ECHA
EUROPEAN CHEMICALS AGENCY

Biocides Submission Manual

How to submit an application for technical equivalence

February 2024

Disclaimer

This document aims to assist users in complying with their obligations under the Biocides Regulation. However, users are reminded that the text of the Biocides Regulation is the only authentic legal reference and that the information in this document does not constitute legal advice. Usage of the information remains under the sole responsibility of the user. The European Chemicals Agency does not accept any liability with regard to the use that may be made of the information contained in this document.

Version	Changes	Date
Version 1.0	First version	August 2013
Version 2.0	Second release to include the new ECHA service of chemical similarity check	February 2014
Version 2.1	Updated to reflect a change in submission message following the release of R4BP version 3.1. (Chapter 8, step 5) and inclusion a new sub-chapter 8.2 'Submitting an authority requested task'.	April 2014
Version 2.2	Updated to reflect changes in R4BP 3.1.2 in section 8.1 which include the removal of the 'access level' in the upload steps of the application 'wizard' and relevant screenshots.	June 2014
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Version 4.0	ANNEX entirely revised. Following chapter added: Chapter 5: Withdrawing a case from R4BP 3 Changes in the following chapter: Requesting an extension for a resubmission task in section 4.3	June 2017
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Version 7.0	Removal references to applications for chemical similarity (CS-APP). Following the decision at the ECHA management board meeting MB65 in March 2022 the chemical similarity check service has been discontinued.	September 2022
Version 7.1	Removal of references to SPC Editor.	February 2024

BSM: How to submit an application for technical equivalence

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European Chemicals Agency

P.O. Box 400, FI-00121 Helsinki, Finland

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1. Introduction

1.1. Objective

This manual gives instructions on how to submit applications concerning biocidal product authorisations that assist the making available on the market and use of biocidal products through the Register for Biocidal Products (R4BP 3) according to the Biocidal Products Regulation[1] (BPR). This manual covers applications for technical equivalence (TE).

1.2. Biocides Submission Manuals – application instructions

This manual is part of the Biocides Submission Manual (BSM) series concerning application instructions. It should be used with the following technical guides and process manuals.

Technical guides:

How to prepare a biocides dossier, which describes how to prepare a general IUCLID dossier, giving you details on the different functionalities in IUCLID, as well as explaining the different sections contained within a dossier.

How to use R4BP 3, which describes how to create a valid legal entity in IUCLID, create user accounts in R4BP 3 through ECHA Accounts and gives a detailed description of the generic steps in an application wizard[2].

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 and which dossier information can be claimed confidential.

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

Additional assistance:

In addition to the Biocides Submission Manuals, you can find more information concerning the regulatory context of biocide applications and an overview of the evaluation process from:

Practical guides, which give a more detailed look at the procedures and obligations of certain process under the BPR.

Guidance documents, which help to implement the BPR by describing good practice on how to fulfil the obligations.

[1] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products.

[2] The R4BP 3 application 'wizard' guides you through the various steps of an application form, prompting you to include necessary files such as a dossier and supporting documents.

Q&As on R4BP 3 (e.g. account management, invoicing, submissions) and the Biocidal Products Regulation (e.g. active substance suppliers, data sharing, treated articles).

The ECHA Helpdesk, which is available for specific and general advice on the BPR, particular submissions, as well as the IT tools IUCLID, R4BP 3.

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2. General submission information

This chapter gives a general overview of the different application types concerning the technical equivalence applications. Detailed submission information on each application type is provided in its own specific chapter. Summarised submission information (preparing, submitting, and monitoring an application) for each application can also be found from the ECHA Support pages.

2.1. Application types and ECHA fees and service charges

Table 1 outlines the case abbreviations used in R4BP 3 for the application types covered in this manual and whether there is an associated ECHA fee/service charge (**€**).

ECHA informs the case owner of the fees payable and will reject the application if the fee is not paid **within 30 days**. For more general information regarding ECHA fees and invoicing, please consult the R4BP 3 Q&A .

Table 1: Technical equivalence applications

Case abbreviation	Application
TE-APP	Assessment of technical equivalence **€**

The ECHA fee for technical equivalence is based on the assessment type you are applying for i.e. Tier I or Tier II.

For full details of the fees and charges payable, please refer to Annex II and III of the BPR Fee Regulation[3]

2.2. Application requirements

Depending on the application type and your individual circumstances, you will need to include a IUCLID dossier, an SPC, and/or other additional supporting documents. You can find specific instructions on what is required for your application and where to include it in the relevant sub-chapter of this manual.

For detailed information on how and what you can claim confidential under Article 67(3) of the BPR, please consult BSM 'Process of confidentiality requests for biocide applications'.

2.2.1. IUCLID dossier

A IUCLID dossier (.i6z format) will be required as part of your application. We recommend that you use the designated IUCLID fields wherever possible to store your data.

[3] Commission Implementing Regulation (EU) No 564/2013 of 18 June 2013 on the **fees and charges payable to the European Chemicals Agency** pursuant to Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products

As a guide to help you understand the principles of the specific dossier preparation, you may wish to first consult the ANNEX: How to prepare IUCLID dossier for technical assessment application at the end of this manual.

For full technical assistance on how to enter data into various sections of a IUCLID datasets and prepare a dossier, please refer to the BSM 'Technical guide: How to prepare a biocides dossier'.

2.2.2. Supporting documents

Under the BPR, you often need to submit supporting documents as part of your application. Depending on the type of application you are submitting, the required supporting documents will need to be attached either in your IUCLID dossier or uploaded directly in the R4BP 3 application 'wizard'. You can find direct instructions on where to include individual supporting documents relevant to your application type in the applicable chapter of this manual.

Additional ECHA supporting documents: For many application types, ECHA requires additional supporting documents to enable the correct handling and processing of your application. Consult the relevant chapter for your application for specific details or visit the 'Supporting documents' page from ECHA's website for the full list.

3. Applying in R4BP 3

This chapter gives a general overview on how applicants can launch the submission wizard in R4BP 3 and follow up on their applications.

3.1. Submitting an application in R4BP 3

Make sure that you have fulfilled all of the application requirements in IUCLID and have all the necessary documents ready in your dossier or ready for uploading before you begin the submission process in R4BP 3.

When you launch an application in R4BP 3, the application wizard automatically prompts you in a step-wise fashion to upload the files such as a dossier and other supporting documents required for each application. Specific help texts and tool tips in R4BP 3 will further help you during the application procedure.

You can find additional guidance on working in R4BP 3 in 'BSM Technical guide: How to use R4BP 3'.

3.2. Post submission obligations

As a case owner and/or asset owner, you are required to monitor your case(s) and take the necessary actions.

3.2.1. Check your submission and note the submission number

After submitting your application, an on-screen message will be visible to you containing a submission number, i.e. the unique number identifying your case. Read and pay attention to this on-screen message as it may contain instructions outlining further actions that you may need to do.

If you do not receive a post-submission message, your application has not been submitted correctly and you will have to start the application process again.

3.2.2. Monitor your case (case owner)

It is the case owner's responsibility to monitor individual cases on a regular basis. Through the 'Case details' sub tab, you can manage and view the progress of any of your submitted applications. In addition, email alerts can also be set to inform you of the case status – this is particularly helpful if you need to react to authority requests where a deadline has been set.

You can find more detailed information on how to monitor your case in: 'BSM Technical guide: How to use R4BP 3'.

3.2.3. Resubmission tasks

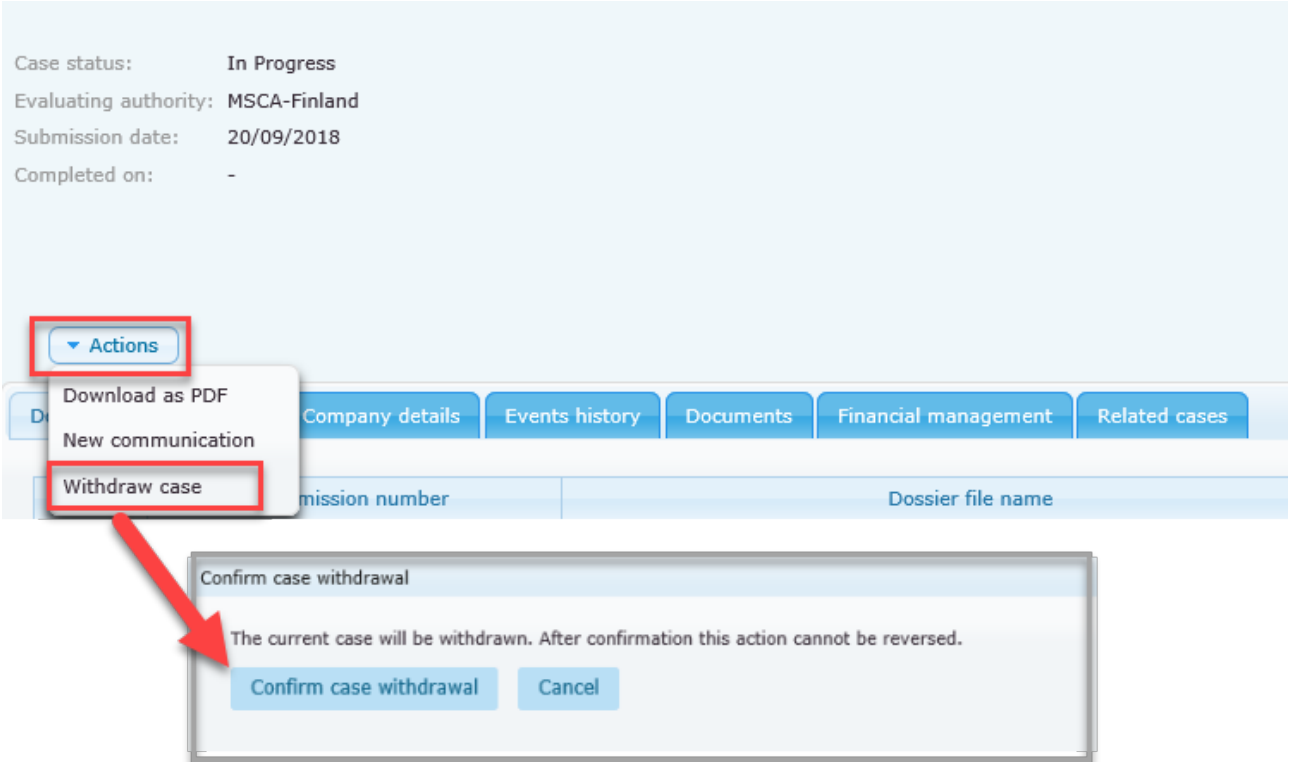
To make sure that an application can be processed correctly, a case owner may need to complete task items assigned by authority users (e.g. a 'Resubmit information' task). You are obliged to monitor your task items and complete them within the defined time. You can access the task items by selecting the 'TASKS' tab on the toolbar (Please refer to BSM Technical guide: How to use R4BP 3 for full details).

