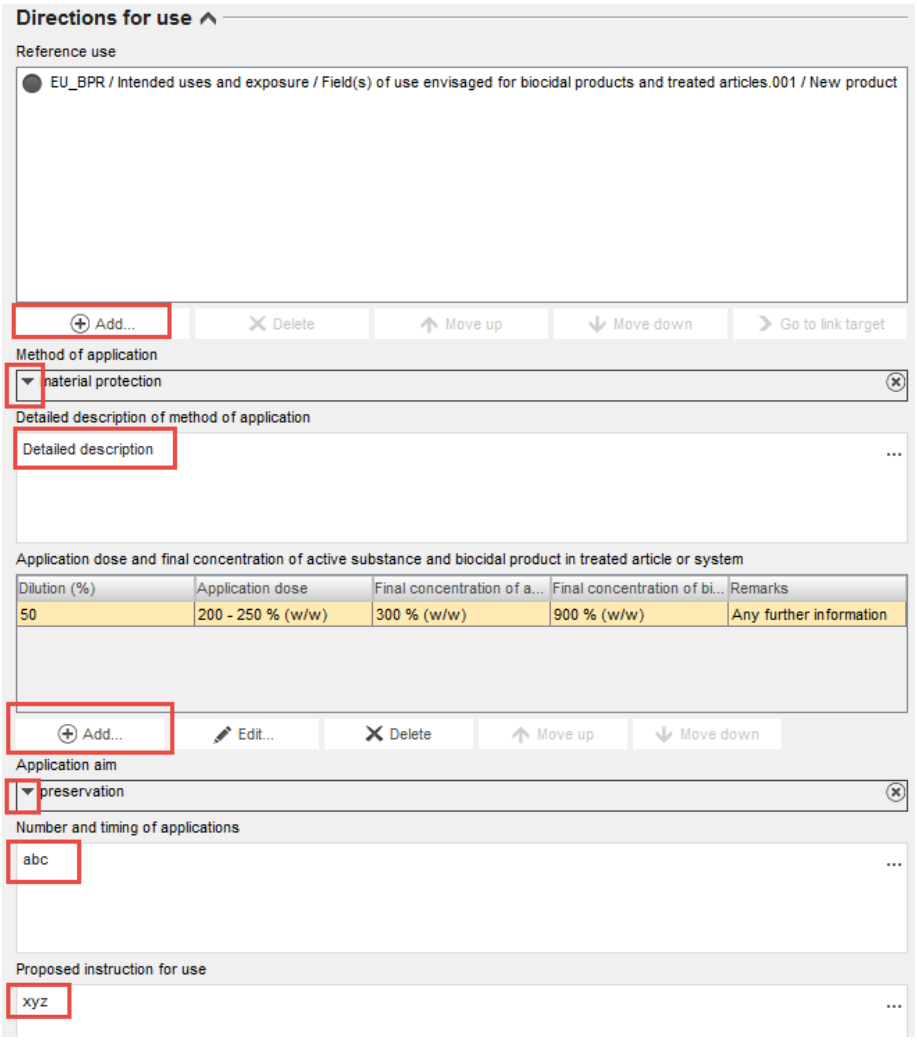
Step 4. Enter the 'Detailed description of method of application' in the free text field provided.

Step 5. Add rows to the table 'Application dose…' (Add...) and fill in the various parameters.

Step 6. Select an 'Application aim' from the available drop-down menu ( ).

Step 7. Enter the 'Number and timing of applications' and 'Proposed instruction for use' in the free text fields provided.

Figure 35: Entering the method of application



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

This endpoint section enables the generation of a systemic overview of measures that ensure the appropriate level of protection of humans, animals, and the environment. Start by creating a 'New record' (right-click) in IUCLID section 11 'Measures to protect humans, animals and the environment'. The 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.

6.3.1. IUCLID section 12.1 'GHS'

Include C&L data according to the GHS by creating a 'New record' (right-click) in IUCLID section 12.1 'GHS'.

Not classified substance: If the substance is not classified, tick the box 'Not classified' and justify in each field 'Reason for no classification' why no classification is given for an endpoint, hazard class or differentiation. In IUCLID 6, the fields 'Reason for no classification' indicate 'data lacking' as a default. Where applicable, change the default reason to the appropriate reason, for example 'inconclusive' or 'conclusive but not sufficient for classification' (Figure 36).

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

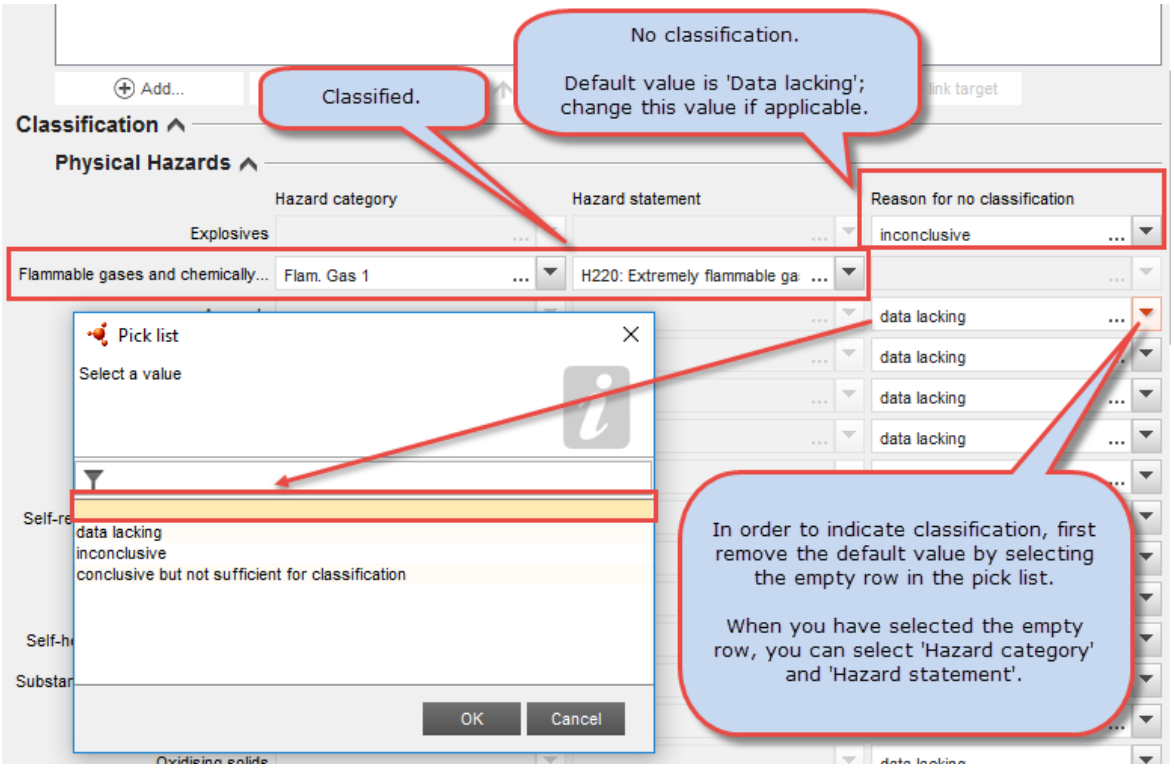
- Select 'data lacking' if you do not have relevant data or other adequate and reliable information that can be compared with the classification criteria.
- Select 'inconclusive' if you have data that is not completely reliable (e.g. data of poor quality), or if you have several equivocal study results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

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).

Classified substance: If the criteria for classification is met, you should specify a 'Hazard category' **and** a 'Hazard statement'. In order to do this, first remove the default value in the field 'Reason for no classification' by selecting the empty row in the pick list (Figure 36). This action activates the 'Hazard category' and 'Hazard statement' pick lists.

Further information on CLP is available from the Regulation's > CLP page from ECHA's website.

Figure 36: How to specify the 'Classification' labels



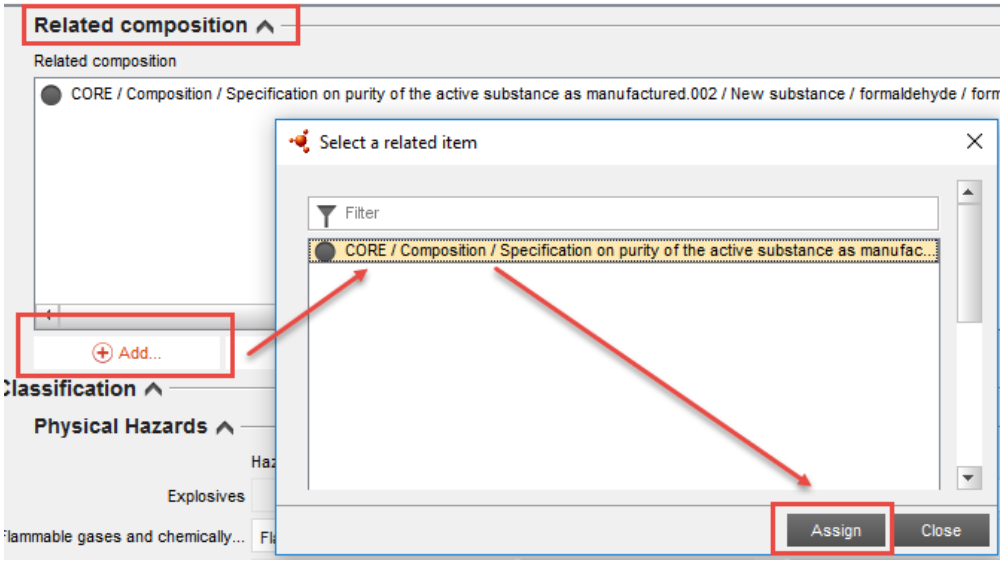
An AS may have multiple C&L records, for instance in the case where the AS contains an impurity with specific hazard properties having an impact on the classification. A BP can also have multiple C&L records, for instance in the case where there are different compositions of the BP. You can create multiple C&L records under section 12.1, allowing the entry of multiple C&L.

If you create multiple records in section 12.1, please ensure all of the records are completed. Delete any unwanted blocks by right-clicking on the record name and selecting 'Delete'.

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

Assign a related composition by clicking the 'Add' button (Add...) and selecting the composition from the list (Figure 37). Several compositions can be linked to the same C&L block.

Figure 37: How to assign 'Related compositions'



6.3.2. IUCLID section 12.3 'Packaging'

In the 'Mixture/Product' dataset, there is the additional endpoint section 12.3 'Packaging (12.7 in Annex III of BPR)'. 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.).

Step 1. Create a 'New record' (right-click) in section 12.3, then enter the packaging information in the fields provided (Figure 38).

Step 2. Add a line in the field 'Packaging' by clicking the 'Add' button (Add...) and assign records containing the composition of the biocidal products to the packaging. These records were created in IUCLID section 2.3 'Biocidal product composition'. Note that this step **only applies if the dataset concerns a product family**.

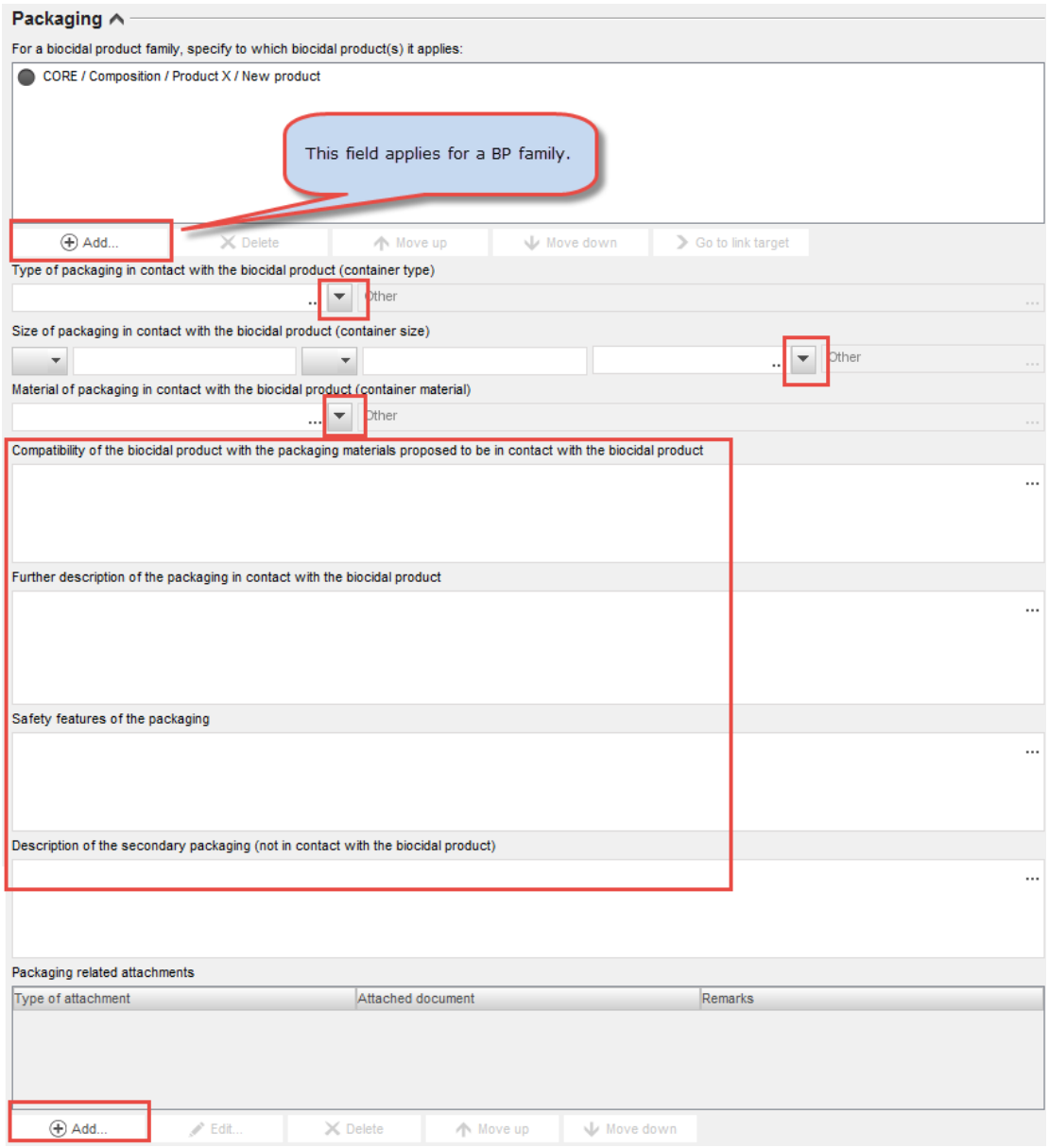
Step 3. Select a type of packaging from the available drop-down menu ( ).

