

# Biocides Submission Manual

## How to prepare a biocides dossier

February 2024

ABC

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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.
4.2	Update of Annex II. Information on how to create datasets for precursor(s) of an in situ active substance accordingly to the Data requirements for active substances generated in situ and precursors of in situ generated active substances with regard to identity, physical, chemical and physical hazard, prepared by the Working Group Analytical methods and Physico-Chemical Properties (APCP) to the Biocidal Products Committee on 29/30 May 2017. Possibility to

	report the exact compositions before and after the reaction.
4.3	Update to reflect transition from IUCLID 6.2 to IUCLID 6.3.
4.4	Update to reflect transition from IUCLID 6.3 to IUCLID 6.4, and from the classic user interface to the web user interface.
4.5	Update to reflect transition from IUCLID 6.4 to IUCLID 6.5. Update to reflect new working context and dossier type implemented for assessment of technical equivalence applications.
4.6	Update of Annex II. Improvement of text.
4.7	Update of Annex 4.
4.8	Update of screenshots reflecting improvements in the system. Annex 2; Update of terminology: "technical active substance generated in situ" is changed to "active substance generated in-situ" and "active substance" changed to "pure active substance".
4.9	Updates reflecting implementation of SPC to IUCLID, new chapter added: 4.2 Preparing a mixture/product dataset for BPR summary of product characteristics (SPC).

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## 1. Introduction

### Objective

This manual gives guidance on how to create a IUCLID<sup>1</sup> dossiers concerning biocidal active substances<sup>2</sup> (AS), biocidal products<sup>3</sup> (BP) and also how to create Summary Product Characteristics (if you need to prepare only SPC, please go directly to chapter: 4.2 Preparing a mixture/product dataset for 'BPR Summary of product characteristics (SPC)') for applications made under the Biocidal Products Regulation<sup>4</sup> (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:

**How to use 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.

#### Application instructions:

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

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

#### Process manuals:

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

**Process of 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

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<sup>1</sup> International Uniform Chemical Information Database

<sup>2</sup> An AS may refer to a substance, a substance in a mixture, or a microorganism

<sup>3</sup> 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

<sup>4</sup> 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>)

instructions and related processes can be found from the [ECHA website](#).

## 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 microorganisms; 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<sup>5</sup>. 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: [Home IUCLID - ECHA \(europa.eu\)](#). For more details about the installation and use of IUCLID 6 go to the website's [Support](#) tab.

Information about IUCLID Cloud services can be found on the following website: [ECHA Cloud Services - ECHA \(europa.eu\)](#)

### 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:

a 'Substance' dataset (  ), and

a 'Mixture/Product' dataset (  )

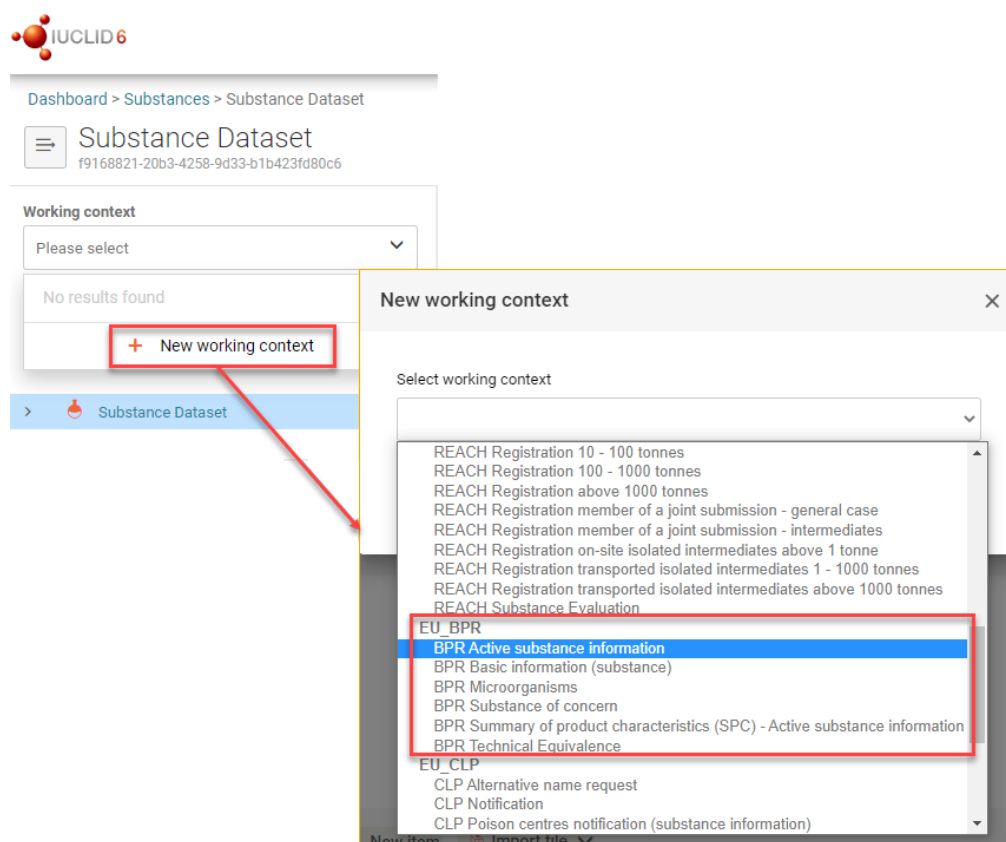
---

<sup>5</sup> Meaning ECHA, member state competent Authorities, or the Commission.

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 should define the working context of the dataset. By default, the working context of a substance or mixture dataset is not selected. Selecting arrow in the 'Working context' field to open a drop-down list (Figure 1). Note that this list contains numerous dataset templates accommodating various chemical regulations e.g. BPR, REACH<sup>6</sup>, CLP<sup>7</sup> etc. Customising the dataset working context will ensure that only the sections that are relevant to your dataset are shown.

Figure 1: Selecting the working context of the dataset



### 2.1.1. Main datasets

To create a valid dossier for the active substance or biocidal product, in general two main datasets must be completed (with the exception to Technical Equivalence) (Figure 2):

<sup>6</sup> 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.

<sup>7</sup> 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.

**Substance dataset:** a 'BPR Active substance information' working context - containing information concerning the active substance which is a chemical substance

or 'BPR Microorganisms' – containing information concerning the AS which is a microorganism

or 'BPR Technical Equivalence' working context - containing information concerning the AS which is a chemical substance and other relevant information. The dossier creation must be initiated from the substance dataset directly in that working context.

**Mixture-Product dataset:** a 'BPR Biocidal product authorisation' working context - containing information concerning the BP to be authorised

or 'BPR Summary of product characteristics (SPC) working context – used for SPC creation concerning Biocidal Product to be authorised

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

The dossier creation should be initiated from the Mixture/Product dataset (with the exception to Technical Equivalence), see [chapter 7. How to create a dossier](#).

Dossiers for the active substance approval or biocidal product authorisation must be created from a **Mixture/Product dataset**.

In cases where there is no relevant biocidal product, e.g. Article 95 dossiers, you must use the dataset for the representative product.

Dossier for assessment of technical equivalence must be created from **Substance** dataset directly.

### 2.1.2. Supplementary datasets

The supplementary dataset 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 working contexts are (Figure 2):

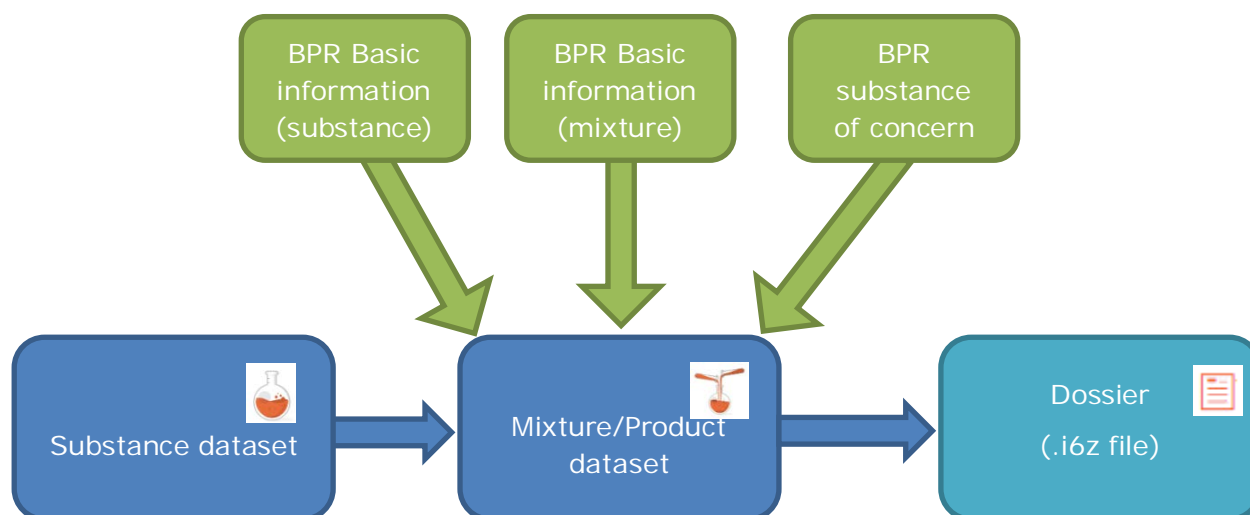
'BPR Basic information (substance)' dataset – containing information about each additional substance component which is not substance of concern according to Article 3(1)(f) of the BPR.

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

'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 relevant datasets to the '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 1](#) and [Annex 2](#) to this manual. For details on how to include several representative products in an active substance application, please refer to [Annex 3](#).

## 2.2. Dossier submission types

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

- a 'BPR Active substance application (representative product)' dossier;
- a 'BPR Biocidal product authorisation' dossier;
- a 'BPR Technical Equivalence' dossier;
- a 'BPR Summary of product characteristics (SPC)' dossier.

Dossiers for the active substance application or biocidal product authorisation or SPC must be created from a **Mixture/Product dataset** and must contain at least one active substance (which might be a microorganism).

A Dossier for assessment of technical equivalence application must be created from the **Substance** dataset with the specific working context – BPR Technical equivalence.

Chapter 3 and 4 of this manual explain how to create a specific datasets before proceeding to dossier creation.



Chapter 7 of this manual explains how to create a specific dossier type. 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](#).

### 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 entity for storing information on the identity of specific substances. 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 substance identifiers (substance name, EC number, CAS number or IUPAC name) and 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. 'Reference substance' can also contain information on a microorganism.

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 main substance dataset.

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 3) 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 dashboard (Figure 3).

Reference substance can be also created along the process of creating your datasets, either creating a dataset for an active substance or mixture/product dataset for biocidal product or mixture/product dataset for summary of product characteristics (SPC). How to can be found in relevant chapters.

Figure 3: Accessing the 'Reference substance' information

The screenshot displays the IUCLID 6 dashboard. On the left, a sidebar menu is visible with a 'Reference substance' option highlighted in red. The main area shows a search for 'eth' with 2 results found. The results are:

Substance Name	CAS number	IUPAC name	Inventory number	Date
Ethane-1,2-diol	107-21-1	ethane-1,2-diol	203-473-3	22/07/2019 13:55
ethyl acetate	141-78-6	ethyl acetate	205-500-4	14/03/2019 12:19

## 2.4. General functions in IUCLID 6

For general IUCLID 6 functionality instructions, please refer to the ['User manual of IUCLID 6'](#).

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

When you open a dataset, select a specific working context, e.g. 'BPR Active substance information', in top left corner of your dataset view. Table of content is displayed on the left side of the screen and editable structure of the dataset is displayed on the right (Figure 4). Table of content is specific to a working context, number of sections may vary.

Figure 4: Navigation window and editable structure.

The screenshot displays the IUCLID 6 web interface for a biocides dossier. The top navigation bar includes the IUCLID 6 logo, a user profile icon, and a 'View Dossiers' button. The main header shows the breadcrumb 'Dashboard > Substances > Substance Dataset' and the title 'Substance Dataset for biocides dossier' with a search bar containing 'Type at least 3 characters'. The left sidebar, titled 'Working context', lists the dossier structure with expandable sections: 1 Applicant\*, 2 Identity of the active substance\*, 3 Physical and chemical properties\*, 4 Physical hazards and respective characteristics\*, 5 Methods of detection and identification\*, 6 Effectiveness against target organisms\*, 7 Intended uses and exposure\*, 8 Toxicological profile for humans and animals\*, 9 Ecotoxicological studies\*, 10 Environmental fate and behaviour\*, 11 Measures to protect humans, animals and the environment\*, 12 Classification & Labelling\*, and 13 Summary and evaluation\*. The main content area is titled 'Location of manufacturing site.001' and shows a search for 'Example site | Tampere | France'. Below this, there are sections for 'Manufacture / own use(s)' and 'Related mixture/product', each with a 'Specify to which mixture/product(s) it applies:' field. A 'Save' button is located at the bottom right.

The sub-sections written in *italic* **are not editable** and **serve only as a guide**. They correspond to the BPR section and refer you in brackets 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. Substance datasets

Information requirements will vary depending on the application type you are submitting, therefore different working contexts of the datasets define specific set of data. Changing selected working context of the Substance dataset to another one will show either less or more data.

#### 3.1. Preparing a dataset for an active substance

This chapter outlines how to prepare a working context 'BPR Active substance information' dataset, containing information about an active substance which is a chemical substance, or 'BPR Microorganisms' dataset, containing information about an active substance which is a microorganism'.

All these datasets can be created in a similar manner but may contain different sections. Supplementary datasets contain information about additional components of a biocidal product (e.g. solvent, emulsifier, etc.).

For full details on how to report a mixture containing an active substance, please refer to Annex 1. How to include a mixture containing an active substance in a biocidal product dossier or

For details on how to include active substances generated in situ, please refer to Annex 2. How to report, in IUCLID, active substance(s) generated in situ.

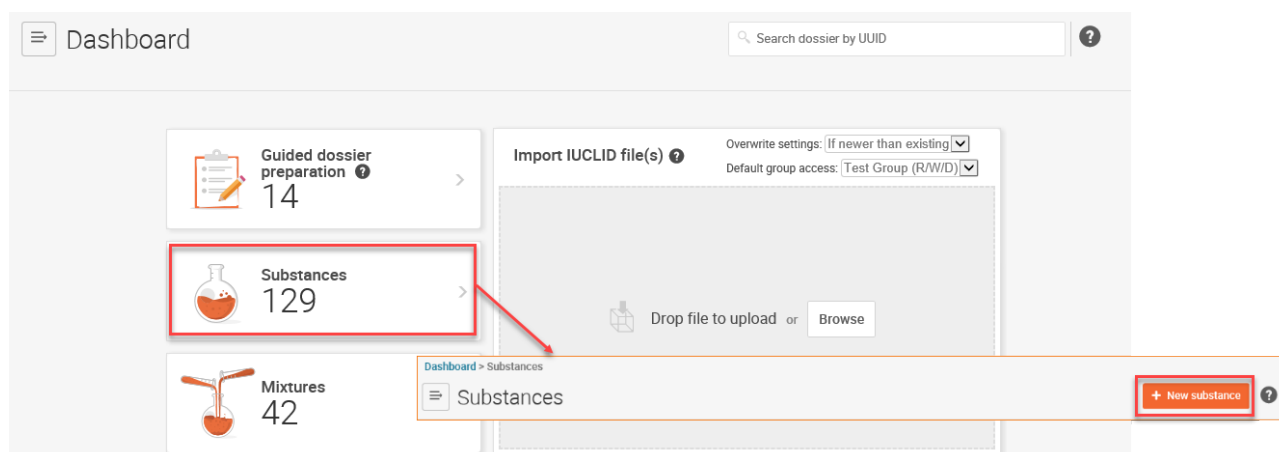
For details on how to include several representative products in an active substance application, please refer to Annex 3. How to include several representative products in an active substance application in IUCLID.

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.

#### I. Create a 'Substance' dataset

In the IUCLID 6 dashboard, create a 'Substance' dataset by clicking on the Substance and then clicking '+ New Substance' (Figure 5).

Figure 5: Creating a 'Substance' dataset



Enter a name for your dataset in the field 'Name', and click the 'Create'. Confirmation message will appear 'Substance has been created successfully'. Click 'Open' to access the new dataset should you wish to start working on your dataset immediately. The new dataset will also appear in the list of datasets in the list of 'Substances' (Figure 6).

Once you have created the dataset you can start filling in the information within it.


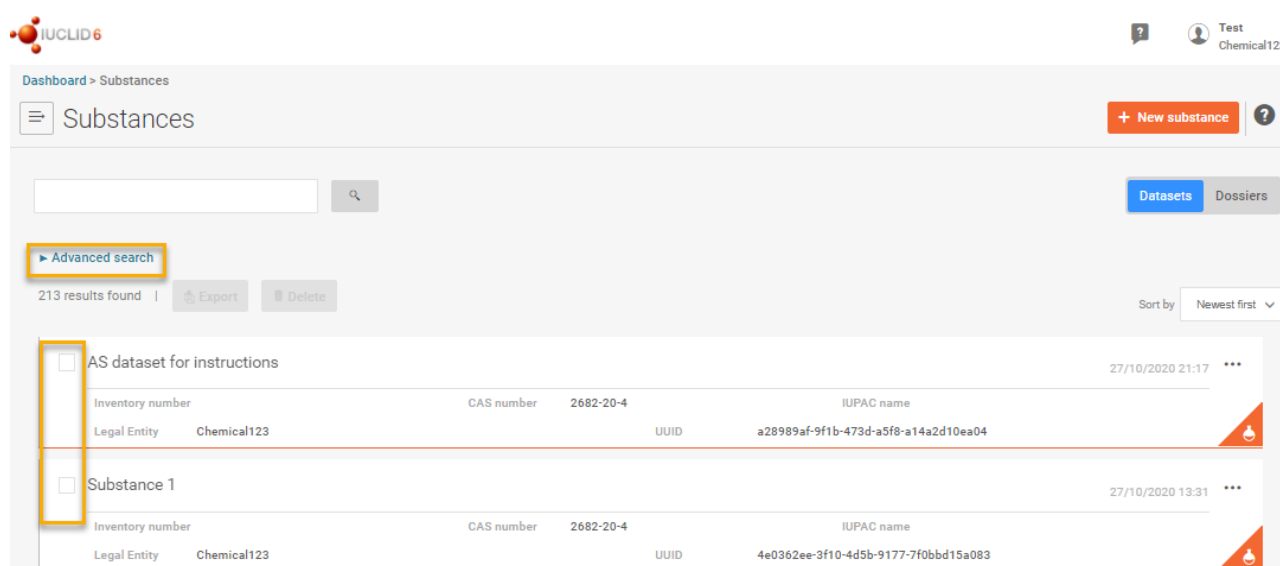
If you have already created a 'Substance' dataset and you wish to update information in this dataset, click the Substance (  ) icon on the IUCLID 6 dashboard (Figure 5). A list of datasets will open under 'Substances'. Search for the correct dataset, click on the substance name to view all of the sections.

Figure 6: 'Substance' dataset(s)



## II. Select the dataset working context

Click the arrow in the 'Working context' field to open the drop-down menu and select the 'main' dataset template ([chapter 2.1](#)), i.e. 'BPR active substance information' or 'BPR Microorganisms' (Figure 1) and 'Apply'.

If you are creating a 'Substance' dataset for additional components of a biocidal product (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.

## III. 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 necessary 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 clicking '+' (Figure 7) to create a new one.

Figure 7: Substance manufacturer

The screenshot displays the IUCLID interface for creating a new substance manufacturer. The left sidebar shows the '1.3 Active substance manufacturer\*' section with a red '+' icon. The main area shows the 'Manufacturer / Importer / Formulator' section with a red box around the '+ Select' button in the 'Name' field. A 'Select Legal entity' dialog box is open, showing a search for 'tes' with 2 results found. The dialog box has a red box around the '+ Create' button. The search results are as follows:

Legal entity name	Legal entity town	Legal entity country	UUID	Date
Test Organization IUCLID				24/03/2022 04:31
		Austria	ECHA-42edf953-4d43- ea11-8116-005056b931	
TestCorporation				16/09/2020 16:14
	Helsinki	Finland	IUC5-a620a92d-32c6- 426a-b6ee-fc338cde093	

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 Mixture product dataset for summary of product characteristics (Chapter 4.1).

Click '+ Select' on the field 'Name' and either search and select from the list of legal entities entered to your database or create new one by clicking 'Create'.

In the 'Create Legal entity' window, enter the Legal entity name, and the applicable details of the manufacturer's Legal entity under the sections 'General information', 'Identifiers' and 'Contact information' (Figure 8: Create new legal entityFigure 8).

Figure 8: Create new legal entity

Create new Legal Entity

General information

Legal entity name\*

Legal entity name field is mandatory.

Legal entity type

Remarks

Other names + New item Import file

#	Flags	Name	Actions
Address	<input type="radio"/> None <input type="radio"/> None		
Address 1			
Address 2			
Postal code			
Town			
Region / State			
Country			
Phone			
Fax			
Email			
Web site			

Identifiers

Legal entity identifiers + New item Import file

#	Flags	Identifier Type	ID	Actions
---	-------	-----------------	----	---------

Regulatory programme identifiers + New item Import file

#	Flags	Regulatory pro...	ID	Remarks	Actions
---	-------	-------------------	----	---------	---------

Other IT system identifiers + New item Import file

#	Flags	IT system	ID	Remarks	Actions
---	-------	-----------	----	---------	---------

Contact information

Contact persons + New item Import file

Save

Under the 'Contact information' section you can assign a contact person for the manufacturer's legal entity. Click the button '+ New item' next to Contact Person, to open the 'Person' section. Click on '+ Select' in the 'Person' field. Select Contact page is opened. Search for relevant contact

person and click on the name, this will add the contact person to the contact information section of the manufacturer (Figure 9).

Figure 9: Assign a contact person for legal entity

The screenshot displays the 'Contact information' form. At the top, there is a 'Contact persons' section with a '+ New item' button. Below it, a dropdown menu is open, showing a 'Person' entry with a '+ Select' button. A 'Select Contact' dialog is open, showing a search bar with the text 'Type at least 3 characters' and '34 results found'. The search results list includes 'LastName, FirstName; Test Manufacturer Company' with columns for 'First Name' and 'Organisation'. A 'Save' button is located at the bottom right of the form.

It may be the case that the contact person has not yet been entered into your database. In this case, click the button '+ New item' next to Contact Person, to open the 'Person' section. Click on '+ Select' in the 'Person' field.

On Select Contact page click '+ Create' this will trigger the opening of the contact person creation dialogue. Define the contact type, enter the rest of the contact person details, modifications will be automatically updated by clicking the 'Save' button.

### IUCLID section 1.3.1. 'Location of manufacturing site'

You should now add information on location of manufacturing plant(s). Start by creating a 'record' in a section 1.3.1 Location of manufacturing plant(s) by clicking '+ '.

Click '+ Select' on the field 'Site' and either search and select from the list of sites entered to your database or create new one by clicking 'Create'. Enter the site name, and the applicable details of the site under the section 'General information', and 'Contact address'. (Figure 10).



Figure 10: Location of manufacturing site in section 1.3.1

Dashboard > Substances > Active chlorine released from hypoc...

Active chlorine released from hypochlorous acid  
968377f3-569e-435d-b5f2-832e5b43d3be

Working context  
BPR Active substance information

Type at least 3 characters

Active chlorine released from hypochlorous acid

1 Applicant\*

1.1 (Cf. 2.1) Name and address

1.2 (Cf. 2.1) Contact person

1.3 Active substance manufacturer\*

1.3.1 Location of manufacturing site(s)\*

Location of manufacturing site.001

Location of manufacturing site.001  
UUID: a4f95756-3c93-49e2-8de7-c7ff457a17c3

Site

Select Site

+ Create

1 item found

Advanced search

Show results 25

Site 1 of the manufacturer 15/06/2023 15:20

Legal Entity name	UUID
	fd319326-eacb-4459-8c39-020ccb2eed5d

#### IV. Identify the active substance.

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

This section allows the identification of the active substance, by filling in pre-defined fields. The fields indicate the name of the active substance, the Legal entity assigned to the dataset (e.g. the prospective authorisation holder, i.e. asset owner), the role they play in the supply chain, i.e. either manufacturer\* or importer (or both), along with contact details of the applicant. The name of the active substance is defined during creating a 'Substance' dataset) but it can be changed at any point when editing the dataset (Figure 11).

Substance name is one of the identifiers to match the substance with the information in R4BP3, therefore it has to be spelled correctly, it is a case sensitive field.

**Special note for formulators:** In section 2.1 of the active substance dataset, you may leave this section empty if none of the options apply to you.

Figure 11: Section 2.1 'Common name and synonyms'

Dashboard > Substances > New Substance for IUCLID dossier te...

Oxalonitrile  
e1733f31-7929-4285-8ef2-855f94e779ed

UID: e1733f31-7929-4285-8ef2-855f94e779ed

Other substance identifiers | Contact persons | Identification of substance | Type of substance | Role in the supply chain

Substance name\*  
Oxalonitrile  
Public name

Legal entity\*  
ECHA | PO Box 400 | Finland  
Third party

Other substance identifiers + New item Import file

#	Flags	Identifier	Identity	Country	Relation
		Reference substance + Select			

Type of substance  
Type of substance

Origin

Role in the supply chain  
None None

Manufacturer  
 Importer  
 Only representative  
 Downstream user

2.1 Common name and synonyms

Oxalonitrile

ECHA

2.2 (Cf. 2.1) Chemical name (IUPAC and CA nomenclature or other international chemical name(s))

2.3 Manufacturer's development code number(s)

2.4 (Cf. 2.1) CAS number plus EC, INDEX and CIPAC numbers

2.5 (Cf. 2.1) Molecular and structural formula (including SMILES notation)

2.6 (Cf. 2.1) Information on optical activity and full details of any isomeric composition

2.7 (Cf. 2.1) Molar mass

2.8 Method of manufacture (syntheses pathway) of the active substance

2.9 Specification of purity of the active substance as manufactured\*

2.10 (Cf. 2.9) The identity of any impurities and additives

2.11 (Cf. 5) Analytical profile of at least five representative batches

2.12 (Cf. 2.1) The origin of the natural active substance or the precursor(s) of the active substance

2.13 Assessment approach (assessment entities)

3 Physical and chemical properties\*

### 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 '+ Select', 'Select Legal entity' page is opening, select the correct legal entity from the search results, and click on the name to assign it or create new one by clicking '+ Create'.

### Other substance identifiers

Enter all the trade (commercial) names and alternative names by which the substance is known. For each entry, add a new row in the table by clicking on the '+ New Item' 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.

If you are creating a dataset for a microorganism, specify here collection and culture reference number, taxonomic name and strain and whether a microorganism is a wild type, mutant or genetically modified.

## Contact person

Assign contact persons by clicking on '+ New Item'. Click on '+ Select' in the Person field to open list of contacts existing in your database. Search for relevant contact person and click on the name, this will add the person to your substance dataset (Figure 9).

Create new contact person, if needed, on the Select Contact page by clicking '+ Create', this will trigger the opening of the contact person creation dialogue. Define the contact type, enter the rest of the contact person details, modifications will be automatically updated by clicking the 'Save' button. This person may be contacted e.g. to provide assistance or ask about the information submitted.

## Reference substance

The reference substance in the 'Substance' dataset identifies the AS for which this dataset has been created; the active substance may be a chemical substance or a microorganism.

Reference substance name and EC and CAS number in inventory section, are the identifiers to match the substance with the information in R4BP3. These fields have to be filled in, if relevant for the active substance. Please note 'Reference substance name' is case sensitive field.

Most convenient option is to choose the reference substance identifiers from the ECHA list (Figure 12), this would facilitate later on the dossier submission in R4BP 3, correct formatting and set of identifiers would be ensured when using that option.

Establish or change the reference substance by clicking '+ Select' in the 'Reference substance' field to open page of 'Reference Substances' entered to your database or select one from ECHA BPR Active Substance database by selecting relevant radio button at first and then search for relevant reference substance and click on the name, this will add the reference substance to your substance dataset (Figure 12).

Figure 12: Linking a 'Reference substance' to the 'Substance' dataset

The screenshot shows the 'Identification of substance' interface. The 'Reference substance' field is highlighted with a red box and a '+ Select' button. A red arrow points from this button to a search dialog titled 'Select Reference Substance from:'. The dialog has a search input field containing 'Permethrin' and a search icon. Below the search field, there are two radio buttons: 'Local IUCLID database' (unselected) and 'ECHA BPR Active Substances' (selected). A blue information banner states: 'Selecting a reference substance from ECHA list will result to either creating a new one or replacing an existing to local inventory.' Below the banner, there is a 'Show results' button and a dropdown menu set to '25'. The search results are displayed in a table:

Permethrin			
CAS number	52645-53-1	IUPAC name	
BAS number	1342	EC number	258-067-9

It may be that the reference substance has not yet been entered into your database. In this case, click '+ Select' in the Reference substance field and click on '+Create' to open the 'Create reference substance' page. In this page, enter the Reference substance name, and the details of the reference substance (Figure 13).

In order to indicate the EC number of your reference substance, click on the 'Inventory number' field. Enter some search criteria (part of EC Number or name of the substance) and select the relevant one from the list

If you are creating a dataset for a microorganism, then enter the scientific name of the microorganism into the 'IUPAC name' field.

Figure 13: Entering the details of the 'Reference substance'

Create new Reference Substance

Reference substance name\*  
Oxalotrile

IUPAC name

Description

Inventory

Inventory number ? ^ ? ^  
EC / 207-306-5 / oxalotrile / 460-19-5 / C2N2 X  
press Esc to close

No inventory information available - Justification

CAS number  
460-19-5

CAS name

Synonyms

Synonyms + New item Import file

#	Identifier	Identity	Remarks	Actions
---	------------	----------	---------	---------

Molecular and structural information None None

Molecular formula

Molecular weight

SMILES notation

InChI

Structural formula

Remarks

Chemical structure files + New item Import file

#	Structure file	Remarks on structure file	Actions
---	----------------	---------------------------	---------

Related substances

+ New item Import file

#	Identifier	Identity	Remarks	Relation	Actions
---	------------	----------	---------	----------	---------

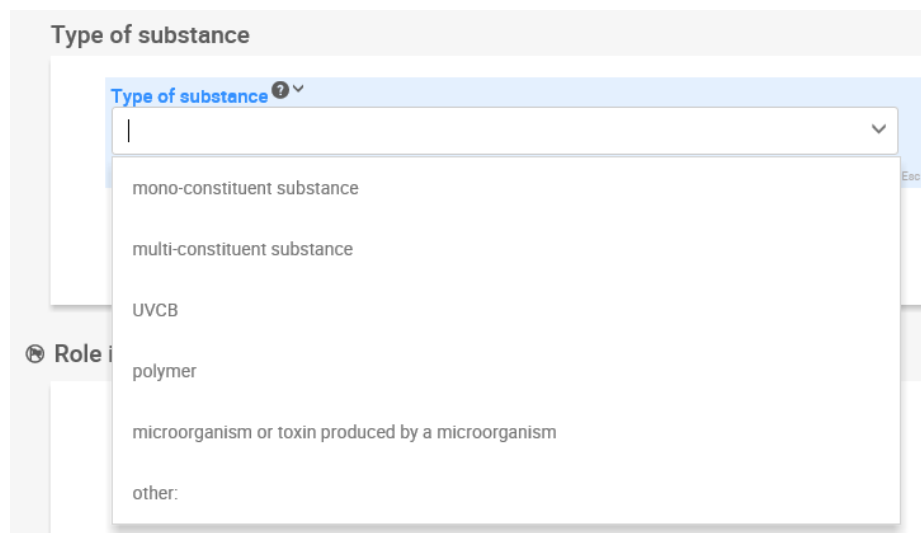
Group / category information

Save

## Type of substance

Select the type of substance (e.g. mono constituent, multi constituent, etc.) of the substance. If you create a dataset for a microorganism, then you have to select 'microorganism or toxin produced by a microorganism' to ensure that the correct table of contents will be used in a dossier (Figure 14).

Figure 14: Type of substance for a microorganism



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

## 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 2.9 'Specification of purity of the active substance as manufactured'

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.

Entry(es) in this section can be either created by using '+' functionality or assigned by using 'Copy data from ...' functionality enabling to search for the data already available in your database.

Create an entry by clicking on '+'. You can create multiple records if needed (Figure 15).

Enter the name, and identify other relevant information of the composition in the fields provided. Add new item(s) under the constituents section assign reference substances to all the constituents of your active substance. If you have any impurities or additives, add new item(s) for each and fill in relevant information, assign reference substances to the impurities.