Only **one** reply to a 'request information' task is permitted in R4BP 3. Please make sure that you include all the information requested in the task item. If you need more time to complete a resubmission task, you can contact the relevant authority to request an extension.

4. Withdrawing a case from R4BP 3

You can withdraw your cases via the Case details page. Click on 'withdraw case' and confirm the case withdrawal.

Figure 1: Withdrawing a case from R4BP



Once you have withdrawn your case, any open task items will be closed immediately, any pending delegations or case transfers will be cancelled and an appropriate event will be recorded.

Note that if you choose to withdraw a reference case while the concerned cases have not yet reached the Business rules step, the system will automatically set them as 'closed'. If the concerned cases have reached the Business rules check step, then the authority will have to withdraw all concerned cases.

Note that this action will also affect delegated cases to other companies.

5. Applications for technical equivalence assessment

Applications for the assessment of technical equivalence can only be made for active substances for which there is a Commission decision on approval. More information can be found from the Guidance and Practical Guides.

The principles and processes behind technical equivalent assessment are described in the Practical Guide 'chapter on technical equivalence' available from ECHA's website.

Guidance on applications for technical equivalence – a guidance document concerning the preparation and evaluation of technical equivalence applications.

Guidance Document on Information Requirements – a general guidance document concerning information requirements for active substances and biocidal products.

The Agency has 90 days to take a decision on technical equivalence. During the assessment, the Agency can ask for additional information ('Resubmit information' task) from the applicant and will ask the applicant to submit the additional information within a specified time limit[4]. The evaluation continues on the date when the updated dossier file is received.

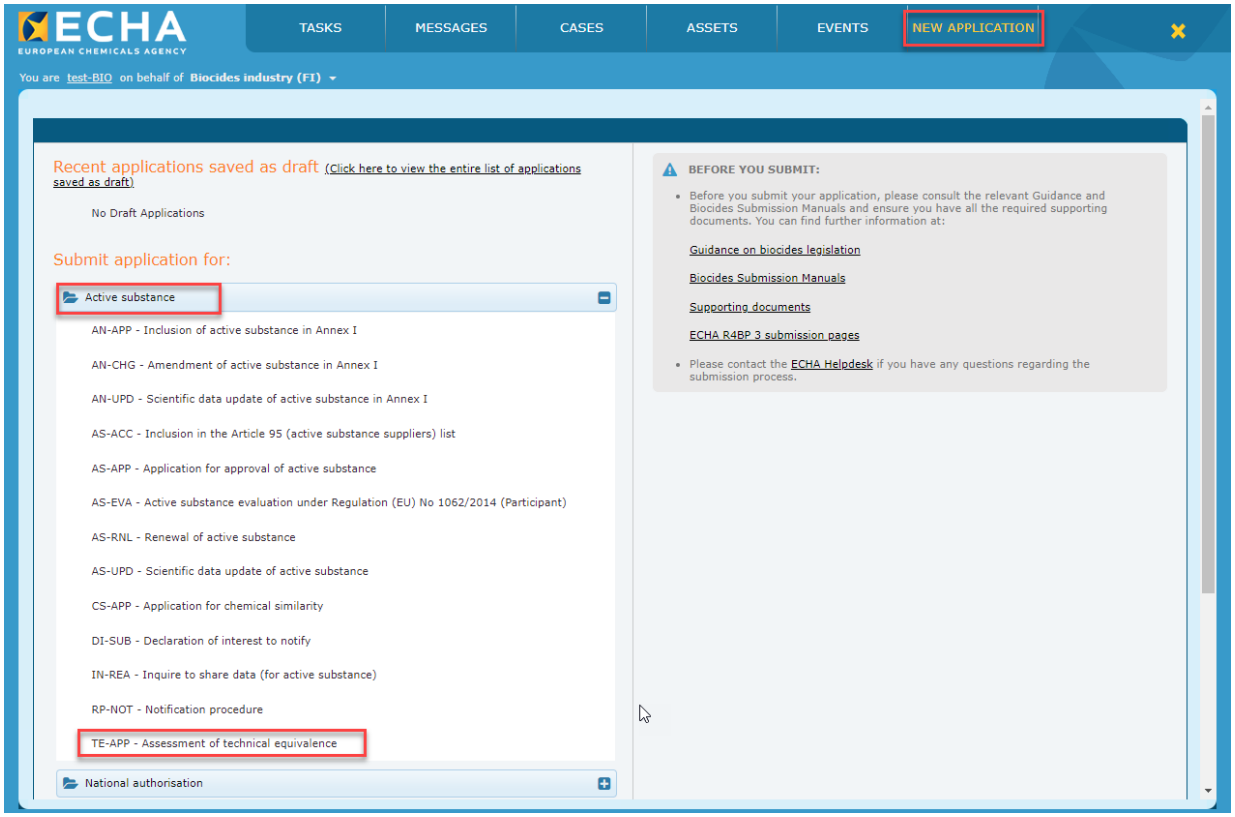
The 90-day period within which ECHA takes the decision is suspended from the date of issue of the request, until the information is received.

5.1. Launching the TE-APP application wizard

The R4BP 3 application wizard for TE-APP is launched as a 'NEW APPLICATION'. You can launch the application wizard as a new application, click on the 'NEW APPLICATION' tab on the R4BP 3 toolbar to see the full list of application types available in alphabetical order. Then, select 'TE-APP - Assessment of technical equivalence' from the list of processes.

[4] This time limit may not exceed 180 days except where justified.

Figure 2: Launching the application 'wizard' for TE-APP



Please note that each application must refer to only one source. If you wish ECHA to assess several sources, please submit separate applications for each source. If you wish ECHA to assess several product types, please include in section 7.1 of the active substance datasetr the product types you wish ECHA to assess. ECHA will check whether the assessment of the indicated product types is possible within one case and may contact you if necessary.

Please refer to Guidance on applications for technical equivalence for a description of the application types for technical equivalence before you start your application.

5.2. Application requirements for TE-APP

This sub-chapter describes the application requirements necessary for each step of the TE-APP application wizard. Additional instructions and guidance are available in R4BP 3 at each wizard step to help you with the application procedure.

Application requirements for TE-APP

Case owner details

A contact person for the case must be specified.

Set submission details

Enter the details of the proposed 'asset owner' and indicate the payment details.

Upload dossier(.i6z) and select the language

The IUCLID dossier must be created in following steps:

- Create a substance dataset identifying working context: 'BPR Technical Equivalence'
- Create a dossier from the substance dataset

For all applications (Tier I and Tier II), the IUCLID dossier must contain in the substance dataset information on:

- name and address of the manufacturer of the active substance and the manufacturing plant location
- the substance identity (chemical composition, analytical profile of five representative batches)
- absorption spectra
- description of the analytical methods used for the determination of the substance and impurities
- product type(s)

Additionally, **for Tier II applications:**

- information on the hazard profile (toxicological & ecotoxicological data)
- a self assessment of TE is to be attached in section 9 in the substance dataset of the IUCLID dossier

Supporting information details in the submission wizard

Indicate the correct assessment type you are applying for to ensure ECHA can issue the correct fee.

Tier I: where the difference between the active substance sources is limited to a change in the manufacturing location **OR** goes beyond a change in manufacturing location.

Tier II: where the previous conditions are not met and the application is based on the analytical data and hazard profile.

Upload other files

In all cases: upload the ECHA 'Supporting document for technical equivalence' and any other files you wish to support you application at this step, e.g. a cover letter.

Confirm application

If the data in the confirmation screen is correct enter the security check text and **submit** your application.

ANNEX: How to prepare IUCLID dossier for assessment of technical equivalence applications

The subsequent sections of this chapter detail how to fill in the specific IUCLID fields relevant for technical equivalence assessment applications. Furthermore, there are instructions on how to create a dossier from a dataset. For a more comprehensive illustration of how to prepare a dataset and generate a dossier using IUCLID, please see the BSM Technical guide: How to prepare a biocides dossier.

Required IUCLID dossier for assessment of technical equivalence application is created in two steps:

1. Create a substance dataset (working context: BPR Technical Equivalence)
2. From the substance dataset create the dossier