Step 4. Enter the size and material of packaging (use the drop-down menus ( ) to include the unit).

Step 5. Enter the compatibility of the BP, and further description of the packaging, safety features and secondary packaging in the free text fields provided.

Step 6. Include any other packaging related attachments if available, e.g. a picture of the package, by clicking on the 'Add' button (Add...).

Figure 38: Entering packaging information



6.4. IUCLID Section 13 'Summary and Evaluation'

In accordance with the BPR, additional documentation may be required for certain applications. 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.

Summary and evaluation

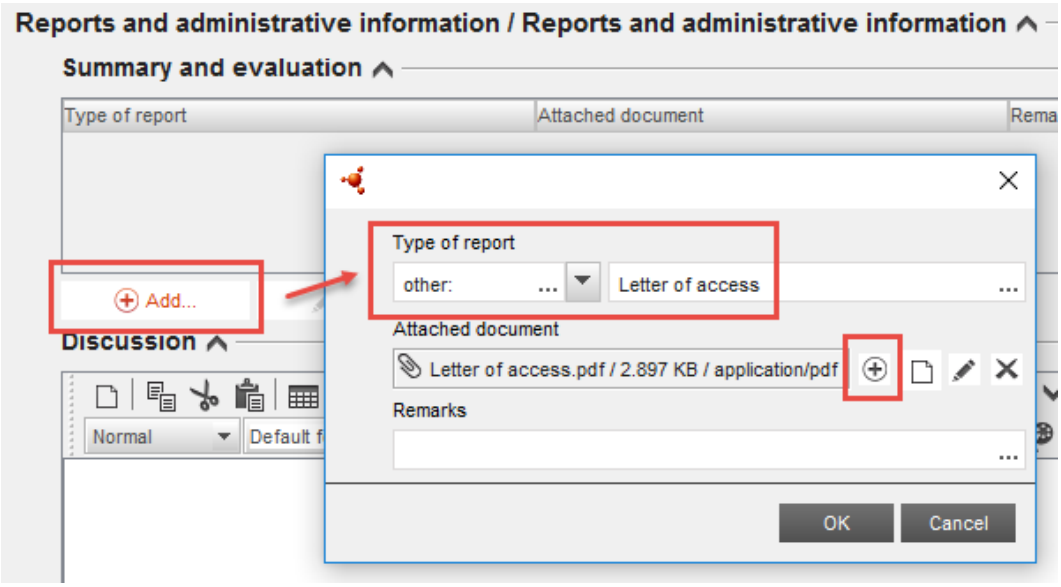
To attach relevant documents and include some important information concerning your AS and BP, right-click on IUCLID section 13 and select 'New summary' ( ). This summary is divided into three sections: 'Summary and evaluation', 'Active substance related information' and 'Biocidal product related information'.

The 'Summary and evaluation' section should be used to attach relevant supporting documentation (including but not limited to, a letter of access, a decision on technical equivalence, a risk assessment report, etc.).

Attach the appropriate documents by adding (Add...) as many lines as needed (Figure 39).

Select the applicable option from the drop-down menu ( ) and attach the documents (, Figure 39). If no applicable option is available in the drop-down menu, then select 'other:' and enter the type of document you are attaching in the adjacent field.

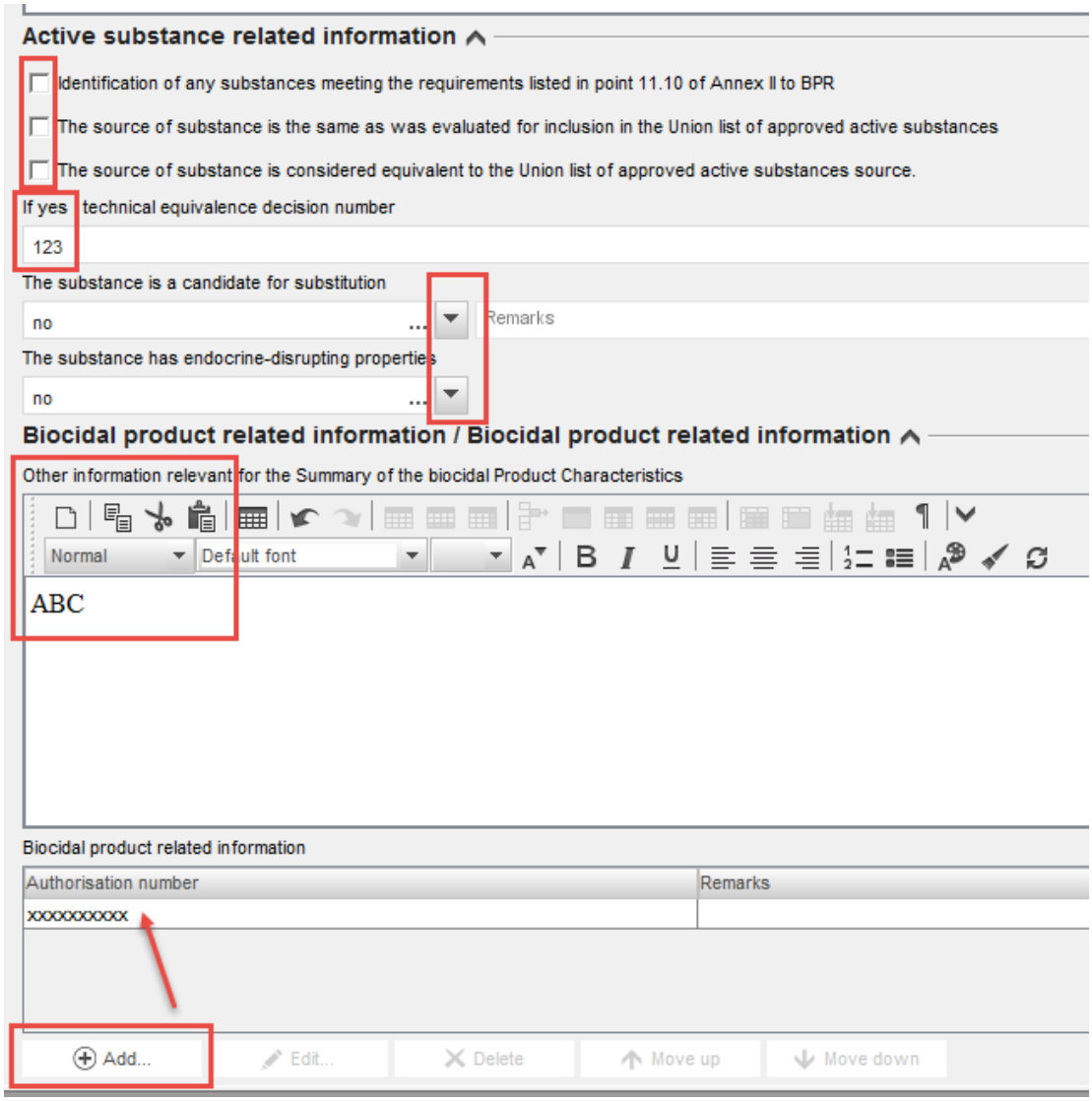
Figure 39: Attaching documents in IUCLID section 13



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 40). 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 40).

The 'Biocidal product related information' free text field should be used to include information concerning the Summary of Product Characteristics if relevant (Figure 40). If you have authorisation numbers related to authorised biocidal products then enter these into the table using the add button (Add...) and typing in the numbers and any remarks you have (Figure 40).

Figure 40: Including a decision on technical equivalence



6.4.1. 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.

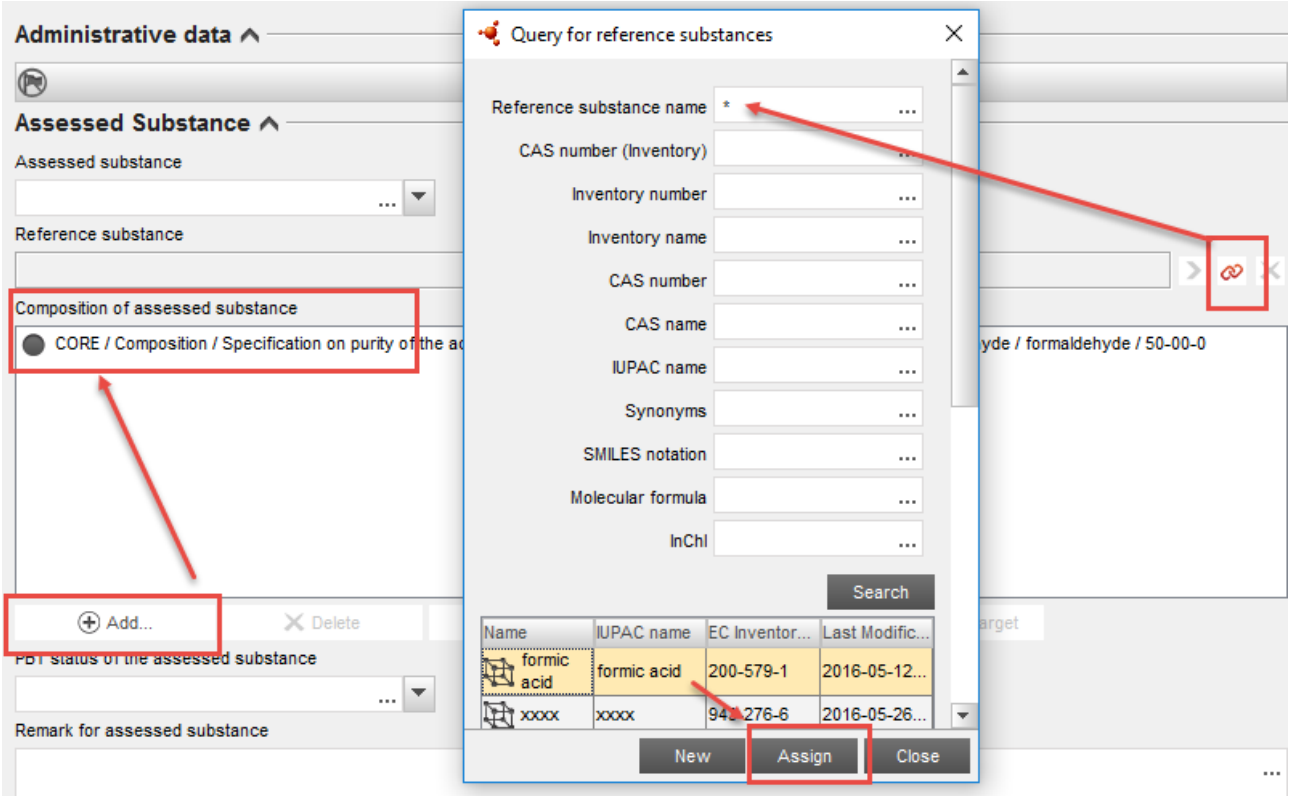
To enter the scientific data for this section, right-click on IUCLID section 13.1 'PBT assessment' and click 'New record' or 'New summary'. A record should contain information related to one given PBT assessment study. Whereas, a summary can be created to give the overall conclusions of the PBT assessment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

PBT record: fill in the relevant fields by either selecting the appropriate option from the drop-down menu ( ) or filling in the free text fields.

Ensure that you link the PBT assessment to a 'Reference substance'. Achieve this by clicking on the link button ( ) that will open a 'Query for reference substances' window. 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 41).

Under 'Composition of assessed substance', assign the relevant composition by clicking the 'Add' button (Add...) and selecting the composition from the list.

