

**Biocides IT training
Helsinki - 27 September 2017**

IUCLID 6

Creation and update of a Biocidal Product Authorisation dossier and use of the report generator

Background information

In the context of Article 20 of the BPR Regulation, the application for authorisation for biocidal products other than biocidal products eligible for the simplified authorisation procedure, shall contain:

- A dossier or letter of access for the biocidal product satisfying Annex II requirements for every single active substance
- A dossier or letter of access for the biocidal product satisfying Annex III requirements; and
- A summary of biocidal product characteristics (SPC).

The technical dossier satisfying requirements of Annex II and Annex III must be submitted in IUCLID format.

Scenario

You are an applicant who needs to fill in a IUCLID 6 application satisfying the requirements as specified in Article 20. The active substance to be included in the biocidal product is considered as approved for the relevant product type.

As an applicant, you will need to:

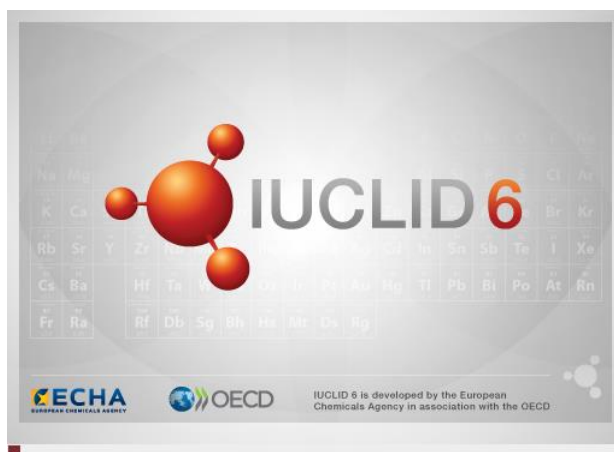
- **PART 1:** Launch IUCLID 6
- **PART 2:** Create a biocidal product authorisation dossier
- **PART 3:** Edit the product dataset
- **PART 4:** Generate an SPC XML file

Please, complete the step-by-step instructions provided in the next pages.

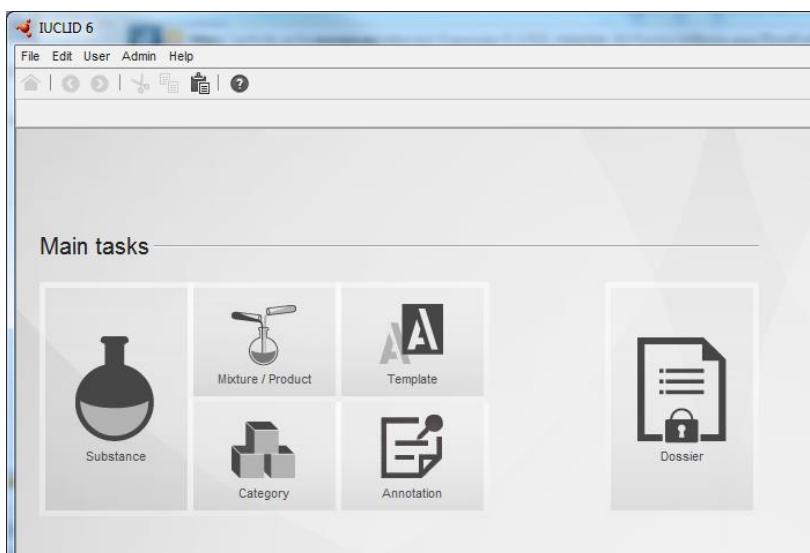
The scientific information provided in the following exercise is not necessarily accurate but will help you to carry out some necessary steps to complete your biocidal products application. Due to the time constraints we cannot go through all mandatory sections during the exercise.

PART 1: Launch IUCLID 6

1. Open IUCLID 6 using the icon available on your Desktop. Please note that under the environment used during the training, the initial launch of IUCLID 6 might take more than one minute.

