SPC in IUCLID training for Industry
Helsinki – 24th of October 2023

IUCLID 6.7

Creation of an SPC in IUCLID

Scenario: You are an applicant who needs to prepare a Summary of Product Characteristics (SPC). At the end of the exercise, you will have the SPC(s) in IUCLID format (.i6z) to be submitted to R4BP 3 and the SPC documents in .rtf format (compatible with MS Word or OpenOffice for example).

Contents

Please, complete the step-by-step instructions provided in the next pages, using IUCLID.
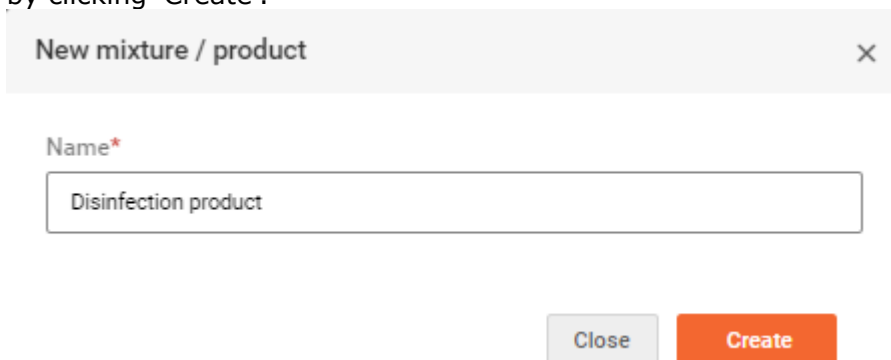
The scientific information provided in the following exercise is not necessarily accurate but will help you to carry out some necessary steps to complete your applications. Due to the time constraints, we cannot go through all fields during this exercise. You can replace the proposed example data by the data of your choice if you prefer.

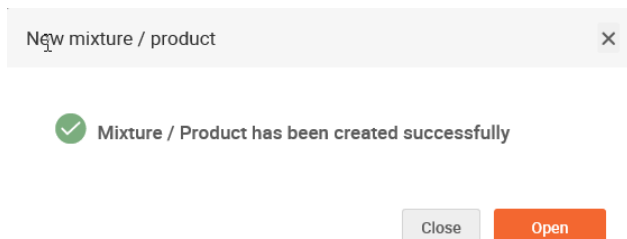## PART 1: Create an SPC dossier (.i6z file) for a single product

The focus of this part is on the IUCLID User Interface and how SPC related data can be captured for a single product application (NA-APP).

1. After logging in to IUCLID, you see the IUCLID home page. Click on the Mixtures section and then on **+ New mixture / product** to create a new mixture / product.
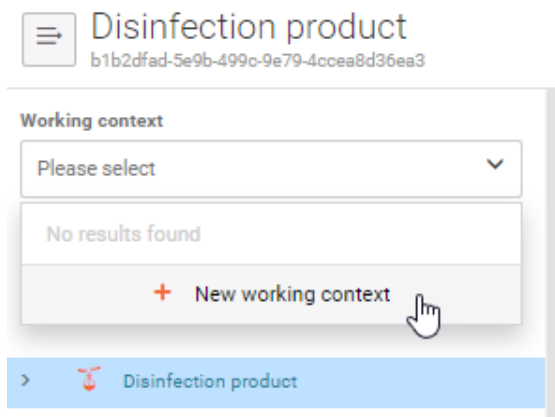
2. Insert the product name, for example "Disinfection product" and create a product dataset by clicking 'Create'.

New mixture / product   ✕

Name*

Disinfection product

Close   Create

3. A new Mixture / Product has been created successfully, and you can open it by clicking 'Open'

New mixture / product   ✕

✓ Mixture / Product has been created successfully

Close   Open

4. The new product opens by default with the *Complete table of contents*. You need to specify the working context relevant to an SPC. It is needed to ensure that the displayed table of contents will follow the structure of an SPC. Select *BPR Summary of Product Characteristics (SPC)* from the drop-down menu:

Disinfection product
b1b2dfad-5e9b-499c-9e79-4ccea8d36ea3

Working context

Please select   ⌄

No results found

+ New working context

⟩ ℧ Disinfection product

New working context

Select working context

EFSA chemicals database (mixture)
EU_BPR
  BPR Active substance application (representative product)
  BPR Basic information (mixture)
  BPR Biocidal product authorisation
  BPR Summary of product characteristics (SPC)
EU_CLP
  CLP Interchangeable Component Group (ICG)
  CLP PCN Standard formula component

5. On the left side, on top, access the *dossier header*, and fill in high-level information such as the dossier name of your choice (e.g. SPC for Disinfection Product), the relevant SPC type: *single product*, the *market area (Ireland)*, and the *language (English)*. You can see that some fields are mandatory. It means that you cannot save the inserted data if those fields remain empty.

    Authorisation details will be added automatically during the authorisation, based on the data stored in R4BP 3. These fields should be left empty for the preparation of the dossier to be submitted.

Working context

BPR Summary of product characteristics (SPC)

Type at least 3 characters

BPR Summary of product characteristics (SPC)

Disinfection product

UUID: 657424df-1a09-4835-9b15-9d10ceadfd45

Specific submissions

Dossier name (given by user)

Dossier submission remark

Specific submissions

SPC type
⊗ This field is mandatory.
Market area
⊗ This field is mandatory.
Language
⊗ This field is mandatory.
Authorisation details