Once all the relevant data are entered, save the information.

The steps to follow when assigning a reference substance are the same as those outlined in [IUCLID section 2.1, Reference substance](#).

Figure 15: Specification on purity of the active substance as manufactured

The screenshot displays the IUCLID 6 interface for the 'Specification of purity of the active substance as manufactured.001'. The left sidebar shows a tree view with section 2.9 highlighted. The main panel shows the 'Specification of purity of the active substance as manufactured.001' form with tabs for General Information, Degree of purity, Constituents, and Impurities. The 'Description' field is highlighted with a red box.

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' in section 2.9. For a microorganism, details on specification of the technical grade active ingredient and method of production and quality control should be indicated here as well.

If needed, additional details for the method of manufacture can be included as an attachment under 'Attached description / justification'.

## V. 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](#).

## 3.2. Preparing a substance dataset for technical equivalence

This chapter outlines how to prepare a dataset containing information relevant to assessment of technical equivalence.

### I. Create a 'Substance' dataset

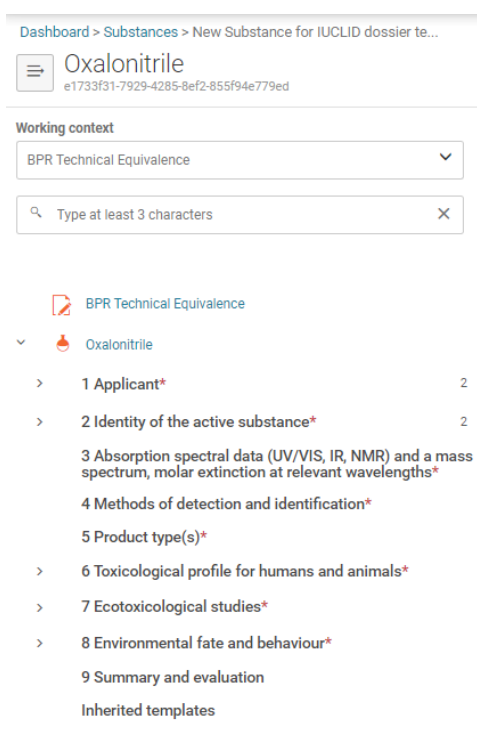
In the IUCLID 6 dashboard, create a 'Substance' dataset by clicking on the Substance clicking '+ New Substance' and then identifying the name of your substance (Figure 5).

### II. Select the dataset working context

Open your newly created dataset and define at first the working context by clicking the drop-down list arrow in the 'Working context' field and select the '**BPR Technical Equivalence**' (Figure 1) and 'Apply'.

Once you have created the dataset with the correct working context you can start filling in the required information by clicking on the relevant section (Figure 16).

Figure 16: 'BPR Technical Equivalence' working context structure



### III. Enter the 'Applicant' details

#### Section 1.3 'Active substance manufacturer' name and manufacturing site location

Entering information in this section follows same steps as in section '3.1 Preparing a dataset for an active substance III Enter the 'Applicant' details'.

Information requirements will vary depending on the application type you are submitting, therefore different working contexts of the datasets define specific set of data. Changing selected working context of the Substance dataset to another one will show either less or more data.

## IV. Identify the active substance

### Section 2.1 - Common name and synonyms

Identify the substance that you wish the assessment of technical equivalence to be carried out by clicking 'Reference substance'<sup>8</sup> field '+Select'.

You may either create new reference substance by clicking '+Create' (Figure 13) or search and select the relevant one already recorded in your database (Figure 12).

Ensure that the substance name, reference substance name and identifiers (EC and CAS numbers) are in line with that of the approved active substance the application refers to. Information on these biocidal active substances and their identifiers can be found at ECHA website: <https://www.echa.europa.eu/web/guest/information-on-chemicals/biocidal-active-substances>.

Furthermore, any synonyms (usual name, trade name, abbreviation), INDEX and CIPAC numbers (if allocated), molecular formula, SMILES notation and molar mass should all be included when available.

Step by step instructions on how to create a reference substance are given in **Section 3. Substance datasets**

**Information requirements will vary depending** on the application type you are submitting, therefore different working contexts of the datasets define specific set of data. Changing selected working context of the Substance dataset to another one will show either less or more data.

Preparing a dataset for an active substance **IV Identify the active substance.**

### Section 2.9 – Specification of purity of the active substance as manufactured

Insert new entry in section 2.9 by clicking '+' (Figure 17).

The entry should include a name and brief description, the degree of purity of the substance, the content of all the main constituents, impurities and additives, **as well as an attachment.**

---

<sup>8</sup> The 'reference substance' is a term used in IUCLID 6 identifying the AS to be assessed and should not be confused with the 'reference source' used in the BPR. The definition of reference source is found in Guidance on applications for technical equivalence, p. 17.



In the General information block enter the name (e.g. Specification of...).

Enter information on the method of manufacture of the active substance into the 'Description' free text field, **and/or** by adding an attachment in the 'Attached description' section.

Figure 17: Entering information on the manufacturing process in section 2.9

The screenshot shows the 'Oxalonitrile' dossier page. The left sidebar lists various sections, with '2.9 Specification of purity of the active substance as manufactured\*' selected. The main content area is titled 'Specification of purity of the active substance as manufactured.001' and includes a 'General Information' tab. The 'Description' field is highlighted with a red box. Below it, the 'Attached description / justification' table shows one attachment named 'Attachment1.docx'.

Then indicate the degree of purity of the substance, with units. This can be either as the minimum degree of purity ( $>$ ,  $\geq$ ) or as a concentration range ( $>$ ,  $\geq$ ;  $<$ ,  $\leq$ ) (

Figure 18).

The degree of purity would normally be given as a minimum for mono-constituent substances and as a range for multi-constituent substances. For UVCB substances the degree of purity is 100% by definition.

Figure 18: Indicate the degree of purity

The screenshot shows the 'Degree of purity' input field. The field is set to '>= 98' with a unit of '% (w/w)'. The 'None' options are also visible.

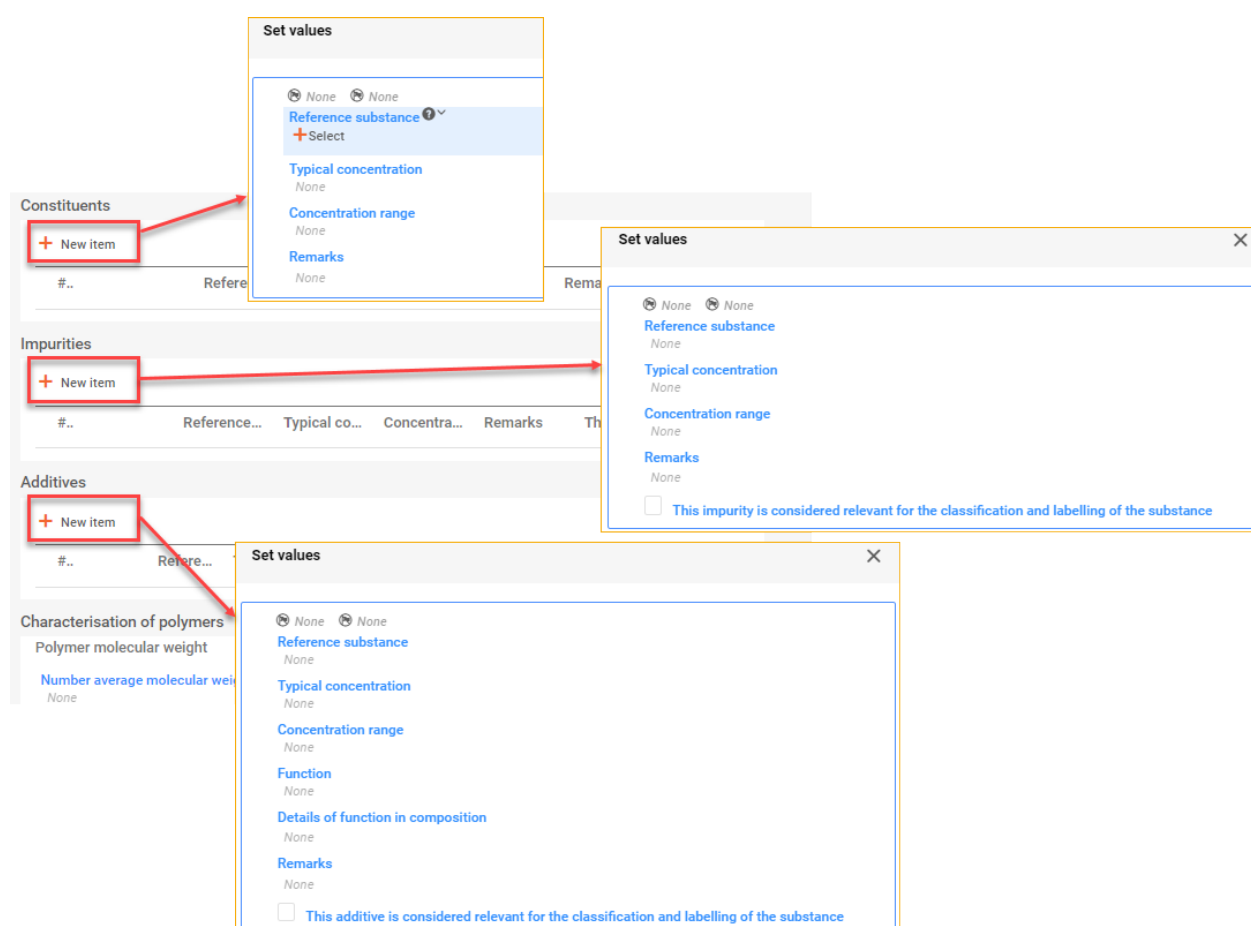
**Do not** give the degree of purity as circa (ca.).

Provide also the full specification of the active substance, including all constituents, impurities and additives (Figure 19), together with an explanation of how these specifications were derived (e.g. based on the 5-batch analysis). The results of the 5-batch analysis should also be attached in this section in 'Attached description/justification'.

Indicate in the remarks field (for each constituent) how the specification has been derived (e.g. based on the 5-batch analysis).

Create an entry for each constituent of the active substance and fill in relevant information, according to your specification. For mono-constituent substances, include only a minimum purity (i.e. no maximum or typical concentration) for the main constituent. If the active substance is a multi-constituent substance, include separate entries for all main constituents and provide a concentration range for each of them. For each impurity and additive (if appropriate), include only a maximum concentration (i.e. no minimum or typical concentration). For UVCB substances, a concentration range for each constituent should be provided. Ensure you link a reference substance to each constituent.

Figure 19: Adding the constituents, impurities, additives



## V. Enter the 'Absorption spectra data' details

### Section 3 - Absorption spectra data

Insert new entry in section 3 by clicking '+' (Figure 20).

Start by inserting information under methods and results of analysis in 'Analytical determination' by clicking '+New item' for each analysis available (Figure 20).

Then indicate in each entry the type of absorption spectra, such as (UV/VIS, IR, NMR) and a mass spectrum, molar extinction coefficient entering relevant values.

For each analysis available set values regarding the analysis type, the test substance, the method used and any remark you consider relevant can be placed in the relevant free text fields (Figure 20).

Ensure you attach the file with the analysis report in the field 'Attached methods/results'.

Figure 20: Including absorption spectra data in section 3

The screenshot displays the 'Oxalonitrile' dossier page. The left sidebar contains a list of sections from 2.3 to 2.13, with section 3, 'Absorption spectral data (UV/VIS, IR, NMR) and a mass spectrum, molar extinction at relevant wavelengths', highlighted. The main content area shows the details for this section. At the top, there is a title 'Absorption spectral data (UV/VIS, IR, NMR) and a mass spectrum, molar extinction at relevant wavelengths' and a 'UID: e837fa75-0e10-4d2f-9a15-0b9b075666ac'. Below this, there is a section for 'Analytical information' and a table for 'Methods and results of analysis'. The table has columns for '#', 'Purpose of...', 'Analysis ty...', 'Type of inf...', 'Attached ...', 'Rationale f...', 'Justification', 'Remarks', and 'Actions'. There are three rows of data. The second row is highlighted with a red box. The 'Attached ...' column for this row shows 'Attachment1.docx'. Below the table, there is a section for 'Analytical determination for nanoforms' and a 'Remarks' section.

## VI. Enter the 'Methods of detection and identification' details

### Section 4 – Methods of detection and identification

Insert new entry in section 4 by clicking '+' and selecting 'Analytical methods' (Figure 21).

You are required to name your new endpoint study record. It is recommended that you name the endpoints in a descriptive way e.g. 'Determination of active substance', 'Determination of Impurity 1', 'Determination of Additive 1', etc.

Include data on the analytical methods used for the determination of the active substance, residues, isomers, impurities and additives (e.g. stabilisers) in this section. Create a new endpoint study record for each analytical method used to determine the active substance, residues, isomers, impurities and additives (e.g. stabilisers).

Information regarding the analytical method used, can be filled into the relevant fields of the endpoint study record, or simply attached as a document in the 'Attached justification' (Figure 21).

Figure 21: Creating a new endpoint study record in section 4

The screenshot displays the 'Oxalotrile' dossier page. The left sidebar shows a tree view of sections, with '4 Methods of detection and identification' selected and highlighted with a red box. Below it, 'Analytical methods' is also highlighted with a red box. The main content area shows the 'Administrative data' tab for 'Methods of detection and identification.001'. The 'Attached justification' section contains a table with one entry: '1 Attachment2.docx'. Above this table, there are buttons for '+ New item' and 'Import file', both highlighted with red boxes. The 'Endpoint' section includes various checkboxes for 'Robust study summary', 'Used for classification', and 'Used for SDS', and a 'Study period' field.

For a detailed explanation on how to fill in the different fields of this endpoint, please see section 8. General IUCLID endpoint sections.

Information on the analytical methods to be used for the determination of the active substance and impurities can be found in the [guidance on technical equivalence](#) and [guidance on information requirements](#).

## VII. Identify Product Type(s)

### Section 5 – Product Type(s)

Insert new entry in section 5 by clicking '+' and identify the product type(s) you wish to apply for (Figure 22).

You may include more than one product type.

The active substance and product type combination must be approved. You can find the approved list on ECHA website: <https://www.echa.europa.eu/web/guest/information-on-chemicals/biocidal-active-substances>.

Figure 22: Adding product type(s) in section 5

The screenshot shows the IUCLID 6 web interface for a TE-APP substance. The main content area displays the 'Product type(s)' section, which includes a dropdown menu for 'Product type(s)' and a list of product types with checkboxes. The selected product types are 'EU BPR Product type 1: Human hygiene (Disinfectants)' and 'EU BPR Product type 2: Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)'. The interface also includes a sidebar with navigation options, a main content area with a dropdown menu for 'Product type(s)', and a list of product types with checkboxes. The selected product types are 'EU BPR Product type 1: Human hygiene (Disinfectants)' and 'EU BPR Product type 2: Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)'.

## VIII. For technical equivalence Tier II assessments:

### a. Include any available study reports from toxicological or ecotoxicological testing

If you are submitting a Tier II application, you may be required to include relevant information in IUCLID 6 endpoint sections 6, 7 and 8. In general, it will be sufficient to include a technical equivalence Tier II report in Section 9 (see below). However, when the applicant provides study reports from experimental tests, robust study summaries for the corresponding IUCLID endpoints should be prepared.

### b. Include a self-assessment of technical equivalence

If you are submitting a Tier II application, you are required to prepare a self-assessment on TE (technical equivalence Tier II assessment conducted by the applicant).

The information submitted in this Tier II report should cover both human health and environmental hazards (for further instructions see Guidance on applications for technical equivalence). You should submit all the available information needed and include the self-

assessment as an attachment in IUCLID 6 section 9 'Summary and evaluation' (Figure 23). Any other supporting documents to the self-assessment can be included in section 9 as separate attachments (e.g. (Q)SAR reports).

The template for technical equivalence Tier II report can be found on the ECHA webpage: <https://echa.europa.eu/support/dossier-submission-tools/r4bp/supporting-documents>.

## IX. Include supporting information

To include the appropriate primary supporting documents click '+New item' in the 'Summary and evaluation' field. In 'Type of report' select 'other:' and enter the type of document you are attaching in the adjacent field, e.g. Tier II self-assessment (Figure 23).

Figure 23: Attaching a supporting document in Section 9

The screenshot displays the IUCLID 6 interface for a substance named 'Oxalonitrile'. The 'Working context' is set to 'BPR Technical Equivalence'. The 'Summary and evaluation.001' section is active, showing a table of reports and administrative information. A red box highlights the '+ New item' button and the 'other: Tier II self-assessment' entry in the table. Another red box highlights the 'Summary and evaluation' section in the left-hand navigation menu.

#	Type of report	Attached document	Remarks	Actions
1	other: Tier II self-assessment	Attachment1.docx		
2	safety data sheet (SDS)	Attachment2.docx		
3	draft risk assessment	Attachment1.docx		

## X. Create a dossier

Dossier for assessment of technical equivalence, must be created from 'Substance' dataset with defined working context 'BPR Technical Equivalence'. Once the dataset is complete refer to [chapter 7](#) ('How to create a dossier').

## 4. Mixture datasets

Information requirements will vary depending on the application type you are submitting, therefore different working contexts of the datasets define specific set of data. Changing selected working context of the Mixture/product dataset to another one will show either less or more data. E.g. when changing working context from 'BPR Biocidal product' to 'BPR Summary product characteristics (SPC)' different and smaller set of data fields are displayed.

Product authorisation requires a full composition (all the components), while Summary Product characteristics (SPC) requires only active substance (s), substance(s) of concern, releaser(s), and non active substance crucial for the composition (some specific substances, related to in situ generated substances)

Product authorisation allows to define mixture in mixture, while SPC structure does not allow that.

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.

### 4.1. Preparing a mixture/product dataset for a biocidal product authorisation or an active substance approval

This chapter outlines how to prepare a dataset containing information of a **biocidal product**. Note that a 'Mixture/Product' dataset must be created, depending 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 biocidal product.

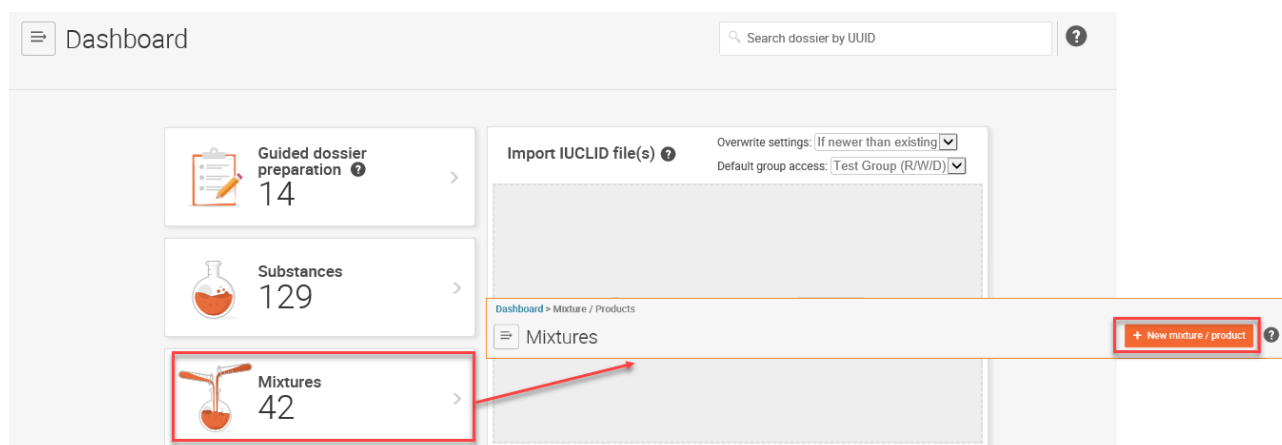
To create a valid dossier for biocidal product authorisation or active substance approval, the 'Mixture/Product' dataset must in general be linked to a main substance dataset ('BPR Active substance information' or 'BPR Microorganisms') (Figure 2). The only exception is Technical Equivalence, for which the dossier is created directly from the 'Substance dataset' and is not linked to the mixture/product dataset.

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 biocidal product (e.g. solvent, emulsifier, etc.).

#### I. Create a dataset for a biocidal product and link it to a Legal entity

In the IUCLID 6 dashboard, create a 'Mixture/Product' dataset clicking on the Mixtures (Figure 24), and then clicking '+ New mixture/product'.

Figure 24: Creating a 'Mixture/Product' dataset

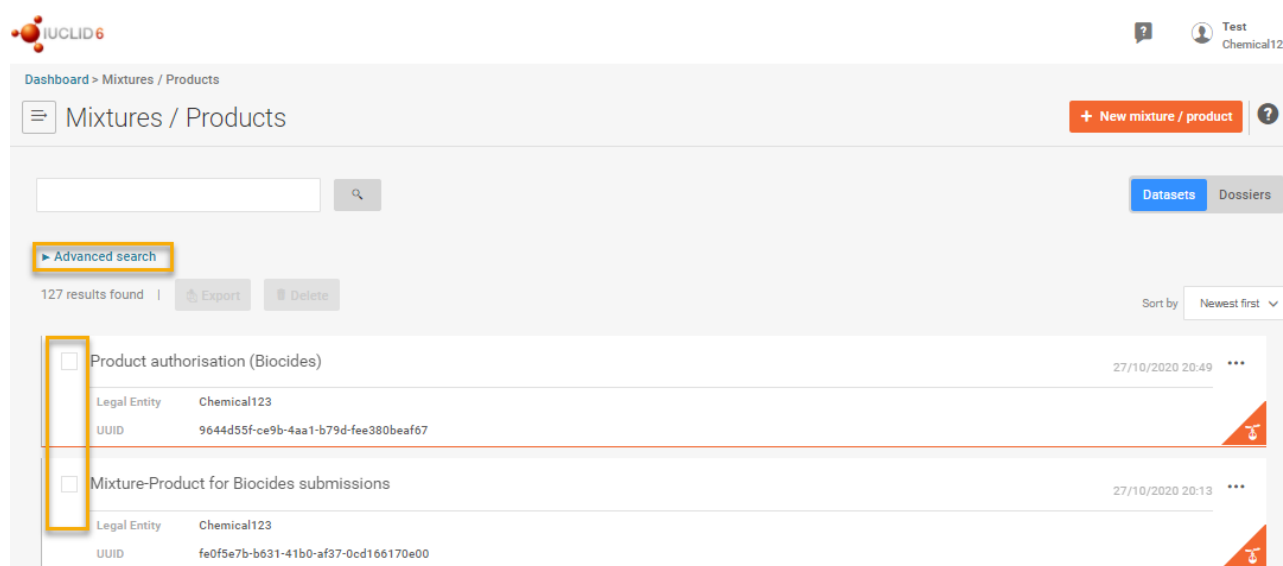


Similar to the creation of your 'Substance' dataset, Enter a name for your dataset in the field 'Name' of New mixture/Product , and click the '+Create'. Confirmation message will appear 'Mixture / Product has been created successfully'. Click 'Open' to access the new dataset should you wish to start working on your dataset immediately. The new dataset will also appear in the list of datasets in the list of 'Mixtures / Products' (Figure 25)

Once you have saved the dataset you can start filling in the information within it.

If you have already created a 'Mixture/Product' dataset and you wish to update information in this dataset, click the Mixtures icon on the IUCLID 6 dashboard (Figure 24). A list of datasets will open in the 'Search' tab. Search for the correct dataset, click on the dataset title, to view all of the sections.

Figure 25: 'Mixture/Product' dataset(s)



## II. Select the dataset working context

Click the arrow to open the drop-down menu in the 'Working context' field, click '+ New working context'.



Depending on the application type, select your mixture/product dataset working context.

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

'BPR Basic information (mixture)' – to be used when creation of additional components of the biocidal product (e.g. solvent) is needed in the 'BPR Biocidal product authorisation'.

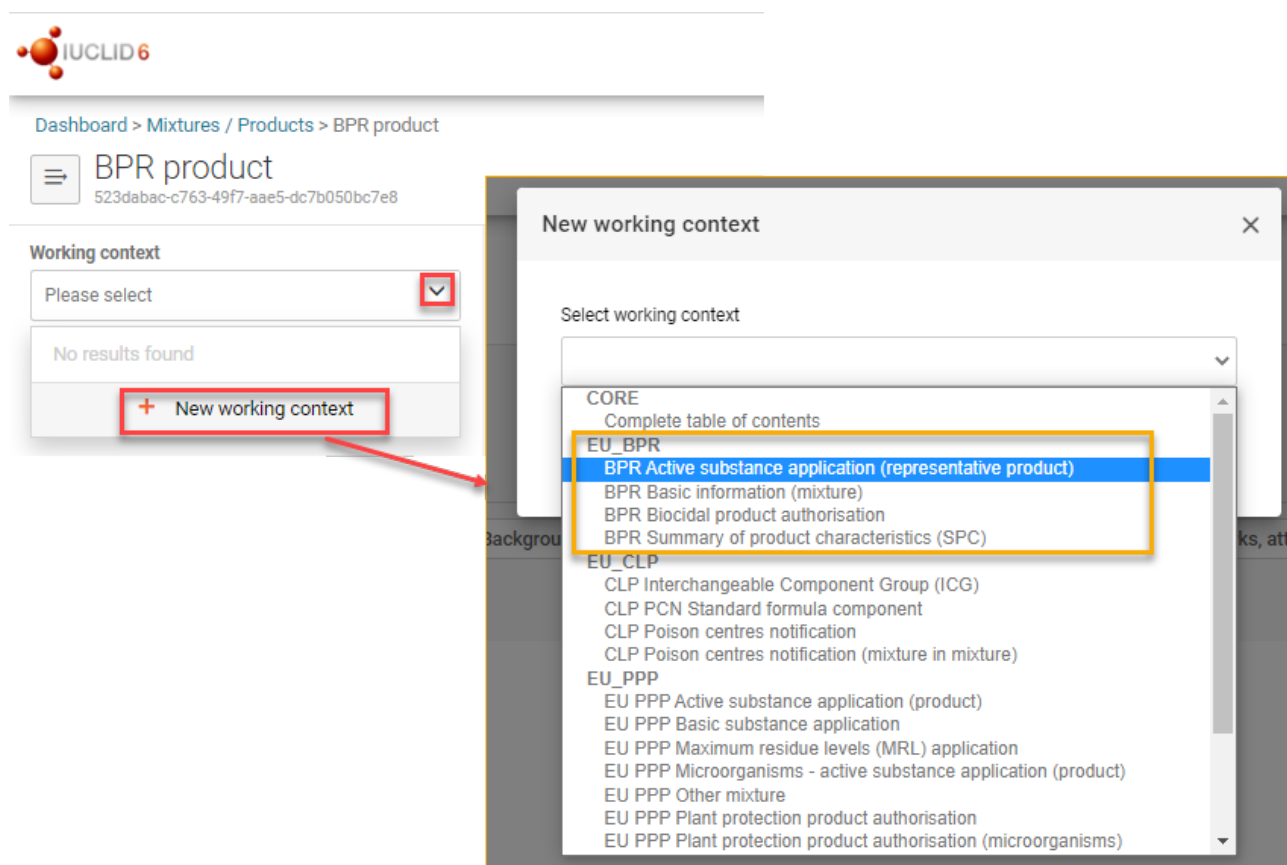
BPR Summary of product characteristics (SPC)' – to be used with biocidal product applications where SPC is required. For detailed instructions go to Section 4.2 Preparing a mixture/product dataset for 'BPR Summary of product characteristics (SPC).

'BPR Active substance application (representative product)' – to be used with active substance applications

Select the appropriate dataset working context for your application (Figure 26). By clicking arrow. Once the working context is selected, you will see all of the sections contained in this dataset.

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

Figure 26: Selecting the dataset working context for mixture/product dataset



### III. Enter the 'Applicant' details

#### IUCLID section 1.3 'Biocidal product manufacturer'

IUCLID section 1.3 contains the name and details of the biocidal product 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.

Entering information in this section follows same steps as in section '3.1 Preparing a dataset for an active substance **III Enter the 'Applicant' details'**.

Information requirements will vary depending on the application type you are submitting, therefore different working contexts of the datasets define specific set of data. Changing selected working context of the dataset to another one will show either less or more data.

### IV. Identify the biocidal product

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

This section allows the identification of the biocidal product, by filling in the pre-defined fields. The fields indicate the name of the biocidal product, the Legal entity assigned to the dataset (e.g. the prospective authorisation holder, i.e. asset owner), the role they play in the supply chain, i.e. manufacturer or importer (or both), along with contact details for the applicant. The name of the biocidal product and the Legal entity are defined during creating a dataset but they can be changed at any point when editing the dataset. Fields of prime importance are indicated in red in Figure 27.

Figure 27: Section 2.1 'Trade name or proposed trade name'

The screenshot displays a web form titled "Test Mixture-Product dataset". It contains several sections:

- Mixture/Product name:** A text input field containing "Test Mixture-Product dataset".
- Public name:** A text input field containing "None".
- Legal entity owner:** A dropdown menu with a radio button icon, currently set to "Test Legal Entity".
- Third party:** A dropdown menu with a radio button icon, currently set to "None".
- Other identifiers:** A section with a "+ New item" button.
- Contact persons:** A section with a "+ New item" button.
- Role in the supply chain:** A section with a radio button icon and a list of roles: "Manufacturer", "Importer", "Only representative", and "Downstream user". This entire section is enclosed in a red rectangular box.

### 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 '+ Select', 'Select Legal entity' page is opening, select the correct legal entity from the search results, and click on the name to assign it.

It may be the case that the representative has not yet been entered into your database. In this case, click '+ Create' in the 'Select Legal entity' page, to open the 'Create new legal entity' dialogue and fill in relevant fields.

### Other identifiers

Enter all the trade (commercial) names and alternative names by which the biocidal product is known. To add a new entry, click 'New item' button. Select the name type; 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 name of the biocidal product, and then select the country in which the name is associated with the biocidal product. You can also add any remark about the name that might be required.

### Contact persons

Create a block using the '+ New Item' functionality, click '+ Select' in 'Person' field and search for the relevant person. Click on the name for assigning it. This person may be contacted e.g. to provide assistance or ask about the information submitted. In case the person has not yet been entered into your database, use '+ Create' functionality to create and assign one.

### 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.

## V. Define biocidal product composition

### IUCLID section 2.3 'Biocidal product composition'

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

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' of your 'Mixture/Product' dataset: If you create a summary or you include more than one active substance in the biocidal product composition, e.g. include more than one record each with a different active substance, your 'BPR active substance application (representative product)' dossier will not be valid, see [chapter 7.1](#).

For full list of sections in which data on a biocidal product containing a microorganism should be inserted, please refer to Annex 4. List of IUCLID sections in which data on a biocidal product containing microorganisms should be inserted .

**For a single biocidal product:** Start by clicking '+' on IUCLID section 2.3 Representative biocidal product composition, and select 'Biocidal product composition'. Only one record of 'Biocidal product composition' should be created and completed (Figure 28).

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

Product name,

Trade names of the product (note that the trade names inserted at the level of the composition will not be retrieved by the Search option provided by IUCLID; this field is dedicated mostly to biocidal products families)

brief description of the biocidal product,

the formulation type from the drop-down menu, and

all of the components, impurities and additives of the biocidal product.

Create entries for the components by clicking the '+New Item' (Figure 28). You will need to create an individual entry for each component of your biocidal product.

- Within the 'Components' block, assign a 'Substance' or 'Reference substance' 'Mixture/Product' dataset to the component of the biocidal product. Clicking on the new item row a 'Set values' window is opened. Clicking '+ Select ' in the 'Name' field opens 'Select substances, mixtures, reference substances' page, in which you can search (Figure 29). From the search results, select the relevant item, and click on the name to 'Assign' it to your dataset.
- For all the product components, including additives, indicate the function. For an impurity select in the field 'Function' an option 'not applicable'.
- Enter the typical concentration value(s) and unit(s).
- Lastly, indicate if any of the substances in the biocidal product is a 'Substance of concern' (in accordance with Article 3(1)(f) of the BPR) by ticking the related box (Figure 28). Be sure to identify all of the components of your biocidal product.

