

IUCLID 5

Guidance and Support

Biocidal Products Regulation

*Creation of dossiers
with IUCLID 5.5*

Quick IUCLID guide



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Contents

1	Introduction.....	1-4
2	IUCLID legislation filters for BPR.....	2-4
3	Datasets management.....	3-5
3.1	How to create a substance dataset	3-5
3.2	How to create a BIOCIDAL product dataset.....	3-7
3.2.1	Product composition (section 2.3).....	3-9
3.2.2	Intended uses and exposure (section 7).....	3-10
3.2.3	Directions for use (section7.6).....	3-11
3.2.4	Packaging (section12.4)	3-12
4	Dossier creation.....	4-13
4.1	Biocidal Product authorisation dossier.....	4-13
4.2	Active substance application dossier.....	4-14
5	Dossier export.....	5-14

1 Introduction

The aim of this document is to briefly describe the dossier creation process, in IUCLID 5.5, for the Biocidal Products Regulation (BPR).

The dossiers that can be generated with IUCLID for the purpose of complying with the Biocidal Products Regulation are the following:

- BPR Biocidal product authorisation
- BPR Active substance application

2 IUCLID legislation filters for BPR

In IUCLID 5.5, a distinction is made between the legislations defined for biocides and the dossier types. The legislations are used to filter the information in a dataset in order to be later on included in a dossier. The dossier types are used to package all the information to be sent to Regulatory Authorities.

The following legislations are defined for the BPR:

- BPR Biocidal product authorisation: used to filter the mixture/product dataset for the preparation of BPR dossiers
- BPR Active substance application: used to filter the substance dataset for the preparation of the BPR dossiers. The active substances are identified in section 2 of the mixture/product: they are all the product constituents flagged with the function 'Active substance'.

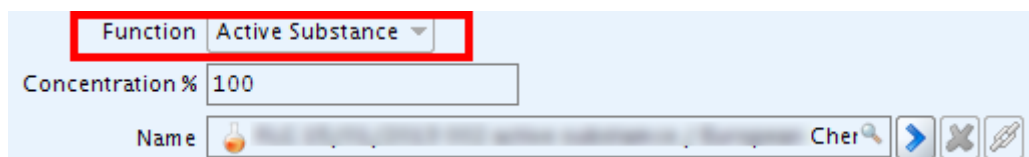


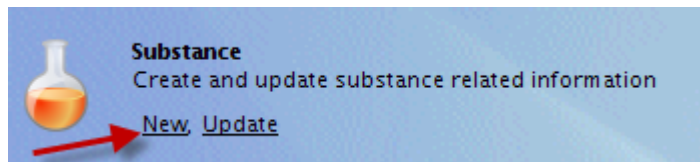
Figure 1: active substance identified in a product dataset, in the composition section

- BPR Basic information: used to filter the substance and mixture/product dataset for the preparation of the BPR dossiers. The 'basic information' filter is applied to all other substances and mixtures identified in section 2 of the mixture/product (i.e. not identified as 'active substance' or 'substance of concern').

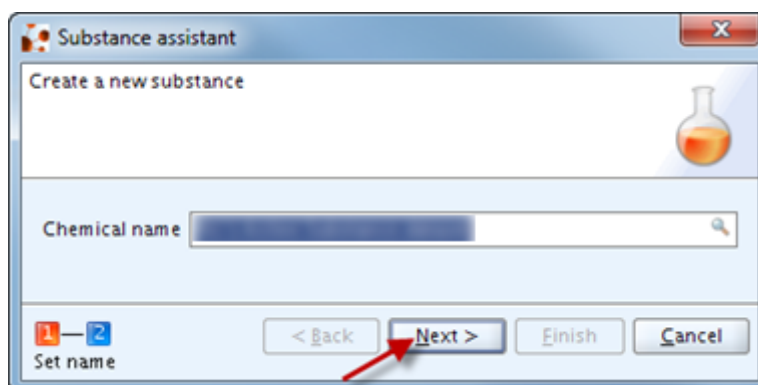
3 Datasets management

3.1 How to create a substance dataset

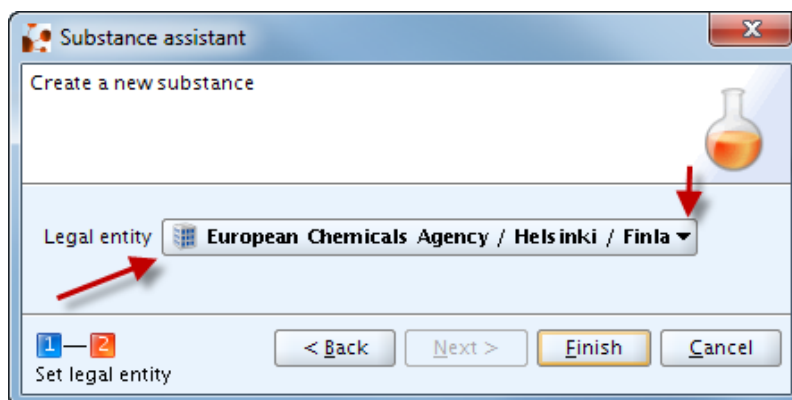
1. Click *new* to create a new substance dataset.