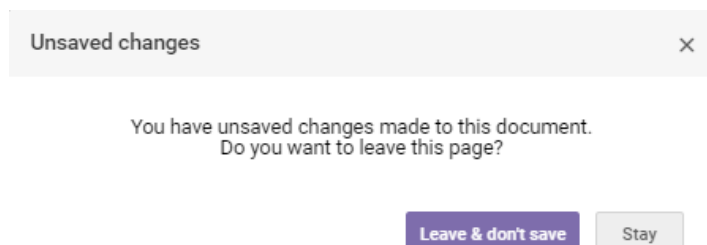Authorisation number

Reference number
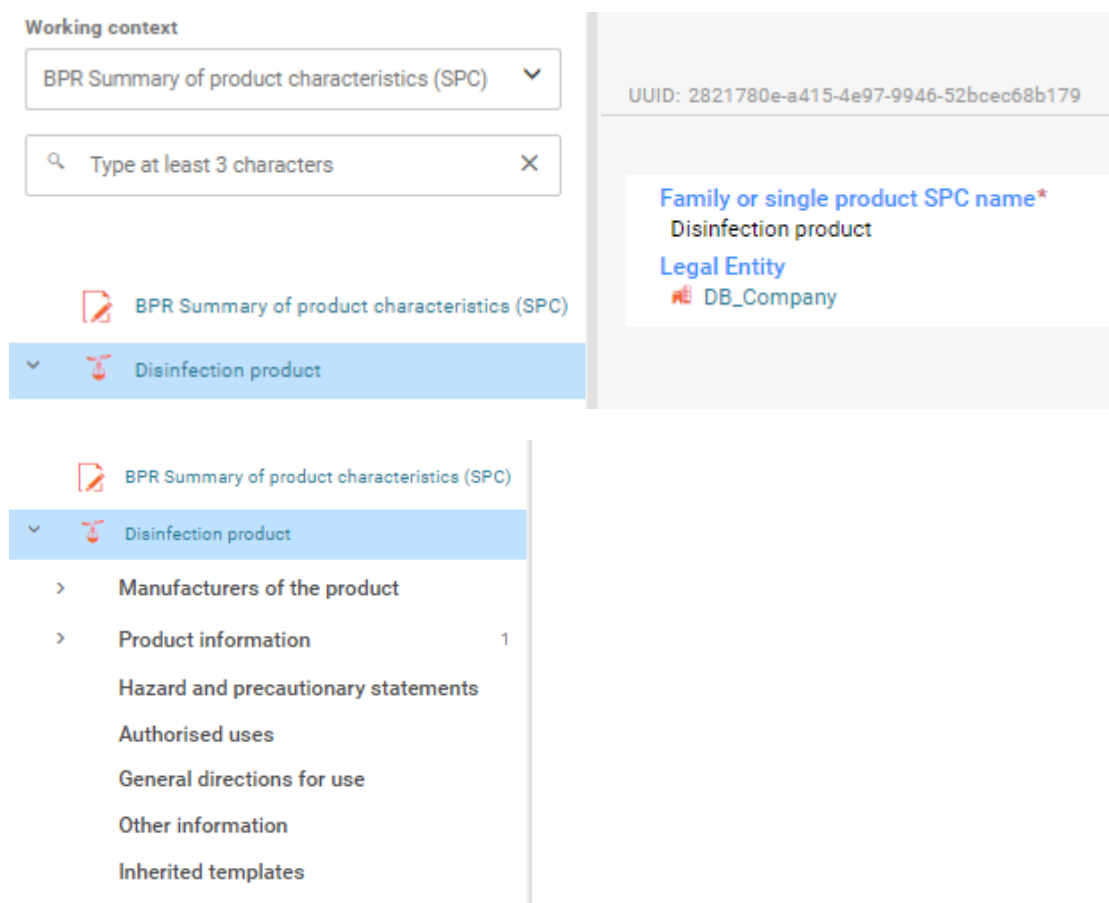
Authorisation date

Expiry date

Authorisation holder

Button **Save** is always located in the bottom right of the page.

If you forget to save and move to another part of the dataset, a reminder is displayed:

Unsaved changes   ✕

You have unsaved changes made to this document.
Do you want to leave this page?

Leave & don't save   Stay

6. Click on the arrow next to the mixture icon to open the table of contents. All the arrows in the table of contents serve to expand and collapse sections and subsections of the table of contents. The field *Legal entity* is populated by default with the working legal entity associated with your IUCLID account.

Working context

BPR Summary of product characteristics (SPC)   ⌄

🔍 Type at least 3 characters   ✕

📝 BPR Summary of product characteristics (SPC)

⌄ 🧪 Disinfection product

UUID: 2821780e-a415-4e97-9946-52bcec68b179

Family or single product SPC name*
Disinfection product

Legal Entity
🏭 DB_Company

📝 BPR Summary of product characteristics (SPC)

⌄ 🧪 Disinfection product

> Manufacturers of the product

> Product information   1

Hazard and precautionary statements

Authorised uses

General directions for use

Other information

Inherited templates

You can now proceed and insert additional data to relevant IUCLID fields.

7. In each section, you need to create documents in which you will add data. To create a document, click on the plus sign. Start with *Manufacturers of the product*.

8. Under *Name of the manufacturer,* you need to select a legal entity of the product manufacturer. If you already have it in the list of legal entities in your database, you will select it from the list that is opening on a sliding window on the right side. If not, you need to create one.

Click on the field, and then *+Select* to add a legal entity.

To select one of the existing legal entities, click on it and then save the document.
To create a new legal entity, click on *+Create*, and fill in the following fields:

Name of the manufacturer: Manufacturer 1.
Legal entity type: company
Address: Street Name 10
Postal Code: 00123
City: Dublin
Country: Ireland

Create new Legal Entity

General information

Name of the manufacturer*

❌ Name of the manufacturer field is mandatory.
Legal entity type

Address

Address

Postal Code

City

Country

Remember to **Save** the data.

9. In a similar way, add the location of the manufacturing site. Start by clicking on the plus sign in the relevant section of the table of contents:

Location of manufacturing sites ➕
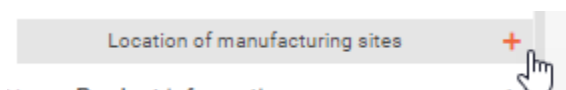
Then click on the field *Site*, and then *+Select* to add a manufacturing site.

Location of manufacturing site.001
UUID: dac2e73c-0094-4ede-a5d3-534d9ed49fa3

Related product

Site ⓘ ^
➕ Select
❌ This field is mandatory.