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

Figure 28: Create a single biocidal product composition record and define it

Dashboard > Mixtures / Products > BPR Product

BPR Product  
516e67e7-3513-4016-b27c-f8bface8c9bb

View Dossier

BPR Product

- 1 Applicant\*
- 2 Identity of the representative biocidal product\*
  - 2.1 Trade name or proposed trade name 1
    - BPR Product
    - ECHA
  - 2.2 Manufacturer's development code and number of the representative biocidal product
  - 2.3 Representative biocidal product composition\* **+**
    - Representative biocidal product composition.001
    - 2.4 (Cf. 2.3) Formulation type and nature of the representative biocidal product
- 3 Physical, chemical and technical properties\*
- 4 Physical hazards and respective characteristics\*
- 5 Methods of detection and identification\*
- 6 Effectiveness against target organisms\*
- 7 Intended uses and exposure\*
- 8 Toxicological profile for humans and animals\*
- 9 Ecotoxicological studies\*
- 10 Environmental fate and behaviour\*

### Representative biocidal product composition.001

UUID: 16ddcc83-d185-4c56-8143-ed5e6a2c140e

Administrative data | General information | Components

#### Administrative data

#### General information

Product name

Trade names of the product **+** New item **+** Import file

1 Country

- ✓ Finland
- Trade name
  - Best product 1

Brief description

Formulation type

#### Components

**+** New item **+** Import file

#	Component	Name
1		

#### Set values

Name

Function

Typical concentration

Concentration range

Remarks

Substance of concern

Substance generated in situ

Figure 29: Assign the relevant dataset from the field 'Name'

The screenshot illustrates the process of assigning datasets to a 'Name' field. The main interface shows a 'Set values' section with a 'Name' dropdown menu and a 'Remarks' section with checkboxes for various substance types. Three pop-up windows are shown: 'Select Mixture / Product' (131 results), 'Select Reference substance' (1476 results), and 'Select Substance' (1 result). Arrows indicate the flow of data from the pop-ups to the 'Name' field and the 'Remarks' section.

**For a biocidal product family:** Start by clicking '+' in IUCLID section 2.3 Biocidal product composition, and select 'Biocidal product summary composition'. You need to create and complete one product summary for the whole family, and one product summary for each meta SPC.

You will then need to create and complete a 'Biocidal product composition' for each product within the family. Figure 30 shows an example of how section 2.3 should look for a biocidal product family containing two meta SPCs, and 4 products. In a summary you have to indicate a concentration range of a component in the whole family or in a meta SPC, while in each record a typical concentration of a component in a single product should be given (Figure 30).

Figure 30: Biocidal product composition with multiple records for a biocidal product family

The screenshot shows the '2.3 Biocidal product composition' section. It displays a list of records for 'Biocidal product family composition 001', 'Meta A', 'Meta B', 'Meta A Product 1', 'Meta A Product 2', 'Meta B Product 1', and 'Meta B Product 2'. Each record has a 'Concentration %' field with a range and a 'Typical concentration' field. Arrows indicate the flow of data from the records to the concentration fields.

Once you have checked that the summary represents meta SPC composition, you will be able to enter information in the fields provided for the following:

the Product family or group name,  
the formulation types from the drop-down menu, and  
all of the components.

You should link (Figure 33) all products records to which the summary is relevant, once they are created (Figure 31).

Create blocks for the components by clicking ' + New item' (Figure 31). You will need to create an individual block for each component of your biocidal product family or meta SPC.

Figure 31: Defining a biocidal product family composition

The screenshot shows the 'BPR Product' interface. The sidebar on the left contains a tree view with the following items:

- BPR Product
  - 1 Applicant\*
  - 2 Identity of the representative biocidal product\* (3)
    - 2.1 Trade name or proposed trade name (1)
      - BPR Product
        - ECHA
          - 2.2 Manufacturer's development code and number of the representative biocidal product
          - 2.3 Representative biocidal product composition\* (1)
            - Representative biocidal product family composition
            - Representative biocidal product composition
          - 2.4 (Cf. 2.3) the representative biocidal product
        - 3 Physical, chemical and technical properties\*
        - 4 Physical hazards and respective characteristics\*
        - 5 Methods of detection and identification\*
        - 6 Effectiveness against target organisms\*
        - 7 Intended uses and exposure\*
        - 8 Toxicological profile for humans and animals\*
        - 9 Ecotoxicological studies\*
        - 10 Environmental fate and behaviour\*

The main content area shows the 'Product summary composition' section. The 'Product summary composition' section has a checkbox for 'Represents Meta SPC composition' and a text field for 'Product family or group name'. The 'Composition' section has a dropdown menu for 'Function' and a 'Name' field with a '+ Select' button. Below the 'Name' field are several checkboxes for component types: 'Substance of concern (note: use for substances not categorised as active substances)', 'Generic component identifier (GCI)', 'Interchangeable component group (ICG)', 'Standard formula (SF) component', and 'Substance generated in situ'. There is also a 'Remarks' field.

- Within the 'Composition' section, indicate the biocidal product function (e.g. active substance, solvent, emulsifier, etc.) using the drop-down menu.
- Enter the concentration % range.
- Assign a 'Substance' or 'Mixture/Product' dataset or 'Reference Substance' to the component of the biocidal product family by clicking '+ Select' in the Name field. Click in the Name field '+ Select', this opens for mixtures /product, substances or reference substances page, in which you can search for the relevant one. From the search results,

select the dataset, and click on it for assigning it to the composition section, modifications will be automatically updated by clicking the 'Save' button.

- Lastly, indicate if any of the substances in the biocidal product is a 'Substance of concern' (in accordance with Article 3(1)(f) of the BPR) by ticking the related box (Figure 31). Be sure to identify all of the components of your biocidal products in individual sections.

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. Each record contains a repeatable block 'Trade names' in which you can specify all trade names used by the product (Figure 32). Trade names inserted at the level of the composition will not be retrieved by the Search option provided by IUCLID.

Figure 32: Trade names

The screenshot displays the IUCLID interface for configuring a BPR Product. The left sidebar shows a tree view of the product structure, with '2.3 Representative biocidal product composition\*' selected. The main panel shows the 'Meta A Product1' configuration, with the 'Trade names of the product' section highlighted. A 'New item' button is visible next to the 'Trade names of the product' label. The 'Components' section at the bottom shows a table with one row for '1'.

You can also start by creating records for each products first, and then prepare summaries.

Once a record for a single product is prepared you need to indicate to which meta SPC it belongs, following the steps:



- Open a summary of the meta SPC to which a product belongs
- Click '+ Select' under Related products (Figure 33)
- Select a related item (record) and click Assign.

Figure 33: Link between a biocidal product and a meta SPC

The screenshot displays the IUCLID interface for a biocidal product record. The main content area shows the 'Representative biocidal product family composition.001' record. The 'Related products' section is visible, listing 'Meta A Product 1' and 'Meta B Product 1'. A red box highlights the '+ Select' button next to 'Meta B Product 1'. The 'Cross Reference' section is also visible, containing a search bar and a list of related items, including '2.3 Representative biocidal product composition' with an 'Add new' button. The 'Cross Reference' list also includes 'Meta B Product 1', 'Meta A Product 2', 'Meta A Product 1', and 'Meta B Product 2'.

All products should be also assigned to the summary which specifies a composition of the whole family.

In several IUCLID sections, there are references fields that allow you to link to which product(s) or meta SPC(s) information provided in a document is relevant, if the check box 'Represents meta SPC composition' has been ticked.

Following documents can be linked to the biocidal product composition record

- Packaging (field 'if relevant, specify to which product(s) it applies' in section 12.3)

Following documents can be linked to the meta SPCs, if the check box 'Represents meta SPC composition' has been checked in:

- GHS (section 12.1)
- Intended uses and exposure (section 7.1)

- Measures to protect humans, animals and the environment (section 11)
- Summary and evaluation (section 13)

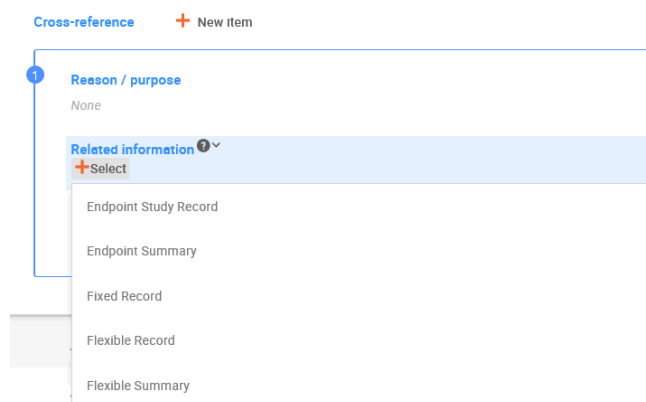
Following documents can be linked to the Uses:

- Target organisms (section 6.1)
- Packagings (section 12.3)
- Application methods (section 7.6)
- Measures to protect humans, animals and the environment<sup>9</sup> (section 11)

Information on how to enter information into the sections mentioned above is provided in subsequent chapters of this manual:

- Section 7 'Intended uses and exposure', [chapter 6.1](#)
- Section 11 'Measures to protect humans, animals and the environment', [chapter 6.2](#)
- Section 12.1 'Classification and Labelling' and section 12.3 'Packaging (12.7 in Annex III of BPR)', [chapter 6.3](#)
- Section 13 'Summary and evaluation', [chapter 6.4](#)

Endpoint study records in sections 3-6 and 8-10 can be linked, via the cross reference fields, to all documents mentioned above (sections 7.1, 7.6, 11, 12.1, 12.3, 13) and to other records, endpoint study records and summaries.



## Copying summaries and records

It is worth to use copy functionality 'Copy data from..' that will copy record(s) already saved in your local database. Once copied then you can edit them according to the needs (useful if there is a lot of meta SPCs and products for example).

---

<sup>9</sup> Field 'Instructions for use' in the document 'Measures to protect humans, animals and the environment' relates only to biocides working context BPR Summary of product characteristics (SPC), the instruction for use for the BPR Active substance application (representative product) and BPR Biocidal product authorisation should be inserted in section 7.6 in field 'Proposed instruction for use'

- Click i '+' then select either 'Endpoint summary' or 'Endpoint study record (Mixture)' as you need and then 'Copy data from...' top right corner (Figure 34)
- Search from existing information for relevant summary or record and click on it for copying
- Open copied endpoint and edit it

Figure 34: Copy from existing record or summary

The screenshot shows the 'BPR Other Product' interface. A dropdown menu is open, highlighting the 'Copy data from...' option. Below it, the 'Copy data from: Entity Selection' dialog box is displayed, showing a search for 'BPR Product' with 2 results found. The results list includes 'BPR Other Product' and 'BPR Product'. The 'BPR Product' entry is highlighted, and a red arrow points to it. The 'Copy data from: Document Selection' dialog box is also visible, showing a list of documents to copy from, including 'BPR Active substance application (representative product)' and 'Identity of the representative biocidal product'.

Figure 35: Copied composition record, ready for edition

The screenshot shows the 'BPR Product' interface. The 'Meta A Product 2.COPY' record is highlighted in the left sidebar. The main content area shows the details for this record, including the 'Administrative data', 'General information', and 'Components' sections. The 'General information' section is expanded, showing the 'Product name' as 'Meta A Product 2', 'Trade names of the product', 'Brief description', and 'Formulation type'. The 'Components' section is also expanded, showing a table with columns for '#', 'Componen...', 'Name', 'Function', and 'Typical co...'. The 'Meta A Product 2.COPY' record is highlighted in the left sidebar, and a red box is drawn around it.

## VI. 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](#).

## VII. 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' or 'BPR Microorganisms' ([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').

## 4.2. Preparing a mixture/product dataset for 'BPR Summary of product characteristics (SPC)'

This chapter outlines how to prepare a dataset containing summary of product characteristics (SPC).

IUCLID is replacing SPC Editor. The SPC s can be created and edited only in IUCLID since the SPC Editor was decommissioned and the SPC xml files cannot be uploaded to R4BP3 anymore.

A new 'BPR Summary of product characteristics (SPC)' can be created for:

- **A Product family:** A set (family) of biocidal products sharing similar properties and same mixture components with compositions comprised within defined ranges.
- **A Single product:** An individual biocidal product with a specifically defined composition.

The key difference between product family SPC and single product SPC is that the first one presents a structure in three levels, family level, meta SPC level and Product level designed in a way that common set of information across products do not need to be repeated.

### I. Create a mixture/product dataset for summary of product characteristics (SPC)

In the IUCLID 6 dashboard, create a 'Mixture/Product' dataset clicking on the Mixtures, and then clicking '+ New mixture/product' (Figure 36). Insert name of the SPC that would represent the product you are going to describe and click '+Create' (Figure 36).

Figure 36: Create SPC

The screenshot displays a dashboard with three main sections: Substances (1836), Mixtures (872), and Articles (50). A search bar at the top right allows searching by UUID. A blue information box provides instructions on importing IUCLID files, stating that datasets will be converted into dossiers to avoid conflicts and that an editable dataset can be extracted with more control. A modal window titled 'New mixture / product' is open, showing a search bar and a 'Name\*' field with the placeholder text 'Type here name of your SPC'. The modal also includes 'Close' and 'Create' buttons. The background shows a search results page for 'Mixtures / Products' with 383 results found.

Open your newly created mixture/product dataset and define that the dataset is representing SPC by selecting correct working context. Click on the drop-down list arrow in the 'Working context' field and select the '**BPR Summary of product characteristics (SPC)**' and 'Apply' (Figure 37). After that the SPC structure is applied to the dataset.

Figure 37: Select correct working context of the dataset to reflect SPC structure

The screenshot illustrates the process of selecting a working context for a dataset. The main page is titled "SPC (example for usermanual)" and shows a "Working context" dropdown menu. A "New working context" button is highlighted. A modal window titled "New working context" is open, displaying a list of options. The option "BPR Summary of product characteristics (SPC)" is highlighted. A second modal window titled "New working context" is also open, showing the selected option "BPR Summary of product characteristics (SPC)" and an "Apply" button.

Once you have created the dataset with correct working context (BPR Summary of product characteristics (SPC)) you can start filling in the required information by clicking on the relevant section in the table of content (Figure 38).

Figure 38: SPC table of content (empty SPC)

Dashboard > Mixtures / Products > SPC (example for use

SPC (example for user manu:  
0614b220-07fd-4ab2-a266-6779480e1441

**Working context**

BPR Summary of product characteristics (SPC) ▼

Type at least 3 characters ✕

BPR Summary of product characteristics (SPC)

- ▼ SPC (example for user manual)
  - ▼ **Manufacturers of the product**
    - Location of manufacturing sites
  - ▼ **Product information** 1
    - ▼ SPC name and legal entity 1
      - ▼ SPC (example for user manual)
        - manufacturer
          - Family, meta SPC, product
  - Hazard and precautionary statements
  - Authorised uses
  - General directions for use
  - Other information
  - Inherited templates

## II. Specific submissions (SPC type)

In order to create a consistent SPC, you are required to provide different type of data. This data can vary significantly from product family SPC to single product SPC.

This section defines your SPC type. It is important to specify your submission correctly in order to submit your application successfully in R4BP3. Specify if you intend to compile the SPC for single product or for product family by selecting the 'SPC type' (Figure 39).

'Market area' and 'Language' (Figure 39) of the SPC is specified also in this section (European Union market includes all EU, EEA and EFTA countries).



'Authorisation details' will be added automatically during the authorisation, based on the data stored in R4BP 3. These fields should be left empty when creating a new SPC for submission in R4BP 3he

Figure 39: Specific submissions (SPC type, market area, etc.)

Dashboard > Mixtures / Products > SPC (example for usermanual)

SPC (example for user manual)  
0614b220-07fd-4ab2-a266-6779480e1441

View Dossiers Validate Create dossier

Working context  
BPR Summary of product characteristics (SPC)

Type at least 3 characters

BPR Summary of product characteristics (SPC)

SPC (example for user manual)

- Manufacturers of the product
- Product information 1
- Hazard and precautionary statements
- Authorised uses
- General directions for use
- Other information
- Inherited templates

UUID: 1a1ce2c3-9b23-4947-93a8-301d923d9927

Specific submissions

Dossier name (given by user)

Dossier submission remark

Specific submissions

SPC type ^  
single product

Market area  
Croatia

Language  
Croatian

Authorisation details

Authorisation number

Reference number ^

Authorisation date

Expiry date

Authorisation holder

Once the data have been corrected or inserted remember to save your data before moving to next steps.

### III. Enter manufacturers details and link manufacturing site(s) to product(s)

#### 'Manufacturers of the product'

This section contains the name and details of the biocidal product manufacturer, importer and/or formulator. It is necessary that you indicate the name and details even if they are the same as the one of the applicant.

To add manufacturer, importer and/or formulator click on '+' in the section 'Manufacturers of products' (Figure 40). Then click on the field 'Name of the manufacturer', list of legal entities stored in your local database is displayed and you may choose one from the list (Figure 40) or if you wish to create new one that does not exist in your list click '+Create' and fill in all the relevant data (Figure 40).

Figure 40: Add manufacturer, importer and/or formulator

The screenshot displays the software interface for adding a manufacturer. The main content area shows a search bar and a list of manufacturers. A modal window titled "Create new Legal Entity" is open, showing a form for entering the name of the manufacturer and other details.

**Manufacturer List:**

Manufacturer	Legal entity town	Legal entity country
manufacturer	Helsinki	Le...
Manufacturer	Tallinn	Le...
LE_TEST123		
	Espoo	Le...

**Create new Legal Entity Form:**

**Name of the manufacturer\*** ⓘ ^  
Type here name of the legal entity

**Legal entity type**

**Address**

Address

Postal Code

City

Country

To add site in section 'Location of manufacturing site' click '+', then click on the field 'Site' and either select from the existing list of your manufacturing sites in your local database or create new one by clicking '+Create'. When creating a new site, fill in all the relevant data including legal entity owner (Figure 41) for that click '+Select' in the field 'Legal entity owner'. You may also create new legal entity owner, if the legal entity is not already existing in your local database. For creating a new legal entity follow the steps described in the section above.

Figure 41: Add manufacturing site

The screenshot displays a web application interface for managing biocides. The main window is titled 'SPC (example for user manual)' and shows a 'Location of manufacturing site.001' entry. A 'Related product' section is visible, with a 'Select Site' dialog box open. The dialog box contains a table of manufacturing sites and a 'Create new Site' form.

Legal Entity name	Manufacturer	UUID
LE_DC_Sites		
Legal Entity name	DC_LE03	UUID

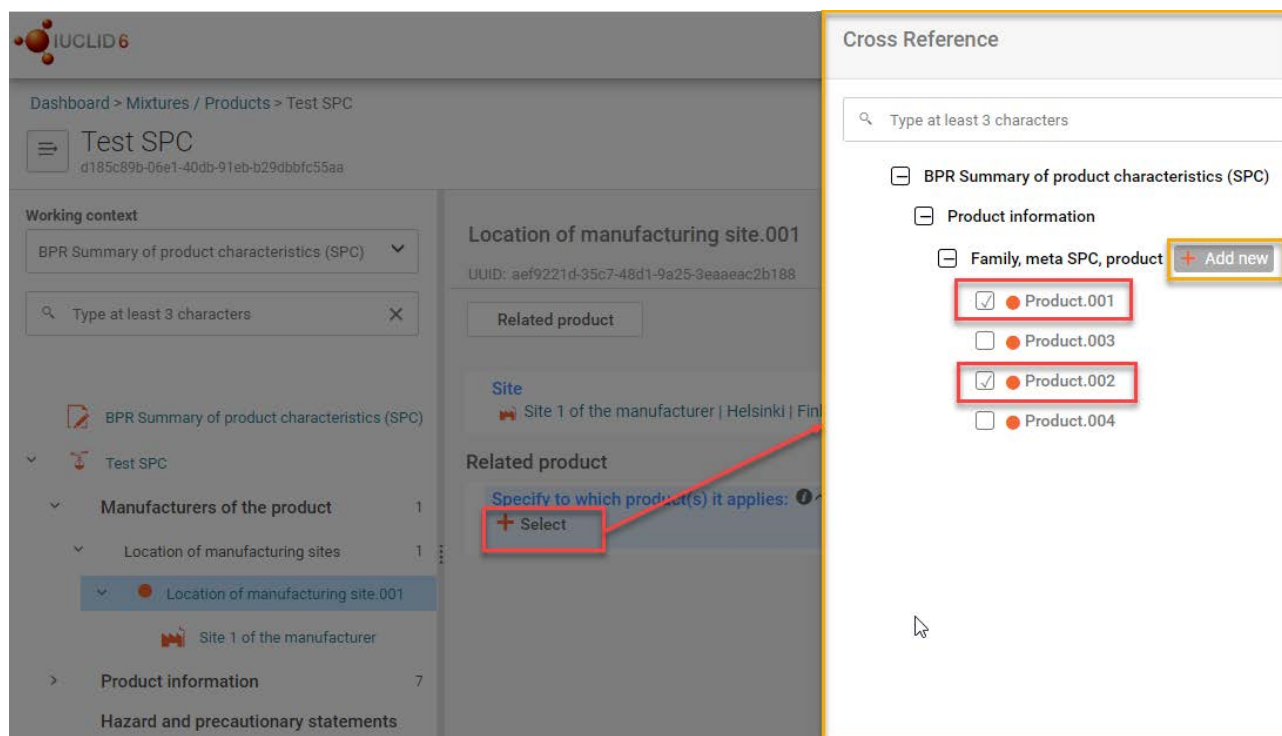
The 'Create new Site' form includes the following fields:

- Site name\* (Mandatory)
- Legal entity owner (Select)
- Address
- Postal Code
- City
- Country

You can link in section 'Related product' which product is related to the manufacturing site only if you have your product(s) already described in 'Product information' section (Define single product). Start by clicking '+Select' and make an appropriate selection (Figure 42).

Or alternatively you can start adding products by clicking '+Add new' (Figure 42) and specify the relevant product. How to specify product information is described in next chapter.

Figure 42: Link manufacturing site to related product



Once the data have been corrected or inserted remember to save your data before moving to next steps.

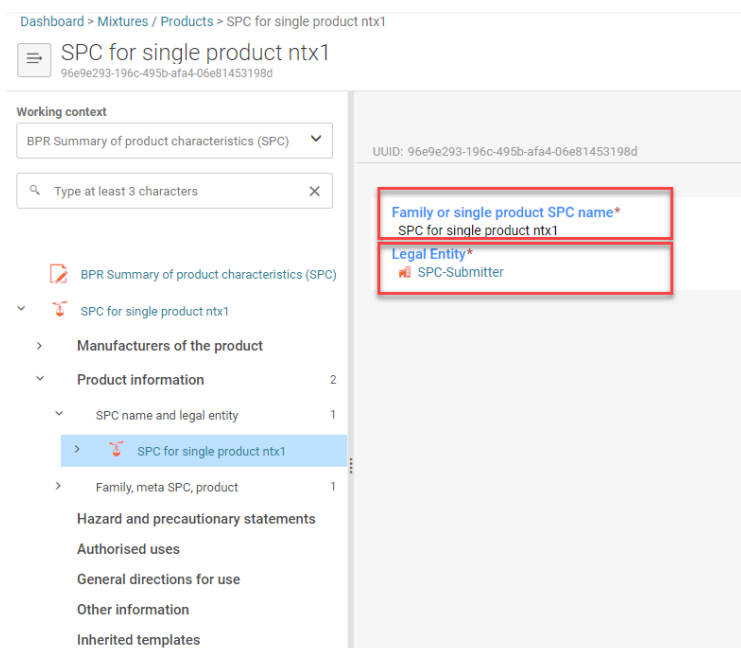
#### IV. Identity of the biocidal product

##### 'Product information' section

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

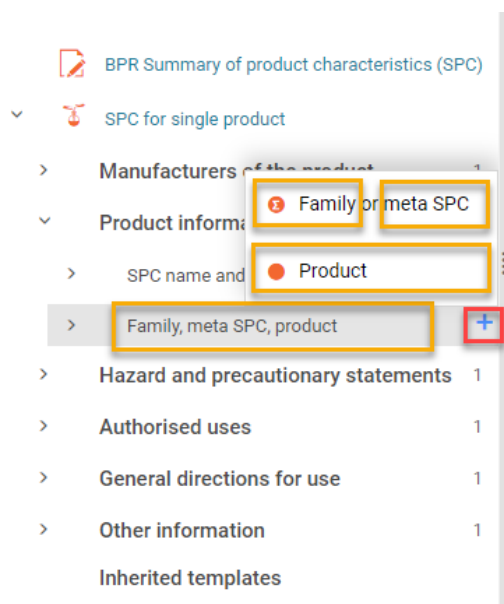
'SPC name and legal entity' section displays name of your SPC and the legal entity name, you may edit both fields also from this section at any time (Figure 43).

Figure 43: Section 'SPC name and legal entity'



'Family, meta SPC, product' section (Figure 44) includes general information about the product or family and meta SPC and specific composition of each biocidal product.

Figure 44: Add a family or meta SPC or product record and insert the record identifier (name)



### Define **biocidal product family**

For **biocidal product family** several records under product information should be inserted: as a minimum family SPC should have one family, one meta SPC and one product linked to it.

Family may also consist of several meta SPC-s and several products linked to it. Each product has to be linked to a meta SPC.

Family biocidal product SPC is composed of three levels:

**Family SPC** – describing the whole family;

**Meta SPC** – describing similar product (s) belonging to the family;

**Product** – describing a product belonging to the family.

To add either **family** or **meta SPC** or **single product** start by clicking '+' in the section 'Family, meta SPC, product' (Figure 44).

Once you have added a record, insert the name (family or meta SPC identifier or product name) in the relevant field and the record name on top of the page (Figure 45), by default a record name depending on its type is assigned but these are not very descriptive and it is recommended you rename your record to the one reflecting either product name or meta SPC name or family name of your product(s).

Figure 45: Insert name/identifier for family, meta SPC and product records

The screenshot displays the 'BPR Summary of product characteristics (SPC)' interface for 'NTX 8 (spray) family'. The interface is divided into several sections:

- Working context:** Shows the current SPC and a search bar.
- Navigation menu:** Lists the hierarchy: 'BPR Summary of product characteristics (SPC)', 'NTX 8 (spray) family', 'Manufacturers of the product', 'Product information', 'SPC name and legal entity', and 'Family, meta SPC, product'. The 'Family, meta SPC, product' section is expanded, showing 'NTX 8 (spray) family', 'Meta SPC 1', and 'NTX 8 TBC'.
- Main content area:** Shows the details for the selected record. Three overlapping windows illustrate the data entry process:
  - Product window (NTX 8 TBC):** Shows the 'Product name' field with 'NTX 8 TBC' entered.
  - Meta SPC window (Meta SPC 1):** Shows the 'Family or meta SPC' field with 'Meta SPC 1' entered and the 'Represents meta SPC composition' checkbox checked.
  - Family SPC window (NTX 8 (spray) family):** Shows the 'Family or meta SPC' field with 'NTX 8 (spray) family' entered and the 'Represents meta SPC composition' checkbox unchecked.

It is necessary to create and complete a biocidal product composition for each product within the family. In the example (Figure 46) the structure of a biocidal product family containing two meta SPCs, and 4 products is presented. In the family record you have to indicate a concentration range of a component in the whole family or in a meta SPC, while in each product record a typical concentration of a component in a single product should be given.

Figure 46: Biocidal product information structure of a biocidal product family

Dashboard > Mixtures / Products > SPC for biocidal product family

SPC for biocidal product family  
eb1313e0-c8f7-4ed0-9ba8-6d50a5e13266

Working context  
BPR Summary of product characteristics (SPC)

Type at least 3 characters

- BPR Summary of product characteristics (SPC)
- SPC for biocidal product family
  - Manufacturers of the product
  - Product information
    - SPC name and legal entity
    - Family, meta SPC, product
      - Family or meta SPC.001
      - Family or meta SPC.002
        - Product
        - Product
      - Family or meta SPC.003
        - Product
        - Product
        - Product
        - Product
        - Product
        - Product
        - Product

Family SPC

Meta SPC - A

Meta SPC - A Product 1

Meta SPC - A Product 2

Meta SPC - B

Meta SPC - B Product 1

Meta SPC - B Product 2

Indicate concentration range of a component in the whole family

Content range (%)

> 1.3 <= 2 % (w/w)

Indicate concentration range of a component in the meta SPC

Content range (%)

> 1.3 < 1.5 % (w/w)

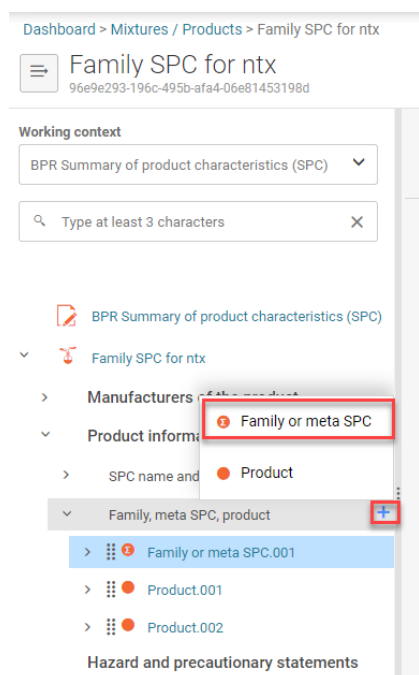
Indicate typical concentration of a component in a single product

Content (%)

>= 1.4 % (w/w)

To add family or meta SPC click '+' in table of content in the section 'Family, meta SPC, product' (Figure 47), once this is done the rest of the information concerning family or meta SPC can be added.

Figure 47: Add family or meta SPC



In the family or meta SPC the name has to be specified in the field 'Family or meta SPC identifier' (Figure 48).

For **product family** identify the family name (Figure 48). Family name is only a technical name and does not refer to the trade name(s) of each single product. The family name will allow you to identify the application you refer to in R4BP 3.

Formulation type(s) of the family should be selected from the drop down list (Figure 48).

'Active substances, Substances of concern, Other substances' in the composition of the family or meta SPC must be inserted. Start adding a new block of a substance information by clicking '+New item' or using the import functionality by clicking 'Import file' (Figure 48)

Once you have added a new block define at first, if it applies to active substance or substance of concern or other substances. Identify the substance, substance of concern or other substance by clicking on the field 'Common Name' (Figure 48).

For detailed instructions on how to define an active substance refer to the chapter: Add active substance, how to define substance of concern or other substance refer to chapter: Add substance of concern or other substances.

Select 'function of the substance' from the drop down list and identify the content range for the whole family.

Single products withing a family must also report content (%); content range is applicable only in family or meta SPC.

If the substance is of a concern tick 'Substance of concern' tick box and if the substance is generated in situ select tick box for 'Generated in situ' (Figure 48).



Figure 48: Family SPC information

The screenshot shows the 'Family or meta SPC' form with the following fields and options:

- Represents meta SPC composition
- Family or meta SPC identifier: Family NTX
- Formulation type(s): AE Aerosol dispenser
- Content range (%): > 1.2, < 5, % (w/w)
- Common Name: (empty)
- Substance of concern
- Generated in situ

The dropdown menu for 'Substance of concern' is open, showing the following options:

- absorbent
- active substance
- active substance (other, not to be assessed)
- adhesive
- adsorbent
- anticaking agent
- anticoagulant
- antifoaming agent
- Please select

### Define **meta SPC** (only for product family)

The 'Meta SPC' includes information on your product(s). You can link one to many related products, depending on how big your family is and how many product types it contains.

You can add as many 'Meta SPC' summaries as needed. For example there are two different products in your family. The first one called "Product A" is a type 1 (PT1) and 2 (PT2), and the second product, called Product B, is a type 3 (PT3) and 8 (PT8). You will need to add four 'Meta SPC' summaries to indicate all the product types of your products (Figure 46).

To add of family or meta SPC click '+' in table of content in the section 'Family, meta SPC, product' (Figure 47), once this is done the rest of the information concerning family or meta SPC can be added.

'Meta SPC' consists of same basic information as product family (Figure 48) and in addition links to related products and Meta SPC information (Figure 49).

Substances described in meta SPC composition should be normally identical to the ones at family level, or if needed to deviate, they may be only less.

To specify that you are going to describe 'Meta SPC', tick 'Represents meta SPC composition' tick box (Figure 49). After that two additional sections of information are displayed: 'Related products' and 'Meta SPC' (Figure 49).

Figure 49: Meta SPC information

Dashboard > Mixtures / Products > SPC for biocidal product family NTX

SPC for biocidal product family NTX  
3dfa08e8-dcf8-4fcd-82a9-0560f779c80b

View Dossiers Validate Create dossier

Working context  
BPR Summary of product characteristics (SPC)

Type at least 3 characters

- BPR Summary of product characteristics (SPC)
- SPC for biocidal product family NTX
  - Manufacturers of the product
  - Product information
    - SPC name and legal entity
    - Family, meta SPC, product
      - Family or meta SPC.001 **Meta SPC**
      - Family or meta SPC.002 **Family SPC**
    - Hazard and precautionary statements
    - Authorised uses
    - General directions for use
    - Other information
    - Inherited templates

Family or meta SPC.001  
UUID: 3a9144db-d0f9-4ce9-bead-592f6baeb564

Family or meta SPC Related products Meta SPC

Family or meta SPC

- Represents meta SPC composition
- Family or meta SPC identifier  
Family NTX
- Formulation type(s)  
AE Aerosol dispenser
- Active substances, Substances of concern, Other substances + New item Import file
- Function  
active substance
- Content range (%)  
> 1.2 - < 1.3 % (w/w)
- Common Name  
Ethanol | EC 200-578-6 | 64-17-5
- Generated in situ

Related products

Related products

Meta SPC

- Hazard and precautionary statements
- Authorised uses
- General directions for use
- Other information

Save

In these sections the relevant information should be linked.