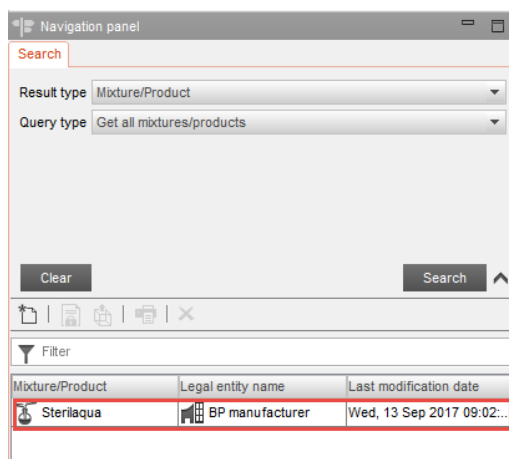


2. Once started, the IUCLID 6 home page will be displayed.

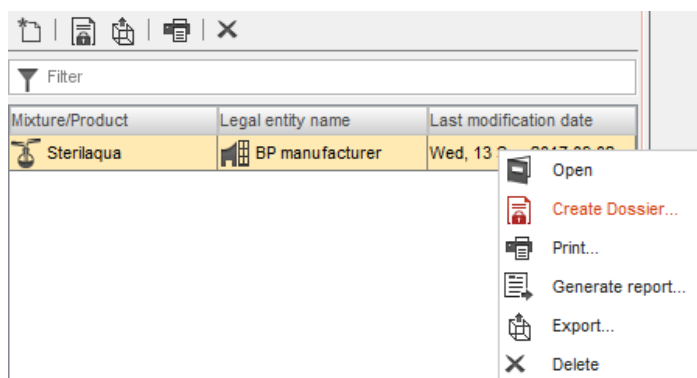


PART 2: Create a biocidal product authorisation dossier

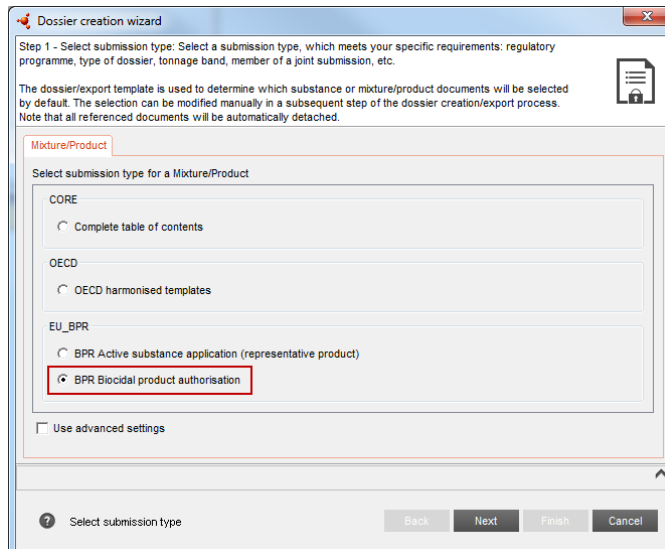
1. Click on the icon 'Mixture / product' and check that the biocidal product dataset is there.



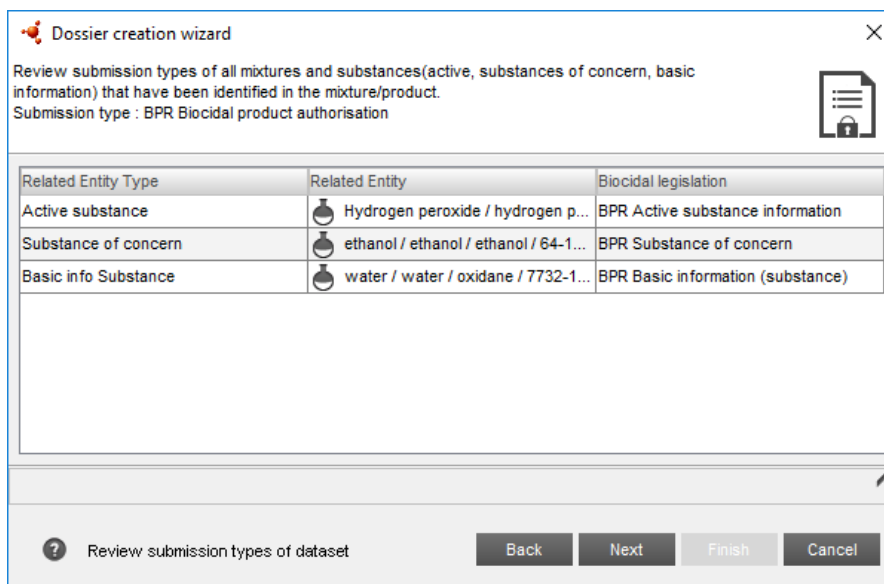
2. In the Navigation panel right click on your biocidal product and select the option "Create Dossier"



3. At the first step of the Dossier creation wizard select the submission appropriate for your biocidal product. In this case, it will be "BPR Biocidal product authorisation". Press Next.

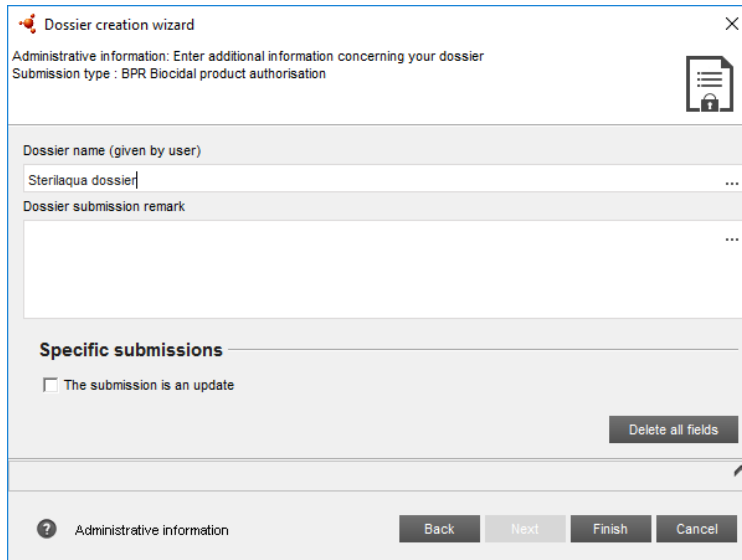


4. At the next step you will see components of the biocidal product, and you can check if all datasets have been prepared using the correct TOC. It should look like on the screen shot below. Press Next.