Select an existing Site or click on *+Create* and fill in the example data:

Name: Product factory
Legal entity owner: Manufacturer 1 (created in previous step, added from the list)
Address: Street Name 10
Postal Code: 00123
City: Dublin
Country: Ireland
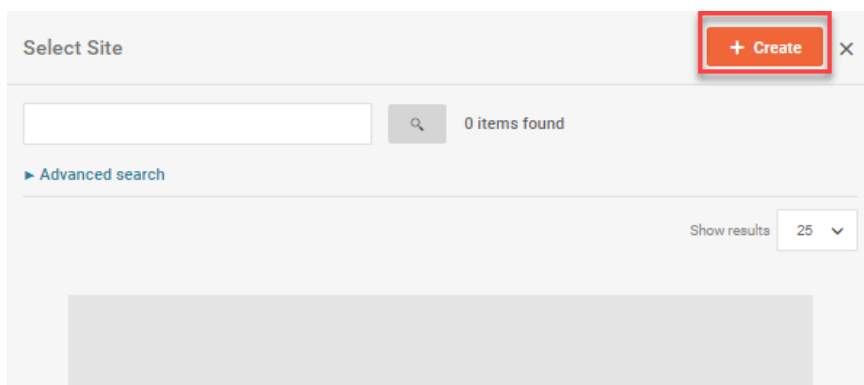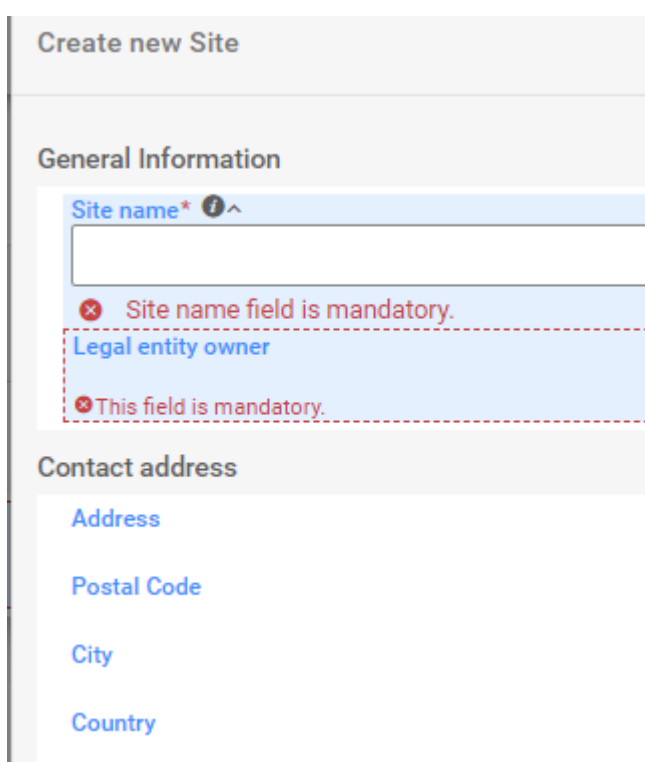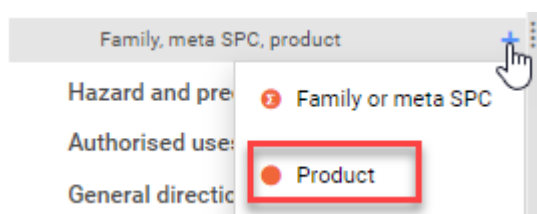
The field *Specify to which product(s) it applies:* will be completed later.

You can add more manufacturing sites if needed by creating more records under the relevant section of the table of contents.

10. The next section you need to fill in is the *Product information*, where you will see two subsections: *SPC name and legal entity* and *Family, meta SPC, product*. *SPC name and legal entity* already contains the product name and your legal entity.

In the section *Family, meta SPC, product* you need to fill in information about the product composition. Click on the plus sign and select *Product*.

The first part is called *General information*. Fill in the fields with example data.
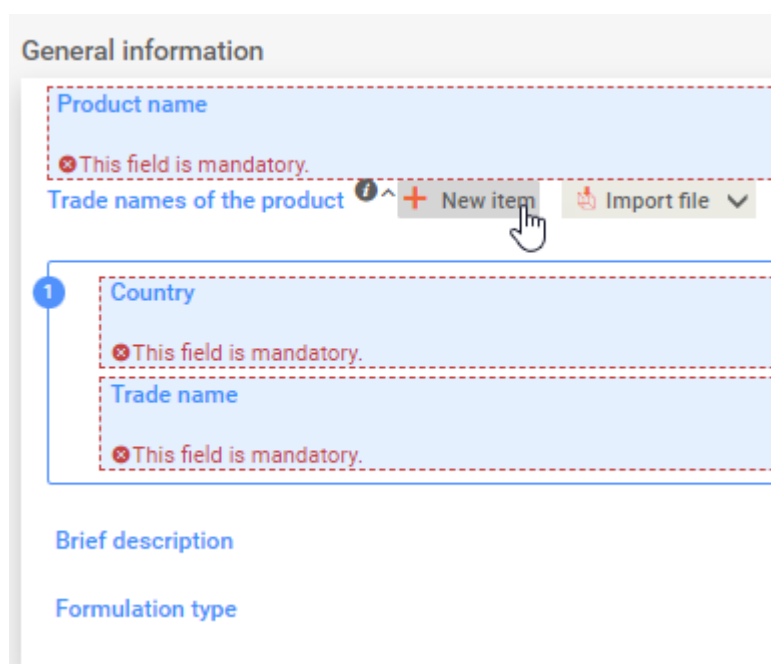
For *Trade names of the product*, click on *+New item* to add a new trade name and relevant country.

Product name: Product 1
Country: Ireland
Trade name of the product: Iodine
Formulation type: AL Any other liquid

In the second part, *Specific composition of each biocidal product*, you will list all relevant components of the product: an active substance, substances of concern, and any other substances knowledge of which essential for the biocidal product.
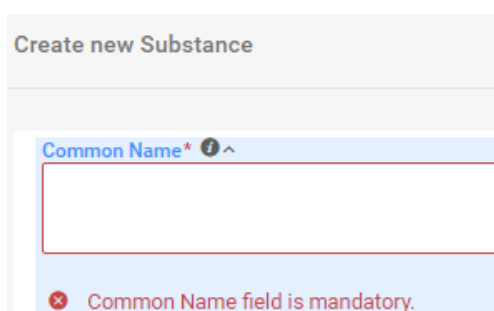
For this, click on *+New item* to add the first component which will be an **active substance**. Then click in the empty row which appears in the table.