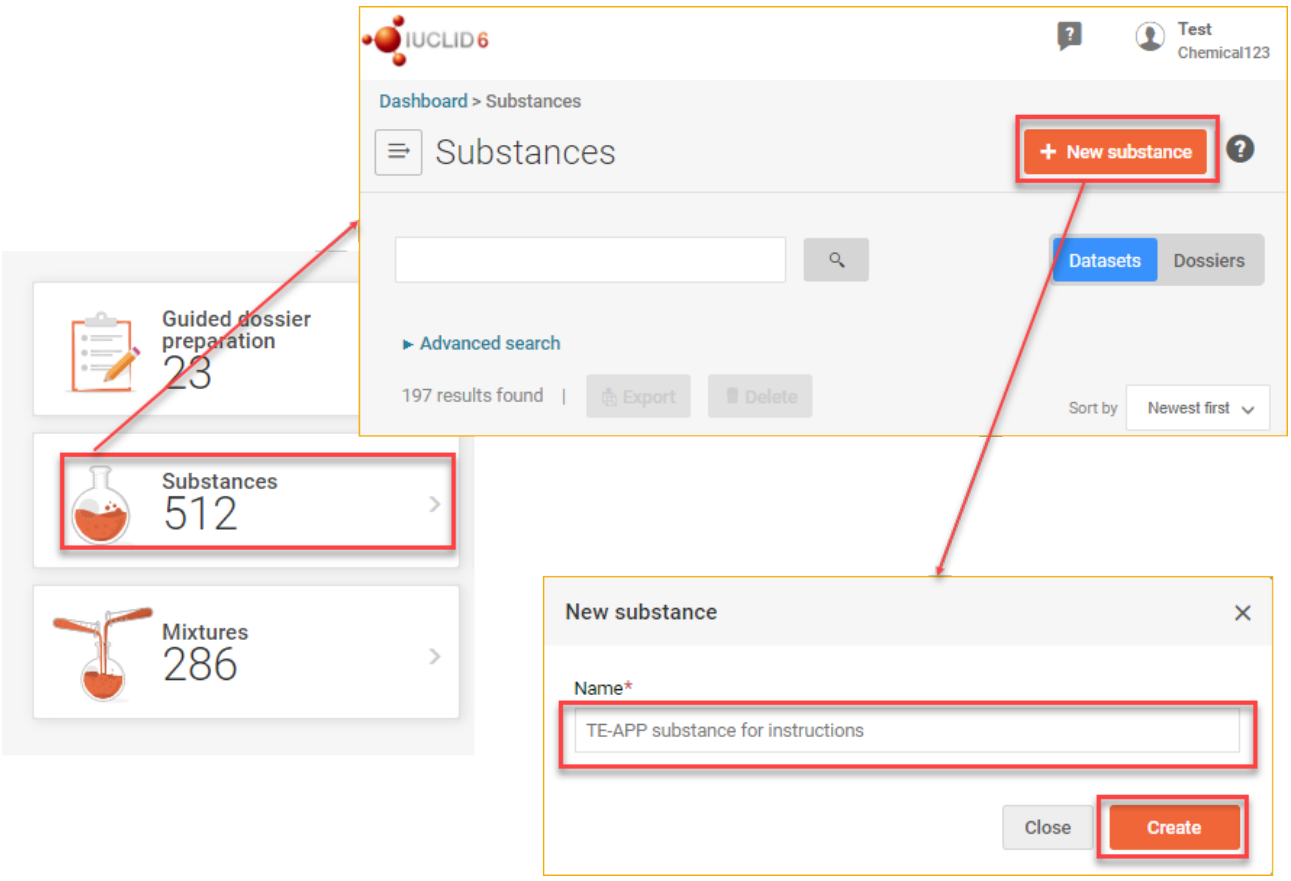
How to prepare a substance dataset

This chapter outlines how to prepare a 'Substance' dataset, containing required information about the active substance, specific for the submission of assessment of technical eqvivalence application.

Step 1: 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.

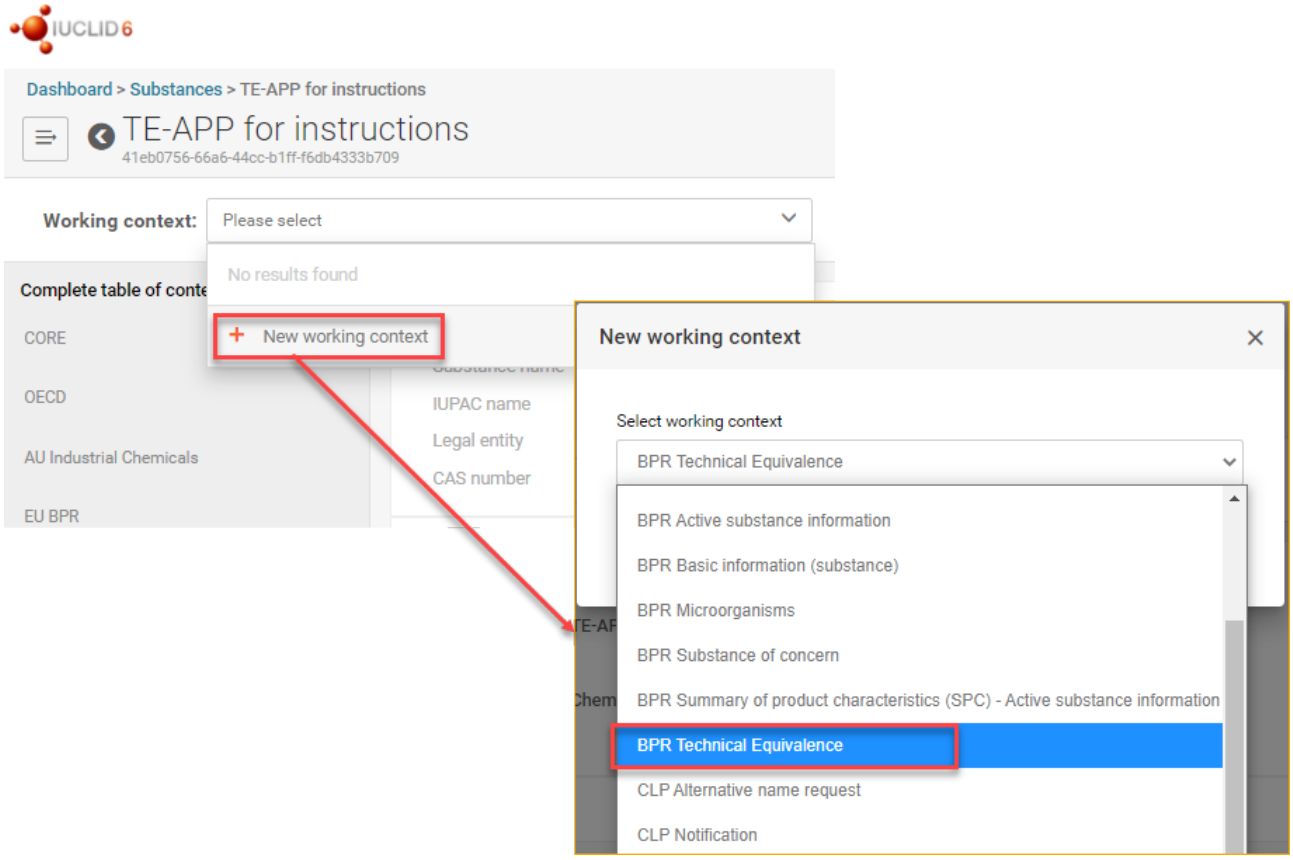
Figure 3: Create a 'Substance' dataset



Step 2: Select the dataset working context

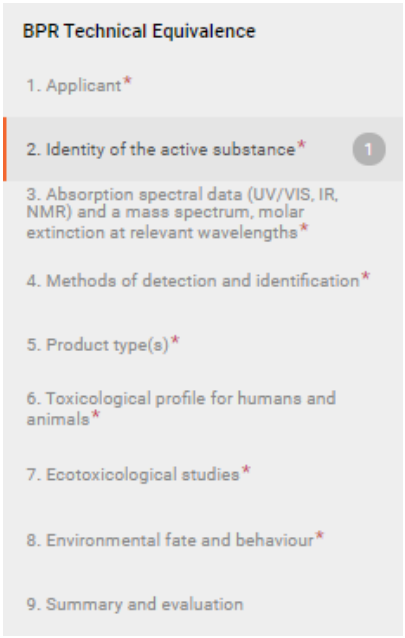
Open your newly created dataset and define at first the working context by clicking the drop-down list arrow in the 'Working context' field and select the 'BPR Technical Equivalence' (Figure 5) and 'Apply'.

Figure 4: Define working context of the substance dataset



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 6).

Figure 5: 'BPR Technical Equivalence' working context structure



Step 3: Enter the 'Applicant' details

Section 1.3 'Active substance manufacturer' name and manufacturing plant location

IUCLID section 1.3 contains the identity of the active substance manufacturer and location of manufacturing plant (s), which must be included. This information is used to identify the source of the active substance.

Start by clicking '+' (Figure 7). You may either assign substance manufacturer from the list of available legal entities '+Select' on the field 'Name' or create new one.

Enter relevant information when creating a new manufacturer and save your entry.

Do the same for inserting location of manufacturing plant(s) (Figure 8). The address included in section 1.3.1 must be the actual location where the active substance is manufactured.

Further details are given in 'Step 3: Enter the 'Applicant details' of the BSM Technical guide: How to prepare a biocides dossier.