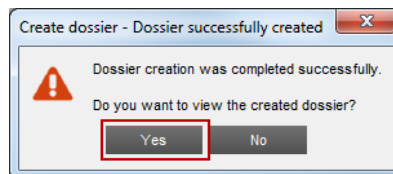


Related Entity Type	Related Entity	Biocidal legislation
Active substance	Hydrogen peroxide / hydrogen p...	BPR Active substance information
Substance of concern	ethanol / ethanol / ethanol / 64-1...	BPR Substance of concern
Basic info Substance	water / water / oxidane / 7732-1...	BPR Basic information (substance)

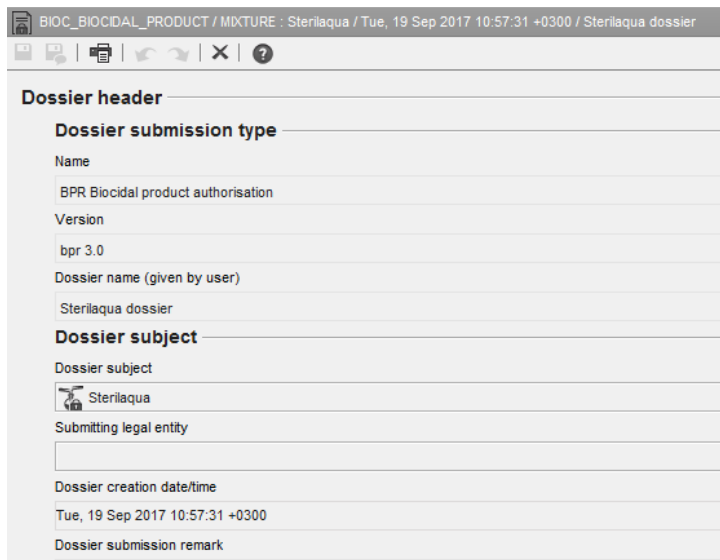
5. At the next step give a name to your dossier. Press Finish.



6. Click "Yes" to access the created dossier



In the main panel a dossier header is displayed. It contains basic information about the dossier: name, version, dossier name given by user, main component of the dossier, legal entity (if required by user during the dossier creation), creation date, information if the dossier is an update and remarks.



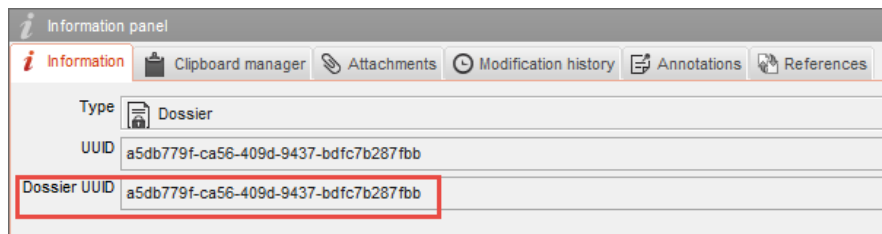
To see all components of the biocidal product in the Navigation Panel, you need to press the plus sign next to main component of a dossier.




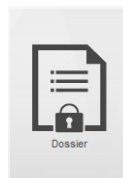
Then, you can open each element by double click.



In the Information Panel the UUID of the dossier is displayed. This is an unique identifier of each dossier. The quickest way for searching for a dossier is by pasting its UUID (Search by UUID) in the upper right corner of the main IUCLID page.




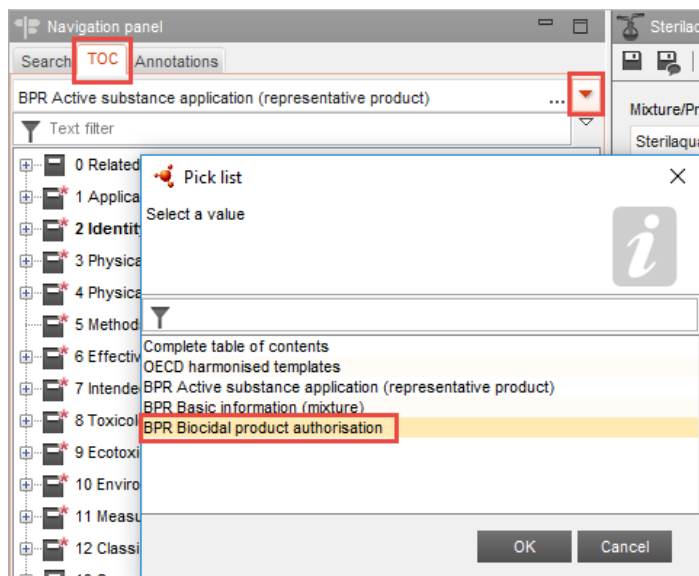
You can access you dossier also by by clicking the icon  (to come back to the main page of IUCLID) and then clicking on the "Dossier" icon.