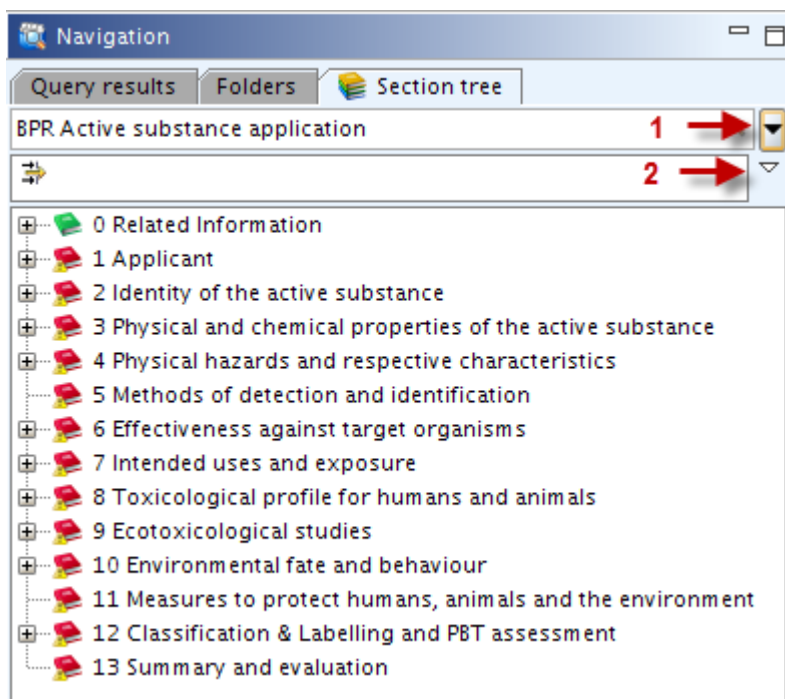
2. Enter the substance name.



3. Assign a legal entity to that substance (you may need to select from more than one).



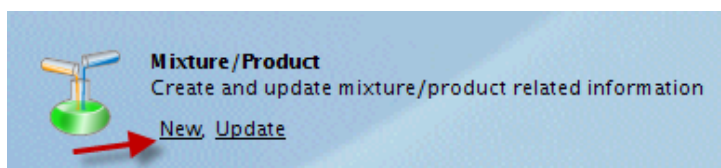
- Click Finish and you will be taken to the navigation window.



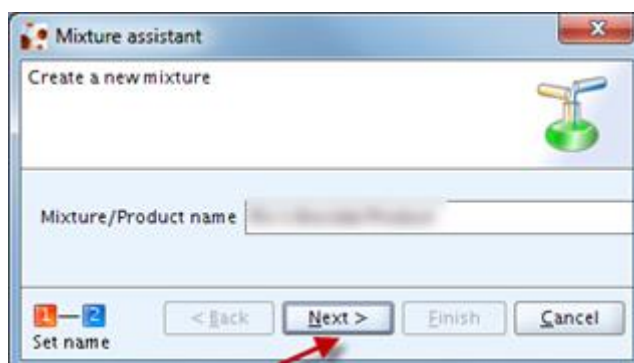
- On the Navigation window, make sure that you have selected 'BPR Active substance application' (use drop down list - **1**). You can also use the drop down list marked with **2** to expand all the sections.
- Fill-in the information available for the active substance in as many sections as needed.

3.2 How to create a BIOCIDAL product dataset

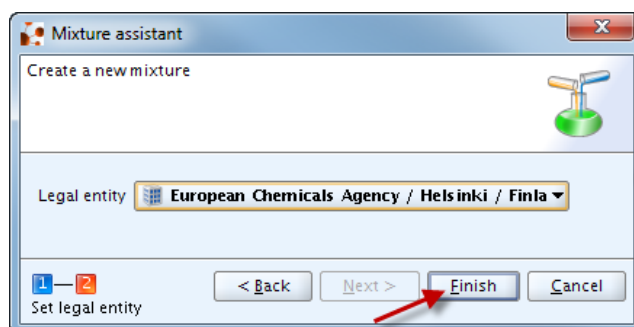
1. Click *new* to create a new mixture/product dataset.