You can link the information, if the relevant records have been already inserted in the main structure (table of content) of the SPC (e.g single products, hazard and precautionary statements, authorised uses, etc) (Figure 50). Remember that you can rename the records to fit for your product description.

Figure 50: Records in table of content of family SPC

Working context	
BPR Summary of product characteristics (SPC)	▼
🔍 Type at least 3 characters	✕
BPR Summary of product characteristics (SPC)	
▼ SPC for biocidal product family NTX	
> Manufacturers of the product	
▼ Product information	6
> SPC name and legal entity	1
▼ Family, meta SPC, product	5
> Family SPC	
> Meta SPC 1	
> Meta SPC 2	
> Product NTX 1 in Meta SPC 1	
> Product NTX 2 in Meta SPC 2	
▼ Hazard and precautionary statements	2
H&P for Meta SPC 1	
H&P for Meta SPC 2	
▼ Authorised uses	2
> Uses for Meta SPC 1	
> Uses for Meta SPC 2	
▼ General directions for use	2
General directions for use for Meta SPC 1	
General directions for use for Meta SPC 2	
▼ Other information	2
Other information - Meta SPC 1	
Other information - Meta SPC 2	
Inherited templates	

To link information in meta SPC, click in the relevant field of the meta SPC section and cross reference dialog will open (Figure 51). Choose from displayed records the relevant one by clicking tick box and select (Figure 51).

Figure 51: How to link relevant record to meta SPC

The screenshot displays the 'SPC for biocidal product family NTX' interface. On the left, a navigation tree shows various sections: 'BPR Summary of product characteristics (SPC)', 'Manufacturers of the product', 'Product information', 'Hazard and precautionary statements', 'Authorised uses', 'General directions for use', and 'Other information'. The 'Product information' section is expanded, showing 'Family, meta SPC, product' as the selected item. A 'Meta SPC' label is overlaid on this section. The 'Cross Reference' dialog box is open on the right, showing a search bar and a list of product information options. The 'Family, meta SPC, product' option is selected, and the 'Add new' button is highlighted. The 'Related products' section is also visible, showing a list of related products. The 'Select' button is located at the bottom right of the dialog box.

Link records in both 'Related products' and Meta SPC records (Figure 51).

After that link to the record is displayed in meta SPC in the relevant section in the relevant field (Figure 52).

Figure 52: Linked records in 'Related products' and 'Meta SPC' sections in meta SPC

The screenshot displays the 'SPC for biocidal product family NTX' interface. On the left, a navigation tree shows the structure of the dossier, with 'Family or meta SPC.001' highlighted and labeled 'Meta SPC'. The main content area is divided into three tabs: 'Family or meta SPC', 'Related products', and 'Meta SPC'. The 'Family or meta SPC' tab is active, showing details for 'Family or meta SPC.001' (UUID: 3a9144db-d0f9-4ce9-bead-592f6baeb564). The 'Family or meta SPC' section includes a checked box for 'Represents meta SPC composition', the identifier 'Family NTX', and the formulation type 'AE Aerosol dispenser'. A table of active substances is shown, with one entry for 'Ethanol' (EC 200-578-6 | 64-17-5). The 'Related products' section lists 'Product.001' as a linked record. The 'Meta SPC' section lists various linked records, including 'Hazard and precautionary statements.001', 'Use.001', 'General directions for use.001', and 'Other information.001'. A 'Save' button is located at the bottom right.

If the information has not been yet inserted in the main structure (table of content) of the SPC (e.g single products, hazard and precautionary statements etc.), you may also start defining those records by clicking on the relevant field and from the cross reference dialoge click '+Add new' (Figure 51).

How to add relevant new item is described in chapters: Define single product; Insert hazard and precautionary statements; Identify authorised uses; Specify general directions for use ; Insert any other information.

## Define single product

For **Single product** only one record of a product should be added (Figure 44) and completed.

Once you have added a record for single product, you will be able to enter general information and specific composition of each biocidal product.

Under section 'General information (Figure 53) following fields should be filled in:

'Product name' - insert the product name.

'Trade names of the product' – insert block of information consisting trade name per country or per several countries. Each trade name should be inserted in a separate block. Add new block by clicking '+ New item' (Figure 53), select country or several countries and insert the trade name. Alternatively 'Import file' functionality' can be used.

'Brief description' – short description of the product can be inserted.

'Formulation type' – select formulation type of the product from the drop-down list.

Figure 53: Insert general information for single product

Dashboard > Mixtures / Products > SPC for single product

SPC for single product  
d190d22b-260c-41cd-8ec3-46a44d80f433

View Dossiers Validate Create dossier

Working context  
BPR Summary of product characteristics (SPC)

Type at least 3 characters

BPR Summary of product characteristics (SPC)

SPC for single product

Manufacturers of the product 1

Product information 2

SPC name and legal entity 1

SPC for single product

manufacturer

Family, meta SPC, product 1

Product.003

Hazard and precautionary statements 1

Authorised uses 1

General directions for use 1

Other information 1

Inherited templates

Product.003  
UUID: 9220238b-798f-462c-858f-34884d98407b

General information Specific composition of each biocidal product

General information

Product name Product NTX

Trade names of the product + New item Import file

Country  
Belgium  
Luxembourg  
Netherlands (the)

Trade name  
Product NTX Benelux

Brief description  
You can insert here brief description of the product

Formulation type  
AE Aerosol dispenser

Specific composition of each biocidal product

+ New item Import file

#	Common n...	Function	Generated i...	Content (%)	Content ra...	Substance ...	Actions
---	-------------	----------	----------------	-------------	---------------	---------------	---------

## Define product composition

Under section 'Specific composition of each biocidal product' (Figure 54) composition of each biocidal product is defined. In this section any 'Active substances', 'Substances of concern' and 'Other substances' are identified. Note that at least one active substance is required.

You should create an individual entry for each component of your biocidal product.

Create entries for the components by clicking the '+New Item' (Figure 54) or using import functionality by clicking 'Import file'.

Figure 54: Create(add) an entry for biocidal product component (active substances, substances of concern and other substances)

The screenshot shows the 'SPC for single product' interface. The main content area is titled 'Product.003' and contains two tabs: 'General information' and 'Specific composition of each biocidal product'. The 'General information' tab is active, showing fields for 'Product name' (Product NTX), 'Trade names of the product', 'Country' (Belgium, Luxembourg, Netherlands (the)), 'Trade name' (Product NTX Benelux), 'Brief description', and 'Formulation type' (AE Aerosol dispenser). The 'Specific composition of each biocidal product' tab is highlighted with an orange border and contains a table with columns: '#', 'Common n...', 'Function', 'Generated ...', 'Content (%)', 'Content ra...', 'Substance ...', and 'Actions'. A red box highlights the '+ New item' button, and a red arrow points to the first row of the table.

#	Common n...	Function	Generated ...	Content (%)	Content ra...	Substance ...	Actions
1			<input type="checkbox"/>			<input type="checkbox"/>	

### Add active substance

Information about the active substance is saved in the substance dataset, that can be created while adding the active substance to the composition of the product.

To create the substance (consisting information about the active substance) in the product composition click on the newly created entry (Figure 54), the 'Set values' dialoge is prompted, then click on '+Select' in the field 'Common name' (Figure 55) and select - Substance.

Figure 55: Identify and add an active substance to the composition of the biocidal product

The screenshot displays the 'SPC for single product' interface. The main content area is titled 'Product.003' and shows a 'Specific composition of each biocidal product' section. A 'Set values' dialog box is open, allowing the user to configure a new substance entry. The dialog has the following fields and options:

- Common name:** A text input field with a '+ Select' button next to it.
- Reference substance:** A dropdown menu with 'Substance' selected.
- Content (%):** A text input field with a unit selector set to '(w/w)'.
- Substance of concern:** A checkbox that is currently unchecked.

The background interface shows a table for the composition with columns for '#', 'Common name', 'Content (%)', 'Content range ...', 'Substance of c...', and 'Actions'. A red box highlights the first row in the table, and a red arrow points from this box to the 'Set values' dialog. The 'Save' button is visible at the bottom right of the dialog.

After that, you can select the active substance from the list of substances saved in your local database (Figure 56) or create new substance by clicking '+Create' (Figure 56).

Once you have clicked '+Create', 'Create new substance' dialog opens (Figure 56).

Identify your new substance by selecting the reference substance, for that click '+Select' on the field 'Reference Substance' (Figure 56) and select the reference substance from pre-populated lists either searching and selecting one from ECHA database by checking the radio button 'ECHA BPR Active Substances' (Figure 56) or from your local database by checking the radio button 'Local IUCLID database'. You must insert the substance name on the field 'Common name' (Figure 56). Make sure common name matches the reference substance name and does not have any formatting errors.



Figure 56: Select existing substance or create new substance in the product composition.

The image shows two overlapping dialog boxes in a software interface. The top dialog, titled "Select Substance", has a search bar and a "10 items found" indicator. A red box highlights the search results entry: "Active chlorine released from hypochlorous acid". Below this is a table with columns: Inventory number, CAS number, IUPAC name, Legal Entity, SPC-Submitter, and UUID. The bottom dialog, titled "Select Reference Substance from:", has a search bar and a "353499 items found" indicator. It features two radio buttons: "Local IUCLID database" and "ECHA BPR Active Substances", with the latter selected and highlighted by a red box. A blue information banner below the radio buttons reads: "Selecting a reference substance from ECHA list will result to either creating a new one or replacing an existing to local inventory." Below this is a "Show results" dropdown set to "25". The dialog displays two sections of substance data: "Confidential or not yet assessed substance" and "Formaldehyde". The "Formaldehyde" section contains a table with columns: CAS number, IUPAC name, BAS number, and EC number.

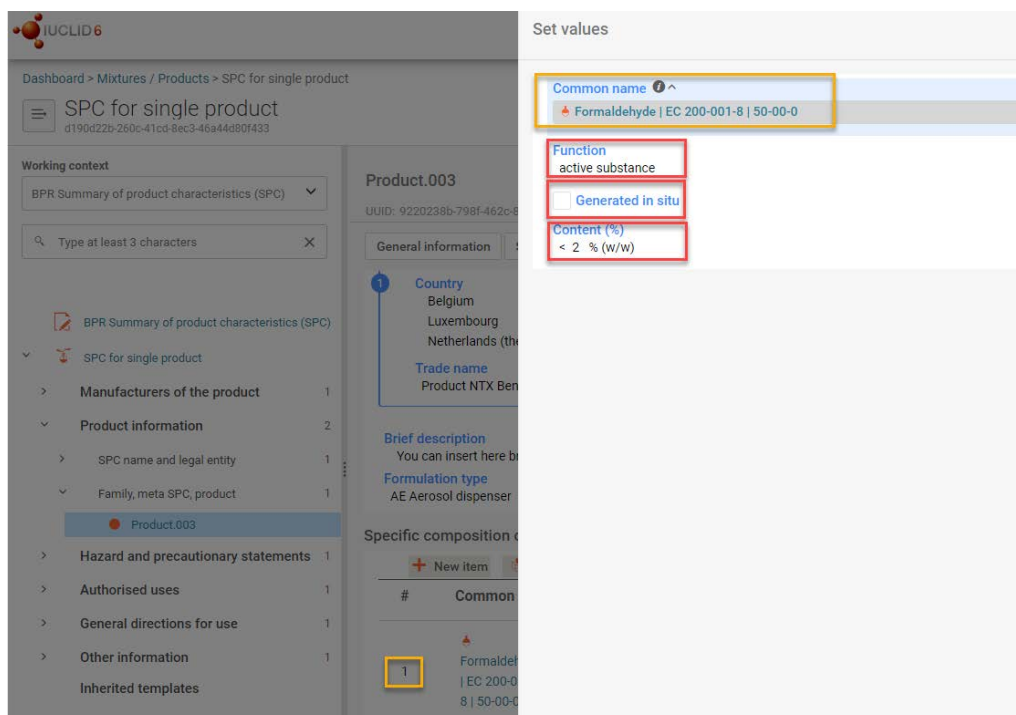
Once you have added or created your substance remember to save, after that you are prompted back to 'Set values' dialog of the substance (Figure 57). Fill in rest of the fields:

Select function from the drop-down list in field 'Function' (Figure 57) and define concentration:  
 'Content (%)': for single product SPC or the (Figure 57)  
 'Content range (%)': for Product family SPC or for substance generated in situ for single product SPC.

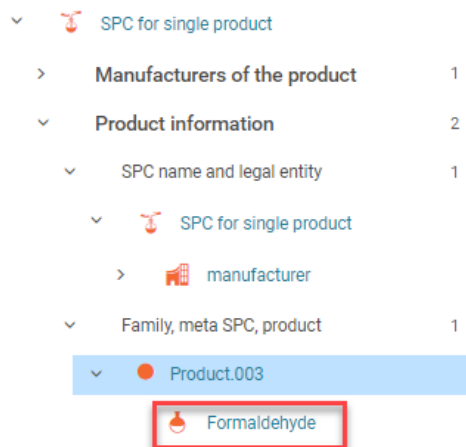
If tickbox for 'Generated in situ' is selected, then the field 'Content range (%)' is enabled for the single product SPC.

The image shows a close-up of a form element. At the top, there is a checked checkbox labeled "Generated in situ" with an information icon and a caret. Below it is a field labeled "Content range (%)" with an information icon and a caret. The field contains three input boxes, each with a dropdown arrow on its right side, indicating a range selection.

Figure 57: Set function, identify if the substance is generated in situ and set concentration of the substance.



Once the values are set, close the 'Set values' dialogue and save the product information after that the substance component is displayed under the product.



The active substance has been identified, now you need to finalise inserting other information relevant for the active substance: 'Manufacturers of the active substance' and 'Location of manufacturing site'. To do so, open active substance information record.

You can access the active substance information record from the SPC table of content (Figure 58) at any time and edit necessary information. Click on the double arrow next to the substance component of the product, then subtree is displayed in the table of content area (Figure 58).

Figure 58: Open active substance information to add information on manufacturer and

## locations of manufacturing sites

Dashboard > Mixtures / Products > Praecox - single product for EU

**Praecox - single product for EU**  
fcae6b7f-4063-46f3-a061-9eb93adb051c

Working context  
BPR Summary of product characteristics (SPC) ▼

Type at least 3 characters ✕

- BPR Summary of product characteristics (SPC)
- ▼ Praecox - single product for EU
  - Manufacturers of the product 2
  - ▼ Product information 2
    - SPC name and legal entity 1
    - ▼ Family, meta SPC, product 1
      - ▼ ● Praecox-002
        - Peracetic acid >>
        - sulphuric acid
      - Hazard and precautionary statements 1
      - Authorised uses 2
      - General directions for use 1
      - Other information
      - Inherited templates

**Praecox-002**  
UUID: 1120c871-fed0-4c34-b83e-454f3f40b5b8

General information | Specific composition of

**General information**

Product name  
Praecox-002

Trade names of

Country  
European

Trade name  
APN-002

Brief description  
Brief description

Location type  
AL Any other lic

**Specific composition**

+ New item

#	Cor
1	79-
2	sulphuric acid   EC 231-639-5   766-93-9

**Working context**  
BPR Summary of product characteristics (SPC)

Type at least 3 characters ✕

← Praecox - single product for EU ● Praecox-002

- ▼ ● Peracetic acid
  - > Identity of the active substance 1
    - ▼ Manufacturers of the active substance +
      - > ● Manufacturer of the active substance.001
    - ▼ Location of manufacturing sites 1
      - > ● Location of manufacturing site.001

Inherited templates

Add and define manufacturer of the active substance and location of manufacturing sites start by creating a record by clicking '+' in relevant sections and insert the data (Figure 59).

Figure 59: Insert manufacturer and location of manufacturing sites of the active substance

The screenshot shows the 'Manufacturer of the active substance.001' section of the Praecox - single product for EU dossier. The left sidebar contains a tree view with the following items: 'Identity of the active substance' (1), 'Manufacturers of the active substance' (1) with a red '+' icon, 'Location of manufacturing sites' (1), and 'Location of manufacturing site of peracetic acid' (1). The main content area shows the 'Name of the manufacturer' field with a red dashed border and a red error message: 'This field is mandatory.' Below the field is a 'Save' button.

To insert the manufacturer of the active substance after you have created the record for it, click on the field 'Name of the manufacturer' and either select from your database the relevant manufacturer or define it by clicking '+ Create' and then fill in all the displayed fields. Remember to save the record.

To insert the location of the manufacturing site of the substance after you have created the record for it, click on the field 'Site' and either select from your database the relevant site or define it by clicking '+ Create' and then fill in all the displayed fields. Remember to save the record. To navigate back to main table of content click on the double arrow in the line of of the product.

The screenshot shows the 'Working context' section of the Praecox - single product for EU dossier. The left sidebar contains a tree view with the following items: 'Identity of the active substance' (1), 'Manufacturers of the active substance' (1), 'Location of manufacturing sites' (1), and 'Location of manufacturing site of peracetic acid' (1). The 'Location of manufacturing site of peracetic acid' item is highlighted in blue. Below the tree view is a 'Go back to previous tree' button. The main content area is empty.

## Add substance of concern or other substances

In order to add the substance of concern or other substances in the product composition click on '+ Select' in the field 'Common name' (Figure 60) and select: Reference substance.

Figure 60: Identify and add a substance of concern or other substances to the composition of the biocidal product

The screenshot displays the IUCLID 6 software interface. On the left, a sidebar shows the navigation menu with 'Product.001' selected. The main area shows the 'Product.001' details, including 'General information' and 'Specific composition of each substance'. A 'Set values' dialog box is open, allowing the user to select a substance for the 'Common name' field. The dialog box has a search bar and a list of options: 'Mixture / Product', 'Reference substance' (highlighted with a red box), 'Substance', and 'Content (%)'. There is also a checkbox for 'Substance of concern'.

After that select the reference substance from one of the the pre-populated lists either searching and selecting one from ECHA database by checking the radio button 'ECHA BPR Active Substances' (Figure 61) or from your local database by checking the radio button 'Local IUCLID database' (Figure 62).

Figure 61: Select reference substance from ECHA database

Select Reference Substance from: + Create X

322 items found

Local IUCLID database  ECHA BPR Active Substances

**!** Selecting a reference substance from ECHA list will result to either creating a new one or replacing an existing to local inventory.

Show results 25 ▾

**Formaldehyde**

CAS number	50-00-0	IUPAC name	
BAS number	1306	EC number	200-001-8

**Lactic acid**

CAS number		IUPAC name	
BAS number	1421	EC number	200-018-0

**Ascorbic acid**

CAS number		IUPAC name	
BAS number	1427	EC number	200-066-2

2-(2-butoxyethoxy)ethyl 6-propylpiperonyl ether (Piperonyl butoxide/PBO)

Figure 62: Select reference substance from your local IUCLID database or create new one

Select Reference Substance from: + Create X

3 items found

Local IUCLID database  ECHA BPR Active Substances

▶ Advanced search

Show results 25 ▾

**Warfarin** 05/10/2023 15:34

CAS number	81-81-2	IUPAC name	(RS)-4-hydroxy-3-(3-oxo-1-phenylbutyl)coumarin
Inventory number	201-377-6	UUID	26c9191a-6721-5a97-a286-4c297105778e

**Ethanol** 04/10/2023 16:57

CAS number	64-17-5	IUPAC name	
Inventory number	200-578-6	UUID	8dbfd19e-2afa-5c32-94f5-2fde29f2a93b

**Formaldehyde** 04/10/2023 10:47

CAS number	50-00-0	IUPAC name	
Inventory number	200-001-8	UUID	0f7914ed-6411-5b0a-b72f-8342f5271641

You may also create a new reference substance for your substance of concern or other substances. Click on '+Create' (Figure 62), 'Create new Reference Substance' dialogue will open and you are requested to fill in the relevant data (Figure 63).

Figure 63: Create new reference substance in your local IUCLID database

Select Reference Substance from:

Local IUCLID database  ECHA BPR Active Substances

3 items found

Warfarin 05/10/2023

CAS number	81-81-2	IUPAC name	(RS)-4-hydroxy-3-(3-oxo-1-phenylbutyl)coumarin
Inventory number	201-377-6	UUID	26c9191a-6721-5a97-a284c297105778e

Ethanol 04/10/2023

CAS number	64-17-5	IUPAC name	
Inventory number	200-578-6	UUID	8dbfd19e-2afa-5c32-94f52fde29f2a93b

Formaldehyde 04/10/2023

CAS number	50-00-0	IUPAC name	
Inventory number	200-001-8	UUID	0f7914ed-6411-5b0a-b72f-8342f5271641

Create new Reference Substance

Reference substance name\*  
Type here name of reference substance

IUPAC name

Inventory

Inventory number

CAS number

Synonyms

Synonyms + New item Import file

#	Confidentiality	Identifier	Identity	Remarks	Actions
---	-----------------	------------	----------	---------	---------

Once you have added or created your the reference substance remember to save, after that you are prompted back to 'Set values' dialoge (Figure 64). Fill in rest of the fields:

You may select function from the drop-down list in field 'Function' (Figure 64) and define concentration:

'Content (%)': for single product SPC or the

'Content range (%)': for Product family SPC or for substance generated in situ for single product SPC.

Figure 64: Set function, identify if the substance is generated in situ and set concentration of the substance.

The screenshot displays the IUCLID 6 software interface. On the left, a sidebar shows the 'Working context' for 'SPC for single product NTX'. The main panel shows details for 'Product.001', including 'Country' (Belgium, Luxembourg, Netherlands (the)), 'Trade name' (Product NTX Benelux), and 'Formulation type' (AE Aerosol dispenser). A table at the bottom lists the 'Specific composition of each' component:

#	Common na...
1	Ascorbic acid   EC 200-066-2
2	Ethanol   EC 200-578-6   64-17-5

Overlaid on the right is the 'Set values' dialog box. It features a search bar for 'Common name' with the value 'Ascorbic acid | EC 200-066-2'. Below the search bar, the following options are visible:

- Function:** complexing agent
- Generated in situ**
- Content (%):** < 4
- Substance of concern**

A red box highlights the 'Function', 'Generated in situ', and 'Content (%)' sections. A 'Close' button is located at the bottom right of the dialog box.

Once the values are set, close the 'Set values' dialogue and save the product information after that the component is displayed under the product in the table of content of SPC (Figure 65).



Figure 65: Product components in the table of content of SPC

Dashboard > Mixtures / Products > SPC for single product NTX

SPC for single product NTX  
bc5000fd-3d71-43a8-bb6e-469a3836630a

View Dossiers Validate Create dossier

Working context  
BPR Summary of product characteristics (SPC)

Type at least 3 characters

BPR Summary of product characteristics (SPC)

SPC for single product NTX

Manufacturers of the product 1

Product information 2

SPC name and legal entity 1

Family, meta SPC, product 1

Product.001

Ascorbic acid Substance of concern or other substance

Ethanol Active substance

Hazard and precautionary statements

Authorised uses

General directions for use

Other information

Inherited templates

Product.001  
UUID: ffeef216-3477-43f3-923a-a1ec3976c51f

General information Specific composition of each biocidal product

Trade names of the product + New item Import file

Country  
Belgium  
Luxembourg  
Netherlands (the)

Trade name  
Product NTX Benelux

Brief description  
You can insert short description of the product here.

Formulation type  
AF Aerosol dispenser

composition of each biocidal product  
Document last modified: Yesterday at 19:08

#	Common na...	Function	Generated i...	Content (%)	Content ran...	Substance o...	Actions
1	Ascorbic acid   EC 200-066-2	complexing agent	<input type="checkbox"/>	< 4		<input type="checkbox"/>	
2	Ethanol   EC 200-578-6   64-17-5	active substance	<input type="checkbox"/>	< 4			

Save

## V. Insert hazard and precautionary statements

### Hazard and precautionary statements

'Hazard and precautionary statements' record includes the hazard and precautionary statements for the product, information about additional labelling and precautionary statements (Figure 66).

For some precautionary statement, it is possible to select the same statement several times. Some of the statements require additional input after their selection.

To create a record to add information start with clicking '+' in the table of content of SPC, and populate all relevant sub-sections with the information by either clicking '+New item' or 'Import file' (Figure 66) in relevant field.

Figure 66: Insert hazard and precautionary statements

The screenshot shows the 'SPC for biocidal product family NTX' interface. The sidebar on the left contains a table of contents with the following items:

BPR Summary of product characteristics (SPC)	
SPC for biocidal product family NTX	
Manufacturers of the product	
Product information	5
Hazard and precautionary statements	
Hazard and precautionary statements.001	
Authorised uses	1
General directions for use	1
Other information	1
Inherited templates	

The main content area is titled 'Hazard and precautionary statements.001' and contains three sections, each with a 'New item' button and an 'Import file' dropdown:

- Hazard Statements:** Includes a 'Hazard statement' text input field.
- Additional labelling requirements:** Includes an 'Additional non-GHS hazard statement' text input field.
- Precautionary statements:** Includes a 'Precautionary statement' text input field.

A 'Save' button is located at the bottom right of the main content area.

Once record under 'Hazard and precautionary statements' is saved it becomes cross referencable and can be linked in the relevant section in meta SPC of family SPC.

## VI. Identify authorised uses

### Authorised uses

The 'Authorised uses' record includes details about the use, target organisms, application methods, packaging and use-specific directions for use.

To create a record for adding information start with clicking '+' in the section 'Authorised uses' in table of content of SPC. For specific authorised use populate all relevant fields with the information (Figure 67) by either selecting value from drop-down list, inserting information in to free text field or linking a record to the relevant field.

Figure 67: Identify Authorised uses

Dashboard > Mixtures / Products > SPC for biocidal product family NTX

SPC for biocidal product family NTX  
3dfa09e8-dcf8-4fcd-82a9-0560f779c80b

View Dossiers Validate Create dossier

Working context  
BPR Summary of product characteristics (SPC)

Type at least 3 characters

BPR Summary of product characteristics (SPC)

SPC for biocidal product family NTX

- Manufacturers of the product
- Product information 5
  - SPC name and legal entity 1
  - Family, meta SPC, product 4
  - Hazard and precautionary statements 1
  - Authorised uses 1
    - Use.001
  - General directions for use 1
  - Other information 1
- Inherited templates

Use.001  
UUID: 5bb22b4f-778f-4f5c-9766-b6ab3493cf93

Authorised use

Product type(s)  
This field is mandatory.

Title for use

Field of use

Field of use description

User categories

Where relevant, an exact description of the authorised use

Target organisms

Packagings

Application methods

Use-specific directions for use

Save

'Product type(s)' - select from drop-down list one or more product type(s).

'Title for use' – insert title for use in the free text field.

'Field of use' –select from drop-down list field of use.

'Field of use description' – insert description of use in the free text field.

'Use categories' – select from drop-down list one or more use categories.

'Where relevant, an exact description of the authorised use' - insert description in the free text field.

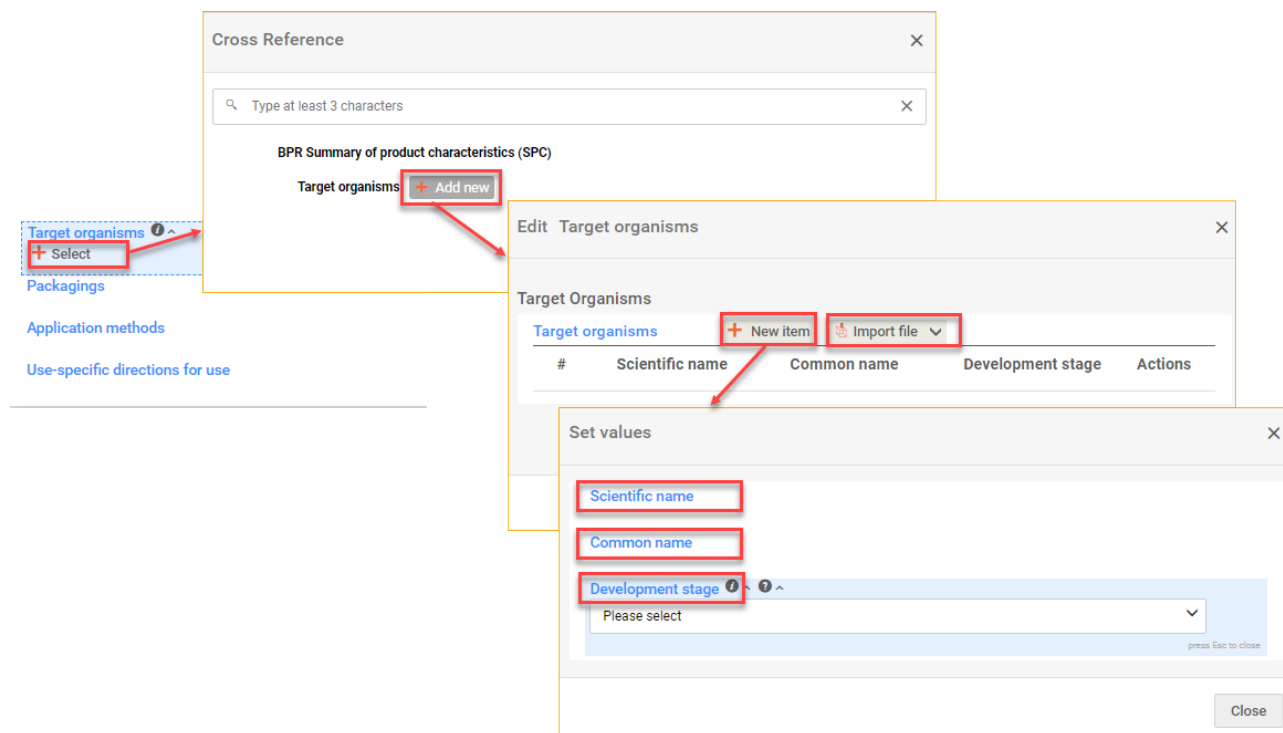
'Target organism' – link target organism record or create new one by clicking '+Select' in the field, after that cross reference dialogue opens and you may select from existing target organism records the relevant one.

Note that target organisms are not translated but that 'Remarks' field can be used to enter names in every official language

To create new target organism record click '+Add New' (Figure 68), edit target organism dialogue opens and you have to insert new one by selecting '+ New item' or you may use import functionality by clicking 'Import file'. After you have clicked '+New item' set values by selecting value from drop down list of each field: 'Scientific name', 'Common name' and 'Development

stage'. You may add a remark to each value once selected. Close set values dialogue and then save your target organism(s). After that the target organism record is linked in cross reference dialogue.