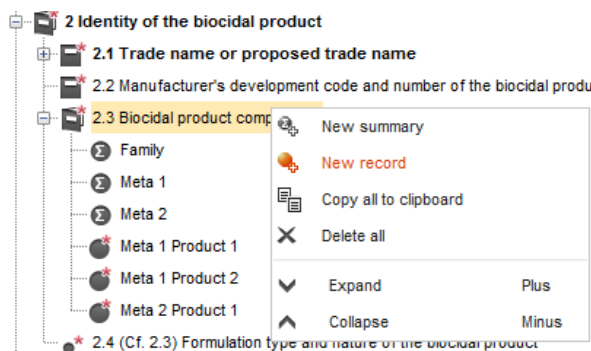
If you have several dossiers in your database, you can use Search to find the needed one.

PART 3: Edit the product dataset

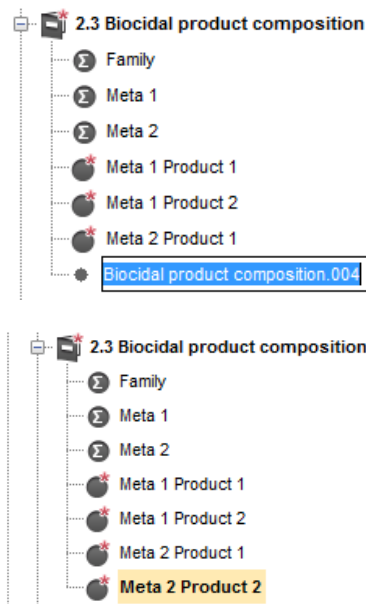
1. Come back to the main page of IUCLID by clicking the icon 
2. Click on the "Mixture / Product" icon
3. Open your product dataset (double click or right click and an option 'Open'), select tab TOC, and select the correct submission type: BPR Biocidal product authorisation



4. Go to section 2.3 'Biocidal Product composition'. You can see there summaries for a family, for meta 1 and meta 2, as well as three records for the biocidal products belonging to meta 1 or meta 2. One biocidal product is missing, therefore:
 - ✓ Right click on the section 2.3 Biocidal product composition, and select an option 'New record'



- ✓ Name new record 'Meta 2 Product 2'

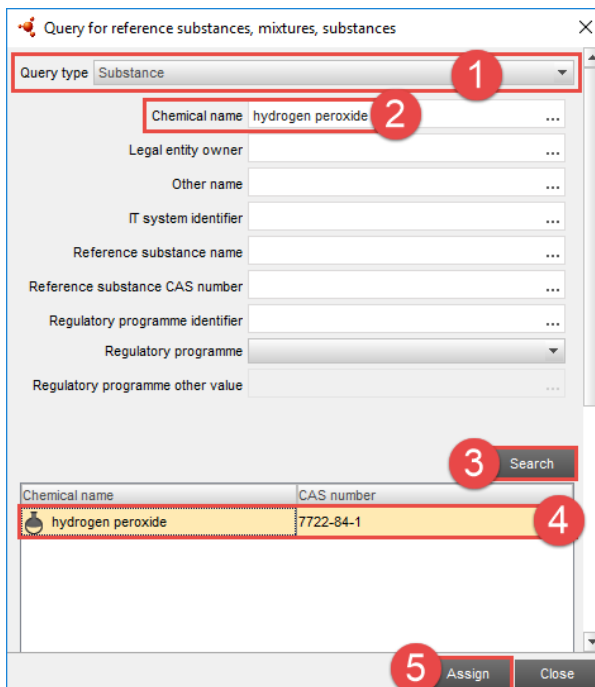


- ✓ Fill in the composition information for this product:

Mixture/product name: Sterilaqua 2
Formulation type: AL Any other liquid

- ✓ Link three components of the biocidal product. For each of them you need to link a substance dataset (1), select a function (2), indicate an exact concentration of a component in a field 'Typical concentration' (3), as explained here below. If any of components is a substance of concern, you need to indicate it by checking in a relevant checkbox (4).

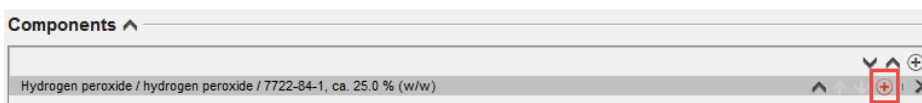
To link a substance dataset, click a chain next to 'Name' field to open a query window, and then select '**Substance**' (1), insert chemical name of the substance (2), press Search (3), select the substance (4) and press Assign (5).