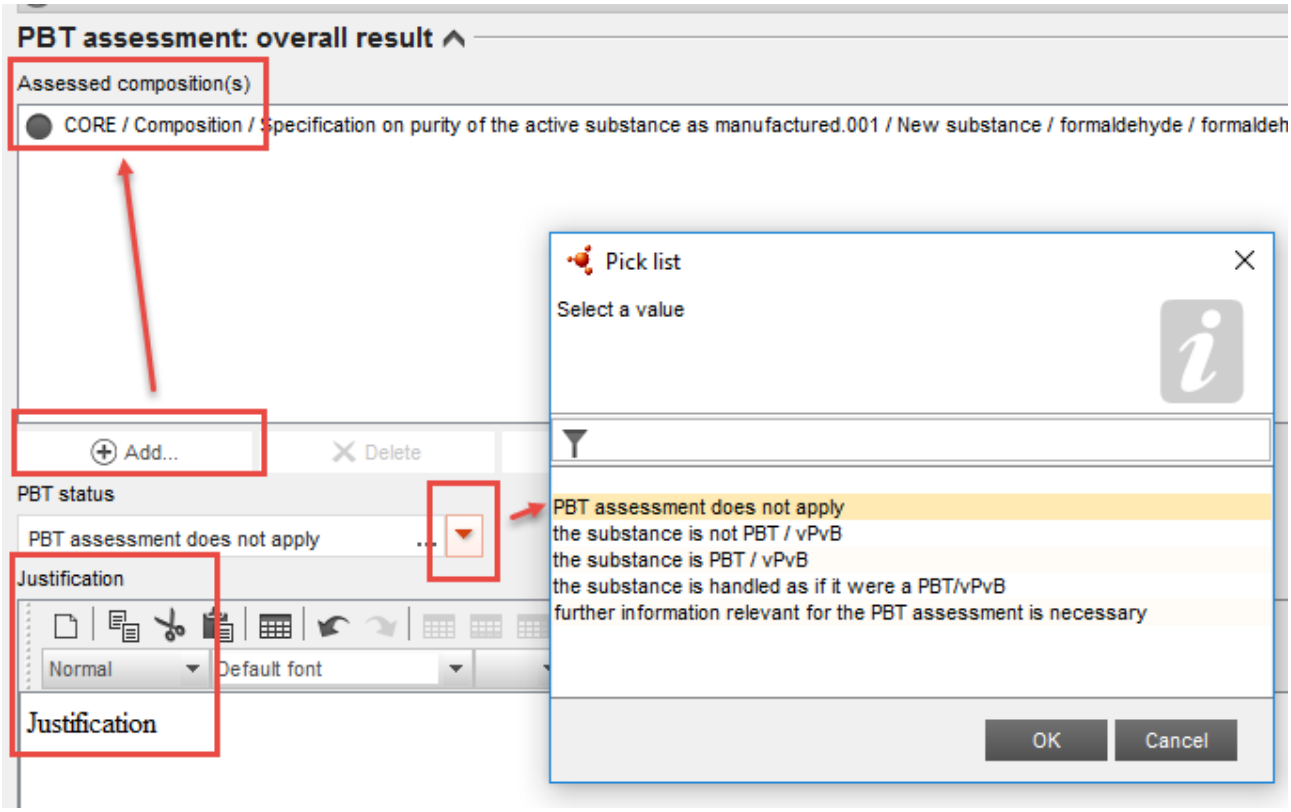
Figure 41: Linking a 'Reference substance' and 'Composition' to a PBT record



PBT endpoint summary: Under 'Assessed composition(s)', assign the relevant composition(s) by clicking the 'Add' button (Add...) and selecting the composition from the list.

Use the drop-down menu ( ) to give an overall result under 'PBT status' (Figure 42), 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 'Additional information' table at the end of the page, by adding lines to the table (Add...).

Figure 42: PBT endpoint summary

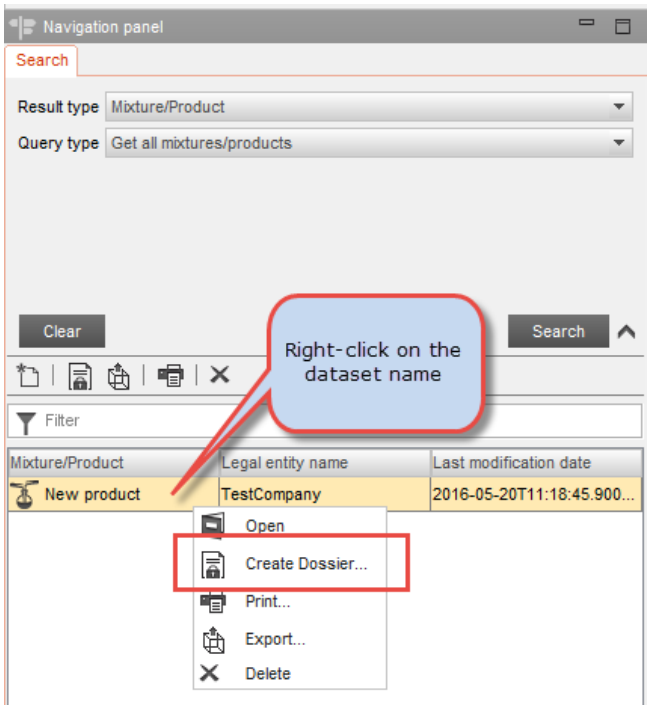


7. How to create a dossier

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 the Mixture/Product icon ( ) on the IUCLID 6 homepage ( ). Then, right-click on the name of your chosen 'Mixture/Product' dataset; listed in the Navigation panel. Click 'Create dossier' (Figure 43); this will launch the dossier creation wizard.

Figure 43: 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 (representative product)' dossier or a 'BPR Biocidal product authorisation' dossier. The type of dossier will vary depending on the process you are applying for.

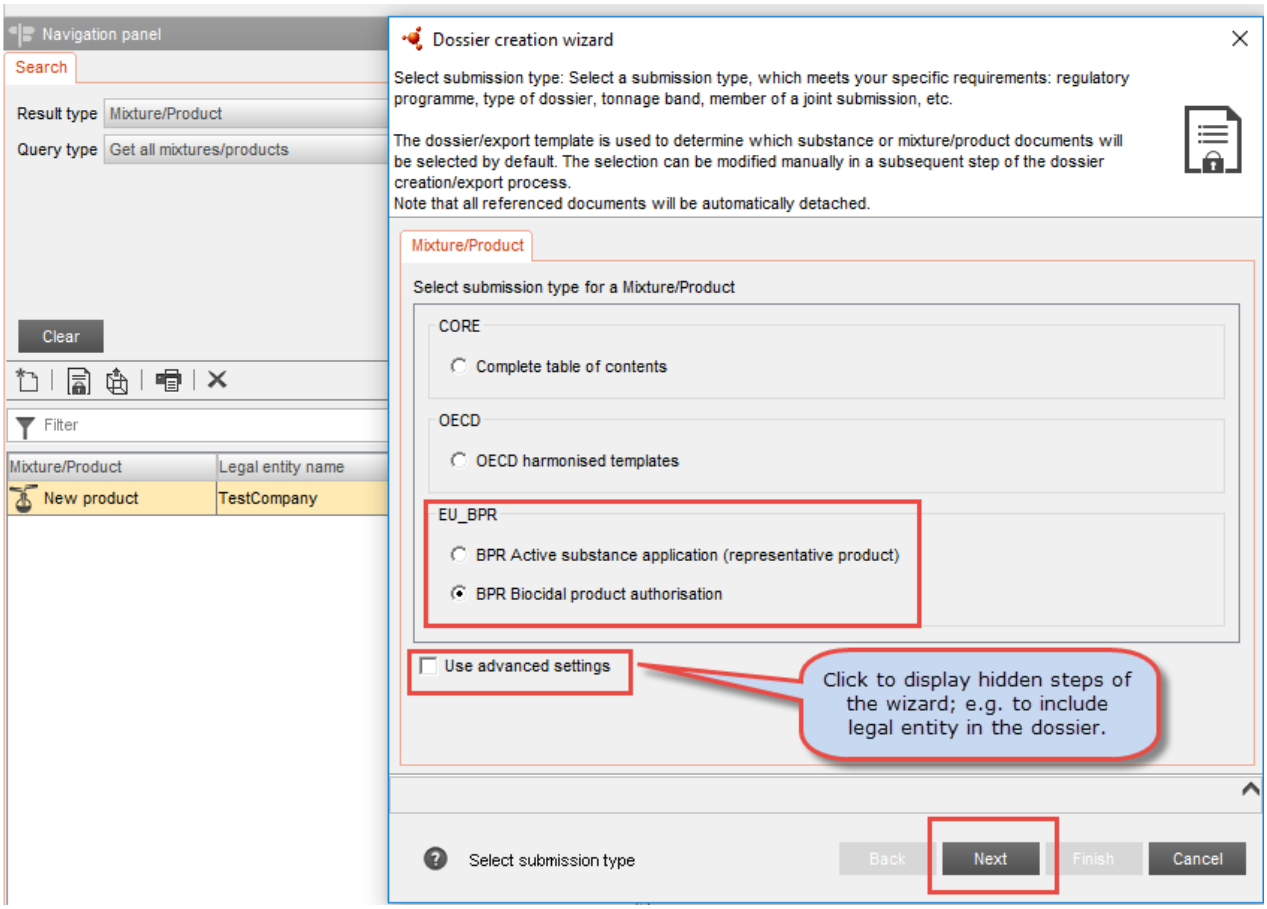
For information on whether a dossier is required for your application type and, if so, which type of dossier is required, please refer to the relevant Biocides Submission Manual.

The steps below explain how to navigate through the dossier creation wizard. Click 'Next' to move to the next step of the wizard. In IUCLID 6 some of the wizard steps have been hidden by default in order to simplify the dossier creation. You can make the steps visible by ticking the box 'Use advanced settings' in the first step of the dossier creation wizard (Figure 44).

Step 1. Select the correct dossier type for your application. Select 'Use advanced settings' if you wish to display the hidden steps of the wizard (Figure 44).

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

Figure 44: Step 1 of the dossier creation wizard



Step 2. Review the related entities, e.g. that correct dataset has been linked.

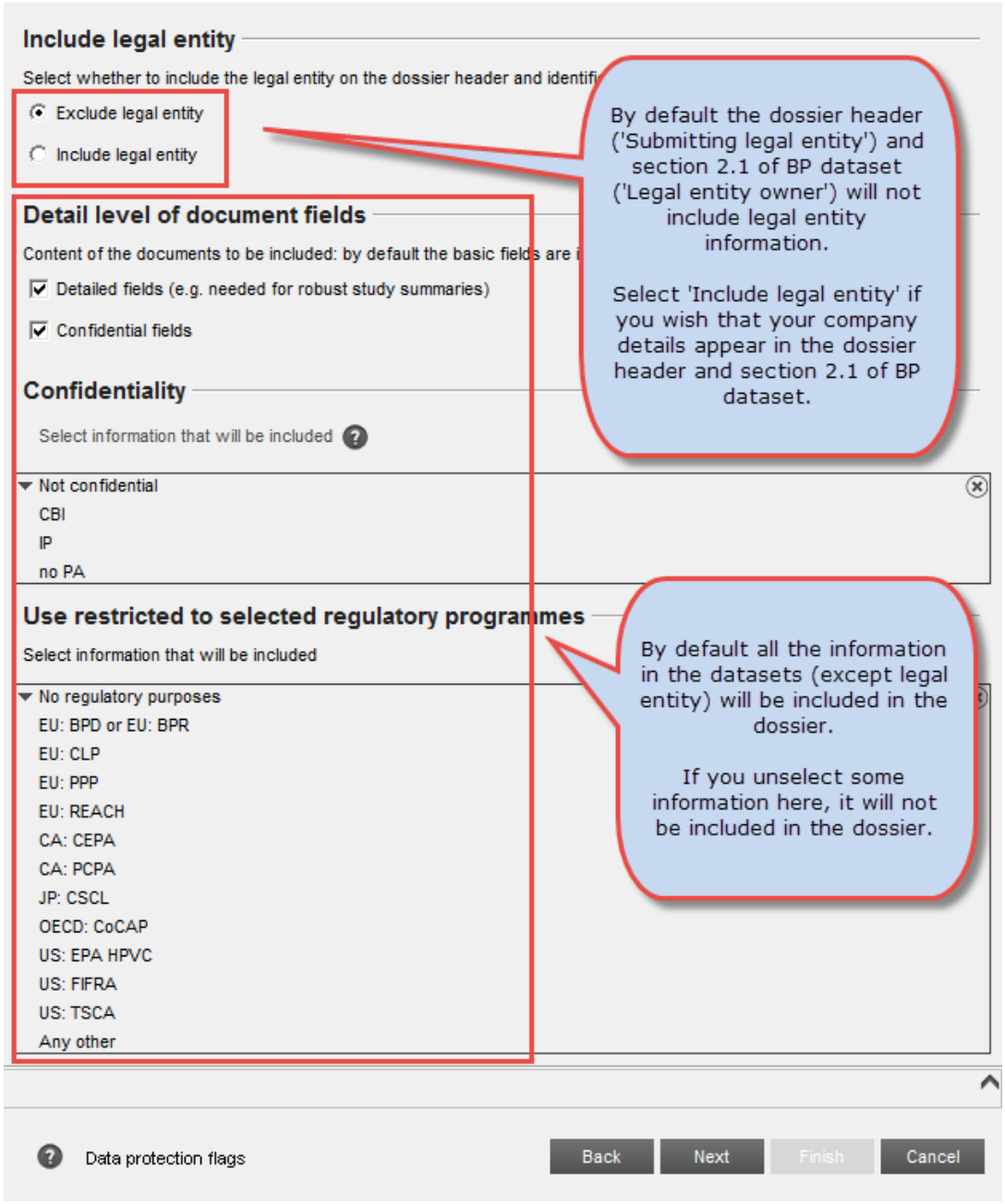
Step 3. (visible by selecting 'Use advanced settings' in step 1)

Filter the information to be included in the dossier.