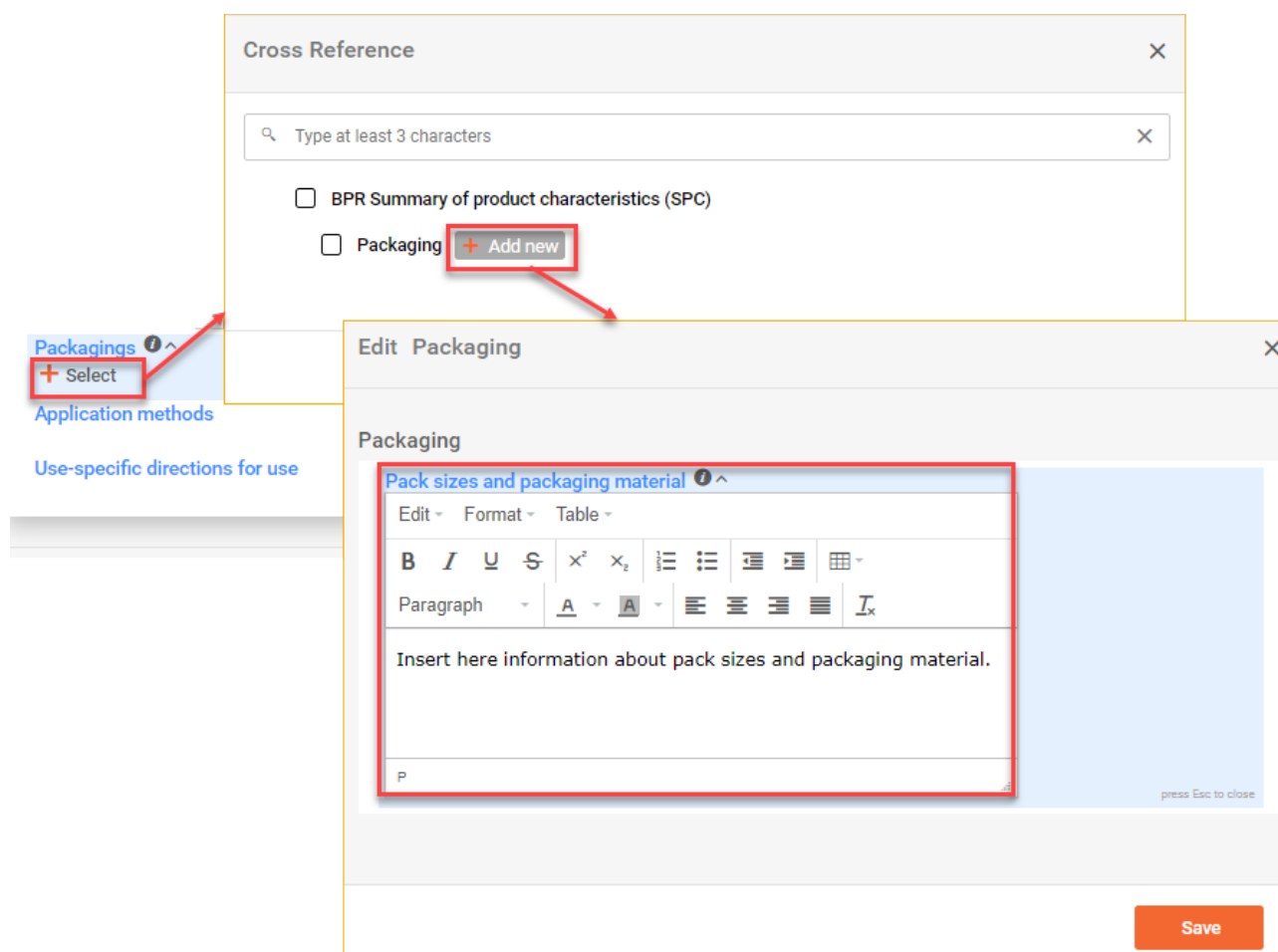
Figure 68: Add new target organism record under authorised use



'Packagings' - link packaging record or create new one by clicking '+Select' in the field (Figure 69), after that cross reference dialogue opens and you may select from existing packagings records the relevant one.

To create new packaging record click '+Add New' (Figure 69), edit packaging dialogue opens and information about pack size and material in the free text field can be inserted (Figure 69). Save packaging information. After that the packaging record is created and linked in cross reference dialogue.

Figure 69: Add new packaging record under authorised use

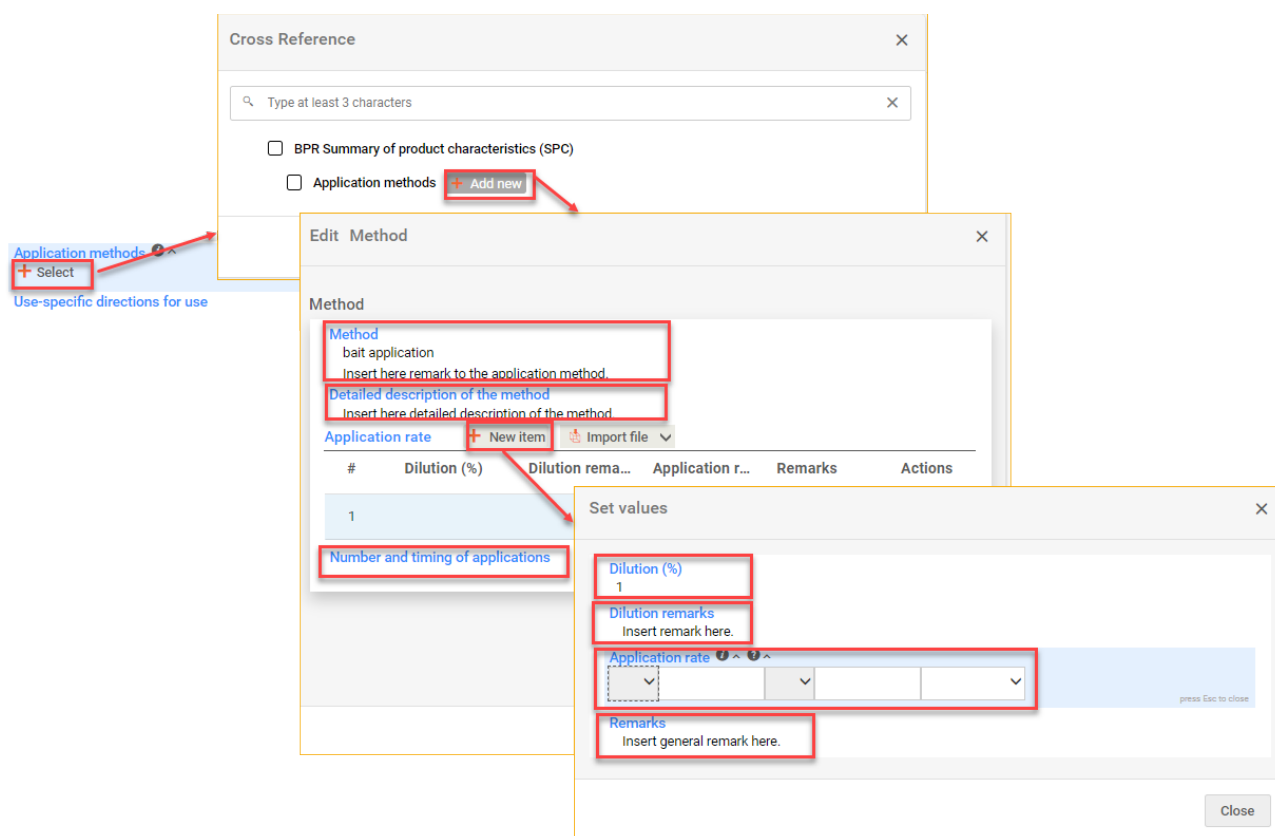


'Application methods' – link application methods record or create new one by clicking '+Select' in the field (Figure 70), after that cross reference dialogue opens and you may select from existing application methods records the relevant one.

To create new application method click '+Add New' (Figure 70), edit method dialogue opens.

Insert new application rate by selecting '+ New item' or you may use import functionality by clicking 'Import file'. After you have clicked '+New item' set values in each field: 'Dilution %', 'Dilution remarks' and 'Application rate' and 'Remarks' (Figure 70). Close set values dialogue. Remember to insert information about number and timing of application in the free text field when necessary and then save the method information dialogue. After that the method record is crated and linked in cross reference dialogue.

Figure 70: Add new application methods record under authorised use



'Use-specific directions for use' – - link use-specific directions for use record or create new one by clicking '+Select' in the field (Figure 71), after that cross reference dialogue opens and you may select from existing use-specific directions for use records the relevant one.

To create new Use-specific directions for use record click '+Add New' (Figure 71), edit Use-specific directions for use dialogue opens and information in free text fields: 'Use-specific instructions for use', 'Use-specific risk mitigation measures', 'Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment', 'Where specific to the use, the instructions for safe disposal of the product and its packaging' and 'Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage' (Figure 71); can be inserted.

Save use-specific directions for use information. After that the Use-specific directions for use record is created and linked in cross reference dialogue.

Figure 71: Add new use-specific directions for use record under authorised use

The image shows two overlapping windows from a software application. The top window, titled 'Cross Reference', contains a search bar with the placeholder text 'Type at least 3 characters' and a close button. Below the search bar, it displays 'BPR Summary of product characteristics (SPC)' and 'Use-specific directions for use' with an '+ Add new' button. A red box highlights the '+ Select' button in a blue sidebar on the left, with an arrow pointing to the '+ Add new' button. The bottom window, titled 'Edit Use-specific directions for use', contains five text input fields with the following labels: 'Use-specific instructions for use', 'Use-specific risk mitigation measures', 'Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment', 'Where specific to the use, the instructions for safe disposal of the product and its packaging', and 'Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage'. A red 'Save' button is located at the bottom right of this window.

Once record under 'Authorised uses' is saved it becomes cross referencable and can be linked in the relevant section in meta SPC of family SPC.

## VII. Specify general directions for use

### General directions for use

This section includes information on general directions for use.

To add information start by clicking '+' in table of content of SPC in section 'General directions of use' (Figure 72), populate information in relevant free text fields (Figure 72).

Insert information in following free-text fields: 'Instruction for use', 'Risk mitigation measures', 'Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment', 'Instructions for safe disposal of the product and its packaging' and 'Conditions of storage and shelf-life of the product under normal conditions of storage'. Save the record.

Figure 72: Identify general directions for use

The screenshot displays the 'SPC for biocidal product family NTX' interface. The breadcrumb trail is 'Dashboard > Mixtures / Products > SPC for biocidal product family NTX'. The main title is 'SPC for biocidal product family NTX' with the ID '3dfa08e8-dcf8-4fcd-82a9-0560f779c80b'. The 'Working context' is set to 'BPR Summary of product characteristics (SPC)'. A search bar contains the text 'Type at least 3 characters'. The left sidebar shows a tree view with 'General directions for use' selected and highlighted in blue, with a red '+' icon next to it. The main content area shows the 'General directions for use.001' record with the UUID '3509869f-7dd5-4ce2-b04b-8e928a7eb5d5'. The record contains five text fields, each with a red border: 'Instructions for use', 'Risk mitigation measures', 'Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment', 'Instructions for safe disposal of the product and its packaging', and 'Conditions of storage and shelf-life of the product under normal conditions of storage'. A 'Save' button is located at the bottom right of the record area.

Once record under 'General directions of use' is saved it becomes cross referencable and can be linked in the relevant section in meta SPC of family SPC.

## VIII. Insert any other information

### Other information

In this section you may enter any additional information.

To add information start with clicking '+' in the table of content of SPC in section 'Other information' and populate information in the free text field 'Other information' (Figure 73)



Figure 73: Insert any other relevant information

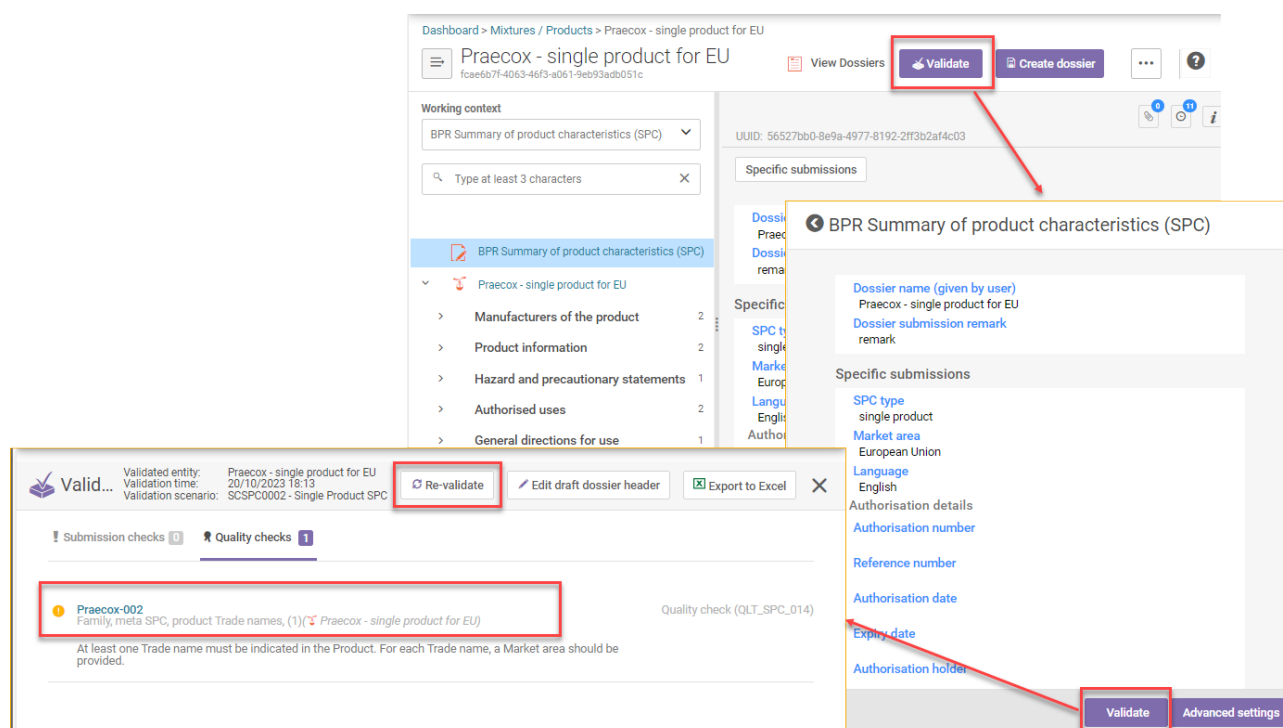
The screenshot displays the 'SPC for biocidal product family NTX' interface. The top navigation bar includes 'View Dossiers', 'Validate', and 'Create dossier' buttons. The left sidebar shows a tree view of the dossier structure, with 'Other information' expanded and 'Other information.001' selected. The main content area shows the 'Other information.001' record, which includes a UUID and a text input field labeled 'Other information' with the placeholder text 'Insert any other information here.'. A red box highlights the text input field, and a blue box highlights the 'Other information' label. A 'Save' button is located at the bottom right of the main content area.

Once record under 'Other information' is saved it becomes cross referencable and can be linked in the relevant section in meta SPC of family SPC.

## IX. Validate data

It is highly recommended to use validation functionality before creating your dossier from the prepared mixture/product dataset. To validate your mixture/product dataset you must have your dataset open, then click on top-right corner 'Validate' (Figure 74). Validation assistant is opening and displays the report (Figure 74). Follow the links in the report to fix the validation errors. Remember to save, if you are updating any of the data before returning to re-validation of your dataset.

Figure 74: Validate data in 'BPR Summary of product characteristics (SPC)'



## X. Create a dossier

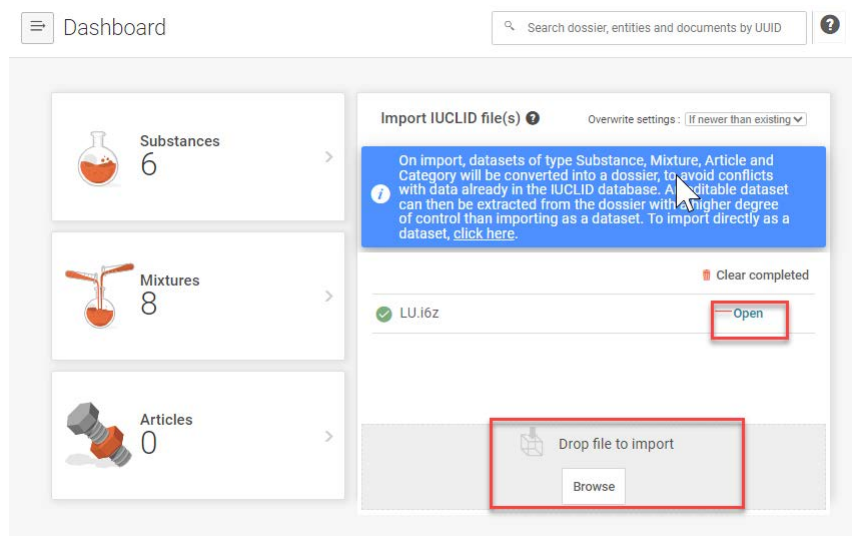
A dossier for BPR summary of product characteristics (SPC), must be created from a 'Mixture/product' dataset with a defined working context 'BPR summary of product characteristics (SPC)'. Once the dataset is complete refer to [chapter 7](#) ('How to create a dossier').

### How to create draft from final SPC dossier

To re-use data from an authorised SPC, the final SPC has to be downloaded from an asset in R4BP3 at first. Then import the downloaded file to your IUCLID instance in the IUCLID dashboard after that you can extract the data from SPC IUCLID dossier to a draft a dataset.

Start with dropping the downloaded dossier in the IUCLID dashboard or click on 'Browse' and select the file downloaded from R4BP 3 (Figure 75). Once the file appears in the dashboard, click 'Open' (Figure 75) this will open the dossier in your IUCLID instance.

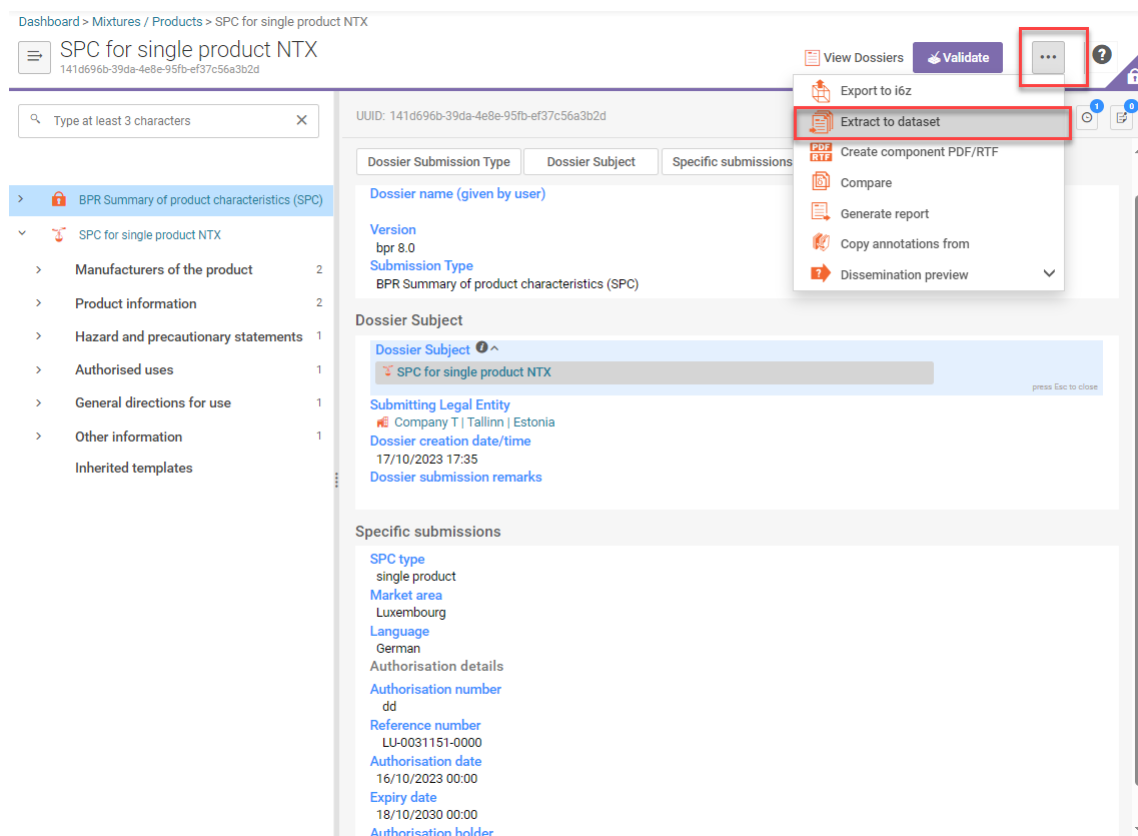
Figure 75: Import SPC dossier that has been downloaded from an asset from R4BP 3



Once you have clicked open, you can view the dossier. To start working on the new draft dataset you have to extract from the dossier the dataset at first, otherwise you can not edit data or create a new dossier.

Once you have opened the dossier click on '...' top-right corner and click on 'Extract dataset' (Figure 76).

Figure 76: Extract dataset from final SPC dossier downloaded from R4BP 3



After that 'Dataset extraction settings' window will open, to extract all records from the final SPC, select all data to be extracted (Figure 77) and click on 'Extract'.

Figure 77: Dataset extraction settings

The screenshot displays the 'Dataset extraction settings' window. On the left, a list of entities is shown with checkboxes and status labels: 'BPR Summary of product characteristics (SP...)' (ADDED), 'SPC for single product NTX' (ADDED), 'Ethanol' (CHANGED), 'Ethanol' (CHANGED), 'Ascorbic acid', 'Company T' (CHANGED (OLDER)), 'Sumitomo Chemical Agro Europe SAS', and 'Product Praecox production site'. The main area is titled 'SPC for single product NTX' and contains a 'Table of Contents' section with a dropdown menu set to 'BPR Summary of product characteristics (SPC)'. Below this is a 'Select documents' dropdown. The main list of items to be extracted includes: 'Manufacturers of the product' (Manufacturer of the product.001 ADDED, Location of manufacturing sites (Location of manufacturing site.001 ADDED)), 'Product information' (SPC name and legal entity (SPC for single product NTX ADDED), Family, meta SPC, product (Product NTX ADDED)), 'Hazard and precautionary statements' (Hazard and precautionary statements.001 ADDED), 'Authorised uses' (Use.001 ADDED), 'Target organisms' (Target organisms ADDED), 'Application methods' (Method ADDED), 'Packaging' (Packaging ADDED), 'Use-specific directions for use' (Use-specific directions for use ADDED), 'General directions for use' (General directions for use.001 ADDED), and 'Other information' (Other information.001 ADDED). At the bottom right, an 'Extract' button is visible. A red arrow points from this button to a smaller dialog box titled 'Extract dossier to dataset' which shows a green checkmark and the message 'Dataset has been extracted successfully'. This dialog box has 'Close' and 'Open' buttons, with the 'Open' button highlighted by a red box.

Once the dataset has been extracted successfully you can open it by clicking 'Open' and start working.

If you need to submit an application in R4B 3 that has a reference, you have to download the SPC IUCLID file from the reference asset. Make sure that family, meta SPC and product records preserve the very same record name/identifier (Figure 45) as in the reference SPC IUCLID. Also Authorisation details in the dataset must be preserved.

If this rule is not respected the submission in R4BP 3 wont be successful because the system cannot identify the reference.

## How to compare SPCs

This is a general IUCLID functionality, please refer to the general IUCLID 6 fuctionality instructions : [‘User manual of IUCLID 6’](#) (Compare documents)

## How to import/export information datasets

This is general IUCLID functionality, please refer to the general IUCLID 6 fuctionality instructions : [‘User manual of IUCLID 6’](#)

## 5. General IUCLID endpoint sections

Endpoint sections (IUCLID sections 3–13) comprise of either an endpoint study record or an endpoint summary (Figure 78). 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 78: IUCLID section tree components

Dashboard > Substances > Test substance

Test substance  
cbd272f8-10cd-4570-a2f0-c8003073a4e8

- Test substance
  - > 1 Applicant\*
  - > 2 Identity of the active substance\* 1
  - 3 Physical and chemical properties\*
    - 3.1 Appearance\*
    - 3.2 Melting point / freezing point\*
    - 3.3 Acidity, alkalinity\*
    - 3.4 Boiling point\*
    - 3.5 Relative density\*
    - 3.6 Absorption spectral data (UV/VIS, IR, NMR) and a mass spectrum, molar extinction at relevant wavelengths\*
    - > 3.7 Vapour pressure and Henry's law constant\*
    - 3.8 Surface tension\*
    - 3.9 Water solubility\*
    - 3.10 Partition coefficient (n-octanol/water) and its pH dependency\*
    - 3.11 Thermal stability, identity of breakdown products\*
    - 3.12 Reactivity towards container material\*
    - 3.13 Dissociation constant
    - 3.14 Granulometry\*
    - 3.15 Viscosity +
      - Viscosity
      - Viscosity
    - 3.16 Solubility in organic solvents, including effect of temperature on solubility
    - 3.17 Stability in organic solvents used in biocidal products and identity of relevant breakdown products
    - > 3.18 Additional physico-chemical properties of nanomaterials
  - > 4 Physical hazards and respective characteristics\*

To enter the scientific data for these sections, 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 lists with pre-selected responses, adding information by clicking '+ New Item' 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 list by clicking in the field.

- 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 lists by clicking in the relevant field. If 'other:' is selected from any of the drop-down menus, then the adjacent field must be filled in or selected (Figure 79).

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 79: Administrative data fields

**Administrative data**

**Endpoint**  
surface tension

**Type of information**  
experimental study

**Adequacy of study**  
key study

Robust study summary

Used for classification

Used for SDS

**Study period**  
None

**Reliability** ⓘ

1 (reliable without restriction)

2 (reliable with restrictions)

3 (not reliable)

4 (not assignable)

other:

**Justification for type of information**  
None

Save

### 'Data Source' block

In order to indicate literature reference under 'Reference' (Figure 80) click '+ Select' in the field. 'Select Literature reference' page is opened. Search for the relevant reference and then click on the title, this will add the reference to your data source.

It may be that the literature reference has not yet been entered into your database. In this case, click '+ Create' in the 'Select Reference' page to open the 'Create new Literature reference' dialogue. In this dialogue, enter the 'Title', and the other details of the literature reference and 'Save'.

As a minimum, the following fields are required:

- Provide 'Reference Type'
- Provide 'Title'
- Provide 'Author'
- 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 facility'. Provide the full address of the testing laboratory including the city and country. In addition, provide either 'Report no.' or 'Study no.' and other relevant information.
- If the data is from a company, fill in field 'Report no.' no.'. In addition, provide information in the fields 'Author' and select in the field 'Reference Type' value: other company data.

In data source block 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 80).

Figure 80: Data source table

The screenshot displays the 'Data source' table with a search and creation interface. On the left, the 'Data source' table has a 'Reference' dropdown menu with a '+ Select' button highlighted. The table shows two entries: 'test' and 'test attach', both with 'Author' and 'Bibliographic source' options. The search interface includes a search bar with '13 results found' and a '+ Create' button. The 'Create new Literature reference' form is open, showing fields for 'Reference Type', 'Title\*' (with a mandatory error message), 'Author', 'Year', 'Bibliographic source', 'Testing facility', 'Report no.', 'Study sponsor', 'Study no.', 'Report date', 'Remarks', 'Attached documents', and 'Attached (sanitised) documents for publication'. At the bottom, there is a '+ New item' button and a table with columns for '#...', 'Study ID', and 'Remarks'.

### '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 '+ New item' button. Alternatively, you may enter this information in the free text field 'Principles of method if other than guideline', since there may be cases where an alternative method has been developed, other than that in a guideline.

If 'other:' 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 81).

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 80).

Figure 81: 'Material and Methods' block for information on testing methods

Methods of detection and identification.002  
UUID: 8252bb10-5065-49bb-9444-49a6aa78db36  
None None

Administrative data | Data source | Background | **Materials and methods** | Results and discussion | Overall remarks, attac

Background  
Background information

Materials and methods  
Test guideline + New item Import file ▼

#	Qualifier	Guideline	Version / remarks
1	GLP compliance		

Set values ✕

Qualifier

Guideline

Version / remarks

Deviations

Principles of method if other than guideline

Other quality assurance

Matrix / medium

Test material  
Test material information

Additional test material information

Specific details on test material used for the study

Specific details on test material used for the study (confidential) ▲

Principles of analytical methods

There may be additional fields to be completed depending on the endpoint section being completed. For example, for substance the 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](#)).

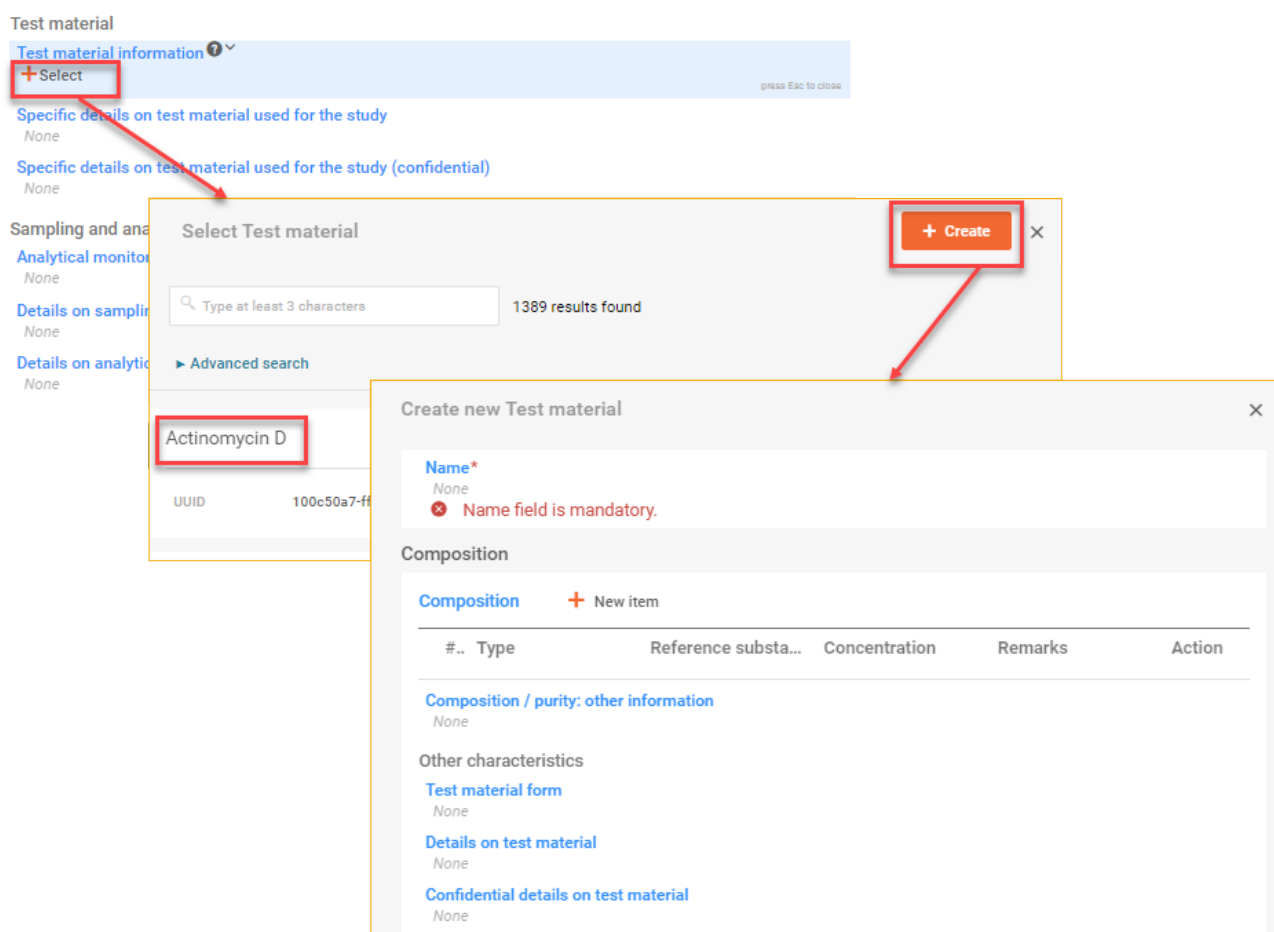
If the test material identity is same as for the substance defined in section 2.1, then it is optional to provide further information about the test material. If the test material is different, then assign

test material under 'Test material information' by clicking '+Select' in the field or fill in the field 'Specific details on test material used for the study' (Figure 82).

In order to indicate test material under 'Test material information', click '+ Select'.. Select the correct test material from the list or perform search.

It may be that the test material has not yet been entered into your database. In this case, click '+ Select', select Test material page is opening, click '+ Create' to open the 'Create new Test material' dialogue. In this dialogue, enter the name and other details of the test material.

Figure 82: 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, for example:

- 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<sub>2</sub>, 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.

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'.