You will need to link three substances:

1.
 chemical name: Hydrogen peroxide
 function: active substance
 typical concentration: 25 % (w/w)

You add new component by clicking on the small plus sign next to an existing component:



2.
 chemical name: ethanol
 function: other: non active substance
 typical concentration: 0.8 % (w/w)
 Substance of concern Substance of concern
3.
 chemical name: water
 function: solvent
 typical concentration: 74.2 % (w/w)

Save the changes every time when you leave the record after having modified data.



You can also look at other products in section 2.3 to compare how the ready record should look like.

- ✓ Check if the range composition for the whole family and meta 2 is correct, and if it is not, correct it to obtain following concentrations:

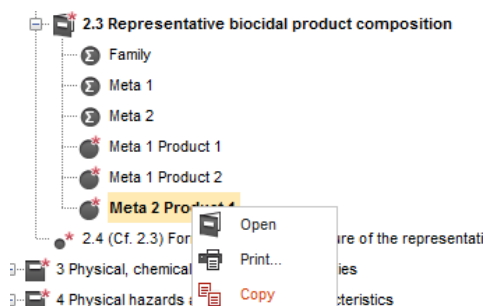
Family:
 20 - 48% Hydrogen peroxide
 0.5 - 1% ethanol
 51 - 79.5% water

Meta 2:
 20 - 25% Hydrogen peroxide
 0.5 - 0.8% ethanol
 74.2 - 79.5% water

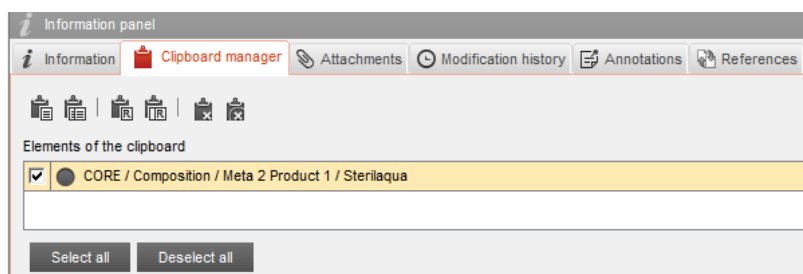
Additional exercise 1 (optional):

You can copy an existing product record, paste it and change only the concentration of the components and mixture/product name (you can modify all data in a pasted document, but it is not needed for this exercise). That should be done in following steps:

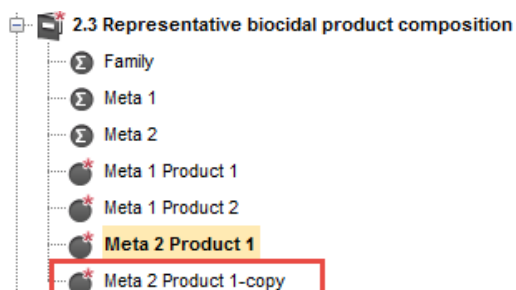
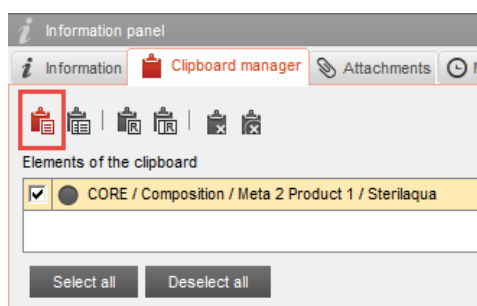
1. Right click on the selected record and select an option 'Copy'



- Go to the Information panel, tab 'Clipboard manager' and select the record you have copied



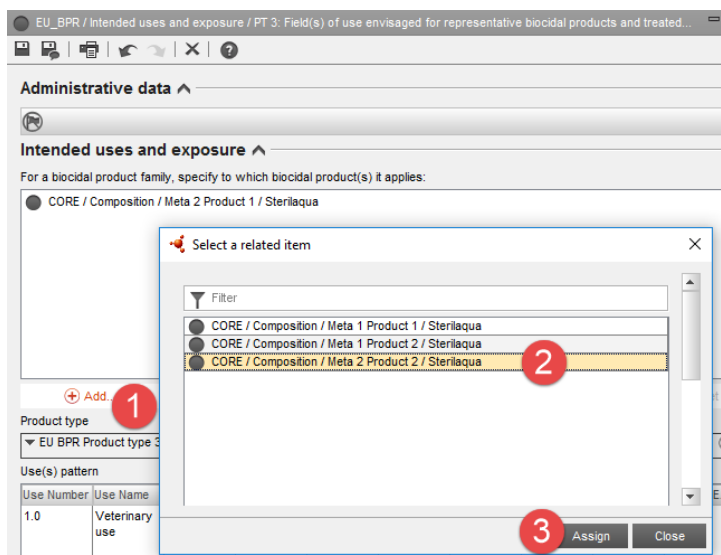
- Press the first icon on the left 'Paste selected'; the record will be pasted in section 2.3