By default, the 'Submitting legal entity' in the dossier header, and the 'Legal entity owner' in section 2.1 of the BP dataset will not be included in the dossier. However, if you wish to include the aforementioned legal entities (i.e. your company name and details) in your dossier e.g. for your personal record keeping purposes, select the radio button 'Include legal entity' (Figure 45).

By default, all the other information except legal entity will be included in the dossier. To exclude records from the dossier, un-select the relevant section in step 3 of the wizard (Figure 45).

Figure 45: Step 3 of the dossier creation wizard



For most cases, ECHA recommends that you do not un-select 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.

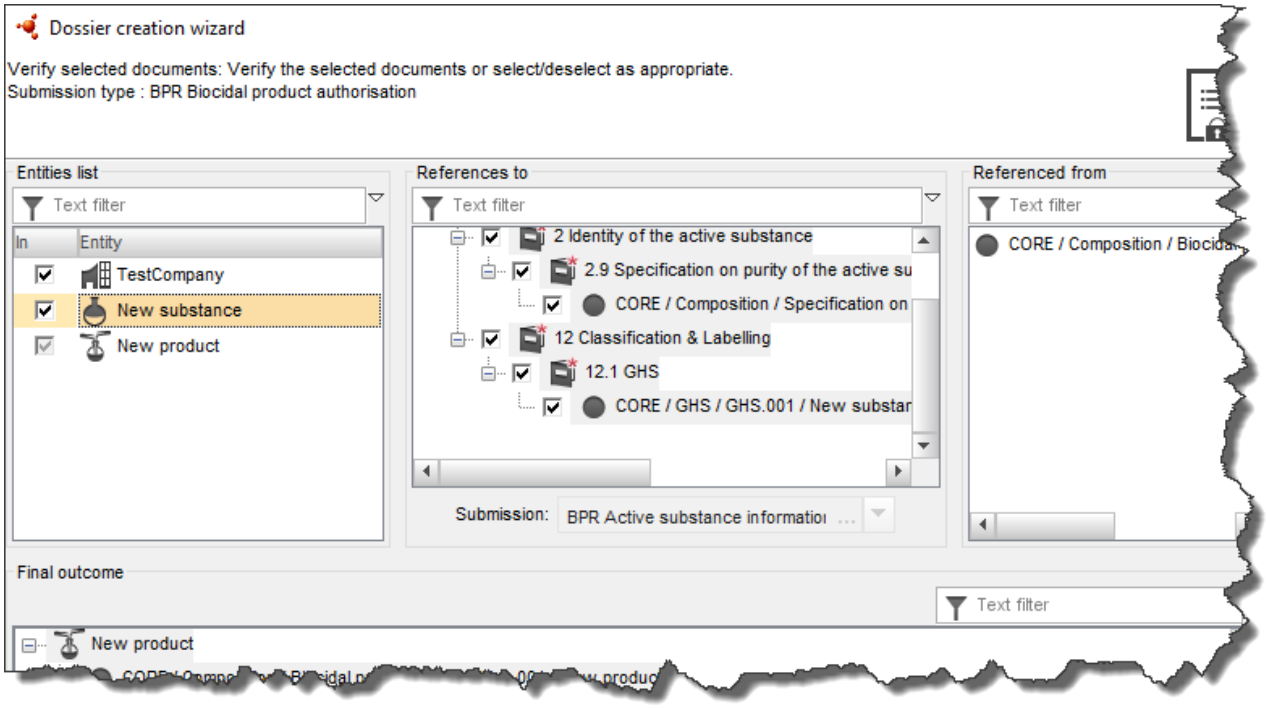
Step 4. (visible by selecting 'Use advanced settings' in step 1)

Verify the inclusion or exclusion of annotations.

Step 5. (visible by selecting 'Use advanced settings' in step 1)

Verify the selected sections for inclusion. All the dossier entities will be displayed in this step. To view the sections of each entity, click the name of the entity e.g. dataset name. By default, all the entities and sections are included in the dossier. To exclude an entity or section, un-tick the pertinent box in the relevant dataset. (Figure 46).

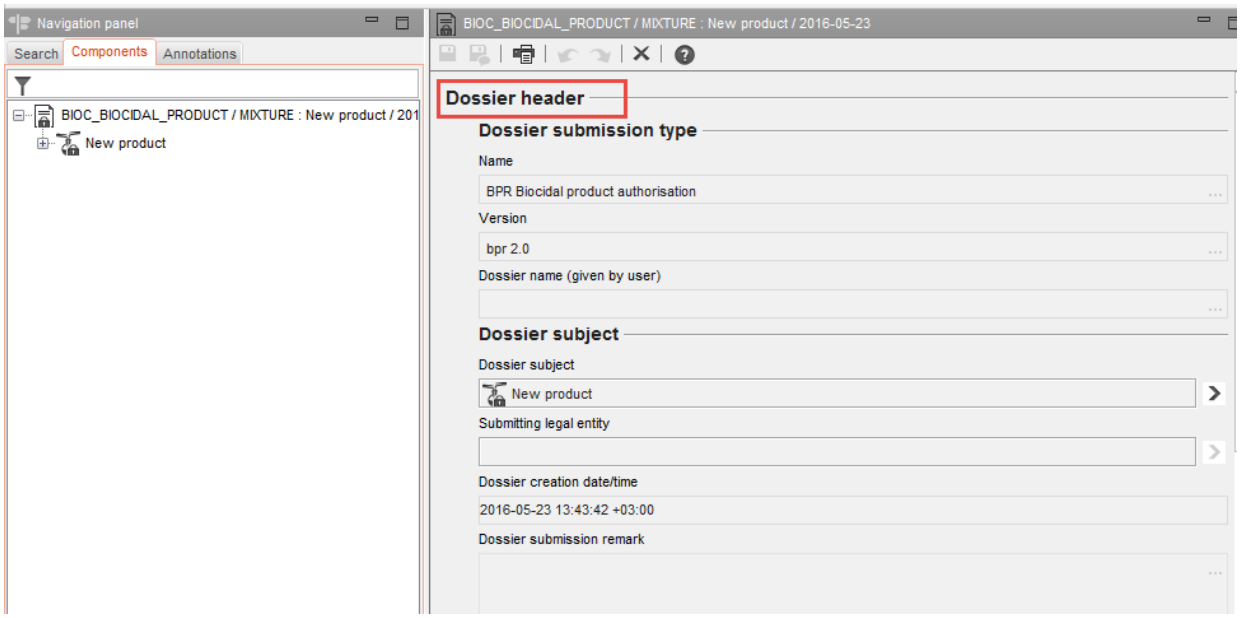
Figure 46: Verifying the sections to be included



Step 6. 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). Click 'Finish' to create the dossier.

Step 7. A prompt window will appear, giving an option to view the newly created dossier. Clicking 'Yes' will direct you to the 'Components' tab which contains the 'Dossier header' section (Figure 47). To view the full dossier content see chapter 7.2.2.

Figure 47: Dossier header

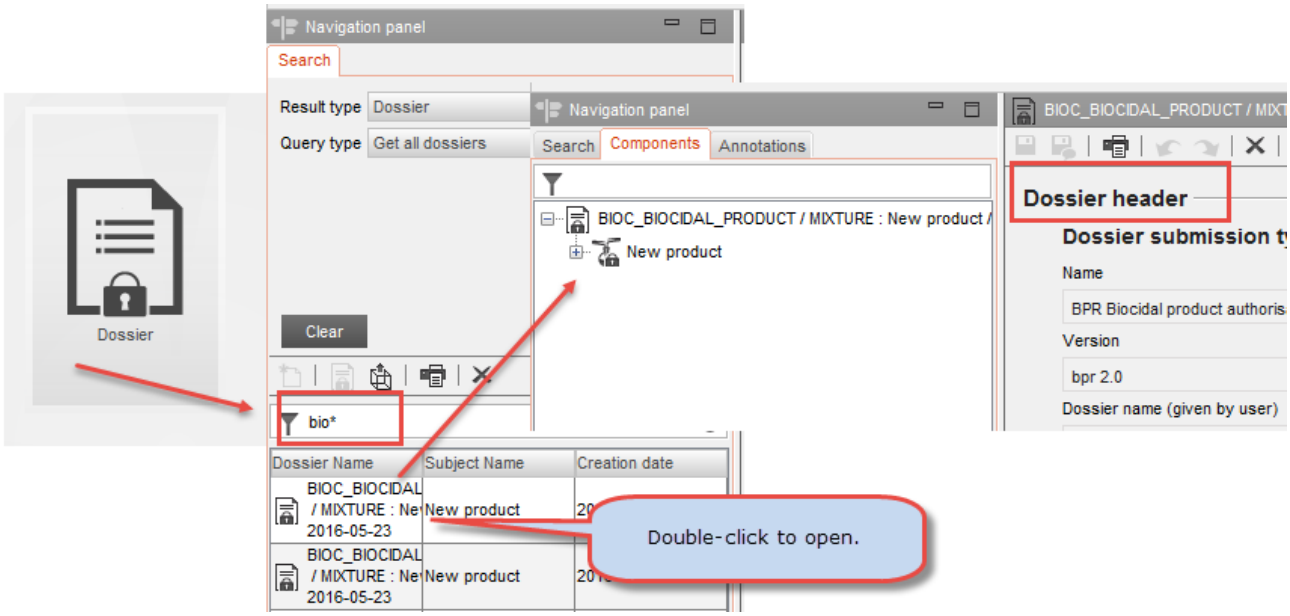


7.2. Viewing a dossier

Searching for a dossier

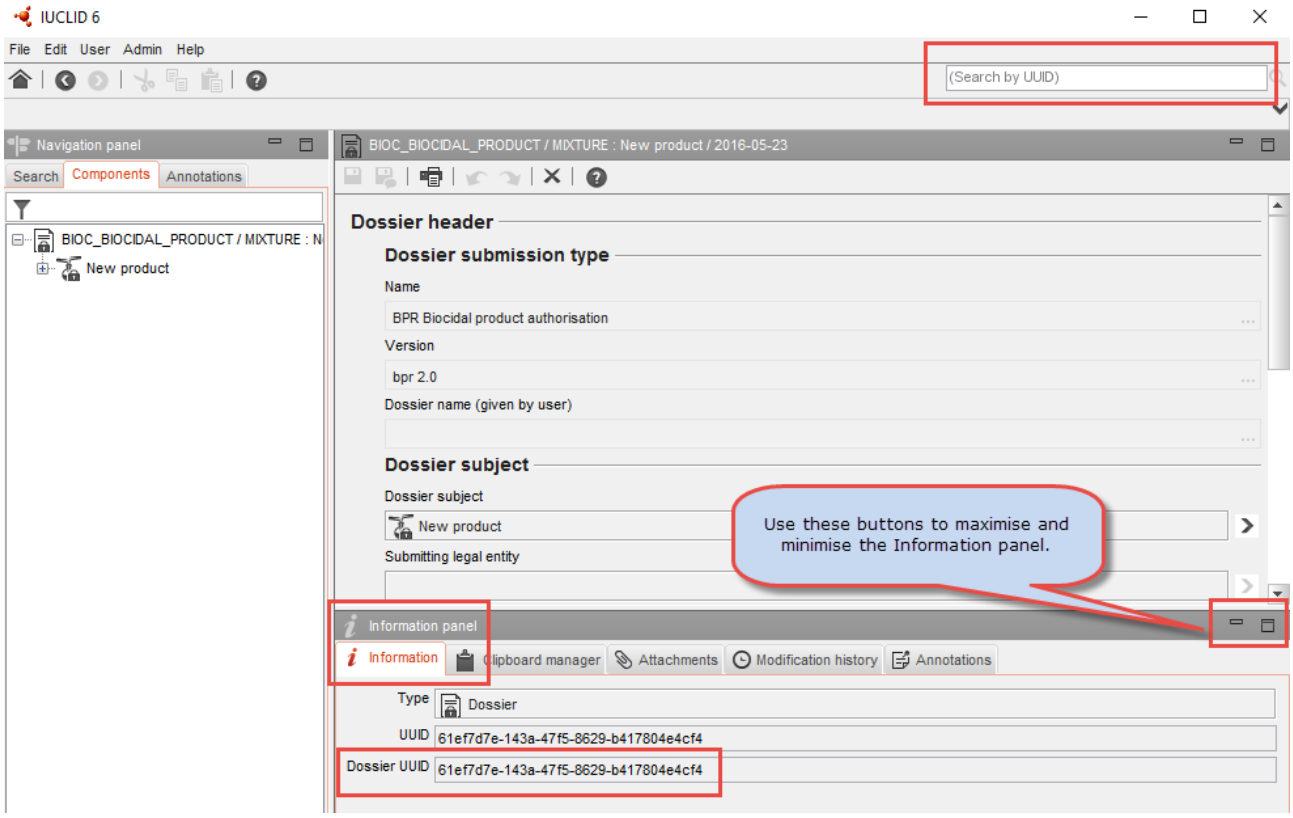
You can view a dossier at any time using the dossier name or the dossier UUID number. To search by dossier name, go to the IUCLID 6 homepage and click on the dossier icon (Figure 48). This will open the 'Navigation panel'. In the field 'Filter', type in the dossier name (to broaden your search, you may use the wildcard *). When you have located the relevant dossier, double-click on the dossier title to open the 'Dossier header' section (Figure 48).