Figure 6: Specify the active substance manufacturer in section 1.3

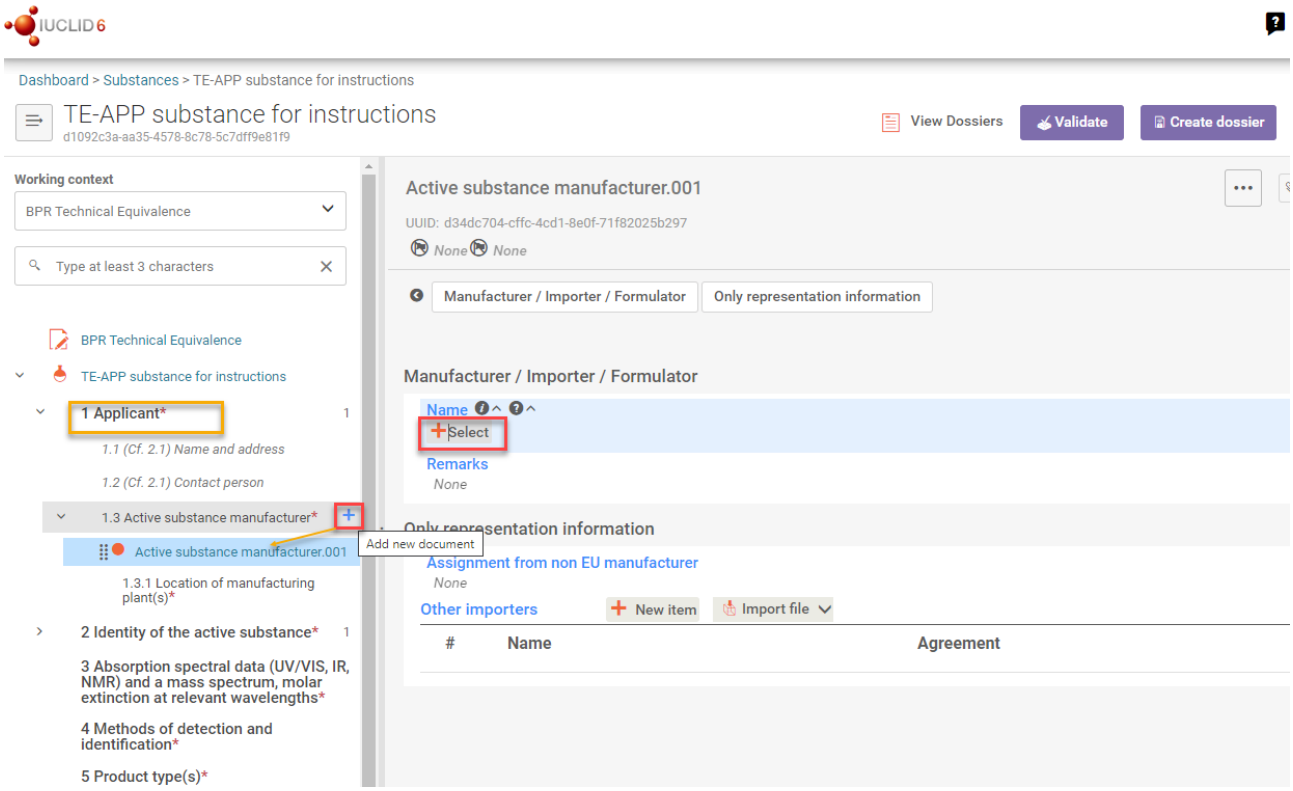
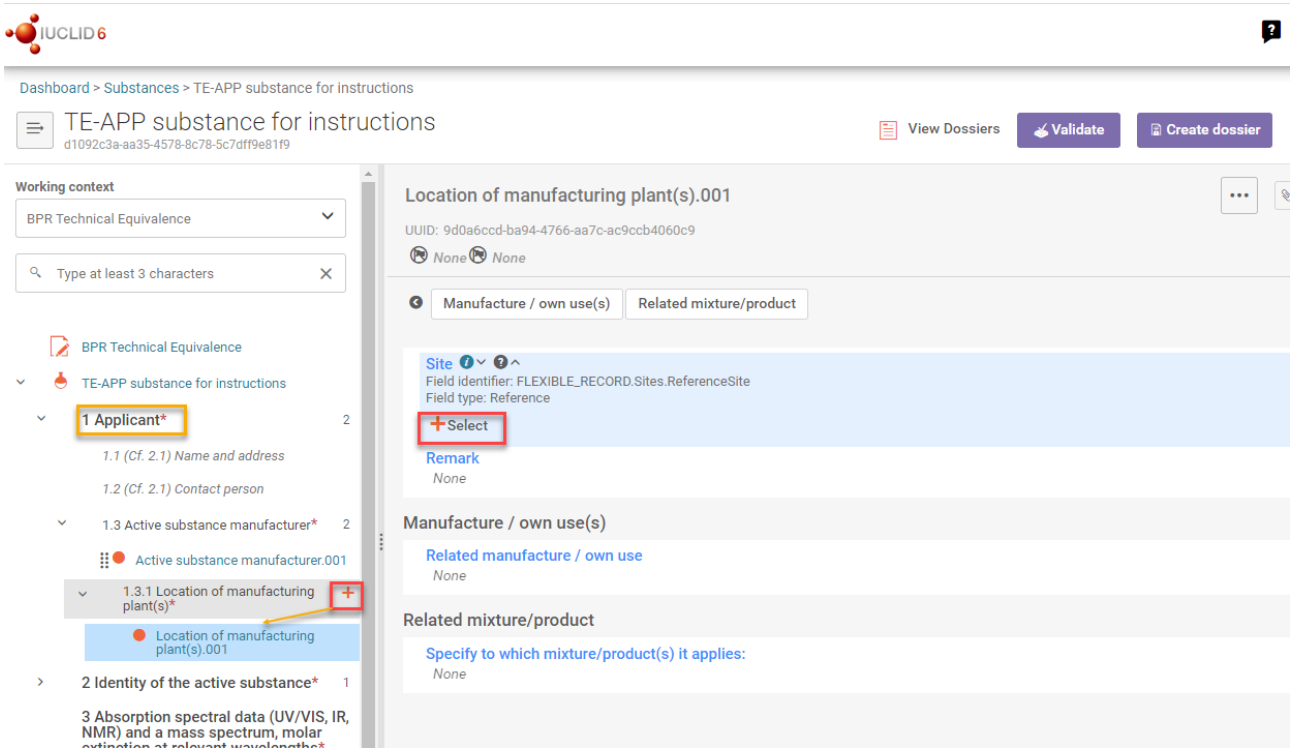


Figure 7: Specify the manufacturing plant location in section 1.3.1



Step 4: Identify the active substance

Section 2.1 - Common name and synonyms

Identify the substance that you wish the assessment of technical eqvivalence to be carried out by clicking 'Reference substance'[5] field '+Select' (Figure 9).

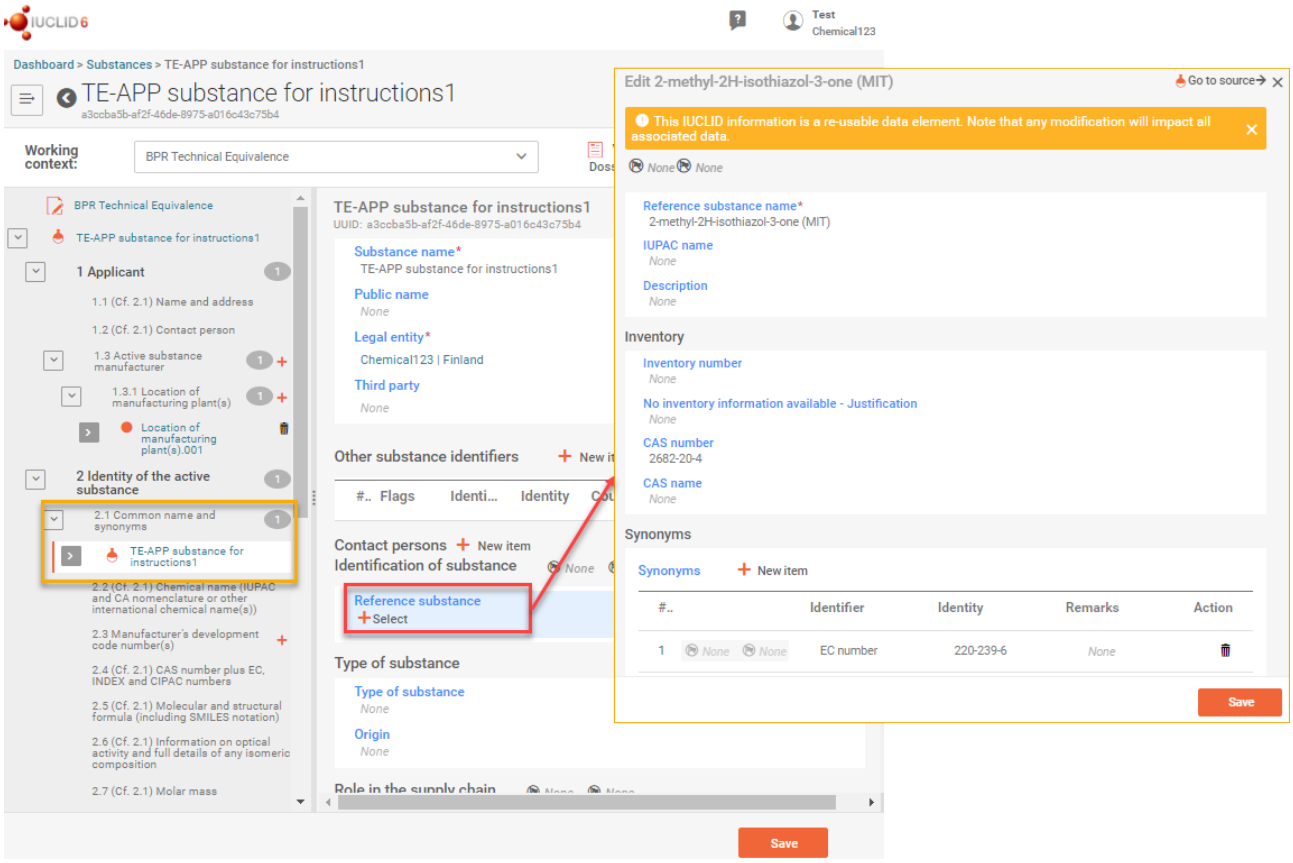
You may either create new reference substance ('+Create') or search and select the relevant one already recorded in your database.

Ensure that the 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 (Figure 9).

Step by step instructions on how to create a reference substance are given in Section 3. Preparing a dataset for an active substance: 'Identify the active substance' of BSM Technical guide: How to prepare a biocides dossier.

Figure 8: Active substance information section 2.1



[5] 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.