A side window will appear.
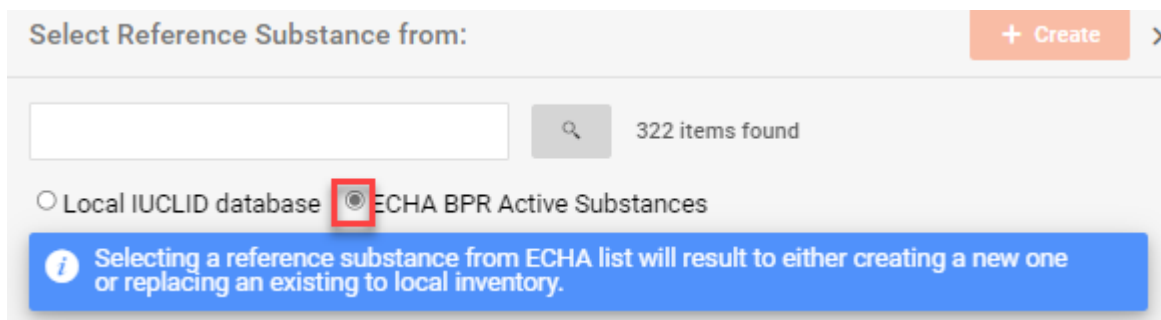
In the *Common name* field select **Substance**.
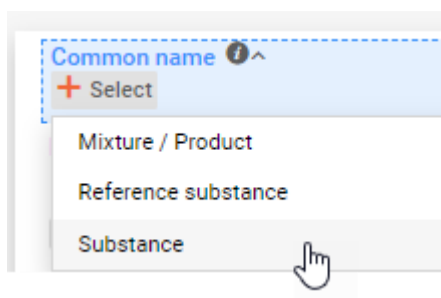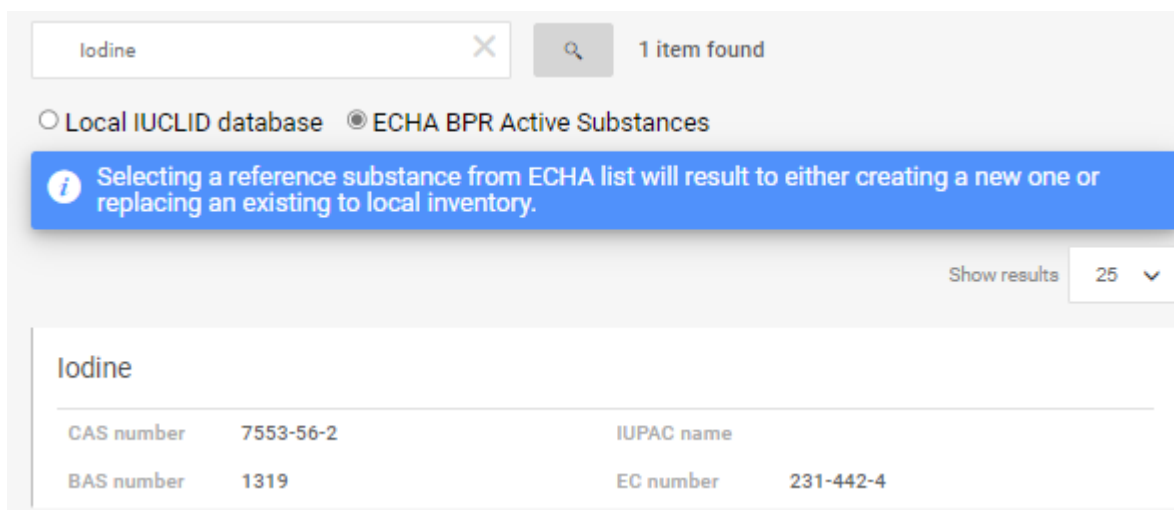
Click on *+Create* to create a new substance, indicate the name of the active substance: *Iodine*.

In the field *Reference substance,* you need to link a reference substance entity. You can select it from your *Local IUCLID database* or from the *ECHA BPR Active Substances* list which contains approved active substances. We recommend using *ECHA BPR Active Substances*.
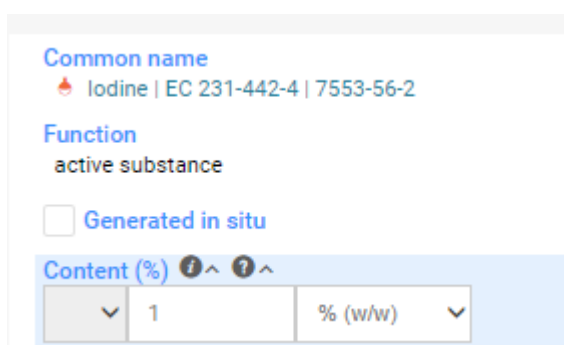
Search for *Iodine* in the Search field:
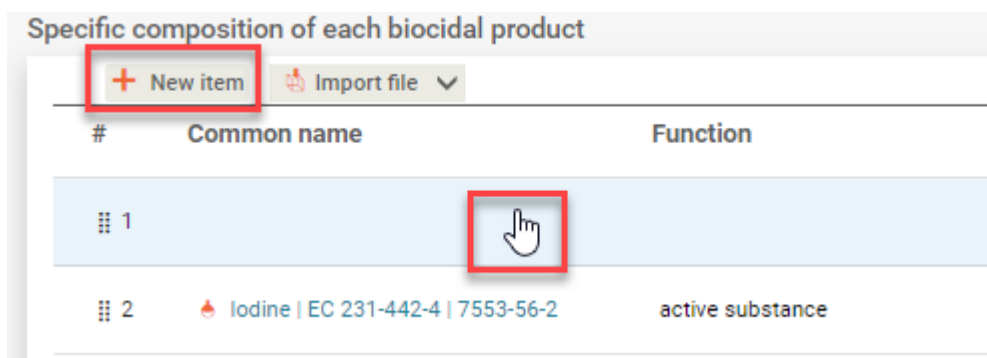
Click on the relevant substance displayed in the list, click *Close* and then *Save*.

You can now indicate the relevant *Function: active substance*, and in the *Content (%)*[1] field select: *1% (w/w)*.

Click *Close*. The sliding window will disappear and click *Save*.

Now, you can add any remaining components for your biocidal product composition, following the same procedure indicated above, with one difference: For all components other than the active substance, select **Reference substance** in the *Common name* field after adding a new component*.* Let's do it.

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[1] Content range (%) if an active substance is generated in situ
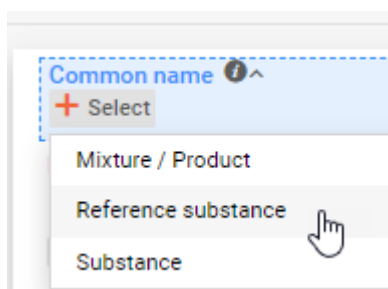
Add a first substance of concern: *propane-1,2-diol*.

Select reference substance from the list of reference substance present in your database or create a new one. Click +*Create*, indicate *Reference substance name – propane-1,2-diol*, and in the field *Inventory name* provide the EC number *200-338-0* (or CAS number *57-55-6*)and select it from the list displayed.