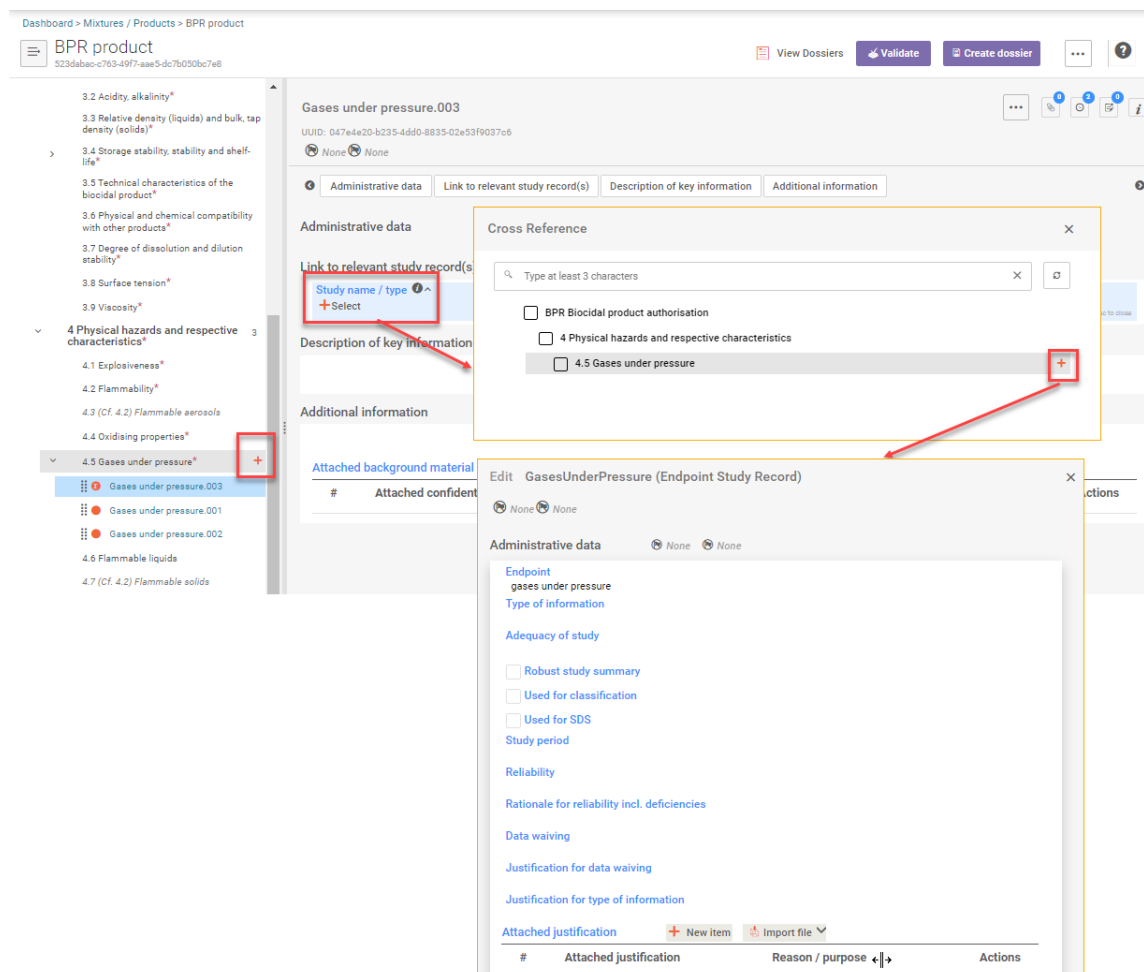
## 5.2. Endpoint study summaries

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 lists with pre-selected responses, adding entries 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 '+ Select' button and selecting the appropriate endpoint study record from the appearing page (Figure 83).

Figure 83: 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 12.1 'Classification and Labelling' and section 12.3 'Packaging (12.7 in Annex III of BPR', [section 6.3](#)
- Section 13 'Summary and evaluation', [section 6.4](#)

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

#### IUCLID section 7.1 'Field(s) of use envisaged for (representative) biocidal products and treated article'

This endpoint section enables the generation of a systemic overview of the intended uses of the (representative) biocidal product in the **Mixture-Product dataset**.

- Create a new record by clicking '+' in section 7.1 'Field(s) of use envisaged for biocidal products...' and enter the information in the fields provided relevant to your submission. For each use one record should be created.
- Select a 'Product type' from the available drop-down menu. Note that for AS applications, you must indicate the product type also in section 7.1 of the **AS dataset**. Depending on your application type you may select more than one product type in this section.

Describe in free text field, establish or create new links (Figure 84) between reported use and a relevant document in following fields:

- 'Detailed description of uses including in treated articles'.
- 'Target organismes'.
- 'Packagings'.
- ['Application methods'](#).
- ['Instructions for use and measures to protect humans, animals and the environment'](#)<sup>10</sup>.

---

<sup>10</sup> Please note that the field 'Instructions for use' in the document 'Measures to protect humans, animals and the environment' relates only to biocides working context BPR Summary of product characteristics (SPC). The instruction for use for the BPR Active substance application (representative product) and BPR Biocidal product authorisation should be inserted in section 7.6 and linked in the field 'Application methods')

Figure 84: Link between an intended use and target organisms

The screenshot displays a biocides dossier interface. On the left, a sidebar shows section 7 'Intended uses and exposure' with sub-sections 7.1 through 7.4. A red box highlights the 'Target organisms' section, which has a '+ Select' button. A red arrow points from this button to a 'Select existing document' dialog box. This dialog box lists a document titled 'EffectivenessAgainstTargetOrganisms' with a date of 29/10/2020 19:03. A red box highlights the document title, and another red arrow points from it to a '+ Create' button in the dialog. On the right, a detailed view of the 'Create new ENDPOINT\_STUDY\_RECORD.EffectivenessAgainstTargetOrganisms' record is shown. This view includes administrative data, endpoint information, and a table for 'Attached justification' and 'Cross-reference'.

**Create new ENDPOINT\_STUDY\_RECORD.EffectivenessAgainstTargetOrganisms**

Administrative data

Endpoint: None

Type of information: None

Adequacy of study: None

Robust study summary

Used for classification

Used for SDS

Study period: None

Reliability: None

Rationale for reliability incl. deficiencies: None

Data waiving: None

Justification for data waiving: None

Justification for type of information: None

Attached justification + New item

#...	Attached justification	Reason / purpose	Action

Cross-reference + New item

#...	Reason / purpose for cr...	Related information	Remarks	Action

Data source

Reference: None

Data access: None

Data protection claimed: None

### 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 '+' in section 7.5 'Likely tonnage to be placed on the market' and add 'New Item' in order to fill in the section (for as many blocks as you require) for each biocidal product type and/or year (Figure 85).

Figure 85: Entering the 'Likely tonnage to be placed on the market'

The screenshot displays the 'Test substance' interface. The sidebar on the left shows a tree view of sections, with '7.5 Likely tonnage to be placed on the market' highlighted and a red '+' icon next to it. The main content area shows the 'Likely tonnage to be placed on the market.001' section. Below the 'Administrative data' tab, there is a table titled 'Likely tonnage to be placed on the market'. The table has columns for '#', 'Product type', 'Year', 'Tonnage placed on L...', 'Remarks', and 'Actions'. A 'New item' button is highlighted in red. A 'Set values' dialog box is open over the table, showing input fields for 'Product type', 'Year', 'Tonnage placed on the market (t)', and 'Remarks'.

### IUCLID section 7.6 'Method of Application...'

This endpoint section enables the generation of a systemic overview of the directions of use for each of the uses described in [IUCLID section 7.1 'Fields of use...'](#) for the (representative) biocidal product.

- Create a new record clicking on '+' 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 86).
- Select a 'Method of application' from the available drop-down menu.
- Enter the 'Detailed description of method of application' in the free text field provided.
- Add rows to the table 'Application rate...' by clicking '+ New Item' and fill in the various parameters.
- Select an 'Application aim' from the available drop-down menu.
- Enter the 'Number and timing of applications' and 'Proposed instruction for use' in the free text fields provided.



Figure 86: Entering the method of application

Dashboard > Mixtures / Products > BPR product

BPR product  
523dabac-c763-49f7-aae5-dc7b050bc7e8

View Dossiers Validate Create dossier

Method of application and a description of this method.001  
UUID: 2a994973-1908-4f72-8968-14ff04f881bf

None None

Administrative data Directions for use

Administrative data None None

Directions for use

Method of application  
bait application

Detailed description of method of application  
Detailed description to be entered here.

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

New item Import file

#	Dilution (%)	Dilution rem...	Application r...	Final concen...	Final concen...	Remarks	Actions
1	10						
2	2						

Application aim  
Number and timing of  
Proposed instruction

Set values

- Dilution (%)  
10
- Dilution remarks
- Application rate
- Final concentration of active substance in treated article or system
- Final concentration of biocidal product in treated article or system
- Remarks

## 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 by clicking '+New document' 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 active substance or biocidal product, depending on the dataset working context you are completing.

-

## 6.3. IUCLID section 12 Classification and Labelling

There is sub-section for entering information related to the classification and labelling (C&L) of an active substance or a biocidal product;

- section 12.1 'GHS' and

Section 12.1 '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](#).

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 clicking '+' 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 87).

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 87). 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 87: How to specify the 'Classification' labels

The screenshot displays the 'Classification' section of a software interface. It is organized into three main hazard categories, each with its own set of fields:

- Physical Hazards**
  - Explosives
    - Hazard category:** Unst. Expl.
    - Hazard statement:** None
    - Reason for no classification:** data lacking
- Flammable gases and chemically unstable gases**
  - Hazard category:** Flam. Gas 1
  - Hazard statement:** H220: Extremely flammable gas.
  - Reason for no classification:** data lacking
- Aerosols**
  - Hazard category:** Aerosol 1
  - Hazard statement:** H223 : Flammable aerosol, H229 : Pressurised container: May burst if heated
  - Reason for no classification:** data lacking (This field is highlighted with a blue background and contains a dropdown menu with an 'x' icon.)

At the bottom of the interface, there is a 'Save' button and a 'TOP' button.

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

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.

Each 'GHS' record has to be referenced in every Biocidal product family composition representing meta SPC composition.

### 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 biocidal product (type, materials, size, compatibility of the biocidal product with proposed packaging materials etc.).

- Create a new record by clicking '+' in section 12.3, then enter the packaging information in the fields provided (Figure 88).
- If relevant, specify to which product(s) it applies: ' by clicking the '+ Select' button 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'](#).
- Select a type of packaging from the available drop-down menu.
- Enter the size and material of packaging (use the drop-down menus to include the unit). You can assign multiple size of packaging by clicking on the '+New item' button.
- Enter the compatibility of the biocidal product, and further description of the packaging, safety features and secondary packaging in the free text fields provided.
- Include additional packaging related attachments if available, e.g. a picture of the package, by clicking on the '+ New item' button.

Figure 88: Entering packaging information

The screenshot displays the IUCLID web interface for a biocidal product dossier. The main content area is titled 'Packaging (12.7 in Annex III of BPR).001'. It features a sidebar on the left with a tree view of sections, including '12.3 Packaging (12.7 in Annex III of BPR)\*' which is highlighted with a red box and a '+' icon. The main content area has tabs for 'Administrative data' and 'Packaging'. The 'Packaging' tab is active, showing a form with several sections: 'Administrative data', 'Packaging', 'Material of packaging in contact with the product (container material)', 'Compatibility of the product with the packaging materials proposed to be in contact with the product', 'Further description of the packaging in contact with the product', 'Safety features of the packaging', and 'Description of the secondary packaging (not in contact with the product)'. The 'Packaging' section includes a table with columns for '#', 'Type of attachment', 'Attached document', 'Remarks', and 'Actions'. A red box highlights the '+ New item' button in the 'Packaging related attachments' section. Another red box highlights the input field for 'Size of packaging in contact with the product (container size)'.

## 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, a supporting document, and/or a letter of access. These and any other pertinent supporting documents can be attached in IUCLID section 'Summary and Evaluation' 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 'Summary and Evaluation'.

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 'Summary and Evaluation' of the 'BPR Basic information (substance)/(mixture)' dataset(s). Please refer to Annex III, 2.3 of the BPR.

### Summary and evaluation

Create a new record by clicking '+' in section 13, then enter reports and administrative information in the fields provided.

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 supporting document, a risk assessment report, etc.). The hazard, exposure and risk assessment of the active substance in either the representative product (for active substance approval) or in the biocidal product to be authorised (for national authorisations or Union authorisations) should be provided.

Attach the appropriate documents by clicking '+ New item' as many times as needed (Figure 89). Select the applicable type from the drop-down menu and attach the documents by selecting the file (Figure 89). If no applicable type is available in the drop-down menu, then select 'other:' and enter the type of document you are attaching in the adjacent field.

Figure 89: Attaching documents in IUCLID section 13

The screenshot displays the 'Administrative data' section of the IUCLID interface. It features a table with the following sections:

- Reference product family composition:** None
- Summary and evaluation:** This section contains a table with a red-bordered '+ New item' button. A modal dialog box is open over this table, titled 'Type of report' (indicated by a blue circle with the number 1). The dialog shows 'other: Letter of access' and an 'Attached document' section with a 'Select file' button and a 'press Esc to close' instruction. Below the dialog is a 'Remarks' field with 'None' entered.
- Discussion:** This section is currently empty.

At the bottom right of the form, there is a red-bordered 'Save' button.

The 'Active substance related information' section contains some checkboxes and drop-down menus. Click on the checkboxes that concern your application, for example if you have a decision on technical equivalence, click the appropriate box and ensure you include the decision number (Figure 90). 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 90).

The Biocidal product related information section contains free text field - 'Other information relevant for the Summary' this should be used to include information concerning the Summary of Product Characteristics, if relevant (Figure 90). If you have authorisation numbers related to authorised biocidal products then enter these into the table clicking '+ New Item' and typing in the numbers and any remarks you have (Figure 90).

Figure 90: Section 13 Summary and evaluation (Including a decision on technical equivalence)

Active substance related information

Identification of any substances meeting the requirements listed in point 11.10 of Annex II to BPR

The source of substance is the same as was evaluated for inclusion in the Union list of approved active substances

The source of substance is considered equivalent to the Union list of approved active substances source.

If yes , technical equivalence decision number

The substance is a candidate for substitution

The substance has endocrine-disrupting properties

Biocidal product related information

Indication on the need for the biocidal product to carry the biohazard sign specified in Annex II to Directive 2000/54/EC

Biocidal product related information + New item 📄 Import file ▼

#	Authorisation number	Remarks
---	----------------------	---------

#### 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 'Endpoint study record' or 'Endpoint 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 '+ Select' that will open a 'Select reference substances' page. From the search results, select the relevant one, this will assign it to the reference substance field (Figure 91).

Under 'Composition of assessed substance', assign the relevant composition by clicking the '+ Select' button and selecting the relevant composition from the list.

Figure 91: Linking a 'Reference substance' and 'Composition' to a PBT record

The screenshot displays the 'PBT assessment.001' record for 'Oxalonitrile\_AS'. The interface is divided into several sections: 'Administrative data', 'Assessed Substance', and 'Results of detailed PBT / vPvB assessment'. The 'Assessed Substance' section is currently active, showing a 'Reference substance' field with a '+ Select' button. A modal window titled 'Select Reference substance' is open, displaying a search bar with 'oxal' and a search button. Below the search bar, a table lists search results, with 'Oxalonitrile' highlighted. The 'Results of detailed PBT / vPvB assessment' section shows 'Persistence' data for 'Oxalonitrile', including CAS number (460-19-5), IUPAC name, and inventory number (207-306-5). The 'PBT status of the assessment' section is partially visible, showing a dropdown menu with 'PBT assessment - EU' selected.

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

Use the drop-down menu to give an overall result under 'PBT status' (Figure 92), 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' section, by adding as many documents as need by clicking 'Select files'.



Figure 92: PBT endpoint summary

The screenshot displays a web application interface for managing biocides dossiers. The breadcrumb navigation at the top reads "Dashboard > Substances > Oxalonitrile\_AS". The main header shows the substance name "Oxalonitrile\_AS" and a unique identifier "96834eb5-9442-4c6b-b856-b203d24ee0ae". On the right, there are buttons for "View Dossiers" and a help icon.

The left sidebar, titled "Working context", shows a dropdown menu set to "BPR Active substance information" and a search input field. Below this is a navigation tree for "Oxalonitrile\_AS" with 13 numbered sections. Section 12, "Classification", is expanded to show "PBT assessment", which is further expanded to show "PBT assessment:002" and "PBT assessment:001".

The main content area is titled "PBT assessment.002" and includes a UUID: "da50d735-d518-4101-828f-8ced9ef47282". It has two tabs: "Administrative data" and "PBT assessment: overall result". The "PBT assessment: overall result" tab is active, showing a list of assessment items. The first item, "Assessed composition(s)", is highlighted with a red box and includes a "+ Select" button. Other items listed are "PBT status", "Justification", "Likely routes of exposure", and "Additional information".

## 7. How to create a dossier

Once you have finalised and validated the data in the relevant dataset, you may proceed with dossier creation.

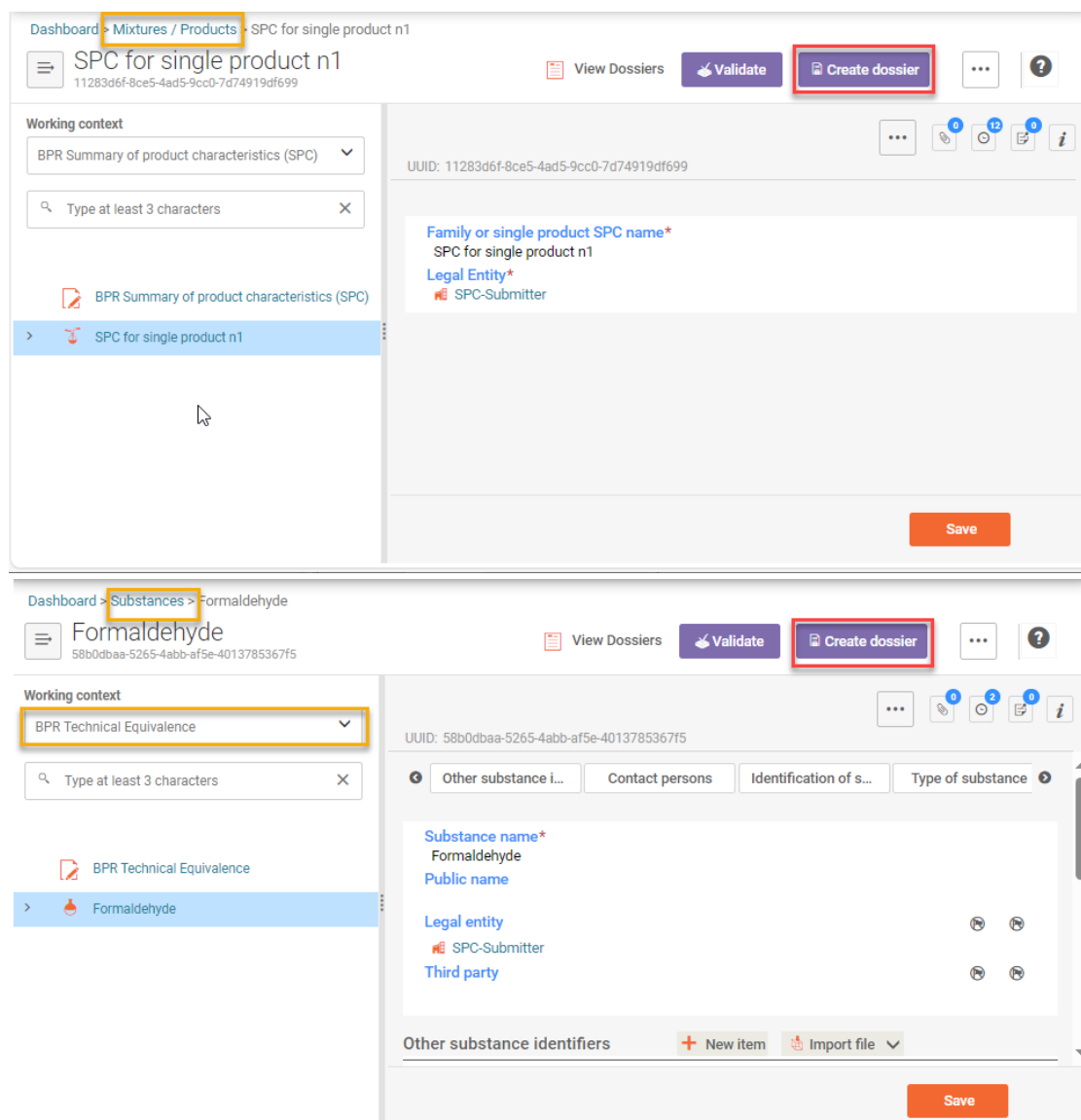
Dossier for a **SPC** is to be created from mixture/product dataset with working context '**BPR Summary of product characteristics (SPC)**'

Dossier for a **product authorisation** is to be created from mixture/product dataset with working context '**BPR Biocidal Product authorisation**', including a link to a 'Substance' dataset in [IUCLID section 2.3 'Biocidal product composition'](#).

Dossier for an **active substance authorisation** is to be created from mixture/product dataset with working context '**BPR Active substance application (representative product)**', including a link to a 'Substance' dataset in [IUCLID section 2.3 'Biocidal product composition'](#).

Dossier for for an assessment of **technical equivalence** is to be created from substance dataset with working context '**BPR Technical equivalence**'

Figure 93: Launching the dossier creation wizard



## 7.1. The dossier creation wizard

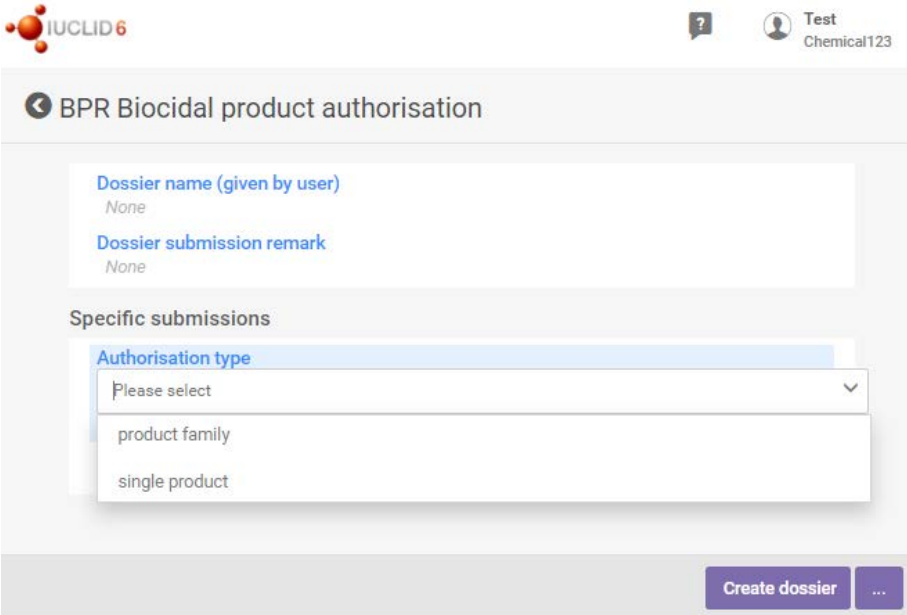
The dossier creation wizard will guide you through a set of steps in order to create the relevant dossier type, either a 'BPR Active substance application (representative product)' dossier or a 'BPR Technical Equivalence' dossier or a 'BPR Biocidal product authorisation' or 'BPR Summary of product characteristics (SPC)' 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](#).

Dossier creation is started by clicking on the button labelled 'Create dossier', which is shown at the upper right of the record of a dataset. If the button is dimmed and cannot be clicked on, select a working context.

Give name to your dossier and insert dossier submission remark, if relevant. You can also indicate whether a submission is an update. For BPR Biocidal product authorisation indicate in the field 'Authorisation type' if you submit a dossier for a single product or product family (Figure 94)

Figure 94: Specific Submission



The screenshot shows the IUCLID 6 interface for creating a BPR Biocidal product authorisation dossier. At the top left is the IUCLID 6 logo. At the top right, there is a help icon (question mark) and a user profile icon labeled 'Test Chemical123'. Below the header, the page title is 'BPR Biocidal product authorisation'. The main form area contains two input fields: 'Dossier name (given by user)' with the value 'None' and 'Dossier submission remark' with the value 'None'. Below these is a section titled 'Specific submissions' containing a dropdown menu for 'Authorisation type'. The dropdown is open, showing the options 'Please select', 'product family', and 'single product'. At the bottom right of the form, there are two buttons: 'Create dossier' and a button with three dots '...'.

Then click on one of the buttons at the foot of the page. To use default settings, click on Create dossier, in which case you can skip the next section. To use advanced settings, click on the button labelled with three dots '...' (Figure 95).

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

Figure 95: Dossier creation wizard, open advanced settings

The screenshot shows the 'BPR Active substance application (representative product)' dossier creation wizard. The main form has three sections: 'Dossier name (given by user)' with the text 'Test Dossier', 'Dossier submission remark' with an empty text area, and 'Specific submissions' with a checkbox 'The submission is an update' which is unchecked. An 'Advanced settings' modal window is open, containing the following sections:

- Include legal entity**: A checkbox labeled 'Include legal entity' which is unchecked.
- Detail level of document fields**: Two checked checkboxes: 'Detailed fields (e.g. needed for robust endpoint summaries)' and 'Fields marked "confidential"'. There is also an unchecked checkbox for 'Fields marked "confidential"'.
- Flags for confidentiality**: A dropdown menu labeled 'Select information to be included' with a list of items: 'Data for which a confidentiality flag may be set, but it is not.', 'CBI', 'IP', and 'no PA'. Each item has an 'X' icon to its right.
- Flags for regulatory programme**: A dropdown menu labeled 'Select information to be included'.

At the bottom right of the main form is a 'Create dossier' button with a red-bordered ellipsis menu icon. A red arrow points from the 'Advanced settings' modal window to this ellipsis icon.

- Review the related entities, e.g. that correct dataset has been linked.
- (visible by selecting 'Use advanced settings')
- Filter the information to be included in the dossier.
- In general, the 'Legal entity owner' in section 2.1 of the biocidal product dataset will not be included in the dossier. However, if you wish to include the legal entity (i.e. your company name and details) in your dossier e.g. for your personal record keeping purposes, select 'Include legal entity' (Figure 96).

However for the mixture dataset with working context 'BPR Summary of product characteristics' it is included by default.

- 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 advanced settings, when creating a dossier (Figure 96).

Figure 96: Dossier creation wizard, advanced settings

**Advanced settings** [X]

**Include legal entity**

Include legal entity

Select "Include legal entity" if you wish that your company details appear in the dossier header and section 2.1 of Mixture / Product dataset

**Detail level of document fields**

Detailed fields (e.g. needed for robust endpoint summaries)

Fields marked "confidential"

**Flags for confidentiality**

Select information to be included

[Dropdown menu]

Data for which a confidentiality flag may be set, but it is not. [X]

CBI [X]

IP [X]

no PA [X]

**Flags for regulatory programme**

Select information to be included

[Dropdown menu]

No regulatory purposes [X]

EU: BPD or EU: BPR [X]

EU: CLP [X]

EU: PPP [X]

EU: REACH [X]

**Create dossier**

By default all the information in the datasets will be included in the dossier.

If you de-select some information here, it will not be included in the dossier.

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.

- Verify the inclusion or exclusion of annotations.

- (visible by selecting advanced settings '...' when creating a dossier)
- 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, deselect it in the relevant dataset. (Figure 97).

Figure 97: Verifying the sections to be included

The screenshot shows the 'Advanced settings' dialog box with the following content:

- Dossier Settings**
  - Detailed fields (e.g. needed for robust endpoint summaries)
  - Fields marked "confidential"
- Flags for confidentiality**
  - Select information to be included
  - Data for which a confidentiality flag may be set, but it is not.
  - CBI
  - IP
  - no PA
- Flags for regulatory programme**
  - Select information to be included
  - No regulatory purposes
  - EU: BPD or EU: BPR
  - EU: CLP
  - EU: PPP
  - EU: REACH
  - CA: CEPA
  - CA: PCPA
  - JP: CSCL
  - OECD: CoCAP
  - US: EPA HPVC
  - US: FIFRA
  - US: TSCA
  - other:
- Included Annotations**
  - Include annotations
- Advanced settings**
  - Document selection**
  - Entities**
    - Representative bio... >
    - Reaction by produ... >
    - Ethane-1,2-diol
    - Test Legal Entity
    - Test Manufacturer
    - LastName, FirstNam...
  - Documents**
    - Representative biocidal product dataset for several representative products
      - 2 Identity of the representative biocidal product
        - 2.3 Representative biocidal product composition
          - Representative biocidal product 1 composition BP1
          - Representative biocidal product 2 composition BP2
      - 6 Effectiveness against target organisms
        - 6.7 Efficacy data to support these claims
          - Efficacy data to support these claims BP1
          - Efficacy data to support these claims BP2
      - 7 Intended uses and exposure
        - 7.1 Field(s) of use envisaged for representative biocidal products and...
          - Field(s) of use envisaged for representative biocidal products and tr...
          - Field(s) of use envisaged for representative biocidal products and tr...
      - 13 Summary and evaluation
        - Draft risk assessment reports

- 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](#)).
- A prompt window will appear, giving an option to open the newly created dossier. The dossier can be run by validation rules in order to verify if basic information is compiled correctly in the dossier. Clicking 'Open dossier' will direct you to the dossier information page (Figure 98). To view the full dossier content see [chapter 7.2.2](#).

Figure 98: Dossier information

View Dossiers **Go to source** Validate

UUID: b152c201-66a7-470a-b694-b0fd3a17210a  Hide empty fields

### Dossier Submission Type

**Dossier name (given by user)**  
Test product authorisation-Biocides Dossier

**Version**  
bpr 6.0

**Submission Type**  
BPR Biocidal product authorisation

### Dossier Subject

**Dossier Subject**  
test product authorisation-Biocides

**Submitting Legal Entity**  
None

**Dossier creation date/time**  
2020-10-29T20:37:54.705

**Dossier submission remarks**  
None

### Specific submissions

**Authorisation type**  
None

The submission is an update

**Last submission number**  
None

**Reason for updating**

Further to a request/decision from a regulatory body

**Number**

Spontaneous update

**Justification**

- You can access from your dossier the mixture/product dataset by clicking 'Go to source' (Figure 98).
- You may run the validation assistant on your dossier or a dataset, for that click 'Validate' (Figure 99). 'Validate' functionality is available either before creating the dossier in the dataset view or once the dossier has been created already in the dossier view.

Once you have clicked 'Validate' the validation assistant will run the set of rules relevant for the working context, and will display the business rules that failed in your dossier (Figure 100). Read a message(s), and correct your data accordingly. You have to open a dataset to correct the data there and re-create dossier, if you decide to fix the errors.



Figure 99: Run the validation

The figure consists of two screenshots from the ECHA system interface. The top screenshot shows the 'Test Mixture-Product dataset' page. The breadcrumb navigation is 'Dashboard > Mixture / Products > Test Mixture-Product dataset'. The page title is 'Test Mixture-Product dataset' with the UUID 'e1ce7ad0-8cfd-46ae-b15c-90fd277b0108'. The 'Submission Type' is 'BPR Active substance application'. A red box highlights the 'Validate' button. The 'Mixture / Product Information' section shows: Mixture / Product name: Test Mixture-Product dataset; Legal entity: Test Legal Entity; UUID: e1ce7ad0-8cfd-46ae-b15c-90fd277b0108. The bottom screenshot shows the 'Test Dossier-2' page. The breadcrumb navigation is 'Dashboard > Mixture / Products > Test Mixture-Product dataset'. The page title is 'Test Dossier-2' with the UUID 'c0fecba9-b0bd-4fc1-861c-146fe446ff85'. The 'Table of contents' on the left lists six sections. The 'Dossier Information' section shows: Submission type: BPR Active substance application (representative product); Dossier name: Test Dossier-2; Subject: Test Mixture-Product dataset; Submitting legal entity; Created on: 19/07/2019 14:35. A red box highlights the 'Validate' button.

Figure 100: Validation assistant wizard

The figure consists of two screenshots from the validation assistant wizard. The top screenshot shows a 'Create dossier' dialog box with a red 'X' icon and the message: 'You have 1 Submission rules which require fixing. We highly recommend you fix these errors before creating and submitting your dossier.' There are two buttons: 'Continue with dossier creation' and 'View/fix errors', with a red box around the latter and a red arrow pointing to it. The bottom screenshot shows the 'Validation assistant report' dialog box. It includes the following information: Validated entity: Biocides test; Validation time: 19/07/2019 14:46; Validation scenario: BPR Biocidal product authorisation. There are buttons for 'Re-validate' and 'Edit dossier settings'. The report shows: Submission checks: 1 (with a red 'X' icon); Quality checks: 0. Business rules: 1; Completeness check rules: 0. Total rules executed: 1. A specific error is listed: '2.3 Biocidal product composition' with the message: 'The selected Biocidal Product dataset is not valid for creating BPR Biocidal product authorisation dossier. Valid Biocidal Product dataset for this dossier type must contain at least one component with function 'active substance' and a linked substance dataset. If there is more components with function 'active substance', a relevant substance or mixture dataset must be linked to each one.' The business rule is identified as 'Business rule (BPR001)'.