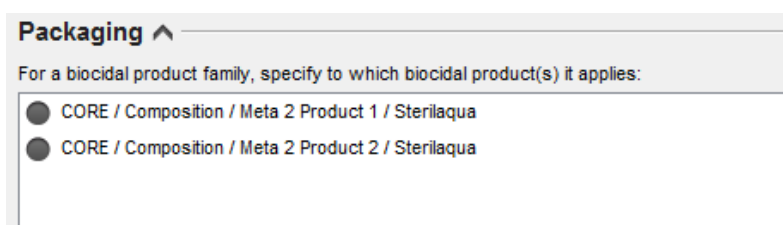
- Change the name of the record (right click → 'Rename'), then open it (double click) and correct data.

Continuation of the basic exercise:

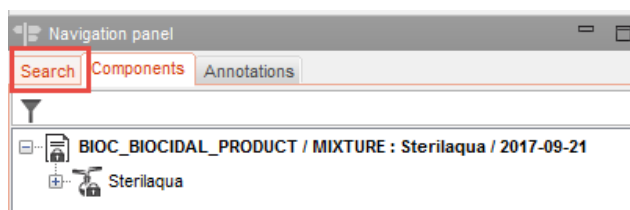
- Go to section 7.1 and open the second record called 'PT 3: Field(s) of use envisaged for biocidal products and treated articles.002' to specify that this information applies to the biocidal product created previously. Add (1) a biocidal product 'Meta 2 Product 2' (2) and press 'Assign' (3). Remember to save your changes.



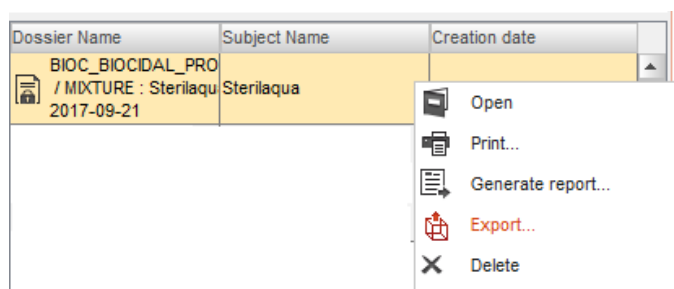
- Go to section 12.3 and open the third record called 'Packaging.003' to specify that this information applies to the biocidal product created previously. Add a biocidal product 'Meta 2 Product 2' and press 'Assign' as in step 5. Remember to save your changes.



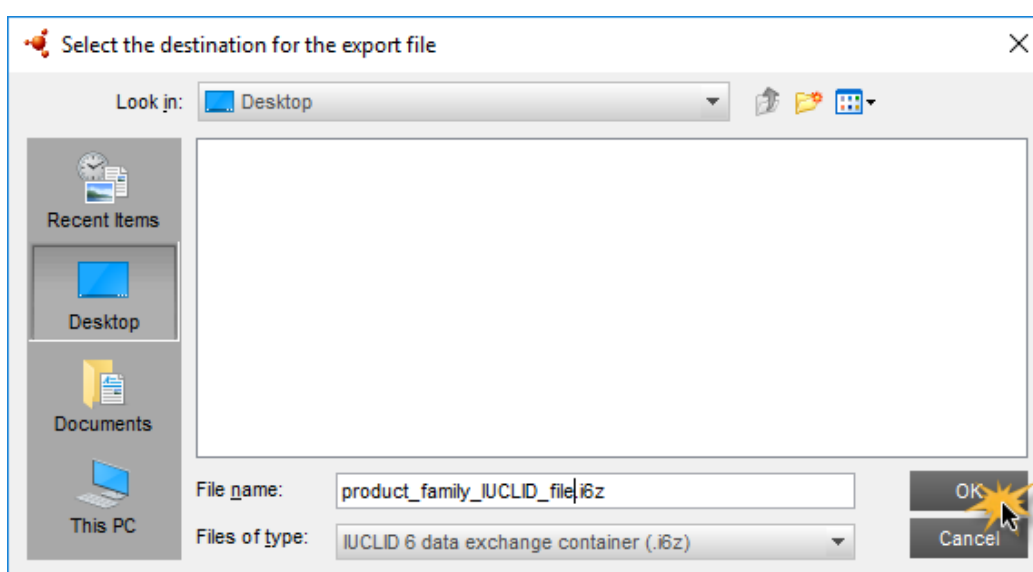
- Create a new dossier (see PART 2 above). Name it 'Sterilaqua final dossier'.
- Export a dossier to a Desktop:
 - Select the tab 'Search'



- Right click and select option 'Export', then press 'Next'




- Indicate a location (Desktop) and a name for the exported dossier 'product_family_IUCLID_file'. Press Finish.