You can also provide *Synonyms*, and then save.

Assign *Function*, *Content (%)* and indicate that this is a *Substance of concern*. *Close* and *save*.

You can add more components to practice, here are some example substances:

- solvent, water, EC 231-791-2, 81% (w/w)

- thickener / thickening agent, trisodium citrate, EC 200-675-3, 0.66% (w/w), SoC

- emulsifier, glycerol, EC 200-289-5, 13% (w/w), SoC

After adding all the components, click Save.

As you have noticed the icon next to the active substance *Common name* differs from the icons next to all other substances. This is because an active substance comes with additional documents where you can report an active substance manufacturer and location of manufacturing sites.

11. In the table of contents on the left, click on an arrow next to Product.001. Notice the double arrows next to the active substance. These are used to access the subtree relevant to this substance. Click on them.
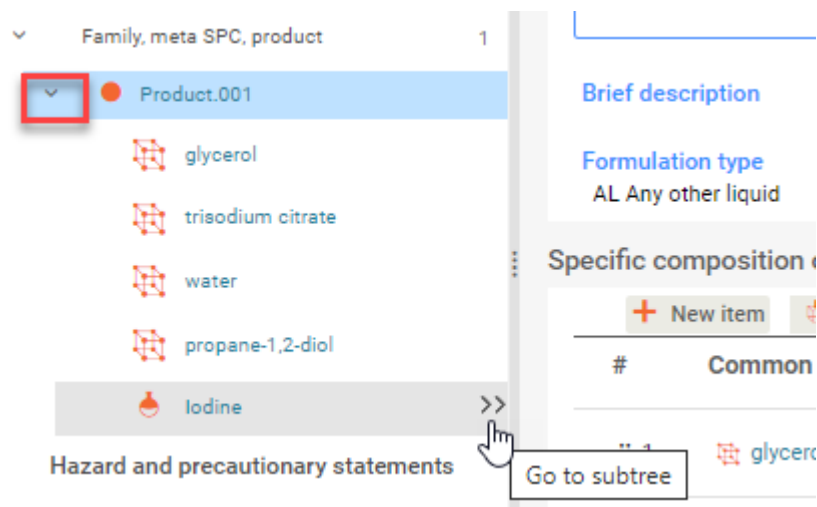
The table of contents now displays only the active substance. Open the subtree of the active substance by clicking on the arrow on the left.
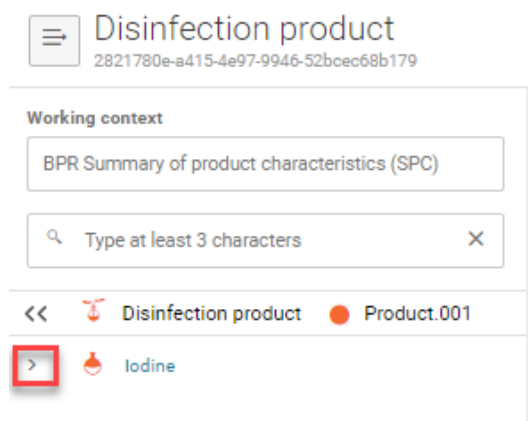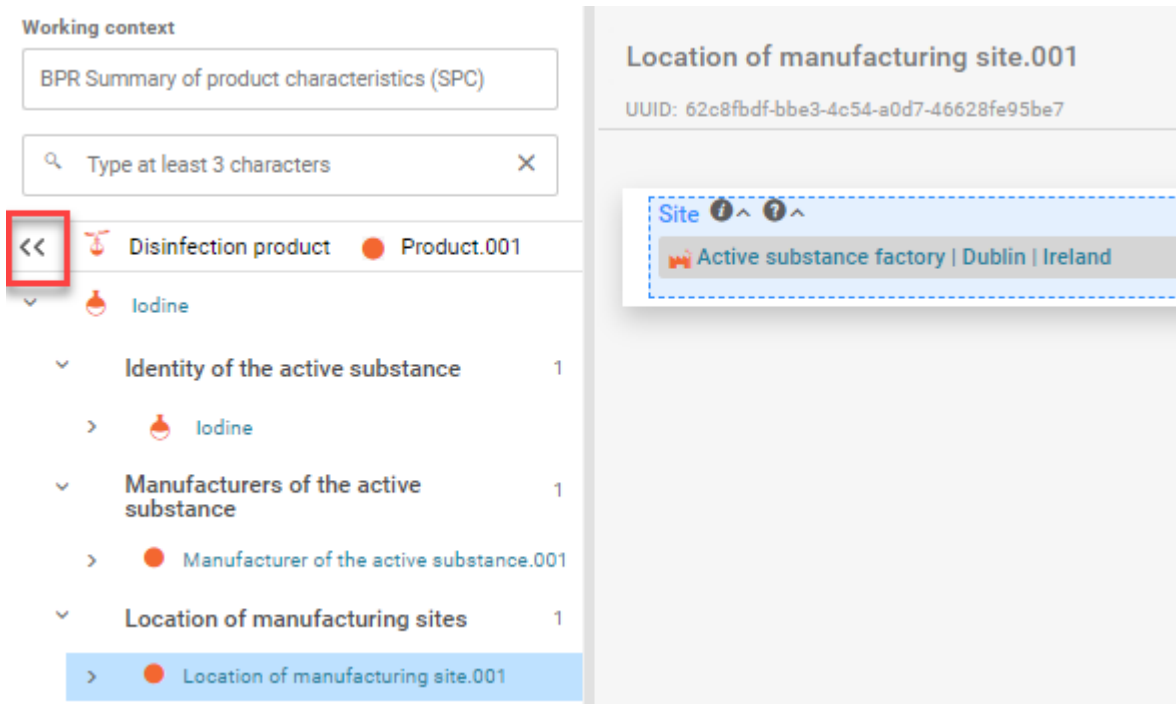

Add *Manufacturers of the active substance* and *Location of manufacturing sites* in a same way as you did for the product in point 7-9 with the following example data:

Name of the manufacturer: AS Manufacturer
Legal entity type: company
Address: Street Name 20
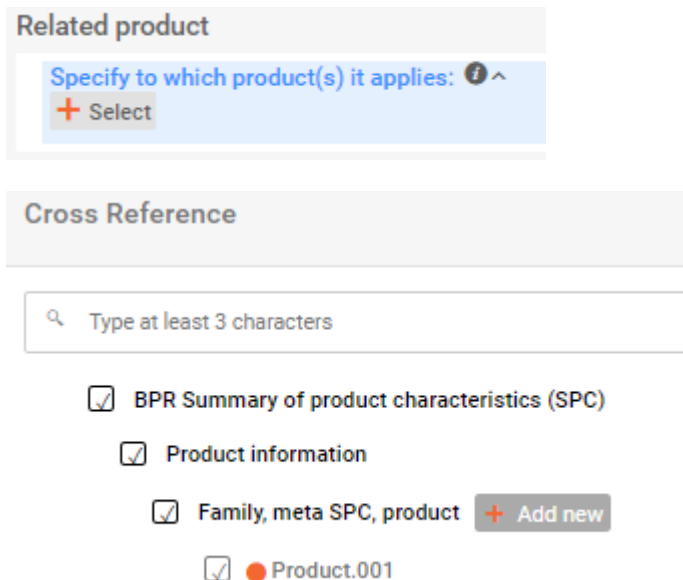*Postal Code: 00123*
City: Dublin
Country: Ireland

Site:
Name: Active substance factory
Legal entity owner: AS manufacturer
Address: Street Name 20
Postal Code: 00123
City: Dublin
Country: Ireland

Save and go back to the main table of product by clicking the double arrows again.

12. Go back to the document *Location of manufacturing site*, and link *Product.001* in the field *Specify to which product(s) it applies. Click Select and then Save.*

13. Back in the Table of Contents, fill in the information for *Hazard and precautionary statements*. For this, add a new document using the + symbol. Select the relevant statements from the drop-down lists using the following example data:.

H319: Causes serious eye irritation.
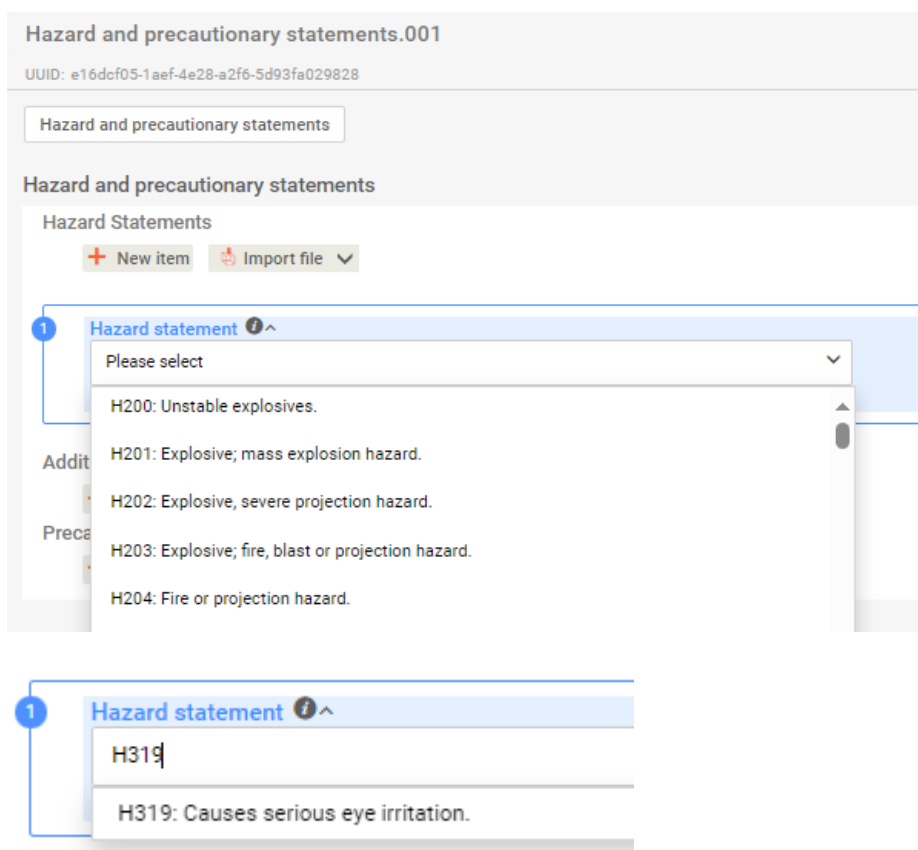
EUH070: Toxic by eye contact.

P264: Wash hands thoroughly after handling.

P280: Wear eye protection.

P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P337+P313: If eye irritation persists: Get medical advice.

To find a phrase, start typing in the field or scroll down.

If a phrase contains a parameter, insert it in the dedicated field:

…or select a value from the drop-down list if this option is available:

Save.

14. Back in the Table of Contents, let's fill in the *Authorised uses.* For that, add a new document clicking the + symbol and using the following example data:

   Product type(s): PT03: Veterinary hygiene
   Title for use: Disinfection for veterinary use by spraying application
   Field of use: indoor use
   Field of use description: additional comments on the indoor use
   User categories: professional

   You can leave the field *Where relevant, an exact description of the authorised use* empty, as this field is relevant only to Product Type 18.

   The last four fields contain references to other documents. Those are: *Target organisms*, *Packagings*, *Application methods* and *Use-specific directions for use*. Each field contains the option +*Select*. Click on it to open a side window.

   In the side window click on +*Add new* to create a first document for Target organisms.
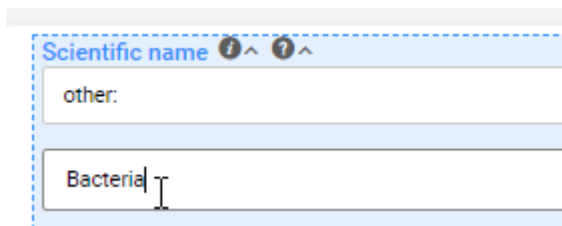
   Click on +*New item* to add first target organism.

   If an organism is not in the list, please use the field *other:* (you need to type the relevant organism in the field to search for it, as the list is very long and not all phrases are visible

in the drop-down list).

After adding each target organism, click *Close*, and after adding all, *Save*.

Example data:

Scientific name: *Bacteria,* Common name: *bacteria, aerobic Gram-***negative***,* Development stage: *not specified*
Scientific name: *Bacteria,* Common name: *bacteria, aerobic Gram-***positive***,* Development stage: *not specified*
Scientific name: *Fungi/Yeast,* Common name: *fungi/yeasts,* Development stage: *not specified*

If you need to come back to the document and complete or edit it, click on the link, to open it again:

In a similar way, complete other reference fields. You can use the option *other:* if there is no relevant value predefined in the picklist.