## 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. More options are available in advanced search option. To search dossier, go to the IUCLID 6

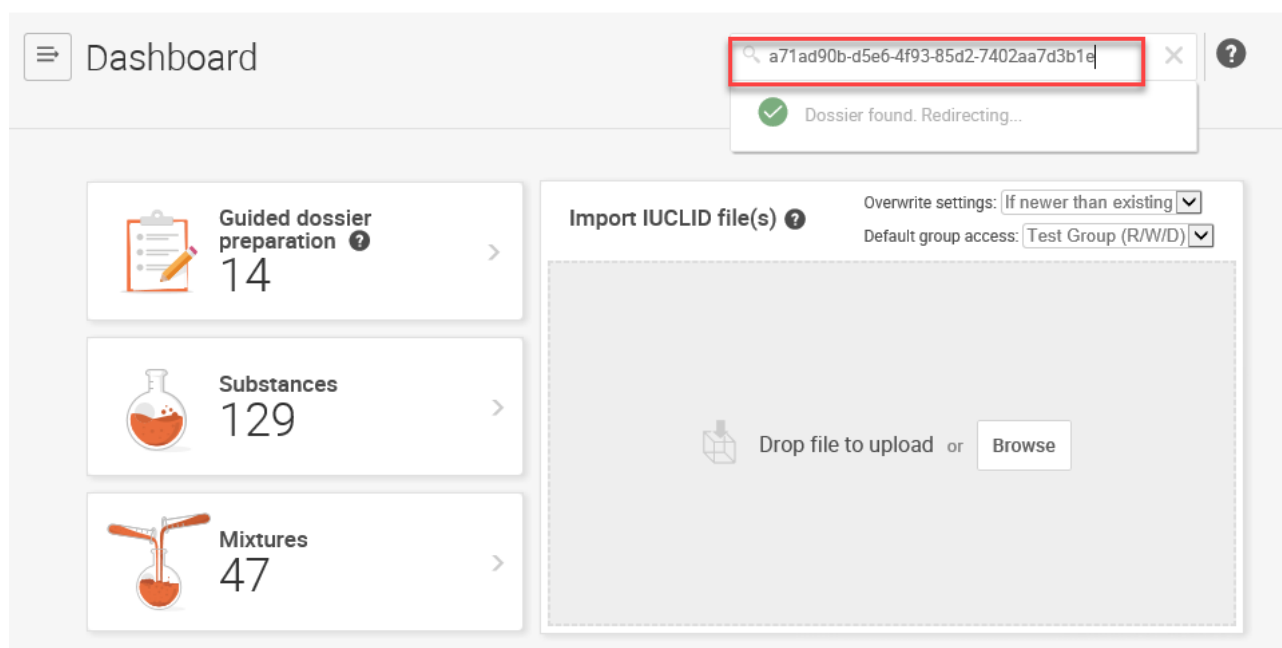
dashboard and click on the 'Mixtures' (Figure 101). This will open the mixtures / products page, click 'Dossiers', and list of your dossiers will be displayed. Type in the name of your dossier either partly or full name and relevant dossier(s) will be listed. When you have located the relevant dossier, click on the dossier title to open the 'Dossier information' page (Figure 101).

Figure 101: Searching for a dossier with the dossier name

The image shows two screenshots of the IUCLID 6 interface. The top screenshot shows the main dashboard with a search bar and several data cards: 'Guided dossier preparation' (23), 'Substances' (545), 'Articles' (26), and 'Mixtures' (306). A red box highlights the 'Mixtures' card, and a red arrow points to the bottom screenshot. The bottom screenshot shows the 'Mixtures / Products' page. A search bar contains the text 'test product authorisation-Biocides'. The 'Dossiers' tab is selected. Below the search bar, it says '2 results found'. A table lists the results, with the first row highlighted: 'Test product authorisation-Biocides Dossier' with a date of '29/10/2020 20:37'. Below the table, the following information is displayed: Subject name: test product authorisation-Biocides, Submission type: BPR Biocidal product authorisation, Dossier UUID: b152c201-66a7-470a-b694-b0fd3a17210a.

To search for a dossier with the unique dossier UUID, use the 'Search entities and dossiers by UUID' field in the upper right corner of the IUCLID 6 dashboard (Figure 102). The dossier UUID can be obtained from the dossier header under the name of the dossier.

Figure 102: Searching for a dossier with the dossier UUID



### Viewing the full dossier content

You can view the dossier components on the dossier page (e.g. the datasets, legal entity etc.). Click the '^' sign to expand the section tree and view all the components (Figure 103).

You can view the dataset content within the dossier by clicking on either the substance component name or 'Go to source'. The mixture / product dataset page is displayed for viewing and editing (Figure 103).

Once you edit your mixture /product dataset you have to create a new dossier.

Figure 103: Viewing the 'TOC'

The screenshot shows a web interface for a BPR product dossier. At the top, there is a breadcrumb trail: "Dashboard > Mixtures / Products > BPR product". Below this, the title "BPR product" is displayed with a unique identifier "523dabac-c763-49f7-aae5-dc7b050bc7e8". A "Working context" dropdown menu is set to "BPR Biocidal product authorisation". A search bar contains the text "Type at least 3 characters". The main content is a list of sections, each with a right-pointing chevron and a page number. The sections are: 1 Applicant\* (1 page), 2 Identity of the biocidal product\* (4 pages), 3 Physical, chemical and technical properties\* (4 pages), 4 Physical hazards and respective characteristics\* (4 pages), 5 Methods of detection and identification\* (1 page), 6 Effectiveness against target organisms\* (2 pages), 7 Intended uses and exposure\* (2 pages), 8 Toxicological profile for humans and animals\* (1 page), 9 Ecotoxicological studies\* (1 page), 10 Environmental fate and behaviour\* (1 page), 11 Measures to protect humans, animals and the environment\* (1 page), 12 Classification & Labelling\* (2 pages), and 13 Summary and evaluation (1 page). Under section 12, there are sub-sections: 12.1 GHS\* (1 page) with a red dot next to "GHS.001", and 12.3 Packaging (12.7 in Annex III of BPR)\* (1 page) with a red dot next to "Packaging (12.7 in Annex III of BPR).001". At the bottom, there is a link for "Inherited templates".

Section	Page Count
1 Applicant*	1
2 Identity of the biocidal product*	4
3 Physical, chemical and technical properties*	4
4 Physical hazards and respective characteristics*	4
5 Methods of detection and identification*	1
6 Effectiveness against target organisms*	2
7 Intended uses and exposure*	2
8 Toxicological profile for humans and animals*	1
9 Ecotoxicological studies*	1
10 Environmental fate and behaviour*	1
11 Measures to protect humans, animals and the environment*	1
12 Classification & Labelling*	2
12.1 GHS*	1
GHS.001	
12.3 Packaging (12.7 in Annex III of BPR)*	1
Packaging (12.7 in Annex III of BPR).001	
13 Summary and evaluation	1

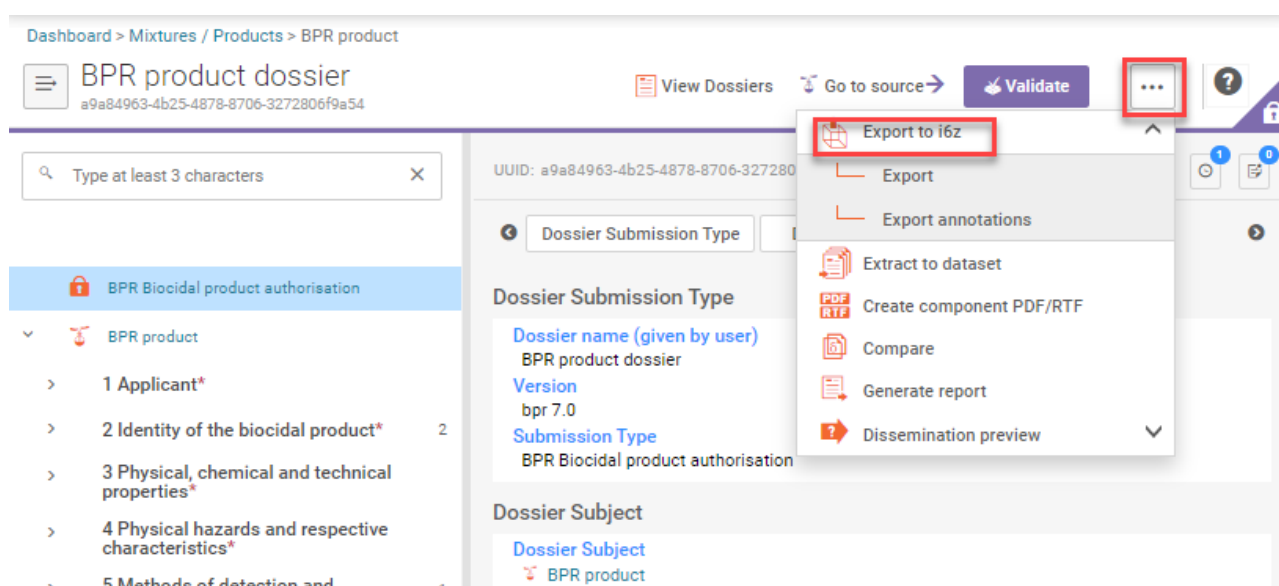
You can edit data either accessing the relevant components via opening mixture / product dataset from your dossier or searching and opening the relevant dataset from the IUCLID 6 dashboard page.

Remember that a dossier is a non-editable snapshot of the datasets. If you find mistakes in the dossier, update the relevant component. Then, create a new dossier and validate it as outlined in [chapter 7.1](#).

### 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 to I6z' (Figure 104). This will launch the Export assistant (Figure 104).

Figure 104: Exporting 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 explain how a mixture containing an active substance shall be included 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 working context '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 asterisk.

**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 (Figure 105). 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 105: Sections of the active substance dataset working context 'BPR Active substance information'

Dashboard > Substances > Oxalonitrile\_AS

Oxalonitrile  
96834eb5-9442-4c6b-b856-b203d24ee0ae

Working context  
BPR Active substance information

Type at least 3 characters

Oxalonitrile\_AS

>	1 Applicant*	2
>	2 Identity of the active substance*	2
>	3 Physical and chemical properties*	1
>	4 Physical hazards and respective characteristics*	1
>	5 Methods of detection and identification*	1
>	6 Effectiveness against target organisms*	
>	7 Intended uses and exposure*	1
>	8 Toxicological profile for humans and animals*	
>	9 Ecotoxicological studies*	
>	10 Environmental fate and behaviour*	
>	11 Measures to protect humans, animals and the environment*	
>	12 Classification & Labelling*	
>	13 Summary and evaluation*	3

Inherited templates

## Step 2: CREATE A MIXTURE DATASET

A new mixture/product dataset should be created for the mixture using the dataset working context 'BPR Basic information (mixture)' (Refer to [chapter 2.1.2 'Supplementary dataset templates'](#) for more details). All mandatory sections, marked with a red asterisk, shall be filled in (Figure 106).

Figure 106: BPR Basic information (mixture) view

Dashboard > Mixtures / Products > BPR product

BPR product  
523dabac-c763-49f7-aae5-dc7b050bc7e8

Working context

BPR Basic information (mixture) ▼

🔍 Type at least 3 characters ✕

▼ BPR product

- > 1 Applicant
- > 2 Identity of the mixture\* 4
- > 3 Physical, chemical and technical properties
- > 4 Physical hazards and respective characteristics 4
- > 5 Methods of detection and identification 1
- > 6 Effectiveness against target organisms
- > 7 Likely tonnage to be placed on the market
- > 8 Toxicological profile for humans and animals
- > 9 Ecotoxicological studies
- > 10 Environmental fate and behaviour
- > 11 Measures to protect humans, animals and the environment 1
- > 12 Classification & Labelling 1
- > 13 Summary and evaluation 1

Inherited templates

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 (Figure 107).



Figure 107: Section 2.3 of BPR Basic information (mixture)

The screenshot shows the 'BPR product' interface. The sidebar on the left contains a tree view with sections 1 through 13. Section 2.3 'Mixture composition\*' is highlighted, and its sub-item 'Representative biocidal product composition.001' is selected. The main content area displays the details for this composition, including 'Country' (Best product 1), 'Trade name' (Best product 1), and a table of components. The table has columns for '#', 'Compo...', 'Name', 'Function', 'Typical ...', 'Concen...', 'Remarks', 'Substa...', 'Generic...', 'Interch...', 'Standar...', 'Substa...', and 'Actions'. One component is listed with '# 1', 'Name Oxalotrile', and 'Function active substance'.

### Step 3: SPECIFY THE BIOCIDAL PRODUCT COMPOSITION AND CREATE BIOCIDAL PRODUCT DATASET

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 components should be created in IUCLID section 2.3 'Biocidal product composition' (both in the same endpoint, see Figure 108).

The first component should have:

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

The second component 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 108: Section 2.3 of BPR Biocidal product authorisation or BPR Active substance application (representative product) - two components related to a mixture that contains an active substance

Dashboard > Mixtures / Products > BPR product

BPR product containing a mixture  
523dabac-c763-49f7-aae5-dc7b050bc7e8

Working context  
BPR Basic information (mixture)

Type at least 3 characters

BPR product containing a mixture

1 Applicant

2 Identity of the mixture\* 2

2.1 Common name and synonyms 1

2.2 Manufacturer's development code number(s)

2.3 Mixture composition\* 1

Representative biocidal product composition.001

3 Physical, chemical and technical properties

4 Physical hazards and respective characteristics 4

5 Methods of detection and identification 1

6 Effectiveness against target organisms

7 Likely tonnage to be placed on the market

8 Toxicological profile for humans and animals

9 Ecotoxicological studies

10 Environmental fate and behaviour

11 Measures to protect humans, animals and the environment 1

12 Classification & Labelling 1

13 Summary and evaluation 1

Representative biocidal product composition.001  
UUID: e203701f-6523-4f97-9563-6cac28e25b02

None None

Administrative data General information Components

Administrative data None None

General information

Mixture/product name  
Mixture 1

Trade names + New item Import file

Brief description

Formulation type

Components

+ New item Import file

#	Compo...	Name	Function	Typical ... C
1	None None	BPR product containing a mixture	active substance	5 % (w/w)
2	None None	Oxalotrile   EC 207-306-5   460-19-5	active substance	0 % (w/w)

### 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).

You can view the dataset content within the dossier by clicking on the mixture/product component under the 'Components' section (See [chapter 7.2.2 'Viewing the full dossier content'](#) for more details).

## **I. ACTIVE SUBSTANCE COMPONENT OF THE MIXTURE**

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'.

## **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)'.

## **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)'.

## Annex 2. How to report, in IUCLID, active substance(s) generated in situ

### 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. This is done by including the active substance dataset(s) in the IUCLID dossier submitted for the application.

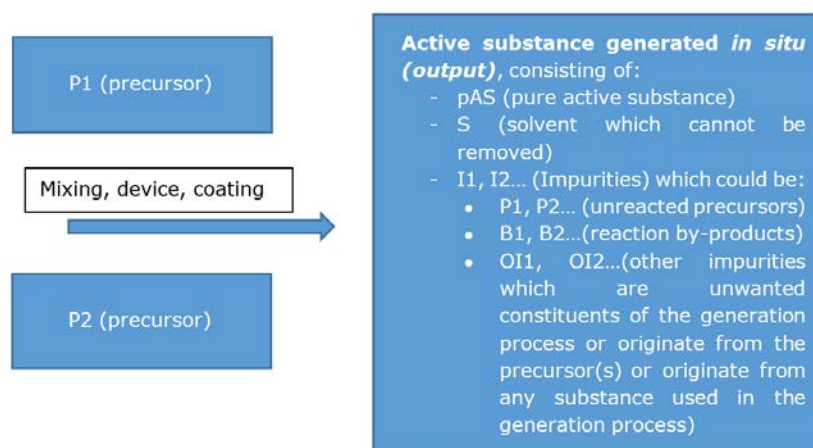
According to Article 6(b) of the BPR, an active substance application dossier shall contain the information satisfying the requirements set out in Annex III for at least one representative biocidal product that contains the active substance. Therefore each active substance application has to include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

### IN SITU GENERATED ACTIVE SUBSTANCES

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

All substances and/or mixtures used as precursors, as well as all constituents of a substance generated in-situ, listed in Figure 109, shall be reported in the IUCLID technical dossier.

Figure 109: In-situ generation reaction scheme<sup>11</sup>



The applicant needs to create a dataset for each precursor, active substance, reaction by-product and impurity in order to provide all required data. All these datasets shall be linked as components of a biocidal product, defined in the composition document of the biocidal product

<sup>11</sup> According to CA-July19-Doc.4.1-Final\_in situ\_rev3; see CIRCABC: <https://circabc.europa.eu/ui/group/e947a950-8032-4df9-a3f0-f61eefd3d81b/library/4e21245b-e359-47a7-900a-40c90785f360/details>

dataset. If the applicant is aware of any disinfection by-products, these also need to be reported. The data requirements for precursors, active substance, reaction by-products, and other impurities, shall be entered in IUCLID using the numbering system for active substance, in essence BPR Annex II. Whenever one or more substance(s) are used as precursor(s), the data for those substances have to be provided in separate substance datasets using the numbering system for active substance (BPR Annex II). Description of the process of preparing the mixture should be provided.

Detailed step by step instructions on how to create relevant datasets and how to link them to a biocidal product dataset are presented hereafter.

## **Creation of the datasets**

### **Step 1: CREATE AN ACTIVE SUBSTANCE (IN SITU) DATASET**

A new substance dataset should be created for the active substance using the working context 'BPR Active substance information'. This dataset will be linked to the biocidal product composition. This is done exactly in the same way as for conventional active substances datasets included in a biocidal product or linked to a representative biocidal product in the case of an active substance application (Refer to [chapter 2.1.1 'Main dataset templates'](#) of this manual).

The reaction pathways describing how the active substance is generated in situ should be inserted in IUCLID section 2.9 of the active substance dataset under 'Description'. If needed, additional details for the method can be included as an attachment under 'Attached description/justification'.

### **Step 2. CREATE DATASET(S) FOR PRECURSOR(S) OF AN IN SITU ACTIVE SUBSTANCE**

For each precursor of an in situ active substance a separate substance dataset shall be created. Depending on the properties of the precursor, the corresponding dataset, i.e. 'BPR Substance of concern' or 'BPR Basic information (substance)' should be used to insert the required data. The substance of concern is defined in the Biocidal Products Regulation. The working context 'BPR Basic information (substance)' should be used for all other substances. The working context 'BPR Basic information (mixture)' should be used for all mixtures, corresponding substance datasets should be linked in the mixture composition. The content of impurities and additives in the precursor(s) need to be always specified.

### **Step 3. CREATE DATASETS FOR REACTION BY-PRODUCTS, IMPURITIES AND DISINFECTION BY-PRODUCTS**

For each reaction by-product and each impurity, as well as for a disinfection by-product (if known), a separate substance dataset shall be created. The relevant substance dataset should be used to insert the required data, e.g. 'BPR Substance of concern' or 'BPR Basic information (substance)'. The substance of concern is defined in the Biocidal Products Regulation. The working context 'BPR Basic information (substance)' should be used for all other substances.

All co-formulants (components) used for the biocidal product need to have also its own dataset including the content of impurities and additives.

-

### - SPECIFY THE BIOCIDAL PRODUCT COMPOSITION

All datasets prepared in steps 1-3 should be inserted as 'Components' of the composition in IUCLID section 2.3 'Biocidal product composition' or 2.3 'Representative biocidal product composition' of the biocidal product dataset.

In order to provide the assessor with the maximum of information, three different compositions should be provided (Figure 110):

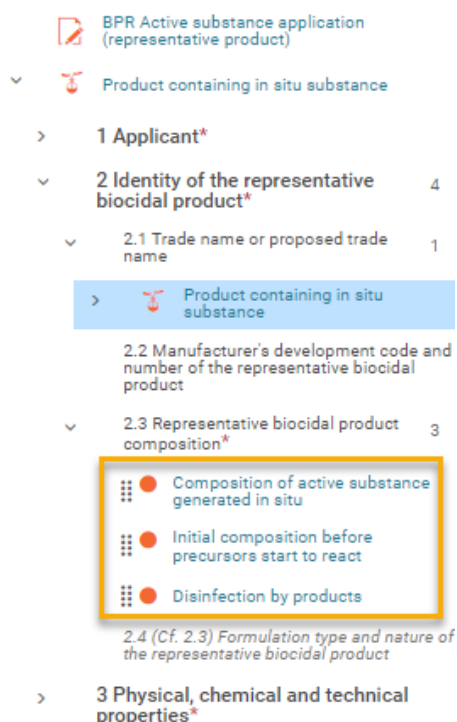
1) Composition of the Active Substance generated in situ: this composition describes the substance generated in situ and contains all related datasets (pure active substance, unreacted precursors, reaction by-products, impurities) (see also Figure 109, right side)

2) Initial composition before precursors start to react (in practice, composition of the biocidal product as defined above in accordance with the BPR): this composition contains all precursor datasets and specifies their concentrations before they start to react (see also Figure 109, left side)

3) Disinfection by-products: this composition contains all datasets of disinfection by-product(s), but does not need to specify their concentrations.

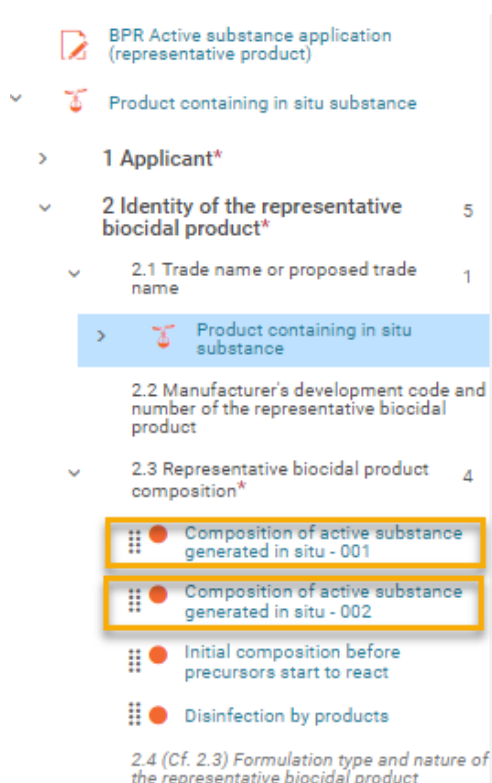
The first two composition types should be provided in all cases while the last one should be provided only when relevant. The first composition should always contain an active substance dataset.

Figure 110: Biocidal product composition for in situ active substance applications



If any of the above mentioned compositions varies depending on conditions, intended uses, or other factors, then more composition records should be provided under section 2.3 (Figure 111).

Figure 111: Biocidal product composition - more composition records if the composition on each stage varies



Filling in the data and linking the component datasets into the compositions is done in the following way:

Initial composition before precursors start to react (reported as a second composition record):

Entered precursor(s) of in situ generated active substance should have the following data provided as 'Components':

- Linked precursor (substance or mixture) datasets (created in step 2 above)
- Function: precursor
- Initial concentration of precursors (substance or mixture) before they start to react.

In an example shown in Figure 112 and Figure 113 there are two precursors. The first one is a substance, therefore the substance dataset is linked. The dataset has been created using a dataset template 'BPR Substance of concern', and the check box 'Substance of concern' is checked. The second precursor is a mixture, therefore the mixture dataset is linked. The mixture dataset has been created using a dataset template 'BPR Basic information (mixture)'. In this dataset there is an exact composition of the mixture under section 2.3, including the corresponding substance datasets.

The concentration of both precursors needs to be an exact value. If there is a need to indicate that the precursors may react in different proportions, then more composition records have to be created, each one providing the exact composition.

Figure 112: Initial composition before precursors start to react - precursor (substance)

#	Compon...	Name	Function	Typical ...	Concent...	Remarks	Substan...	Generic ...	Intercha...	Standar...	Substan...	Action
1		BPR Substance of concern	precursor	ca. 50 % (w/w)	None	None	<input checked="" type="checkbox"/> Substance of concern	<input type="checkbox"/> Generic component identifier (GCI)	<input type="checkbox"/> Interchangeable component group (ICG)	<input type="checkbox"/> Standard formula (SF) component	<input type="checkbox"/> Substance generated in situ (from one or more precursors, at the place of use)	

Figure 113: Initial composition before precursors start to react - precursor (mixture)

2		mixture	precursor	ca. 50 % (w/w)	None	None	<input type="checkbox"/> Substance of concern	<input type="checkbox"/> Generic component identifier (GCI)	<input type="checkbox"/> Interchangeable component group (ICG)	<input type="checkbox"/> Standard formula (SF) component	<input type="checkbox"/> Substance generated in situ (from one or more precursors, at the place of use)	
---	--	---------	-----------	----------------	------	------	---	---	--	--	---	--

#### Composition of AS generated in situ (reported as a first composition record):

The composition of the active substance generated in situ will include the pure active substance, unreacted precursors or their components, reaction by-products and other impurities. For an impurity, 'not applicable' should be selected in a field 'Function'. (Figure 114).

Figure 114: Composition of AS generated in situ - Components/Impurities

#	Component flag	Name	Function	Typical concen...	Concentration r...	Remarks	Substance of c...	Generic compo...	Interchangeabl...	Standard form...	Substance gen...	Action
1		Percetic acid   peracetic acid   79-21-0	active substance	ca. 20 % (w/w)	None	Pure active substance of the in situ generated substance. The details of the process in the description of the composition in section 2.9 of the active substance dataset.	<input type="checkbox"/> Substance of concern	<input type="checkbox"/> Generic component identifier (GCI)	<input type="checkbox"/> Interchangeable component group (ICG)	<input type="checkbox"/> Standard formula (SF) component	<input checked="" type="checkbox"/> Substance generated in situ (from one or more precursors, at the place of use)	
2		reaction by product 1	not applicable	ca. 10 % (w/w)	None	reaction by product regarded as impurity	<input checked="" type="checkbox"/> Substance of concern	<input type="checkbox"/> Generic component identifier (GCI)	<input type="checkbox"/> Interchangeable component group (ICG)	<input type="checkbox"/> Standard formula (SF) component	<input type="checkbox"/> Substance generated in situ (from one or more precursors, at the place of use)	
3		reaction by product 2	not applicable	ca. 10 % (w/w)	None	reaction by product regarded as impurity	<input checked="" type="checkbox"/> Substance of concern	<input type="checkbox"/> Generic component identifier (GCI)	<input type="checkbox"/> Interchangeable component group (ICG)	<input type="checkbox"/> Standard formula (SF) component	<input type="checkbox"/> Substance generated in situ (from one or more precursors, at the place of use)	

The identified active substance generated in situ should have the following data provided:

- Linked substance dataset (created in step 1 above)
- Function 'active substance'
- Concentration of the pure active substance in an active substance generated in situ
- Check box 'Substance generated in situ (from one or more precursors, at the place of use)' checked in



In the example shown in Figure 115 there is an active substance generated in situ. The substance dataset is linked. The dataset has been created using a dataset template 'BPR Active substance information'. The concentration of the pure active substance needs to be an exact value.

If there is a need to indicate that the active substance may be generated at different concentrations in an active substance generated in situ, then more composition records have to be created, each one with exact concentrations.

Figure 115: Composition of AS generated in situ – pure active substance

#	Component flag	Name	Function	Typical concen...	Concentration r...	Remarks	Substance of c...	Generic compo...	Interchangeabl...	Standard form...	Substance gen...	Action
1		Peracetic acid   peracetic acid   79-21-0	active substance	ca. 20 % (w/w)	None	Pure active substance of the in situ generated substance. The details of the process in the description in section 2.9 of the active substance dataset.						

The reaction pathways describing how the active substance is generated should be inserted in section 2.9 of the active substance dataset under 'Description'. If needed, additional details for the method can be included as an attachment under 'Attached description / justification' (Figure 116).

Figure 116: 'Description' of composition in an active substance dataset

Dashboard > Substances > Oxalonitrile

Oxalonitrile  
96834eb5-9442-4c6b-b856-b203d2Aee0ae

(including SMILES notation)

2.6 (Cf. 2.1) Information on optical activity and full details of any isomeric composition

2.7 (Cf. 2.1) Molar mass

> 2.8 Method of manufacture (syntheses pathway) of the active substance

▼ 2.9 Specification of purity of the active substance as manufactured\* 1

● Specification of purity of the active substance as manufactured.001

2.10 (Cf. 2.9) The identity of any impurities and additives

2.11 (Cf. 5) Analytical profile of at least five representative batches

2.12 (Cf. 2.1) The origin of the natural active substance or the precursor(s) of the active substance

> 2.13 Assessment approach (assessment entities)

> 3 Physical and chemical properties\* 1

> 4 Physical hazards and respective characteristics\* 1

> 5 Methods of detection and identification\* 1

> 6 Effectiveness against target organisms\*

Specification of purity of the active substance as manufactured.001  
UUID: aa6eb6f6-1267-4968-ac90-60aeb71da22f

General Information Degree of purity Constituents Impurities Additives

General Information

Name  
Specification of ...

Type of composition  
legal entity composition of the substance

State / form

Description

- The reaction pathways describing how the active substance is generated in situ:  
- The reaction pathways describing how the disinfection by-product is generated, amounts of generated disinfection by-product

Justification for deviations

Attached description / justification + New item Import file

#	Attached document	Remarks
1	how active substance has been generated.docx	Document referring to the description.

The identified unreacted precursors or their components should have the following data provided:

If certain amount of precursor remains unreacted:

- Linked precursor (substance or mixture) dataset (created in step 2 above)
- Concentration of this unreacted precursor (substance or mixture) in an active substance generated in situ

If only some substances being components of a precursor remain in the active substance generated in situ:

- Linked substance datasets (created in step 2 or 3 above)
- Concentration of a substance originating from the precursor in the active substance generated in situ

In the example shown in Figure 117 there is an unreacted precursor which is a substance. The same dataset is linked in the first record 'Initial composition before precursors start to react', but with a different concentration. The concentration of the substance in an active substance generated in situ needs to be an exact value.

If there is a need to indicate that these substances may remain at different concentrations in an active substance generated in situ, then the maximum expected value must be reported (as an exact value) and in the remarks field the range of possible concentration values needs to be specified.

It is recommended to indicate in the 'Remarks' field the origin of the impurity as shown in Figure 117.

Figure 117: Composition of an active substance generated in situ - unreacted precursor reported as impurity

#	Component flag	Name	Function	Typical concen...	Concentration r...	Remarks	Substance of c...	Generic compo...	Interchangeabl...	Standard form...	Substance gen...	Action
1	None	Ethane-1,2-diol	not applicable	ca. 10 % (w/w)	None	Unreacted precursor	Substance of concern	Generic component identifier (GCI)	Interchangeable component group (ICG)	Standard formula (SF) component	Substance generated in situ (from one or more precursors, at the place of use)	

In an example shown in Figure 118 there are substances that have been components of a precursor mixture. Every substance that originates from the precursor mixture needs to be reported as impurity of an active substance generated in situ. The concentration of the substance in an active substance generated in situ needs to be an exact value.

If there is a need to indicate that these substances may remain at different concentrations in an active substance generated in situ, then the maximum expected value must be reported (as an exact value) and in the remarks field the range of possible concentration values needs to be specified.

It is recommended to indicate in the 'Remarks' field the origin of the impurity as shown in Figure 118.

Figure 118: Composition of an active substance generated in situ - substances originating from a precursor, reported as impurities

#	Component flag	Name	Function	Typical concen...	Concentration r...	Remarks	Substance of c...
1	None None	2-(2-ethoxyethoxy)ethanol	not applicable	ca. 5 % (w/w)	None	Impurity originating from precursor (former additive in precursor mixture). Concentration may vary between 4.5 and 6 % (w/w).	<input checked="" type="checkbox"/> Substance of concern
2	None None	substance X	not applicable	ca. 10 % (w/w)	None	Unreacted precursor (reacting component of precursor mixture)	<input checked="" type="checkbox"/> Substance of concern

Identified reaction by-products should have the following data provided:

- Linked reaction by-product dataset (created in step 3 above)
- Concentration of the reaction by-product in an active substance generated in situ

In an example shown in Figure 119 there is a reaction by-product. This is a substance, therefore the substance dataset is linked. The dataset has been created using a dataset template 'BPR Substance of concern' and the check box 'Substance of concern' should be checked in. The concentration of a reaction by-product needs to be an exact value.

If there is a need to indicate that these substances may remain at different concentrations in an active substance generated in situ, then the maximum expected value must be reported (as an exact value) and in the remarks field the range of possible concentration values needs to be specified.

Each reaction by-products have to be reported separately as an impurity, so the function will be indicated as 'not applicable'..

Figure 119: Composition of AS generated in situ - reaction by-product

7	None None	reaction by product 1	not applicable	ca. 10 % (w/w)	None	reaction by product regarded as impurity	<input checked="" type="checkbox"/> Substance of concern
---	--------------	-----------------------	----------------	----------------	------	--	--

Composition of disinfection by-products (reported as a third composition record):

Disinfection by-products may be generated when the active substance generated in situ (i.e. any of the substances AS, B, P, OI shown in Figure 109) reacts with microorganisms or other organic

matter when exerting its biocidal effect. It is recommended that they are reported as 'impurities'<sup>12</sup> in IUCLID, so the function should be indicated as 'not applicable'.