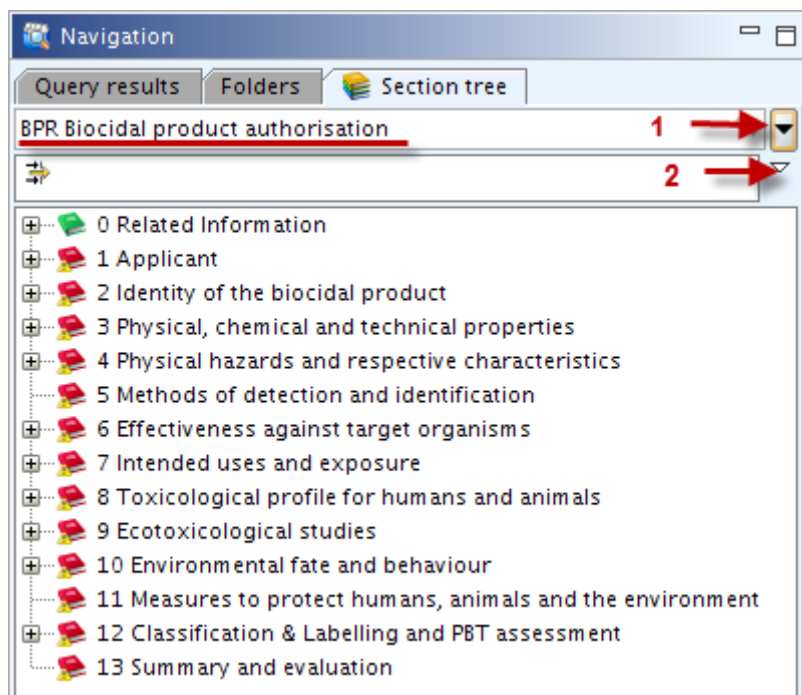
2. Enter the mixture/product name.



3. Assign a legal entity to that product (you may need to select from more than one).



- Click Finish and you'll be taken to the navigation window.



- On the Navigation window, make sure that you have selected 'BPR Biocidal product authorisation' (use drop down list - **1**). You can also use the drop down list marked with **2** to expand all the sections.
- Fill-in the information available for the Biocidal product in as many sections as needed. Refer to the next section for more information on a selection of specific templates available for Biocidal Products.

Note that from now on, the IUCLID sections indicated in this document are the one indicated in the BPR views (and not the IUCLID standard sections names and numbers).

3.2.1 Product composition (section 2.3)

1. Right-click on the product composition section to create a composition
 - You can define a biocidal product family (select 'endpoint summary'). You will then have to define individual product compositions.
 - You can define one product composition (select 'endpoint study record').

The screenshot shows the 'Administrative Data' section with a search bar. Below it is the 'Biocide Product' section, which includes a search bar for 'Biocidal product name', a dropdown for 'Formulation type', and a 'Composition' table. The table is currently empty, with a search bar and a green plus sign icon for adding a new component.

2. Enter the biocidal product name
3. Select the formulation type for the biocidal product or formulation type(s) for the biocidal product family
4. Add a component by clicking the green plus sign. For each component:
 - a. Specify the function (you need at least one active substance)
 - b. Indicate the concentration (or the concentration range for the product family)
 - c. Link the component to a substance or a mixture dataset that you previously created (see section 3.1)
 - d. Indicate if the substance is a 'substance of concern'

The screenshot shows the 'Administrative Data' section with a search bar. Below it is the 'Biocide Product' section, which includes a search bar for 'Biocidal product name' containing 'product name', a dropdown for 'Formulation type' set to 'EP Emulsifiable powder', and a 'Composition' table. The table has one component added with 'Function' set to 'Active Substance', 'Concentration %' set to '23', and 'Name' set to '/ 1,1,1,3,3-t'. A checkbox for 'Substance of concern' is present and unchecked.

3.2.2 Intended uses and exposure (section 7)

1. Right-click on section 7.1 and add a new record

Administrative Data

Intended uses and exposure

For a biocidal product family, specify to which biocidal product(s) it applies:

Product type

Use(s) pattern

Use Number	Use Name	Local UUID ...	Field of use	User	Estimated O...	Estimated D...	Estimated I...	Estimated T...	External Ex...	External Ex...
Add...	Edit...	Delete	Move up	Move down						

Detailed description of uses including in treated articles

Remarks

2. (optional: Link the record to a specific biocidal product in case you have defined a biocidal product family)
3. Select a product type
4. Define the use patterns in the table
5. Add a detailed use description
6. Add Remarks

You can then create additional records to report more uses.