Next example data is for the Packaging:

Pack size and packaging material: *Drum, Plastic: HDPE, 35 kg*

Now you need to enter the following example data for the section Application methods:

Method: *open system: spray treatment*
Detailed description of the method: *Fill the spray flask with the indicated quantity of undiluted product straight from the original packaging. Let act a few seconds and wipe.*
Dilution: *100%*
Application rate: *6.5 ml per treatment*
Number and timing of applications: *2 times per day*

Finally, use the following example data for the Use-specific directions for use part:

- Use-specific instructions for use: *Treat the entire surface with the product, let act a few seconds and wipe.*

- Use-specific risk mitigation measures: *To protect water & soil organisms it is not allowed to release residues of the treatment solution in the sewage, soil or surface water. Residues should be discharged to manure storage.*

- Where specific to the use, the particulars of likely direct or indirect effects, first aid

instructions and emergency measures to protect the environment:
First aid: general information: immediately remove any clothing soiled by the product
After inhalation: Supply fresh air; consult doctor in case of complaints.
After skin contact: Generally, the product does not irritate the skin.
After eye contact: Rinse opened eye for several minutes under running water.
*After swallowing: If symptoms persist consult doctor.*

- Where specific to the use, the instructions for safe disposal of the product and its packaging: *To protect water & soil organisms it is not allowed to release residues of the treatment solution in the sewage, soil or surface water. Residues should be discharges to manure storage.*

- Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage: *Protect from frost. Store in a tempered place, away from direct sunlight and out of reach from children. No particular precaution of use.*

Remember to save the data.

15. Back to the Table of content, fill in *General directions for use*. Add a new document by clicking on the + symbol. For the exercise, you might use the same data as for use-specific instruction for use, or enter new information.

    To fill in *Other information*. Add a new document by clicking on the + symbol. You can insert here information relevant to the SPC, not covered by other sections. For this, you can use the following example data: *Here is some other information to provide.*

16. The dataset is now, technically, complete. To submit this data to ECHA using R4BP3, you need to create a dossier out of it. This is a read-only copy of the data you have just entered. To do it, click on *Create dossier*.
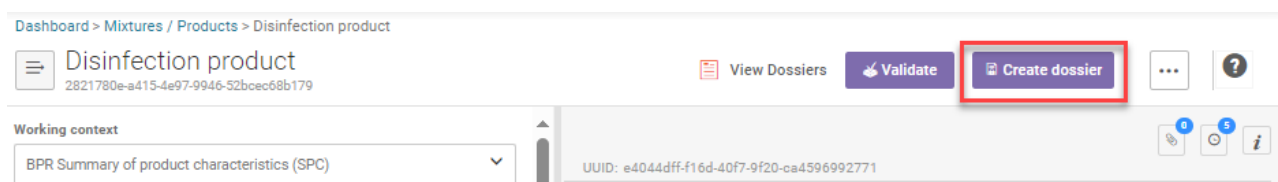
After clicking on the *Create dossier* button, a window displays the data inserted in the dossier header. Check it and confirm by clicking the *Create dossier* button on the right corner of the screen.

BPR Summary of product characteristics...

Dossier name (given by user)
SPC for Disinfection Product
Dossier submission remark

Specific submissions

SPC type
single product
Market area
Ireland
Language
English
Authorisation details

Authorisation number

Reference number

Authorisation date

Expiry date

Authorisation holder

Create dossier   **Advanced settings**

Once the dossier is created, there is a confirmation message, and you can open the dossier.

Note: If you see the warning message shown below, it means that there are some mistakes or missing data. In this case, please see the part 5 of this exercise.

Create dossier   ×

❌   You have 1 Submission rules which require fixing.
Fix these errors before creating and submitting your dossier.

Continue with dossier creation   **View/fix errors**

17. Last step is to export the dossier in '.i6z' format, in order to submit it to R4BP3.

When the dossier is opened, in the top right corner, select the first option under the three-dot menu:
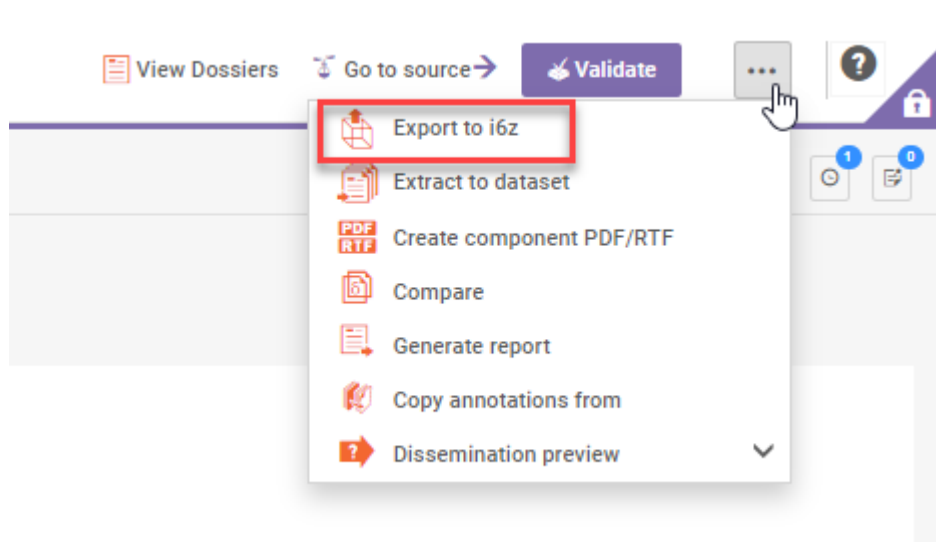
The *Export settings* window will open. Accept the default settings by clicking *Export to local file*.

You will be asked to save The generated '.i6z' file.