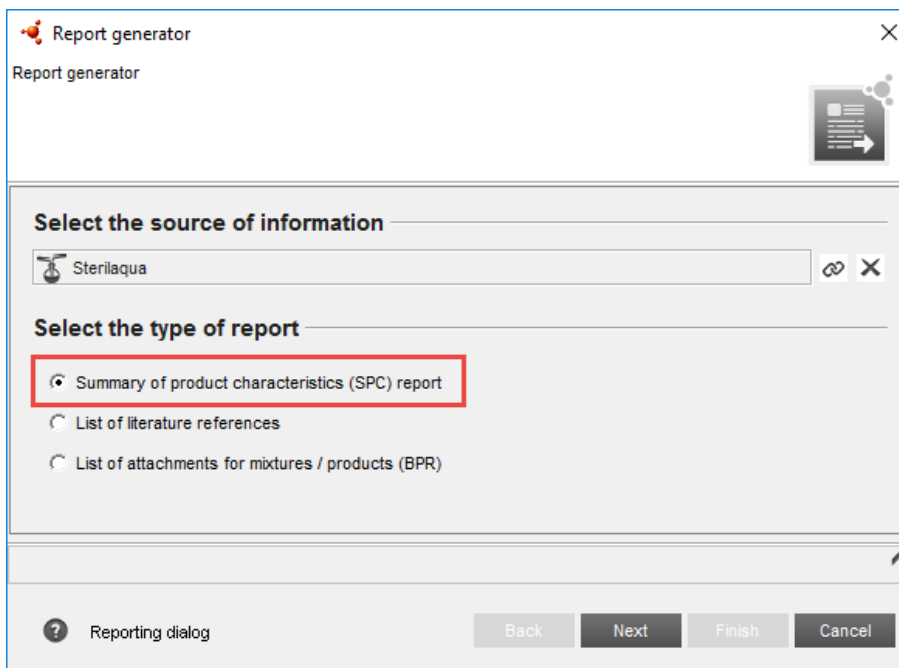
- Check if your file is on the Desktop. You will need this file during the next part of the training.



PART 4: Generate an SPC XML file

1. Come back to the main page of IUCLID by clicking the icon 
2. Click on the "Mixture / Product" icon.
3. Right-click your product dataset and select 'Generate report...'.

4. Select 'Summary of product characteristics (SPC) report'. Press Next.



Report generator

Select the source of information

Sterilaqua

Select the type of report

Summary of product characteristics (SPC) report

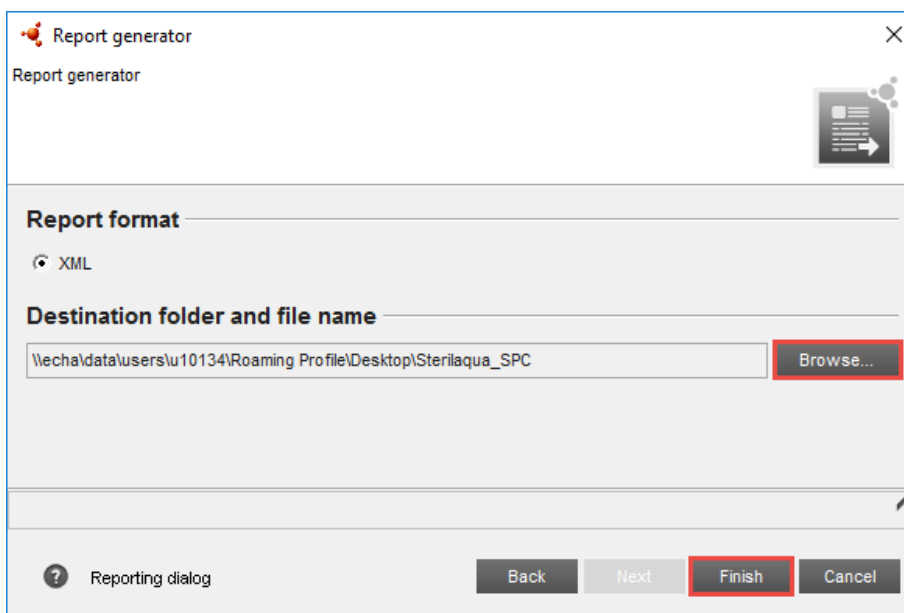
List of literature references

List of attachments for mixtures / products (BPR)

Reporting dialog

Back Next Finish Cancel

5. Select 'Browse' and indicate a location (Desktop) and a name for the SPC XML file to be generated. Press Finish.



Report generator

Report format

XML

Destination folder and file name

\\echa\data\users\lu10134\Roaming Profile\Desktop\Sterilaqua_SPC



Browse...