Figure 48: 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 6 screen (Figure 49). The dossier UUID can be obtained from the 'Information' tab in the 'Information panel' at the bottom of any section in the dossier. Figure 49 shows the 'Information panel' in the 'Dossier header' section.

Figure 49: Searching for a dossier with the dossier UUID

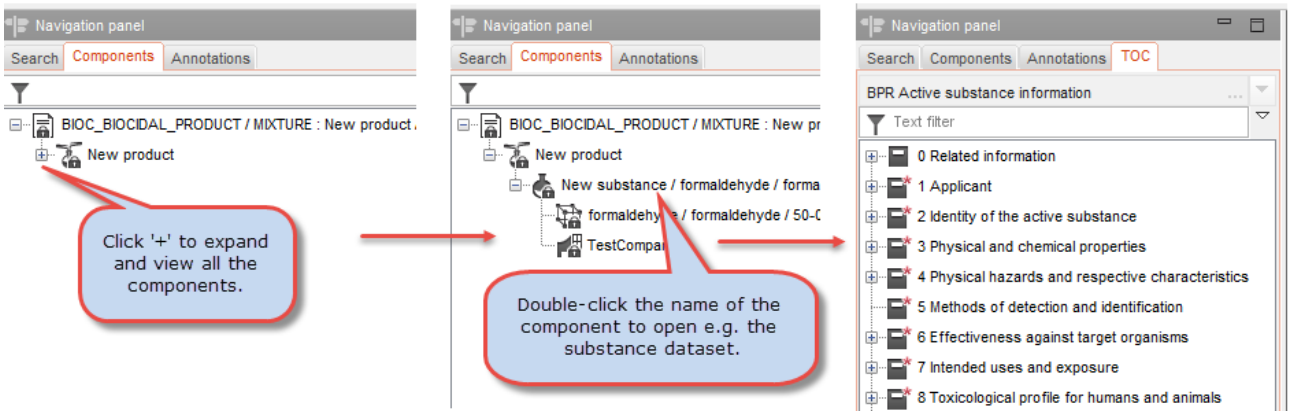


Viewing the full dossier content

You can view the dossier components under the 'Components' tab in the 'Navigation panel' (e.g. the datasets, legal entity). Click the '+' sign to expand the section tree and view all the components (Figure 50).

You can view the dataset content within the dossier by double-clicking on either the substance component ( ) or the mixture/product component ( ). The 'TOC' tab will appear in the 'Navigation panel'; TOC allows you to open all the sections contained in the dataset (Figure 50).

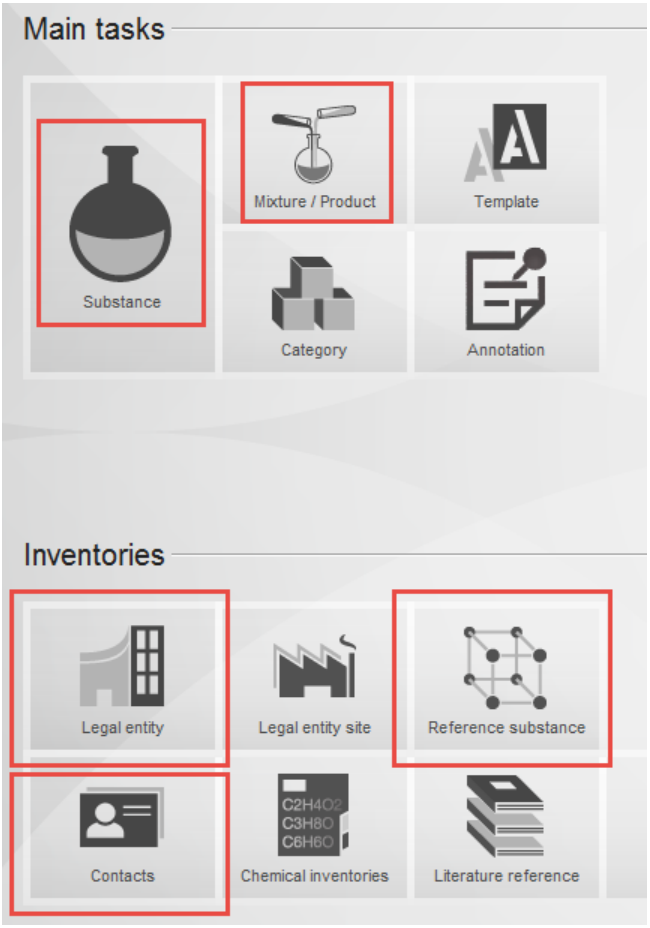
Figure 50: Viewing the 'TOC'



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.

Remember that a dossier is a non-editable snapshot of the datasets. If you find mistakes in the dossier, update the relevant component by clicking the appropriate icon (Figure 51). Then, create a new dossier as outlined in chapter 7.1.

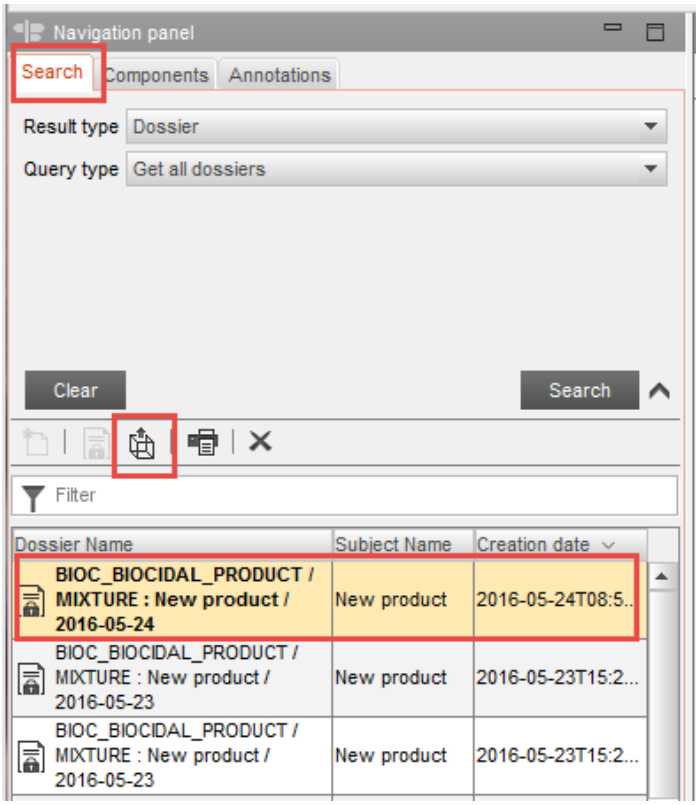
Figure 51: Updating data



7.3. Dossier export

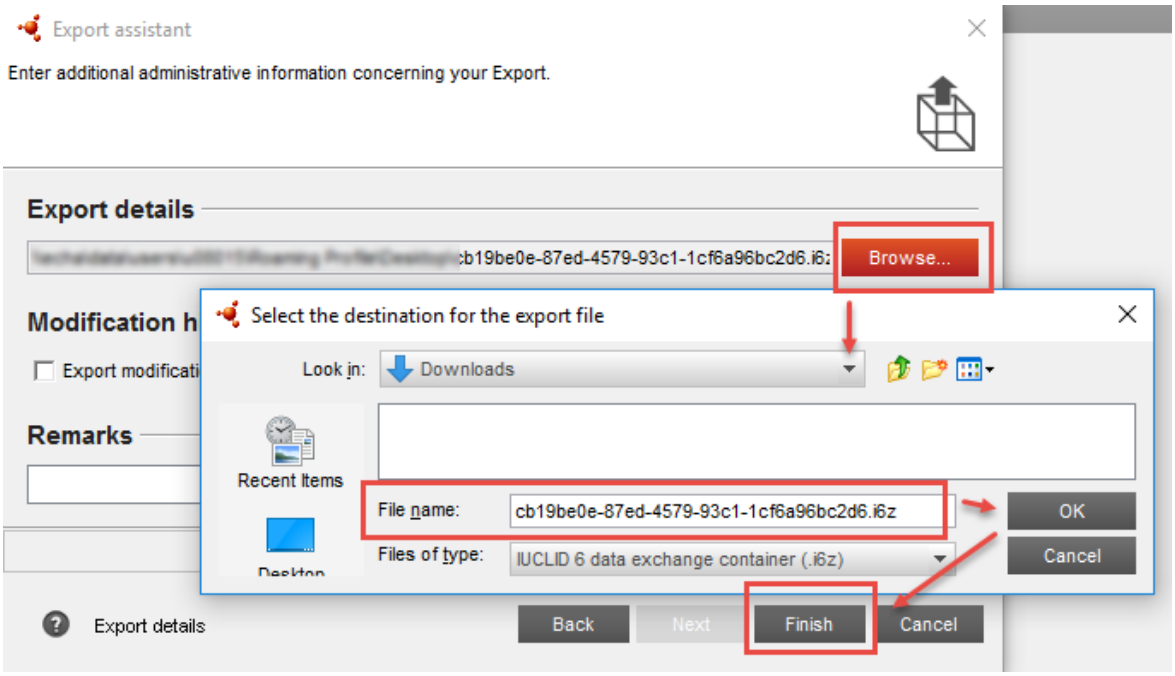
When you are satisfied with a dossier, export the final dossier from IUCLID 6 and save it on your local IT environment. Exporting the dossier file (.i6z) allows you to upload it in an R4BP 3 application wizard as part of an application. To start the export, select the dossier in the 'Search' tab of the 'Navigation panel'. Then click on the 'Export' icon ( ) (Figure 52). This will launch the Export assistant (Figure 53).

Figure 52: Exporting the dossier



Follow the steps in the Export assistant to select the appropriate option for annotation export and click 'Next'. Then click the 'Browse' 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', and click 'Finish' (Figure 53). The dossier can now be located in an .i6z file format in the location specified in the Export assistant.

Figure 53: Saving the dossier



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 1. 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

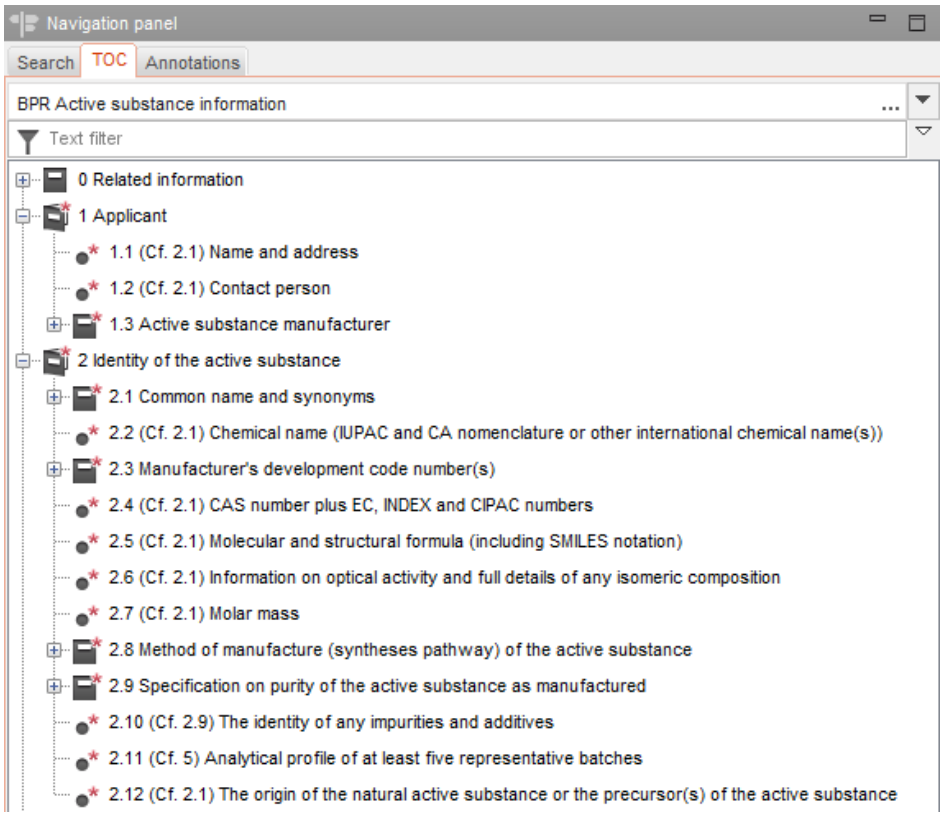
Step 1. CREATE AN ACTIVE SUBSTANCE DATASET

A new substance dataset should be created for the active substance (using the main 'substance' dataset template 'BPR Active substance information'). 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 with a red asterix.