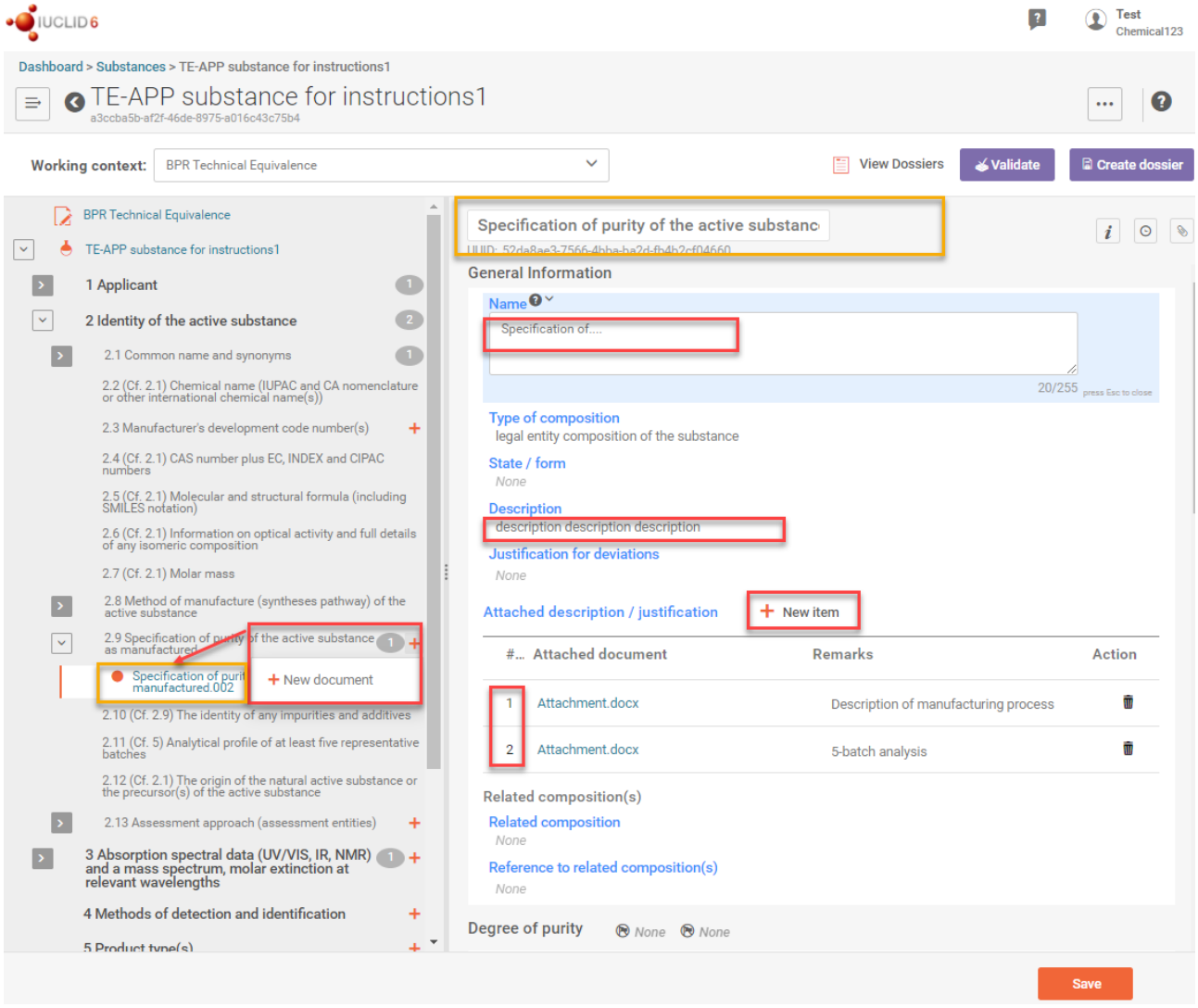
Section 2.9 – Specification of purity of the active substance as manufactured

Insert new entry in section 2.9 by clicking '+New document' (Figure 10).
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**.

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

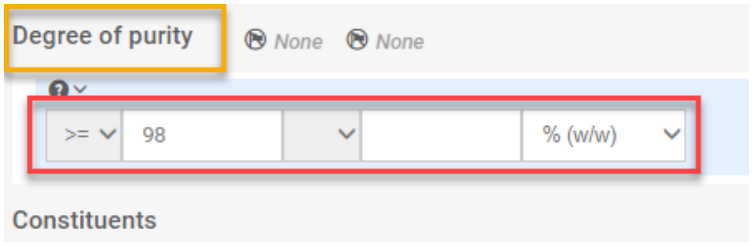
Enter information on the method of manufacture of the active substance into the 'Description' free text field, **and/or** by adding an attachment in the 'Attached description' section (Figure 10).

Figure 9: Entering information on the manufacturing process in section 2.9



Then indicate the degree of purity of the substance, with units. This can be either as the minimum degree of purity (>, ≥) or as a concentration range (>, ≥; <, ≤) (Figure 11). 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 10: Indicate the degree of purity



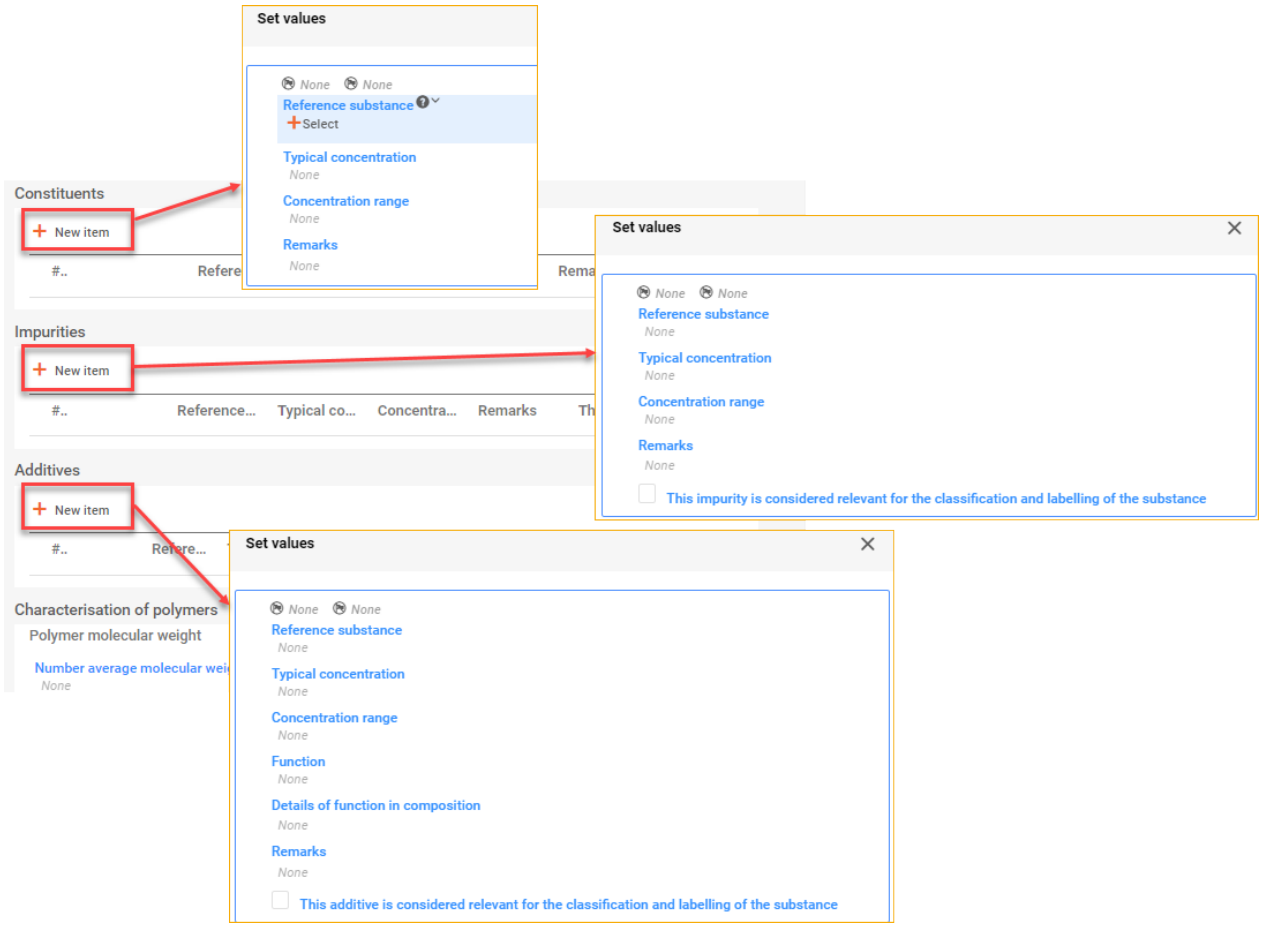
Do not give the degree of purity as circa (ca.).

Provide also the full specification of the active substance, including all constituents, impurities and additives (Figure 12), 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 11: Adding the constituents, impurities, additives



Step 5: Enter the 'Absorption spectra data' details

Section 3 - Absorption spectra data

Insert new entry in section 3 by clicking '+' (Figure 13).

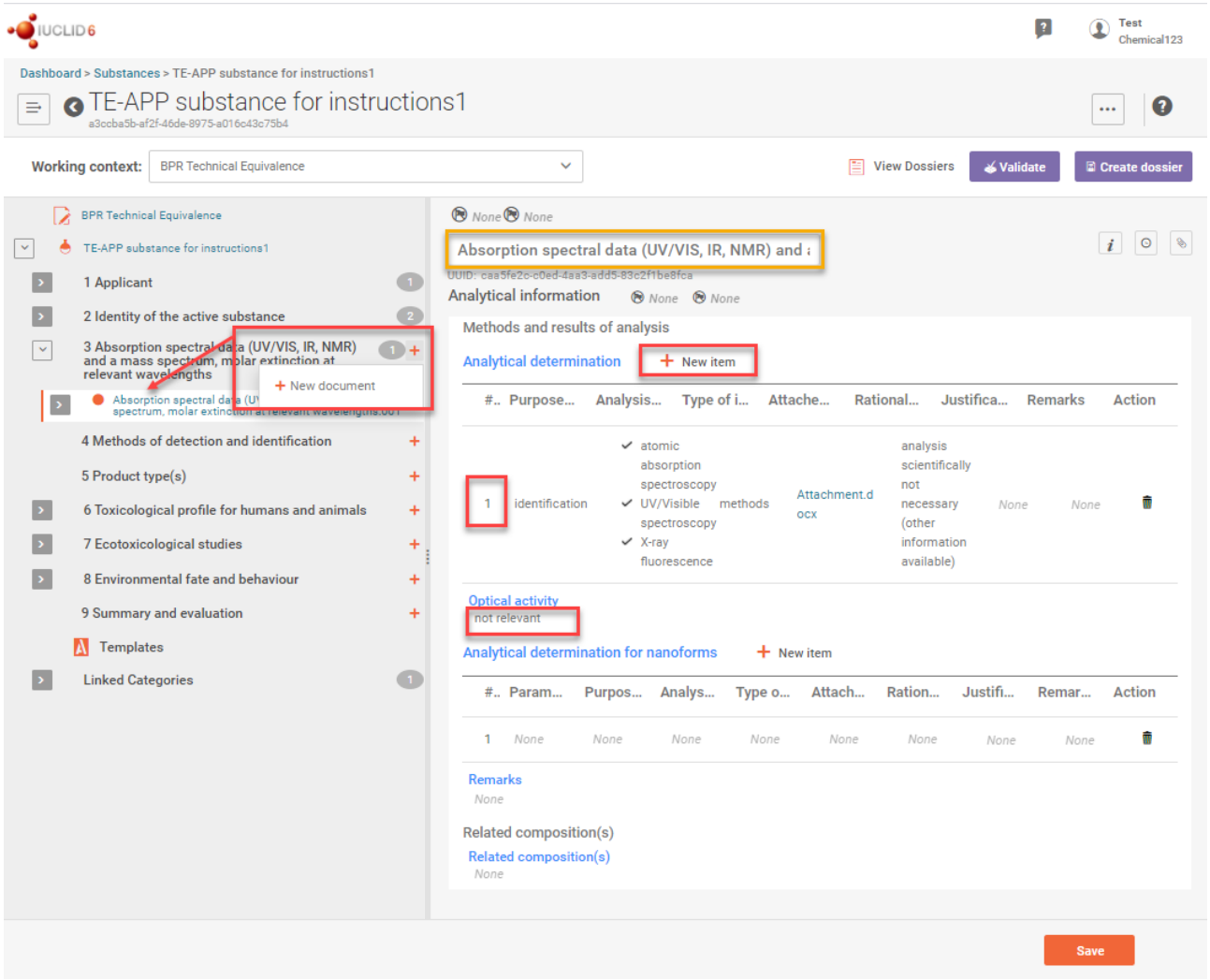
Start by inserting information under methods and results of analysis in 'Analytical determination' by clicking '+New item' for each analysis available (Figure 13).