Identified disinfection by-products should have the following data provided:

- Linked disinfection by-product dataset (substance or mixture dataset created in step 3 above)
- Concentration of the disinfection by-product should be always defined as 0%; the relative amount formed should be given in the risk assessment

The reaction pathways describing how the disinfection by-product is generated and amounts of disinfection by-product generated should be inserted in IUCLID section 2.9 of a substance dataset under 'Description' or in section 2.3 of a mixture dataset, in the field 'Brief description' (Figure 120). If needed, additional details for the method can be included as an attachment under 'Attached description' in IUCLID section 2.9 of a substance dataset or as an attachment to section 2.3 of a mixture dataset.

Figure 120: 'Brief description' of a composition in a mixture dataset

The screenshot displays the IUCLID interface for a BPR product containing a mixture. The breadcrumb trail is 'Dashboard > Mixtures / Products > BPR product containing a mixture'. The main title is 'BPR product containing a mixture' with a UUID of '523dabac-c763-49f7-aae5-dc7b050bc7e8'. The 'Working context' is set to 'BPR Basic information (mixture)'. The navigation tree on the left shows the following structure:

- BPR product containing a mixture
  - 1 Applicant
  - 2 Identity of the mixture\* (2)
    - 2.1 Common name and synonyms (1)
    - 2.2 Manufacturer's development code number(s)
    - 2.3 Mixture composition\* (1)
      - Representative biocidal product composition.001
    - 3 Physical, chemical and technical

The main panel displays the details for 'Representative biocidal product composition.001' (UUID: e203701f-6523-4f97-9563-6cac28e25b02). It includes tabs for 'Administrative data', 'General information', and 'Components'. The 'Administrative data' section shows 'None' for both 'None' and 'None'. The 'General information' section includes:

- Mixture/product name: Mixture 1
- Trade names: + New item, Import file
- Brief description: This disinfection by-product is generated when the active substance reacts with...
- Formulation type

The 'Components' section is currently empty.

### 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 4), 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 can be found under section 2.3 (Figure 121). The in situ generated active substance,

<sup>12</sup> Note that disinfection by-products are not strictly speaking defined as "impurities" because they are not part of the substance, but have been generated during its use.

all precursors, impurities and disinfection by-products are among the components of the biocidal product dossier. To view each component dataset please refer to section 7.2.

Figure 121: Biocidal product dossier components in the navigation window in IUCLID

The screenshot displays the IUCLID interface for a BPR product dossier. The navigation window on the left lists 13 components, with 'Oxalonnitrile' selected under '2.3 Biocidal product composition'. The main panel shows the dossier details for 'Oxalonnitrile', including the 'Dossier Submission Type' (BPR product dossier, version bpr 7.0), 'Dossier Subject' (BPR product), and 'Specific submissions' (The submission is an update, last submission number, reason for updating, and justification).

Dashboard > Mixtures / Products > BPR product

BPR product dossier  
a9a84963-4b25-4878-8706-3272806f9a54

View Dossiers Go to source Validate

BPR Biocidal product authorisation

UUID: a9a84963-4b25-4878-8706-3272806f9a54

Hide empty fields

Dossier Submission Type Dossier Subject Specific submissions

Dossier Submission Type

Dossier name (given by user)  
BPR product dossier  
Version  
bpr 7.0  
Submission Type  
BPR Biocidal product authorisation

Dossier Subject

Dossier Subject  
BPR product  
Submitting Legal Entity

Dossier creation date/time  
2023-02-23T13:28:29.583  
Dossier submission remarks

Specific submissions

Authorisation type

The submission is an update  
Last submission number

Reason for updating

Further to a request/decision from a regulatory body  
Number  
 Spontaneous update  
Justification

Go to subtree

1 Applicant\*  
2 Identity of the biocidal product\* 2  
2.1 Trade name or proposed trade name 1  
2.2 Manufacturer's development code and number of the biocidal product  
2.3 Biocidal product composition\* 1  
Representative biocidal product composition.001  
Oxalonnitrile  
2.4 (Cf. 2.3) Formulation type and nature of the biocidal product  
3 Physical, chemical and technical properties\*  
4 Physical hazards and respective characteristics\*  
5 Methods of detection and identification\* 1  
6 Effectiveness against target organisms\*  
7 Intended uses and exposure\* 2  
8 Toxicological profile for humans and animals\*  
9 Ecotoxicological studies\*  
10 Environmental fate and behaviour\*  
11 Measures to protect humans, animals and the environment\*  
12 Classification & Labelling\*  
13 Summary and evaluation  
Inherited templates

## Annex 3. How to include several representative products in an active substance application in IUCLID

### REPRESENTATIVE BIOCIDAL PRODUCT(S)

According to Article 6 (a) of the BPR, an application for approval of an active substance shall contain the information for the active substance, satisfying the requirements of Annex II. This is done by including the active substance dataset in the IUCLID dossier submitted for the application.

Article 6 (b) states that the information requirements of Annex III shall be provided for at least one representative biocidal product that contains the active substance.

In a representative biocidal product dataset prepared for an active substance application, only one active substance is allowed as an application can be made on one active substance only according to the legal text. However this can create confusion when an applicant has to submit several representative products in the application.

In the next sections we will describe how several representative products shall be defined in the same active substance application.

### Section 2.3 Representative biocidal product composition

In this section, a record should be created for each representative biocidal product. **The active substance dataset should be linked to each composition record.** The name of the representative product should contain product type(s) relevant for this product.

Examples of two compositions are given below.

Figure 122 First representative biocidal product composition in an active substance application

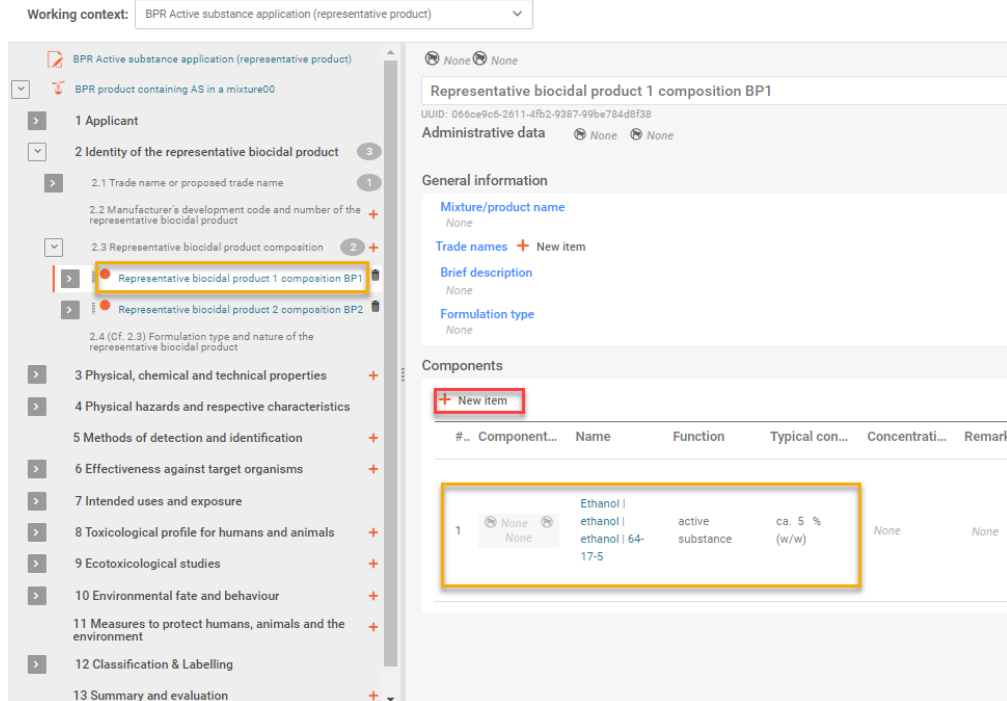
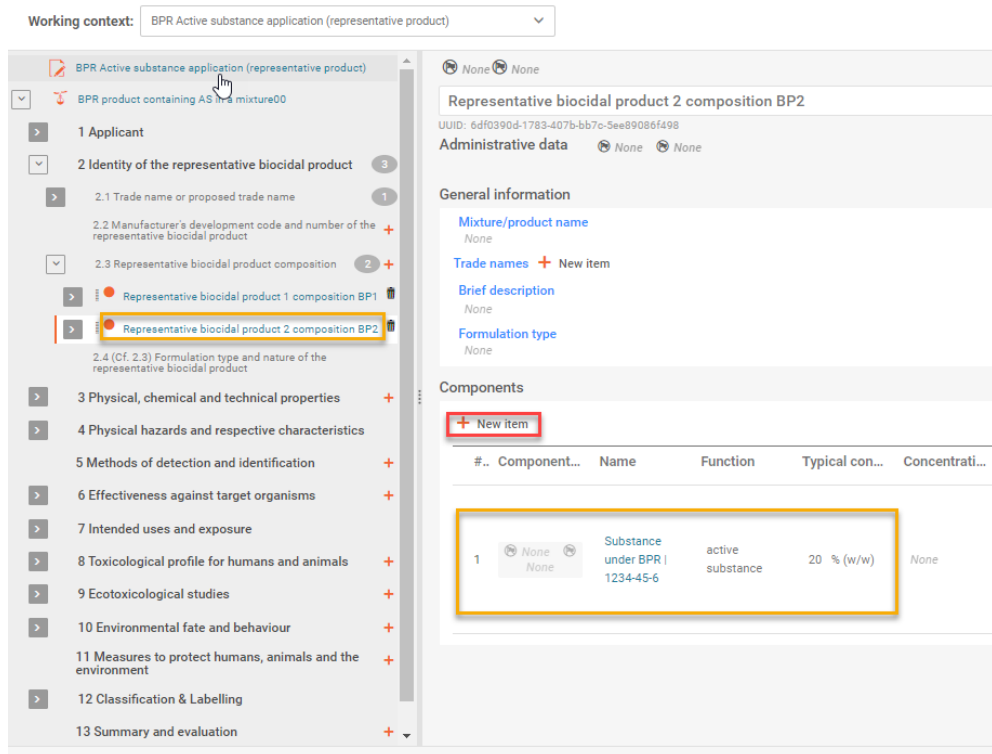


Figure 123: Second representative biocidal product composition in an active substance application



In order to relate specific information to the relevant biocidal product in the whole product dataset, it is proposed to assign an identifier to each representative product and to use it as a reference in the different record names in different sections.

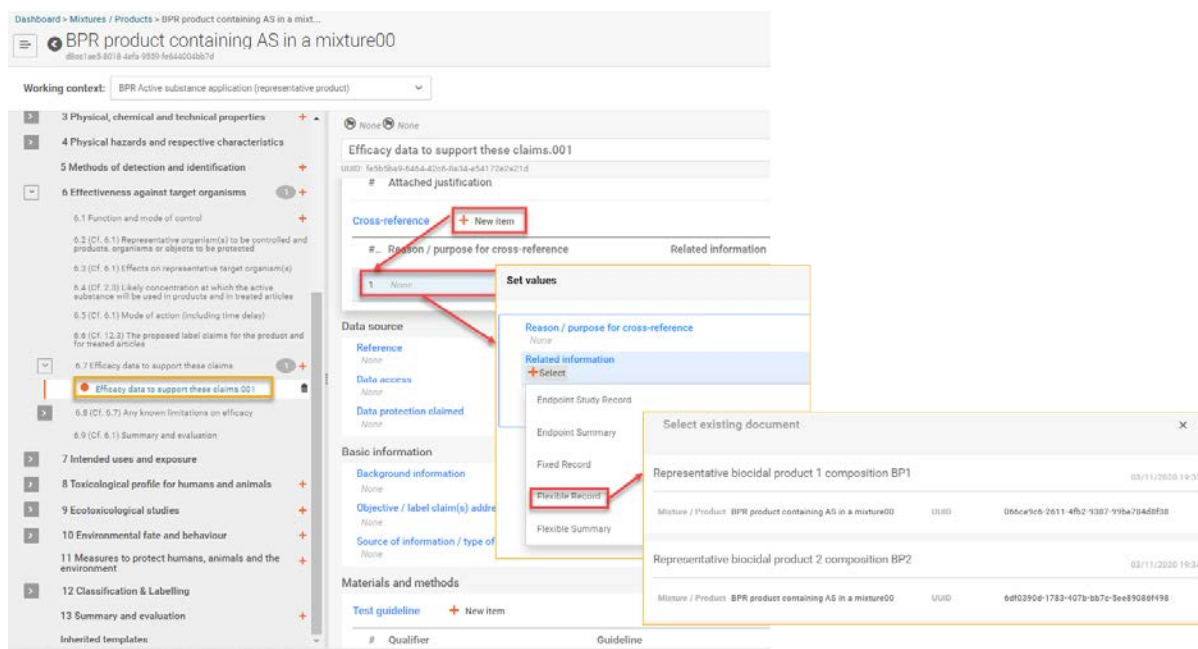
Examples of the sections are given below.

### Section 6.7 Efficacy data to support these claims

In section 6.7 of the representative biocidal product dataset the link can be established between the representative biocidal product identified in section 2.3 and the data inserted in a record in section 6.7.

In the example below, the first record in section 6.7 has been created for biocidal product1 and then was linked to the composition corresponding to biocidal product1 in section 2.3. Another record can be created in section 6.7 to provide data for biocidal product2 and then link to the corresponding composition.

Figure 124: Efficacy data linked to the relevant representative biocidal product



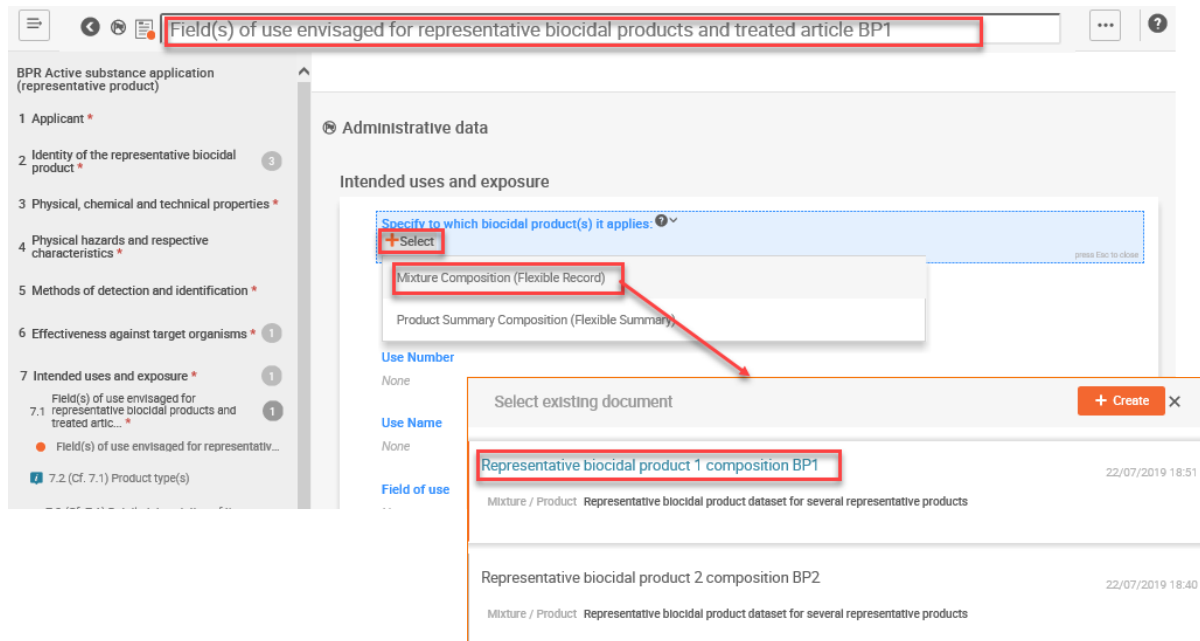
### Section 7 Intended uses and exposure

In the example below, the first record has been created for biocidal product1 and the record was linked to the composition corresponding to biocidal product1 in section 2.3.

Another record can be created in section 7.1 for biocidal product and a link to the corresponding composition can be established.



Figure 125: Section 7.1 Field(s) of use envisaged for representative biocidal products and treated article



### Section 13

In this section, the relevant risk assessment documents should be stored for the different representative biocidal products. An example of how this information could be recorded is given below. It is important to name records in a way which allows to identify which summary and evaluation relates to which representative product.

Figure 126: Risk assessment reports for different representative biocidal products

Working context: BPR Active substance application (representative product)

The interface displays the following sections:

- Working context:** BPR Active substance application (representative product)
- Left sidebar:** A list of 13 sections for a biocides dossier, with '13 Summary and evaluation' selected and 'Summary and evaluation.001' highlighted.
- Main content area:** Shows 'Summary and evaluation.001' with a 'New item' button and a table for 'Type of report'.

#	Type of report
1	None
2	draft risk assessment
- Set values dialog box:** A modal window with fields for 'Type of report' (set to 'draft risk assessment'), 'Attached document' (with 'Attachment docx' highlighted), and 'Remarks' (set to 'None').

## Annex 4. List of IUCLID sections in which data on a biocidal product containing microorganisms should be inserted

Information required by the Annex III, title 2 of the Biocidal Products Regulation shall be reported in IUCLID in a mixture/product dataset. This dossier should be created for the biocidal product using the dataset template 'BPR Biocidal product authorisation' or 'BPR Active substance application (representative product)'. The list of sections in which the data relevant for biocidal product containing microorganisms is specified in a table below. Additional instructions can be found in chapter 4 '[Preparing a dataset for a biocidal product; IUCLID section 2.3 Biocidal product composition](#)'.

Before the mixture/product can be completed, a substance dataset should be created for the active substance (using the main 'substance' dataset template 'BPR Microorganisms'). 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).

Based on the biocidal product dataset, 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).

**Table 1. Information required by the Annex III, title 2 of the BPR and corresponding sections in IUCLID Mixture/Product dataset**

<b>Information required by the Annex III, title 2 of the BPR (MICROORGANISMS Core data and additional dataset)</b>	<b>In which IUCLID section of Mixture/Product dataset relevant data shall be reported</b>
1. APPLICANT	2.1 Trade name or proposed trade name
1.1 Name and address	2.1 Trade name or proposed trade name
1.2 Contact person	2.1 Trade name or proposed trade name
1.3. Manufacturer and formulator of the biocidal product and the microorganism(s) (names, addresses, including location of plant(s))	1.3 Representative biocidal product manufacturer / 1.3 Biocidal product manufacturer 1.3.1 Location of manufacturing plant(s)
<b>2. IDENTITY OF THE BIOCIDAL PRODUCTS</b>	<b>2 Identity of the representative biocidal product</b>
2.1 Trade name or proposed trade name	2.1 Trade name or proposed trade

	name
2.2 Manufacturer's development code and number of the product, if appropriate	2.2 Manufacturer's development code and number of the representative biocidal product / 2.2 Manufacturer's development code and number of the biocidal product
2.3 Detailed quantitative (g/kg, g/l, % w/w (v/v), cfu/g, cfu/l or IU/mg or any other appropriate unit) and qualitative information on the constitution, composition and function of the biocidal product, e.g. microorganism, active substance(s) and product non-active substances and any other relevant components. All relevant information on individual ingredients and the final composition of the biocidal product shall be given	2.3 Representative biocidal product composition / 2.3 Biocidal product composition
2.4 Formulation type and nature of the biocidal product	2.3 Representative biocidal product composition / 2.3 Biocidal product composition
2.5 Where the biocidal product contains an active substance that has been manufactured in locations or according to processes or from starting materials other than those of the active substance evaluated for the purpose of approval pursuant to Article 9 of this Regulation, evidence has to be provided that technical equivalence has been established in accordance with Article 54 of this Regulation or has been established, following an evaluation having started before 1 September 2013, by a competent authority designated in accordance with Article 26 of Directive 98/8/EC	13. Summary and evaluation
<b>3. BIOLOGICAL, PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES OF THE BIOCIDAL PRODUCT</b>	3 Physical, chemical and technical properties
3.1 Biological properties of the microorganism in the biocidal product	<b>Substance dataset:</b> 3. Biological properties of the microorganism
3.2 Appearance (at 20 °C and 101,3 kPa)	3.1 Appearance (at 20 °C and 101.3 kPa)
3.2.1 Colour (at 20 °C and 101,3 kPa)	
3.2.2 Odour (at 20 °C and 101,3 kPa)	

3.3 Acidity, alkalinity and pH value	3.2 Acidity, alkalinity
3.4 Relative density	3.3 Relative density (liquids) and bulk, tap density (solids)
3.5 Storage stability, stability and shelf-life	3.4.1 Storage stability tests
3.5.1 Effects of light	3.4.2.1 Light
3.5.2 Effects of temperature and humidity	3.4.2.1 Light
3.5.3 Reactivity towards the container	3.4.1 Storage stability tests
3.5.4 Other factors affecting stability	3.4.1 Storage stability tests
3.6 Technical characteristics of the biocidal product	3.5 Technical characteristics of the representative biocidal products / 3.5 Technical characteristics of the biocidal products
3.6.1 Wettability	
3.6.2 Suspensibility and suspension stability	
3.6.3 Wet sieve analysis and dry sieve test	
3.6.4 Emulsifiability, re-emulsifiability, emulsion stability	
3.6.5 Particle size distribution content of dust/fines, attrition and friability	
3.6.6 Persistent foaming	
3.6.7 Flowability/Pourability/Dustability	
3.6.8 Spraying patterns – aerosols	
3.6.9 Other technical characteristics	
3.7 Physical, chemical and biological compatibility with other products including biocidal products with which its use is to be authorised or registered	3.6 Physical and chemical compatibility with other products
3.7.1 Physical compatibility	
3.7.2 Chemical compatibility	
3.7.3 Biological compatibility	
3.8 Surface tension	3.8 Surface tension
3.9 Viscosity	3.9 Viscosity
<b>4. PHYSICAL HAZARDS AND RESPECTIVE CHARACTERISITICS</b>	<b>4 Physical hazards and respective characteristics</b>
4.1 Explosives	4.1 Explosiveness

4.2 Flammable aerosols	4.2 Flammability
4.3 Flammable liquids	4.6 Flammable liquids
4.4 Flammable solids	4.2 Flammability
4.5 Oxidising liquids	4.4 Oxidising properties
4.6 Oxidising solids	4.4 Oxidising properties
4.7 Corrosive to metals	4.16 Corrosive to metals
4.8 Other physical indications of hazard	4.17 Additional physical indicators for hazards
4.8.1 Auto-ignition temperatures of products (liquids and gases)	
4.8.2 Relative self-ignition temperature for solid	
4.8.3 Dust explosion hazard	
<b>5. METHODS OF DETECTION AND IDENTIFICATION</b>	<b>5 Methods of detection and identification</b>
5.1 Analytical method for determining the concentration of the microorganism(s) and substances of concern in the biocidal product	
5.2 Analytical methods for monitoring purposes including recovery rates and the limit of quantification and detection for the active substance, and for residues thereof, in/on food of plant and animal origin or feeding stuffs and other products where relevant (not necessary if neither the active substance nor the article treated with it does not come into contact with food-producing animals, food of plant and animal origin or feeding stuffs)	
<b>6. EFFECTIVENESS AGAINST TARGET ORGANISM</b>	<b>6 Effectiveness against target organisms</b>
6.1 Function and mode of control	6.1 Function and mode of control
6.2 Representative pest organism(s) to be controlled and products, organisms or objects to be protected	6.1 Function and mode of control
6.3 Effects on representative target organisms	6.1 Function and mode of control
6.4 Likely concentration at which microorganism will be used	2.3 Representative biocidal product composition / 2.3 Biocidal product composition

6.5 Mode of action	6.1 Function and mode of control
6.6 The proposed label claims for the product	12.3 Packaging (12.7 in Annex III of BPR)
6.7 Efficacy data to support these claims, including any available standard protocols, laboratory tests, or field trials used including performance standards, where appropriate and relevant	6.7 Efficacy data to support these claims
6.8 Any other known limitations on efficacy including resistance	6.7 Efficacy data to support these claims
6.8.1 Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies	6.1 Function and mode of control
6.8.2 Observations on undesirable or unintended side effects	6.1 Function and mode of control
<b>7. INTENDED USES AND EXPOSURE</b>	<b>7 Intended uses and exposure</b>
7.1 Field of use envisaged	7.1 Field(s) of use envisaged for representative biocidal products and treated article / 7.1 Field(s) of use envisaged for biocidal products and treated article
7.2 Product-type	7.1 Field(s) of use envisaged for representative biocidal products and treated article / 7.1 Field(s) of use envisaged for biocidal products and treated article
7.3 Detailed description of intended use	7.1 Field(s) of use envisaged for representative biocidal products and treated article / 7.1 Field(s) of use envisaged for biocidal products and treated article
7.4 User e.g. industrial, trained professional, professional or general public (non-professional)	7.1 Field(s) of use envisaged for representative biocidal products and treated article / 7.1 Field(s) of use envisaged for biocidal products and treated article
7.5 Method of application and a description of this method	7.6 Method of application and a description of this method
7.6 Application rate and if appropriate the final concentration of the biocidal product or the microorganism active substance in a	7.6 Method of application and a description of this method

treated article or the system in which the product is to be used (e.g. in the application device or bait)	
7.7 Number and timing of applications and duration of protection Any particular information relating to the geographical location or climatic variations including necessary waiting periods for re-entry or necessary withdrawal period or other precautions to protect human health, animal health and the environment	7.6 Method of application and a description of this method
7.8 Proposed instructions for use	7.6 Method of application and a description of this method
7.9 Exposure data	7.1 Field(s) of use envisaged for representative biocidal products and treated article / 7.1 Field(s) of use envisaged for biocidal products and treated article
7.9.1 Information on human exposure associated with the proposed/ expected uses and disposal	7.1 Field(s) of use envisaged for representative biocidal products and treated article / 7.1 Field(s) of use envisaged for biocidal products and treated article
7.9.2 Information on environmental exposure associated with the proposed/expected uses and disposal	13. Summary and evaluation
<b>8. TOXICOLOGICAL PROFILE FOR HUMANS AND ANIMALS</b>	<b>8 Toxicological profile for humans and animals</b>
8.1 Skin corrosion or irritation	8.1 Irritation
8.2 Eye irritation	8.1.2 Serious eye damage or eye irritation
8.3 Skin sensitisation	8.3.1 Skin sensitisation
8.4 Respiratory sensitisation	8.3.2 Respiratory sensitisation
8.5 Acute toxicity — Classification using the tiered approach to classification of mixtures for acute toxicity in Regulation (EC) No 1272/2008 is the default approach	8.5 Acute toxicity
8.5.1 Oral	8.5.1 Acute toxicity: oral
8.5.2 Inhalation	8.5.2 Acute toxicity: inhalation
8.5.3 Dermal	8.5.3 Acute toxicity: dermal
8.5.4 Additional acute toxicity studies	8.10 Other test(s) related to exposute



	to humans
8.6 Information on dermal absorption if required	8.6 Dermal absorption
8.7 Available toxicological data relating to: — non-active substance(s) (i.e. substance(s) of concern), or — a mixture that a substance(s) of concern is a component of  If insufficient data are available for a non-active substance(s) and cannot be inferred through read-across or other accepted non-testing approaches, targeted test(s) described in Annex II, shall be carried out for the substance(s) of concern or a mixture that a substance(s) of concern is a component of	8.7 Available toxicological data relating to: 8.7.1 other endpoints 8.7.2 (Cf. biocidal product component dataset) non-active substance(s) (i.e. substance(s) of concern) 8.7.3 (Cf. biocidal product component dataset) a mixture that a substance(s) of concern is a component of
8.8 Supplementary studies for combinations of biocidal products  For biocidal products that are intended to be authorised for use with other biocidal products, the risks to humans, animals and the environment arising from the use of these product combinations shall be assessed. As an alternative to acute toxicity studies, calculations can be used. In some cases, for example where there are no valid data available of the kind set out in column 3, this may require a limited number of acute toxicity studies to be carried using combinations of the products	8.5.4 Acute toxicity: product combinations
8.9 Residues in or on treated articles, food and feedingstuffs	8.9 Effects on industrial processing and/or domestic preparation on the nature and magnitude of residues of the biocidal product
<b>9. ECOTOXICOLOGICAL STUDIES</b>	<b>9 Ecotoxicological studies</b>
9.1 Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning the classification of the product is required — Where there are valid data available on each of the components in the mixture and synergistic effects between any of the components are not expected, classification of the mixture can be made according to the rules laid down in Directive	9.2 Further ecotoxicological studies

<p>1999/45/EC, Regulation (EC) No 1907/2006 (REACH) and Regulation (EC) No 1272/ 2008 (CLP)</p> <p>— Where valid data on the components are not available or where synergistic effects may be expected then testing of components and/or the biocidal product itself may be necessary</p>	
<p>9.2 Further ecotoxicological studies</p> <p>Further studies chosen from among the endpoints referred to in Section 8 of Annex II ‘Microorganisms’ for relevant components of the biocidal product or the biocidal product itself may be required if the data on the active substance cannot give sufficient information and if there are indications of risk due to specific properties of the biocidal product</p>	<p>9.2 Further ecotoxicological studies</p>
<p>9.3 Effects on any other specific non-target organisms (flora and fauna) believed to be at risk</p>	<p>9.2 Further ecotoxicological studies</p>
<p>9.4 If the biocidal product is in the form of bait or granules:</p>	<p>9.2 Further ecotoxicological studies</p>
<p>9.4.1 Supervised trials to assess risks to non-target organisms under field conditions</p>	<p>9.2 Further ecotoxicological studies</p>
<p>9.4.2 Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk</p>	<p>9.2 Further ecotoxicological studies</p>
<p>9.5 Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated</p>	<p>9.2 Further ecotoxicological studies</p>
<p><b>10. ENVIRONMENTAL FATE AND BEHAVIOUR</b></p>	<p><b>10 Environmental fate and behaviour</b></p>
<p>10.1 Foreseeable routes of entry into the environment on the basis of the use envisaged</p>	<p>10.1 Foreseeable routes of entry into the environment on the basis of the use envisaged</p>
<p>10.2 Further studies on fate and behaviour in the environment</p> <p>Where relevant, all the information required in Section 9 of Annex II ‘Microorganisms’ may be required for the product For products that are used outside, with direct emission to soil, water or</p>	<p>10.2 Further studies on fate and behaviour in the environment</p>

surfaces, the components in the product may influence the fate and behaviour (and ecotoxicity) of the active substance. Data are required unless it is scientifically justified that the fate of the components in the product is covered by the data provided for the active substance and other identified substances of concern	
10.3 Leaching behaviour and/or mobility	10.3 Leaching behaviour and, if needed, 10.4 Testing for distribution and dissipation
10.4 If the biocidal product is to be sprayed outside or if potential for large scale formation of dust is given then data on overspray behaviour may be required to assess risks to bees under field conditions	10.2 Further studies on fate and behaviour in the environment
<b>11. MEASURES TO BE ADOPTED TO PROTECT HUMANS, ANIMALS AND THE ENVIRONMENT</b>	<b>11 Measures to protect humans, animals and the environment</b>
11.1 Recommended methods and precautions concerning: handling, storage, transport or fire	
11.2 Measures in the case of an accident	
11.3 Procedures for destruction or decontamination of the biocidal product and its packaging	
11.3.1 Controlled incineration	
11.3.2 Others	
11.4 Packaging and compatibility of the biocidal product with proposed packaging materials	
11.5 Procedures for cleaning application equipment where relevant	
11.6 Monitoring plan to be used for the active microorganism and other microorganism(s) contained in the biocidal product including handling, storage, transport and use	
<b>12. CLASSIFICATION, LABELLING AND PACKAGING</b> Example labels, instructions for use and safety data sheets shall be provided	<b>12 Classification &amp; Labelling</b>

<p>12.1 Indication on the need for the biocidal product to carry the biohazard sign specified in Annex II to Directive 2000/54/EC</p>	<p>13. Summary and evaluation (check box)</p>
<p>12.2 Precautionary statements including prevention, response, storage and disposal</p>	<p>12.1 GHS</p>
<p>12.3 Proposals for safety-data sheets should be provided, where appropriate</p>	<p>13. Summary and evaluation</p>
<p>12.4 Packaging (type, materials, size, etc.), compatibility of the product with proposed packaging materials to be included</p>	<p>12.3 Packaging (12.7 in Annex III of BPR)</p>
<p><b>13. SUMMARY AND EVALUATION</b> The key information identified from the endpoints in each subsection (2- 12) is summarised, evaluated and a draft risk assessment is performed</p>	<p><b>13 Summary and evaluation</b></p>

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