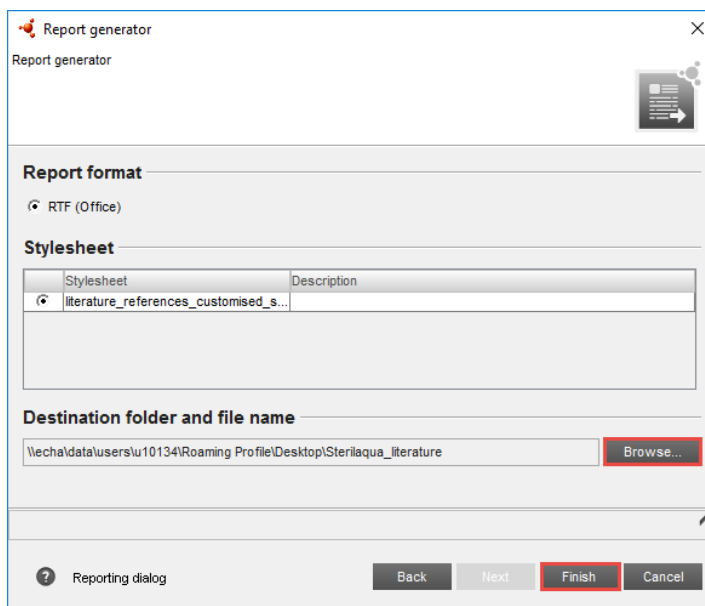
Reporting dialog

Back Next Finish Cancel

6. The XML file is generated and the relevant information is extracted from the IUCLID product dataset. The XML file opens in a browser.

Additional exercise 2 (optional):

1. Come back to the main page of IUCLID by clicking the icon 
2. Click on the "Mixture / Product" icon.
3. Right-click your product dataset and select 'Generate report...'.

4. Select 'List of literature reference'. Press Next.
5. Select 'Browse' and indicate a location (Desktop) and a name for the list of literature references file to be generated. Press Finish.



Report generator

Report generator

Report format

RTF (Office)

Stylesheet

Stylesheet	Description
<input checked="" type="checkbox"/> literature_references_customised_s...	

Destination folder and file name

Wecha\data\users\u10134\Roaming Profile\Desktop\Sterilaqua_literature

Reporting dialog


6. The rtf file is generated and the relevant information is extracted from the IUCLID product dataset.

1. Literature References

Table 1.1. Literature References generated from a Mixture/Product (including Literature References in Substance)

Type		Section information		Annex II/III requirement		UUID
Biocidal product		Section No. 3.1 Section Name: Appearance (at 20°C and 101.3 kPa) Name given to the Document: Appearance (at 20°C and 101.3 kPa).001		Appearance (at 20°C and 101.3 kPa)		f219b13f-fd81-40e [http://localhost:8080/jnlp?uuid=f219b13f-fd81-40e]
Reference type: study report	Title: 3.1 both appearance	Author: Chris Staley	Bibliographic source: unpublished report Year: 2010	Testing laboratory: SPL, Inc. 8820 Interchange Drive Houston, TX 77054	Report no. 1030-2010040088-011A	Company owned by: Sasol North America, Inc. Company study number: T105
Remarks: no remarks in literature reference						
Biocidal product		Section No. 3.2 Section Name: Acidity, alkalinity Name given to the Document: Acidity, alkalinity.001		Acidity, alkalinity		4eb07758-452c-613 [http://localhost:8080/jnlp?uuid=4eb07758-452c-613]

Additional exercise 3 (optional):

1. Come back to the main page of IUCLID by clicking the icon 
2. Click on the "Mixture / Product" icon.
3. Right-click your mixture dataset and select 'Generate report...'.
4. Select 'List of attachments for mixtures / products (BPR)'. Press Next.
5. Select 'Browse' and indicate a location (Desktop) and a name for the list of literature references file to be generated. Press Finish.
6. The rtf file is generated and the relevant information is extracted from the IUCLID product dataset.

1. Attachments for a biocidal product/mixture

Table 1.1. Attachments in the biocidal product

Type	Section information	Annex II/III requirement	UUID
Biocidal Product Packaging related attachment	Section No. 12.3 Section Name: Packaging (12.7 in Annex III of BPR) Name given to the Document: Packaging.001	CLASSIFICATION, LABELLING, AND PACKAGING As established in point (b) of Article 20(1), proposals including justification for the hazard and precautionary statements in accordance with the provisions set in Directive 1999/45/EC and Regulation (EC) No 1272/2008 must be submitted. Example labels, instructions for use and safety data sheets shall be provided	IUC5-7b d-99ce-0 [http://lo start/la C5-7b0 99ce-0]
Attachment name: label.png	Attachment remarks:	Attachment media type: image/jpeg	Attach 20,207
Biocidal Product Packaging related attachment	Section No. 12.3 Section Name: Packaging (12.7 in Annex III of BPR) Name given to the Document: Packaging.002	CLASSIFICATION, LABELLING, AND PACKAGING As established in point (b) of Article 20(1), proposals including justification for the hazard and	983d9 6-30c9 [http://lo start/la 3d9b24- 30c9b]

END OF THE TRAINING