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 13).

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

Figure 12: Including absoption spectra data in section 3



Step 6: Enter the 'Methods of detection and identification' details

Section 4 – Methods of detection and identification

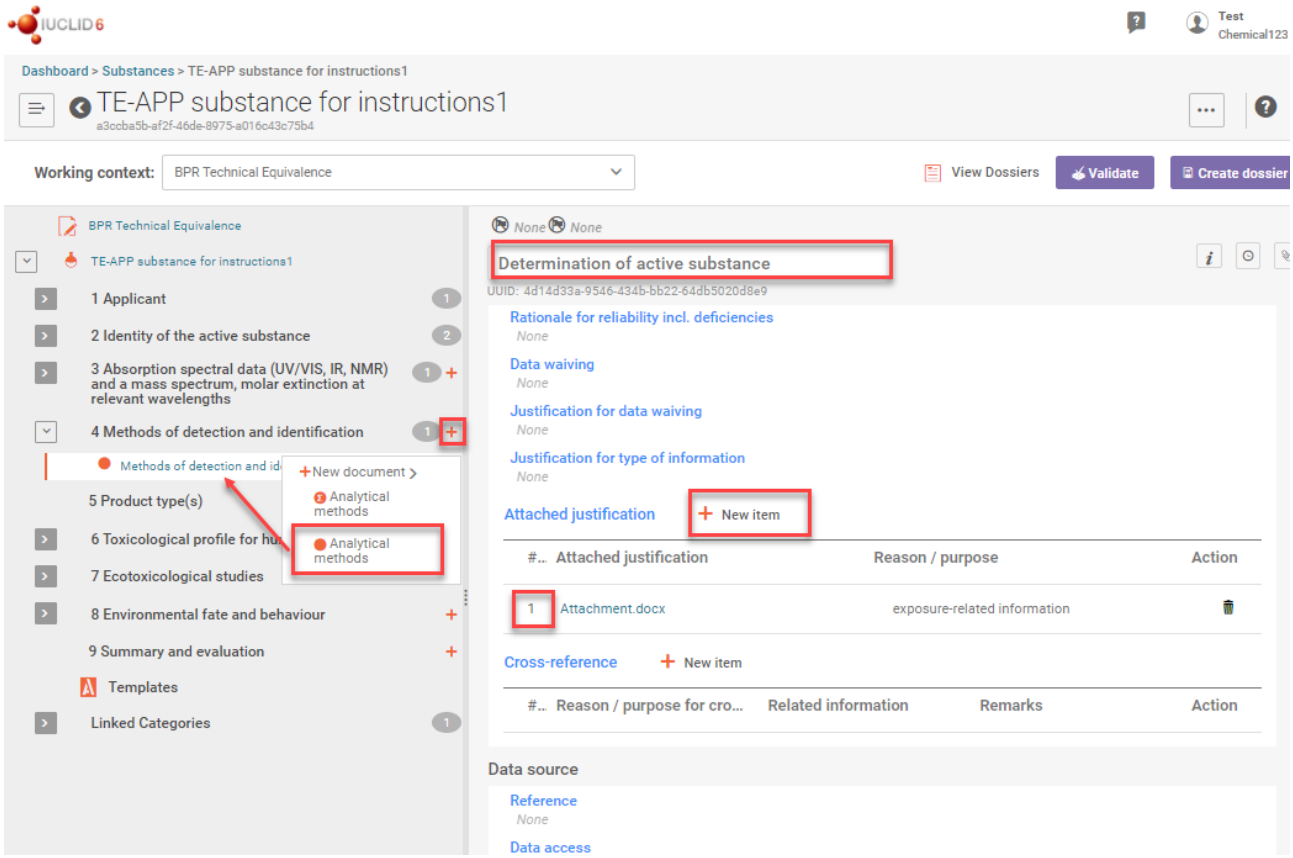
Insert new entry in section 4 by clicking '+' and selecting 'Analytical methods' (Figure 14).

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 14).

Figure 13: Creating a new endpoint study record in section 4



For a detailed explanation on how to fill in the different fields of this endpoint, please see "5 How to complete IUCLID endpoint study records" of BSM Technical guide: How to prepare biocides dossier.

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.

Step 7: Identify Product Type(s)

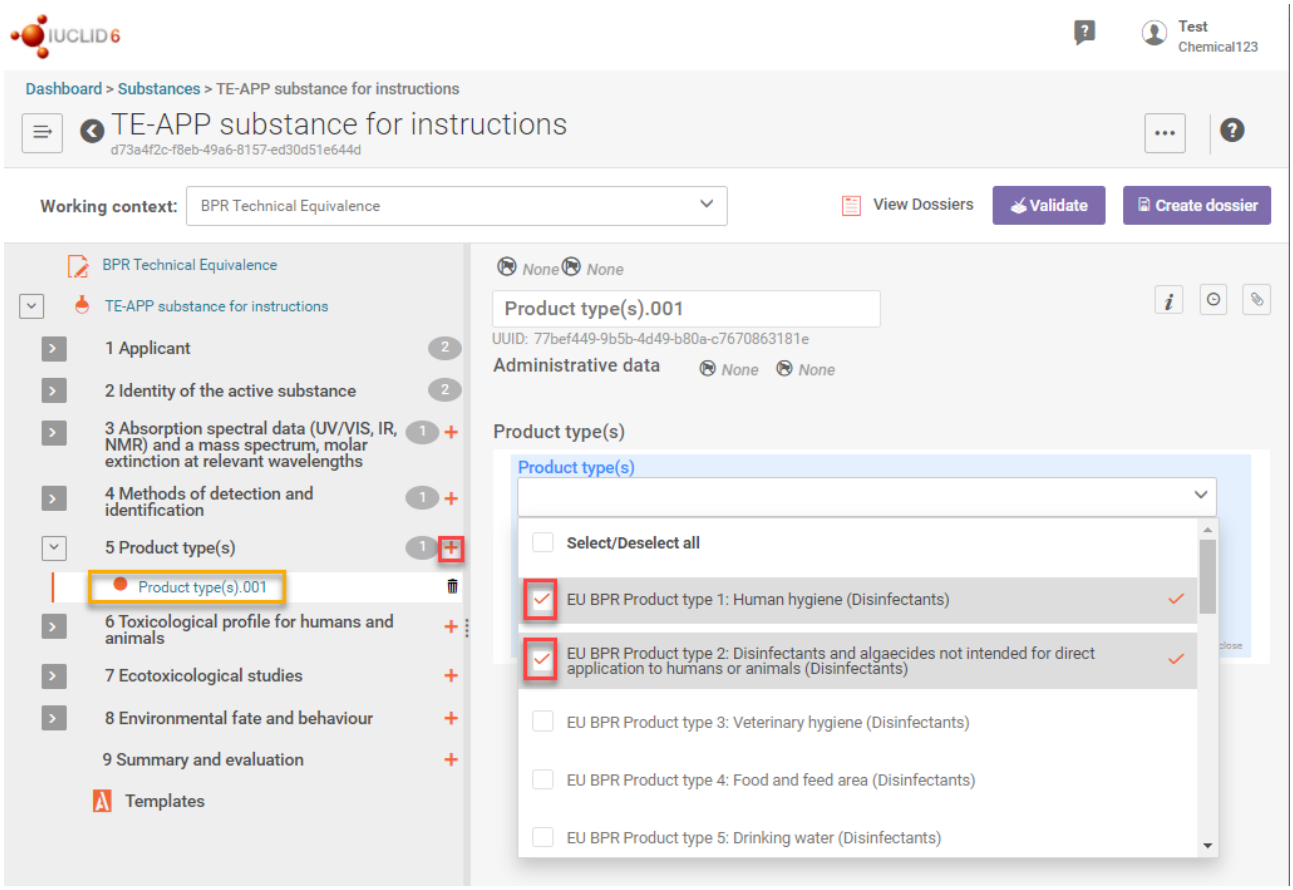
Section 5 – Product Type(s)

Insert new entry in section 5 by clicking '+ New document' and identify the product type(s) you wish to apply for (Figure 15).

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 14: Adding product type(s) in section 5



Step 8: For technical equivalence Tier II assessments

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.