Where there is a letter of access: IUCLID sections 1 and 2 of the active 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).

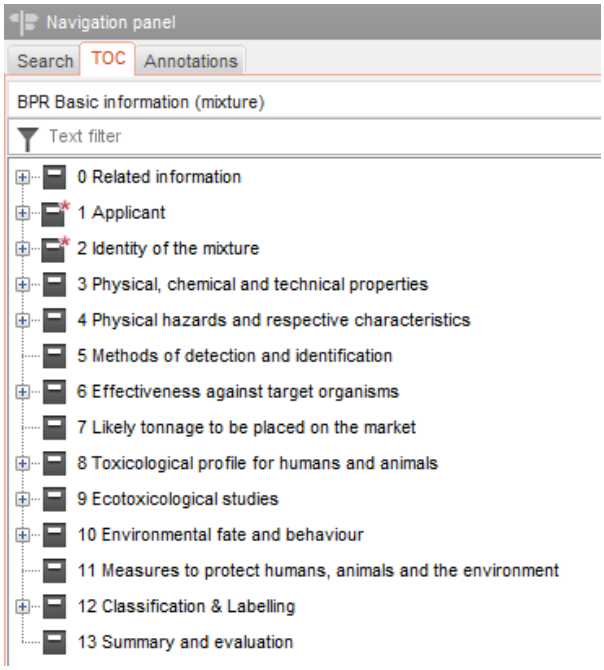
Figure: Sections 1 and 2 of the active substance dataset template 'BPR Active substance information'



Step 2. CREATE A MIXTURE DATASET

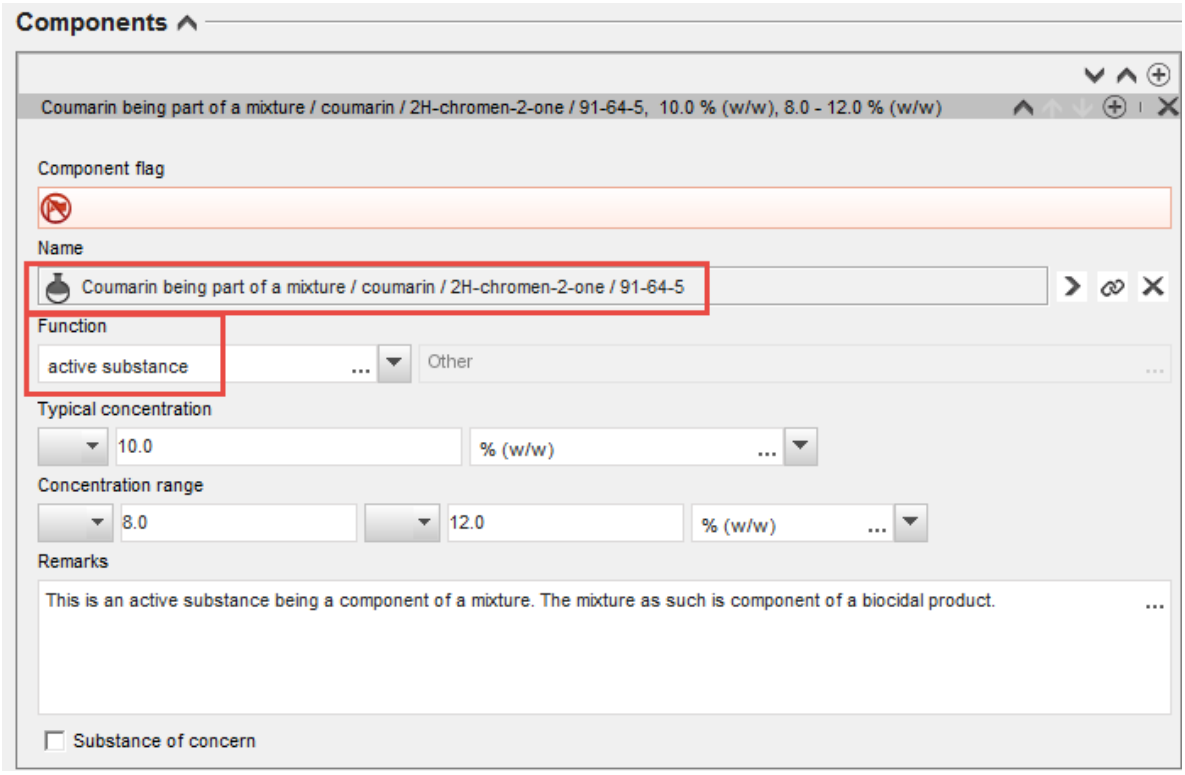
A new mixture/product dataset should be created for the mixture using the dataset template 'BPR Basic information (mixture)' (Refer to chapter 2.1.2 'Supplementary dataset templates' for more details). All mandatory sections, marked with a red asterix, shall be filled in (See figure below).

Figure: BPR Basic information (mixture) view



In IUCLID section 2.3 'Mixture composition', the full composition of the mixture shall be indicated. The active substance dataset 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

A new mixture/product dataset should be created for the biocidal product using the dataset template 'BPR Biocidal product authorisation' or 'BPR Active substance application (representative product)'. Additional instructions can be found in chapter 4 'Preparing a dataset for a biocidal product; IUCLID section 2.3 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).

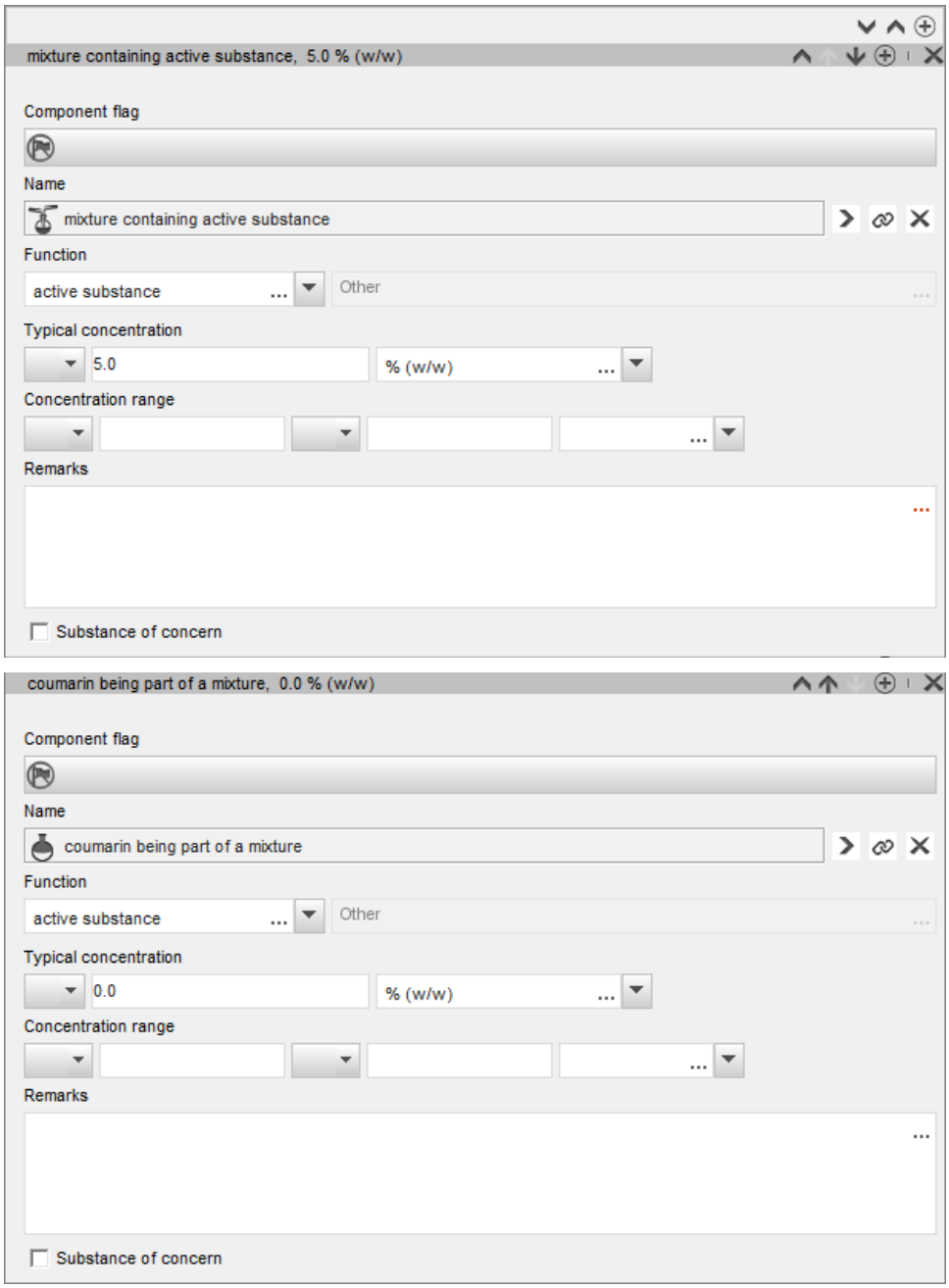
The first composition block should have:

- 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 1)

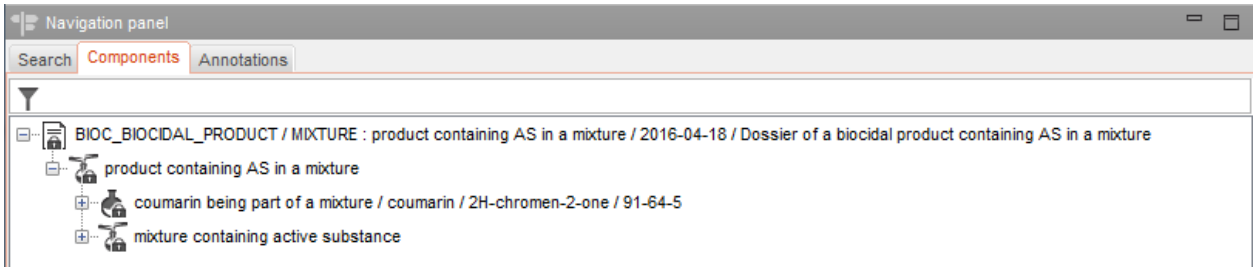
Figure: Two records in section 2.3 Biocidal product composition, related to a mixture that contains an active substance



Information displayed in a biocidal product authorisation dossier

Based on the biocidal product dataset (created in step 3), the biocidal product authorisation dossier (or the dossier for the representative biocidal product) 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,

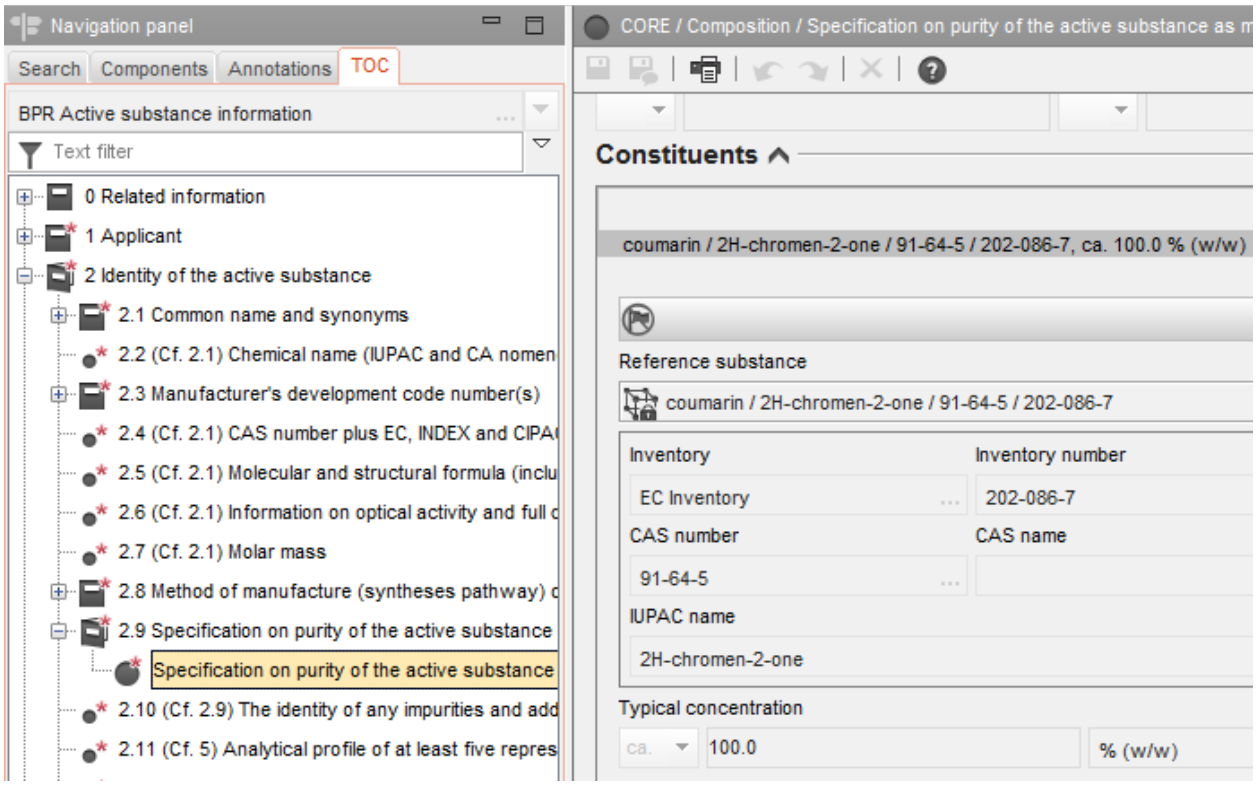
iii. biocidal product containing this mixture.