3.2.3 Directions for use (section 7.6)

1. Right-click on section 7.6 and add a new record

Administrative Data

Directions for use

Reference use

Method of application

Detailed description of method of application

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

Dilution (%)	Application dose	Final concentration of active ...	Final concentration of biocid...	Remarks
<input type="button" value="Add..."/>	<input type="button" value="Edit..."/>	<input type="button" value="Delete"/>	<input type="button" value="Move up"/>	<input type="button" value="Move down"/>

Application aim

Number and timing of applications

Proposed instruction for use

2. Link the record to a previously defined use record ('Reference use'), from section 7.1
3. Select a method of application
4. Add a detailed description of method of application
5. Enter application doses in the table
6. Select an application aim
7. Enter the number and timing of applications
8. Enter the proposed instruction for use

3.2.4 Packaging (section 12.4)

1. Right-click on section 12.4 and add a new record

Administrative Data

Packaging
 For a biocidal product family, specify to which biocidal product(s) it applies:

Form of packaging in contact with the product (container type)

Size of packaging in contact with the product (container size)

Material of packaging in contact with the product (container material)

Compatibility of the product with the packaging materials proposed to be in contact with product

Further description of the packaging in contact with the product

Safety features of the packaging

Description of the secondary packaging (not in contact with the product)

Packaging related attachments

Type of attachment	Attached document	Remarks
Add...	Edit...	Delete
	Move up	Move down

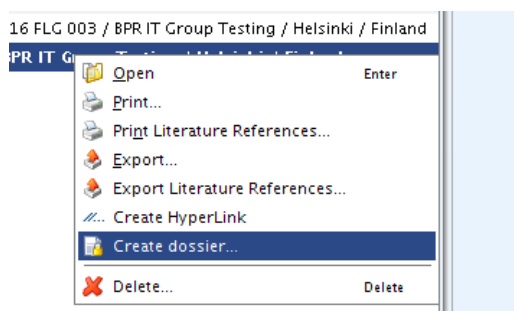
2. Link the record to a biocidal product in case you have defined a biocidal product family
3. Indicate the following information:
 - a. Form of packaging
 - b. Size of packaging
 - c. Material of packaging
 - d. Compatibility of the product with packaging materials
 - e. Further packaging description
 - f. Safety features
 - g. Secondary packaging
 - h. Add attachments (e.g. label pictures)

4 Dossier creation

Dossiers for Biocidal product and for Active substance under the BPR should be created from the mixture/product dataset. This is obvious for the Biocidal product but even for the active substance this should be the case. Indeed even for an active substance dossier the dossier should contain information on a generic biocidal product. Hence, the decision was made to create the active substance dossiers from the generic biocidal product defined.

4.1 Biocidal Product authorisation dossier

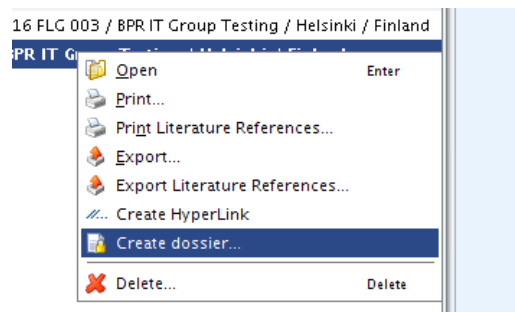
1. Creation of a biocidal product dataset (see section 3.2)
2. Identification of the constituents in the composition section (see section 3.2.1)
3. Creation of the dossier from the biocidal product
 - a. Right click on the product dataset, select 'Create dossier'



- b. Select the template 'BPR Biocidal product authorisation'
- c. Continue the dossier creation wizard until the end by selecting all information
- d. Click finish
- e. Select view dossier

4.2 Active substance application dossier

1. Creation of the active substance dataset (see section 3.1)
2. Creation of a biocidal product dataset (see section 3.2)
3. Identification of the constituents of the generic biocidal product used for active substance application in the composition section of the product dataset (see section 3.2.1)
4. Creation of the dossier from the generic biocidal product
 - a. Right click on the biocidal product dataset, select 'Create dossier'



5. Select the template 'BPR Active substance application'
6. Continue the wizard until the end by selecting all information. Finish. View dossier.

5 Dossier export

Once the dossier has been created and that it is selected, go to 'File | Export' in order to export your dossier as an i5z file and store it on your computer. The dossier is then ready to be submitted.

European Chemicals Agency

IUCLID 5 Support

BPR dossier creation / IUCLID Quick Guide

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