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

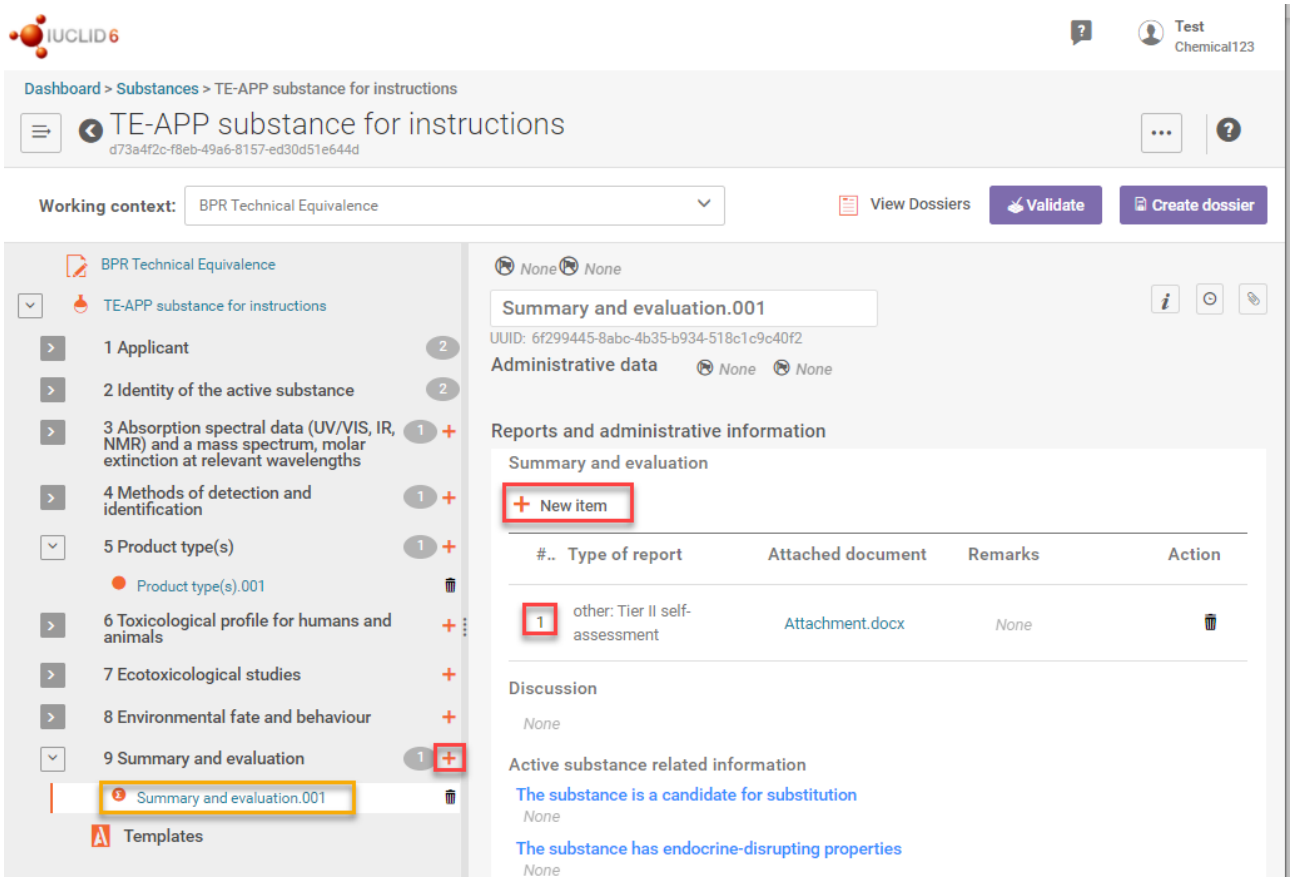
(technical equivalence Tier II assessment conducted by the applicant).

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 16). 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 .

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 16).

Figure 15: Attaching a supporting document in Section 9



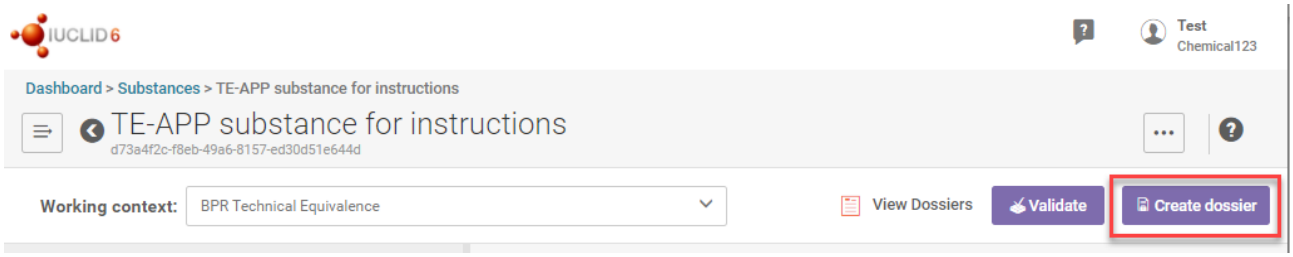
How to create a dossier

Ensure all of the appropriate information is included in the 'Substance' dataset (working context: BPR Technical Eqvivalence) before creating your dossier.

To create a valid dossier open your 'Substance' data set.

Then, click on 'Create dossier' (Figure 17).

Figure 16: Create dossier

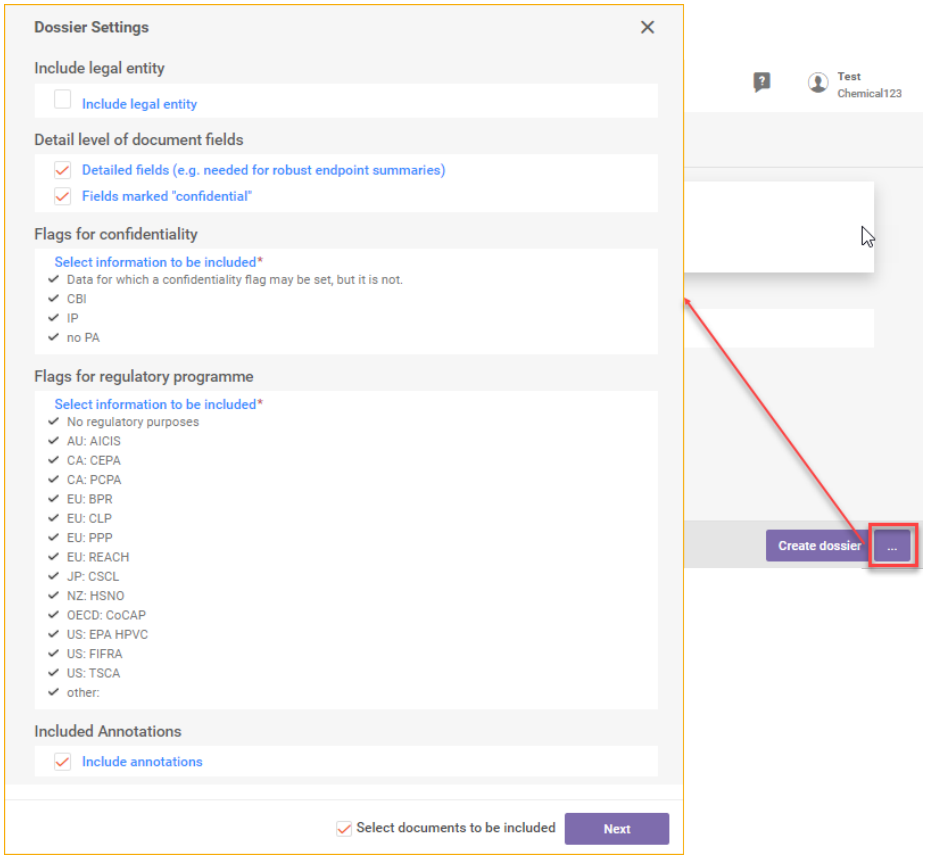


The steps below explain how to navigate through the dossier creation wizard. In IUCLID 6 some of the wizard steps have been hidden by default in order to simplify the dossier creation.

Give name to your dossier and insert dossier submission remark, if relevant.

Click '...' if you wish to display the hidden options of advanced settings of the wizard (Figure 18); otherwise just click 'Create dossier'.

Figure 17: Dossier creation wizard, open advanced settings

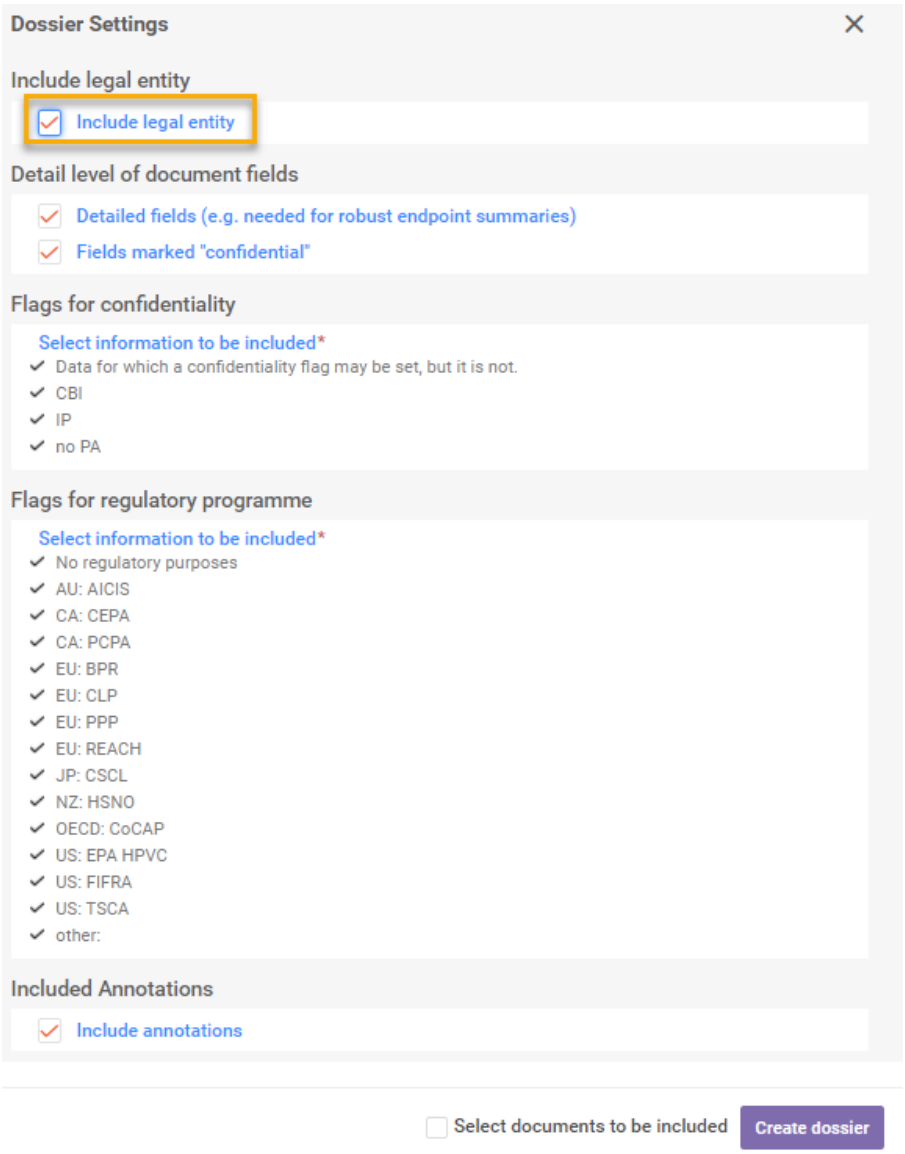


Review the related entities, e.g. that correct dataset has been linked, visible by selecting '…' and then 'Next' (Figure 18).