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 information' (See figure below).

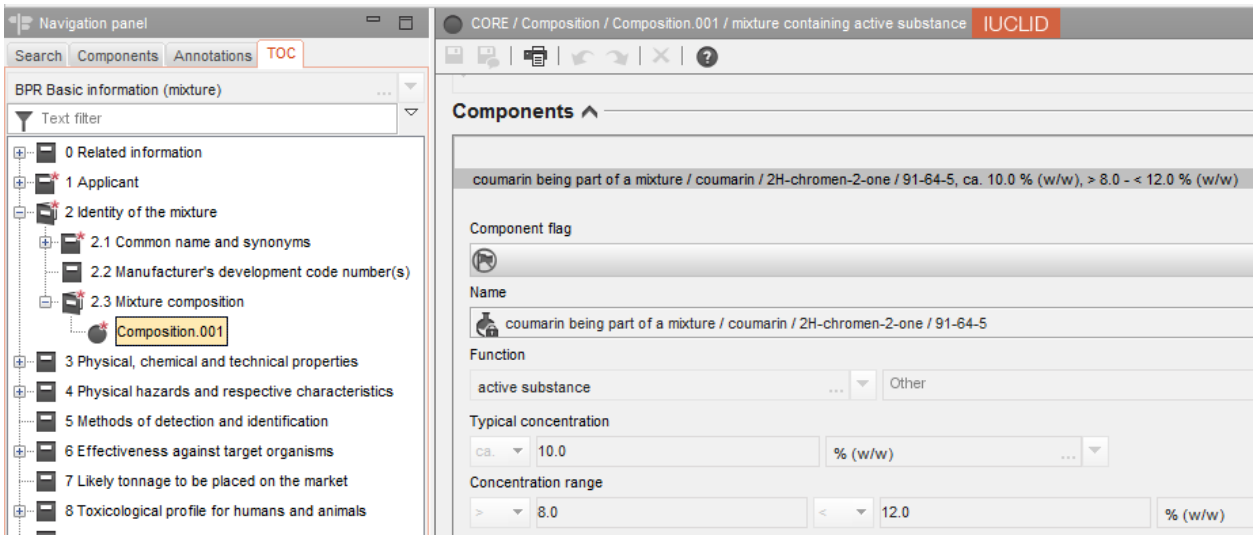
Figure: Active substance inside of a mixture – dossier view



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).

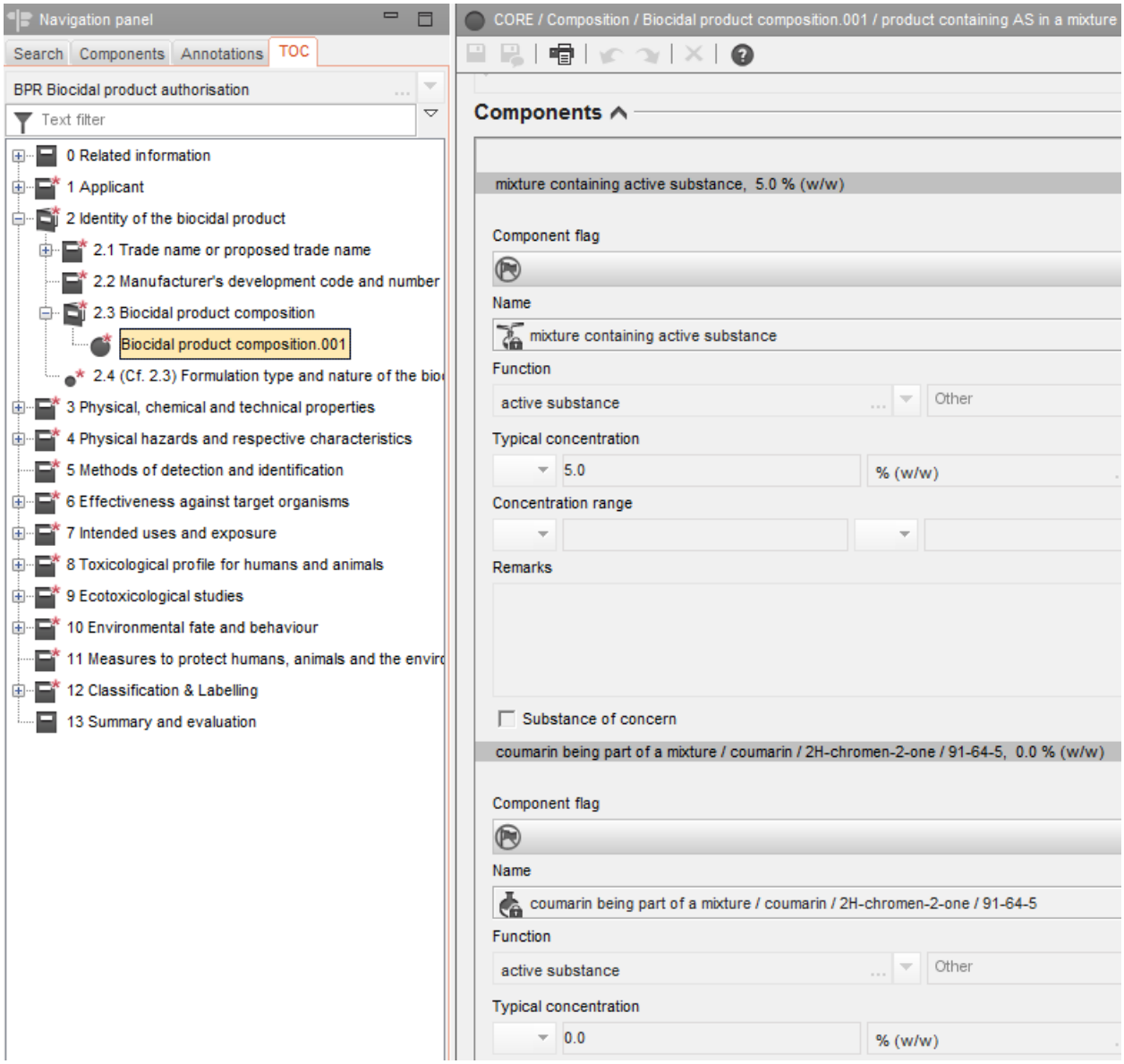
Figure: Mixture in a biocidal product – dossier view



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' or 'BPR Active substance application (representative product)' (See figure below).

Figure: Biocidal product component – dossier view



Annex 2. 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 representative 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 information'). 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 information, 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 2.9 of the active substance dataset under 'Description of composition'. If needed, additional details for the method can be included as an attachment under 'Attached description'.

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:

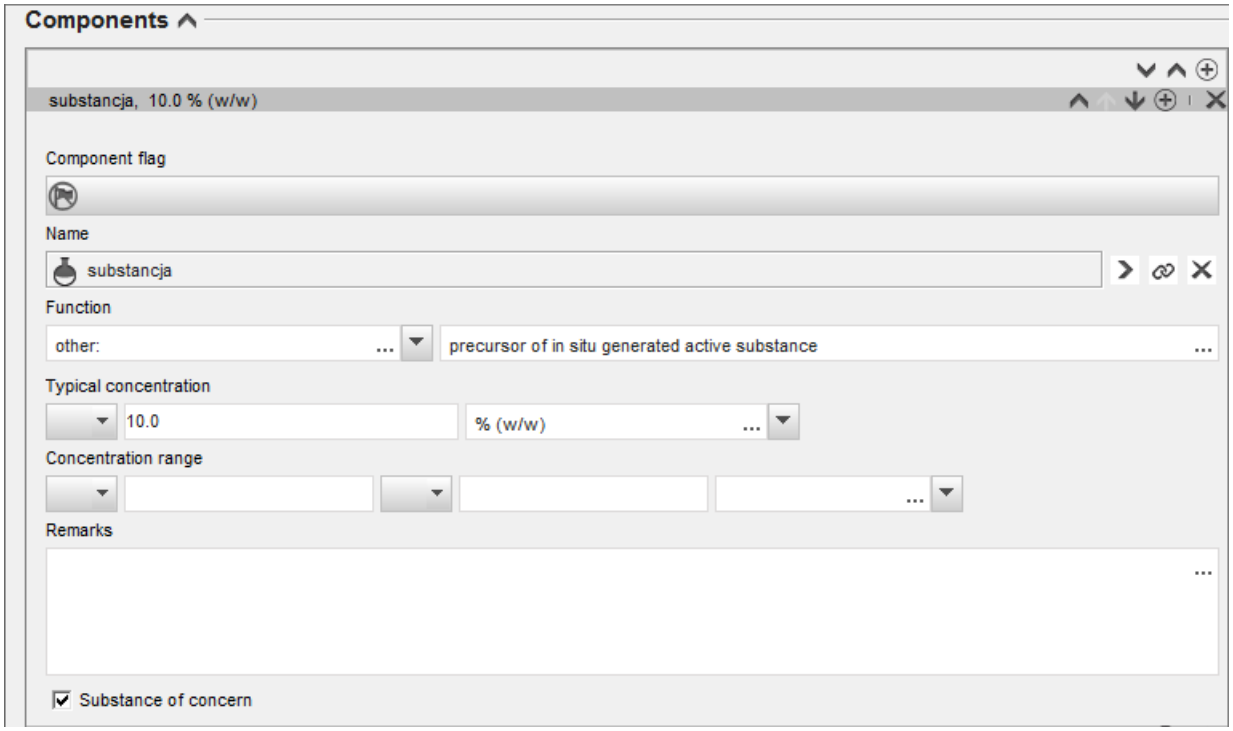
Entries identifying precursor(s) of in situ generated active substance should have the following data provided:

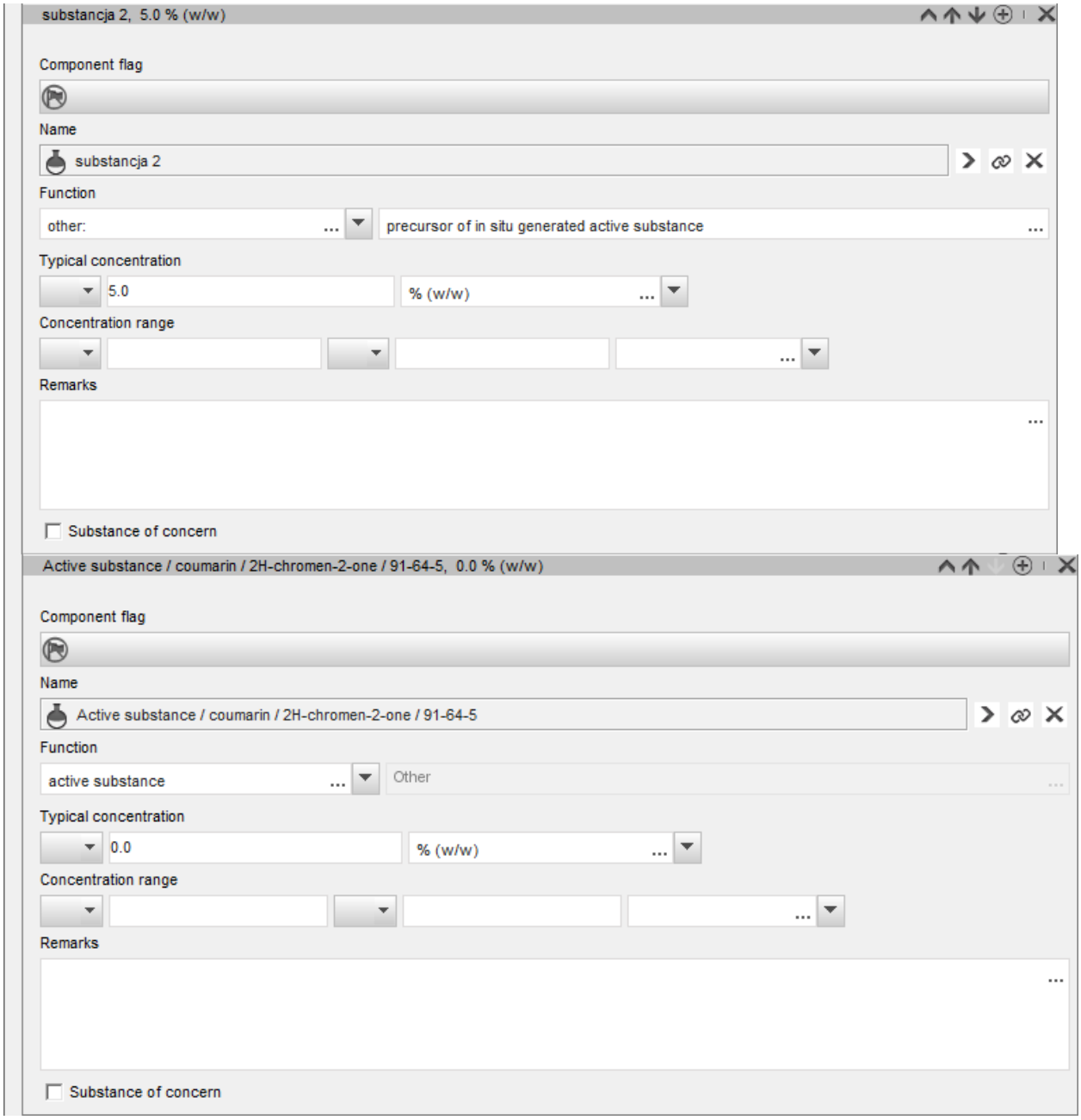
- Linked substance dataset (created in step 2 above)
- Function 'other: precursor'
- Concentration of the substance in the biocidal product

Entry identifying the in situ generated active substance should have:

- Function 'active substance'
- Concentration 0
- 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





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.