By default, the 'Submitting legal entity' in the dossier header, and the 'Legal entity owner' in section 2.1 of the substance dataset will not be included in the dossier. However, if you wish to include the aforementioned legal entities (i.e. your company name and details) in your dossier e.g. for your personal record keeping purposes, select 'Include legal entity' (Figure 19).

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 19).

Figure 18: Dossier creation wizard, advanced settings

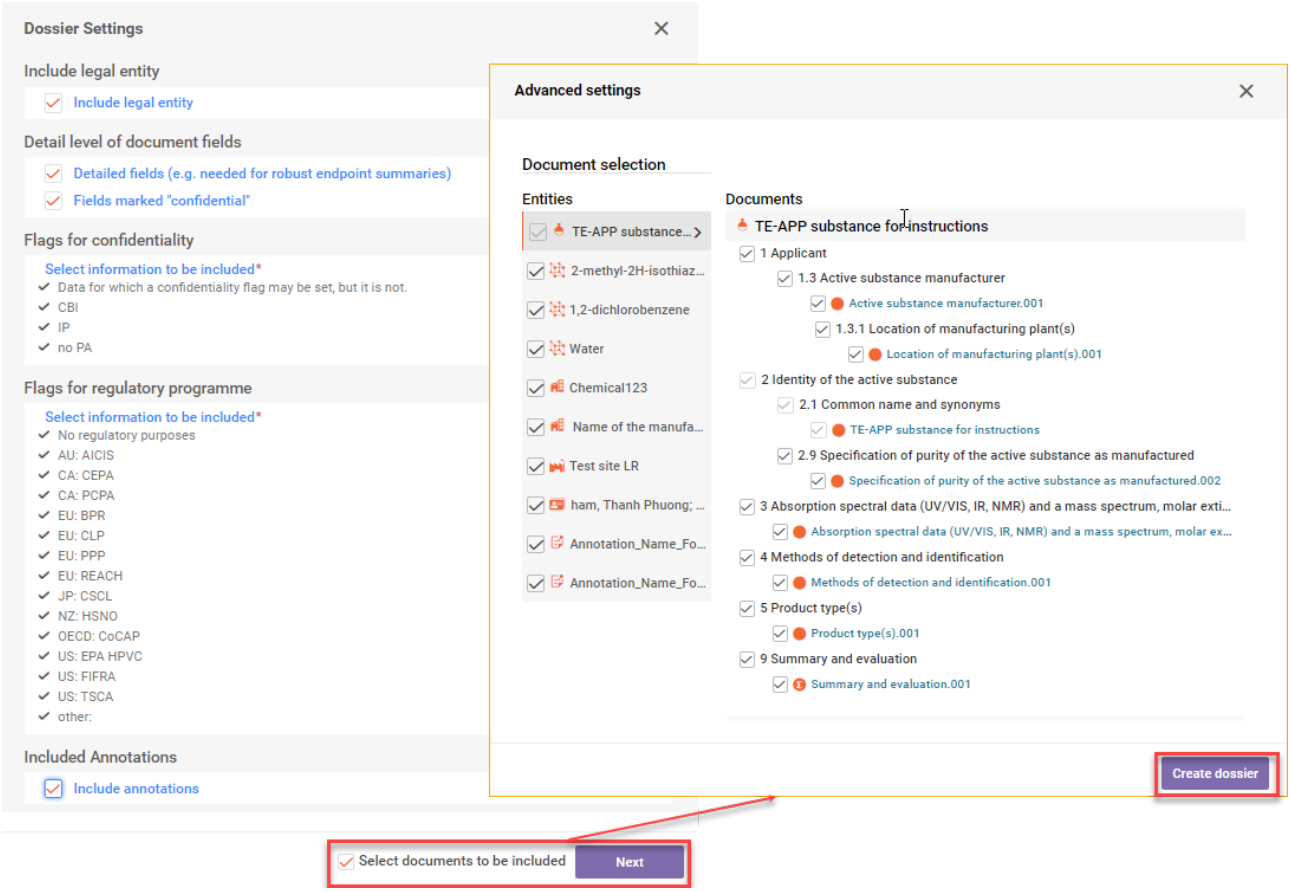


For most cases, ECHA recommends that you do not un-select the checkboxes, making sure that all of the required elements of the dataset are included in the dossier to be submitted.

Verify the inclusion or exclusion of annotations, visible by selecting advanced settings '…' when creating a dossier (Figure 20).

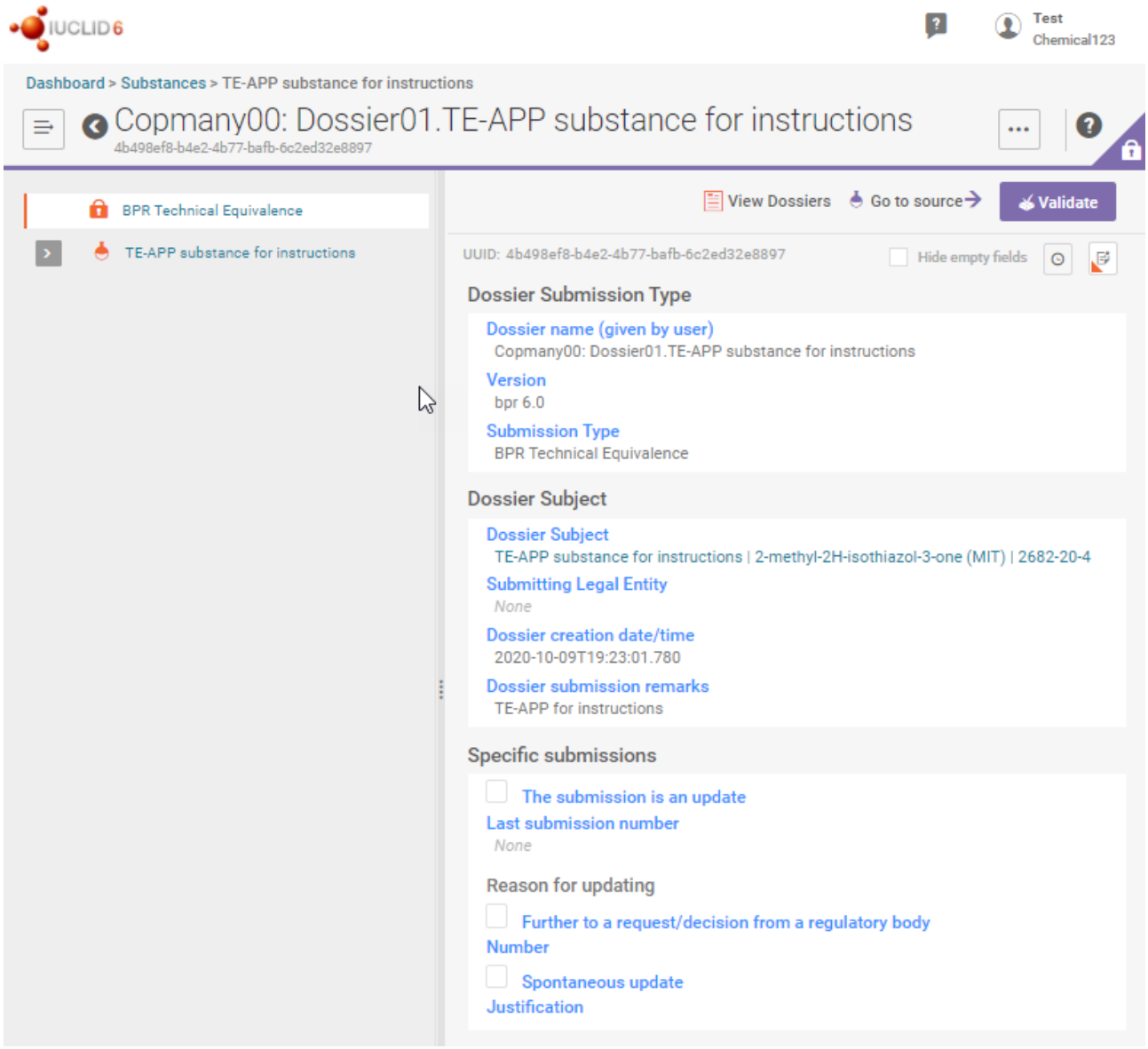
Verify the selected sections for inclusion. All the dossier entities will be displayed in this step. To view the sections of each entity, click the name of the entity e.g. dataset name. By default, all the entities and sections are included in the dossier. To exclude an entity or section, deselect it in the relevant dataset. (Figure 20).

Figure 19: Verifying the sections to be included



Once clicking ‘Create dossier’, a prompt window will appear, giving an option to open the newly created dossier. Clicking ‘Open dossier’ will direct you to the dossier information page (Figure 21).

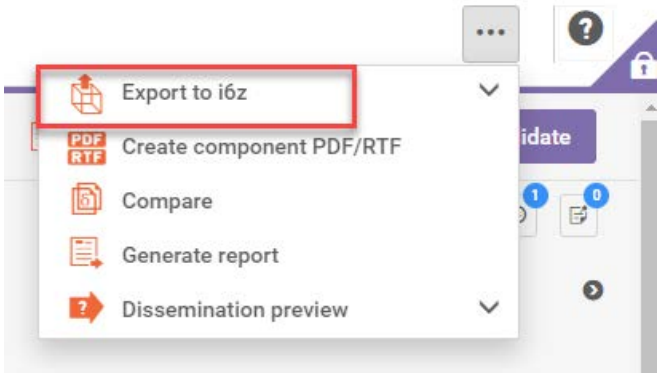
Figure 20: Dossier information page



How to export dossier

When you are satisfied with a dossier, export the final dossier from IUCLID 6. The dossier must be open to launch the export of the dossier (Figure 22) 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.

Figure 21: 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.

EUROPEAN CHEMICALS AGENCY
P.O. BOX 400,
FI-00121 HELSINKI, FINLAND
ECHA.EUROP