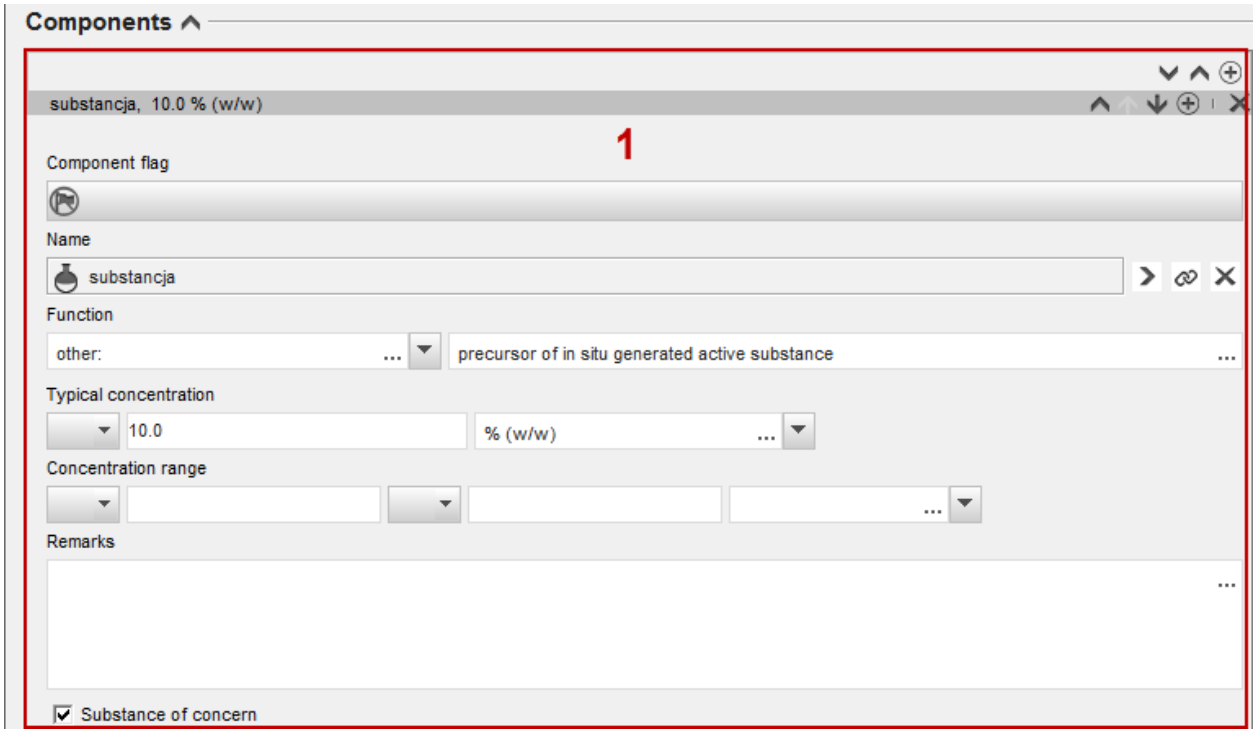
1 - concentration of the first precursor in the biocidal product; this precursor is a substance;

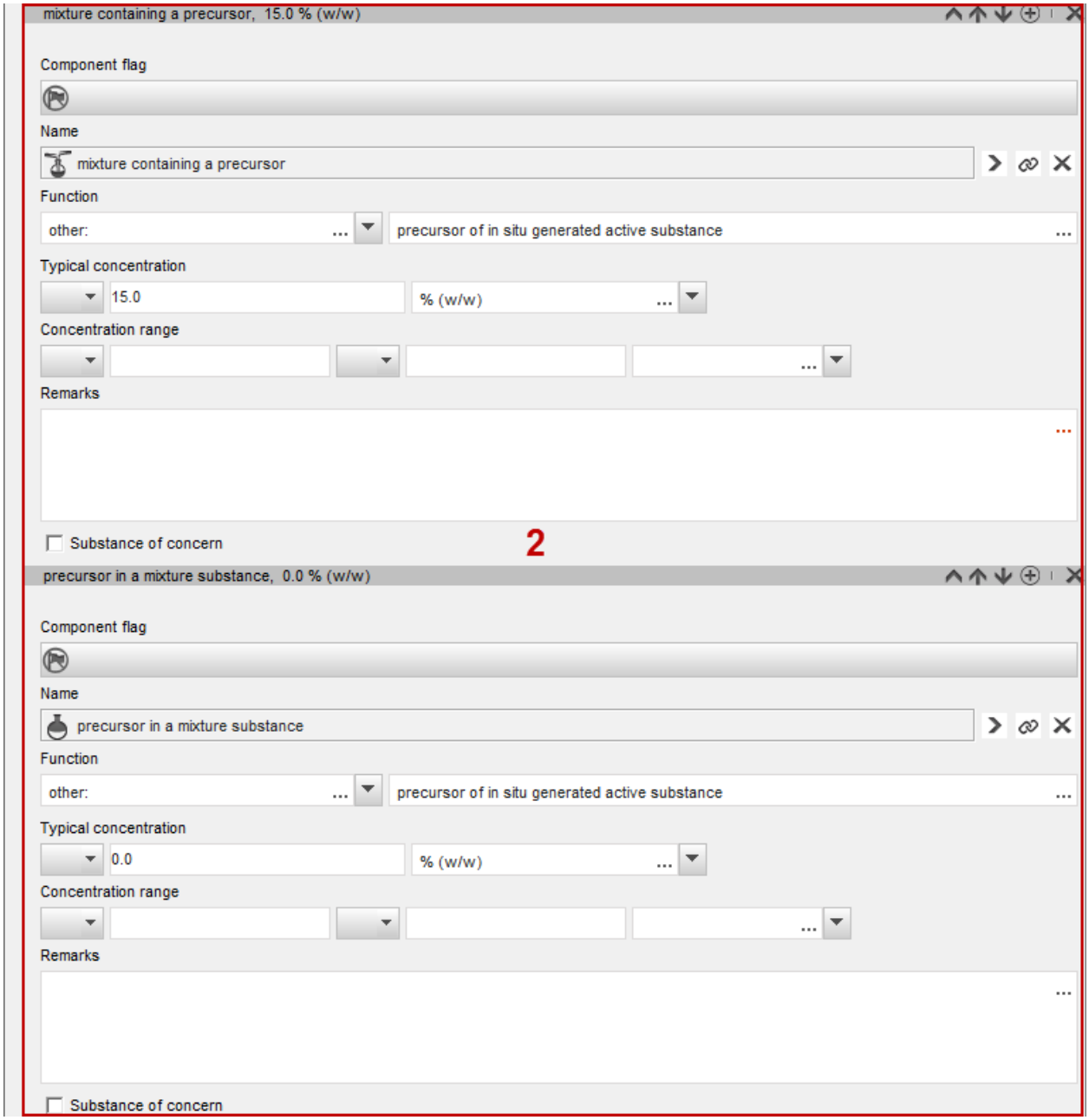
2 - first block: concentration of the mixture containing the second precursor; second block: link to the substance being the second precursor;

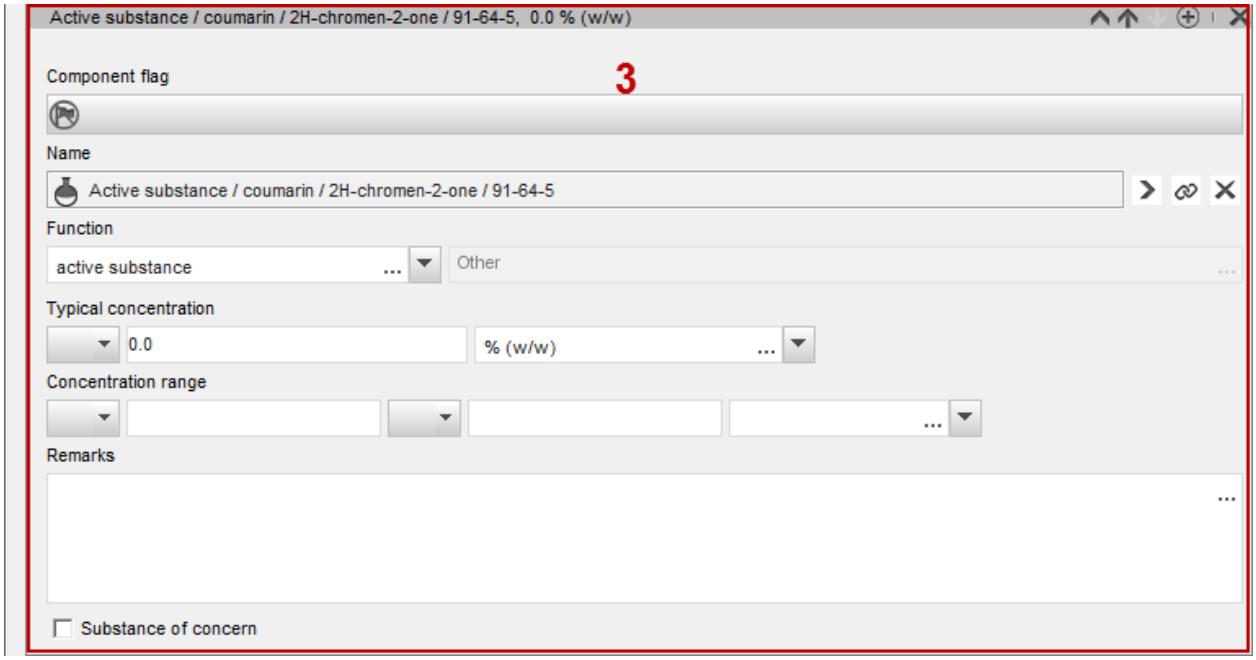
3 - link to the active substance generated in situ based on the first precursor (substance) and the second precursor (substance in a mixture).

.

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



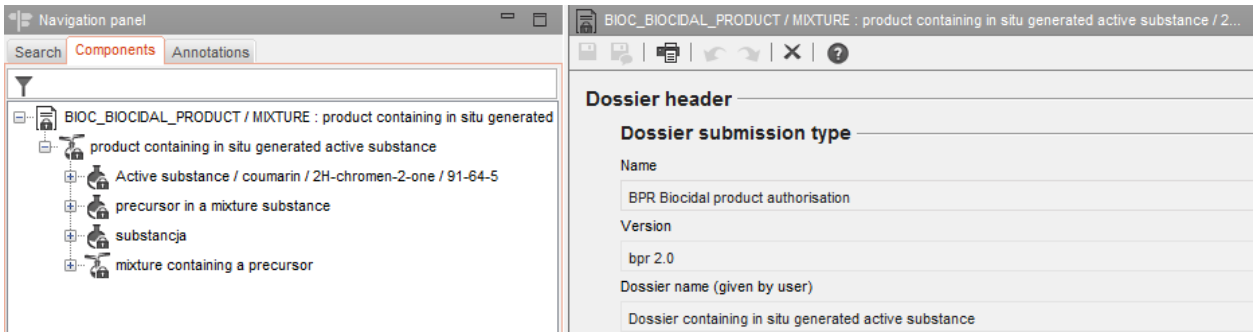

mixture containing a precursor, 15.0 % (w/w)
Component flag
Name
mixture containing a precursor
Function
other:
precursor of in situ generated active substance
Typical concentration
15.0
% (w/w)
Concentration range
Remarks
Substance of concern
2
precursor in a mixture substance, 0.0 % (w/w)
Component flag
Name
precursor in a mixture substance
Function
other:
precursor of in situ generated active substance
Typical concentration
0.0
% (w/w)
Concentration range
Remarks
Substance of concern



Information displayed in a BPR Biocidal product authorisation dossier and in a BPR Active substance application (representative product) dossier

Based on the biocidal product dataset (created in step 3), the 'BPR Active substance application (representative product)' dossier or 'BPR 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 dossier.

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



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