7746d508-c496-4667-bce9-96209ce8d62f.i6z

You might want to change the name of the file, to identify it more easily, for example:

IND_part1_dossier_7746d508-c496-4667-bce9-96209ce8d62f.i6z

> Under this link you can watch the video on how to solve part 1 of the exercise:
> https://youtu.be/03wSL2rrz2o

PART 2: Generate an SPC in .rtf format

18. From the dossier you created, generate the SPC report (note that the report can also be generated from a dataset).

    To start the report generation, select the relevant report in your dossier. To do this, go to the three-dot menu and select 'Generate report'.
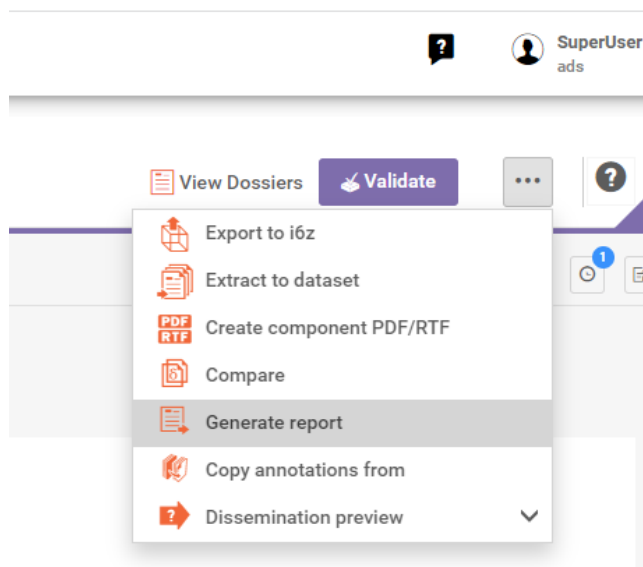
19. You will now see a list of reports available for the SPC working context.

    To quickly find an SPC report, start typing "SPC" in the text filter. (Note that you can also filter by the output type if you wish using the picklist of output types).
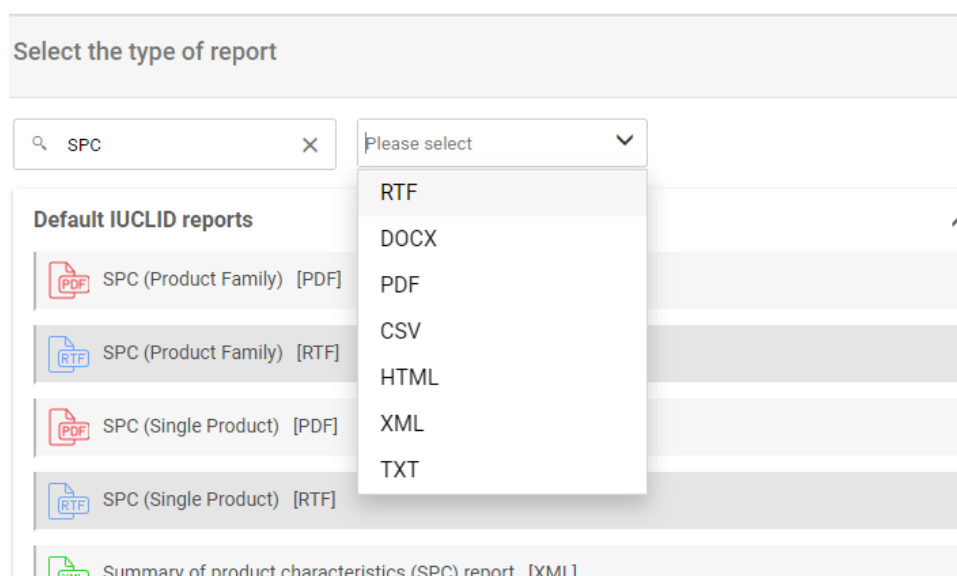
20. You will notice there are two different types of SPC report:

    a. SPC (Product Family)

    b. SPC (Single Product)

Each type of SPC report currently has two available output formats, **RTF** and **PDF**.

Select the report 'SPC (Single Product)' as you have created a single product dossier so far, and choose the output type 'RTF'.

SPC (Single Product) [RTF]

The language that will be used in the report is determined by your selection in the dossier header field 'Language'.

Language
English

21. When you select the report you want to generate, a spinning wheel will appear between the validate button and the 3-dots menu.

Go to source → | Validate | ... | ?
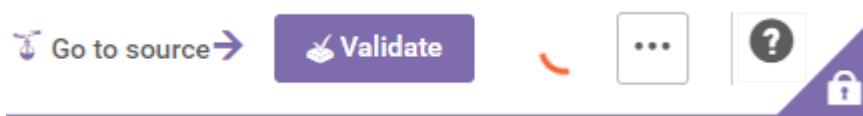
22. Once the generation of the document has been completed, the RTF file will be available to download from your browser. This file type can be opened with MS Word or OpenOffice for example.

The resulting report will contain the essential information from your SPC dossier.

Note that in sections 1.3 and 1.4, the Location information is based on whether the same Legal Entity 🏭 used in the Manufacturer section has been referenced by the Site 🏭 in the Location of the Manufacturing Site. To determine if the same Legal Entity has been used for the Manufacturer and the location of the Manufacturing Site, the unique identifier of the Legal Entity can be used.

| Name of manufacturer	Manufacturer 1
Address of manufacturer	Street Name 10 00123 Dublin Ireland
Location of manufacturing sites	Product factory Street Name 10 00123 Dublin Ireland

Under this link you can watch the
video on how to solve part 2 of
the exercise:
https://youtu.be/92L9xJxnUO8

PART 3: Create a derived SPC ('.i6z' file) for a mutual recognition in sequence

The starting point to apply for a mutual recognition in sequence is to have an Approved NA-APP Asset. When working on real life cases, you will download the relevant SPC dossier from R4BP3. For this exercise, we will use the dossier prepared earlier and authorised in R4BP3. This dossier is available as part of the training material that can be downloaded from the IUCLID website (*IND_part3_authorised_dossier.i6z*).

23. Import the authorised dossier to IUCLID: come back to the *Dashboard* and click *Browse:*
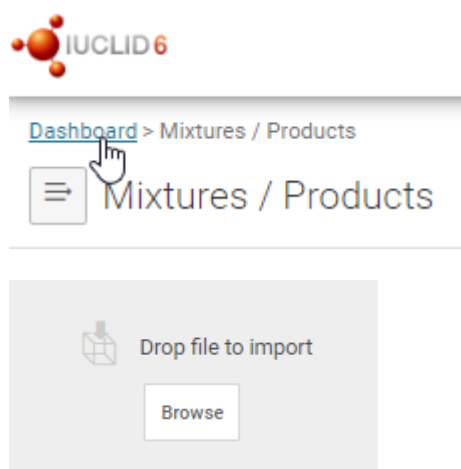
Select the file.

You can see in the Dashboard when the import is completed, and you can open the dossier.
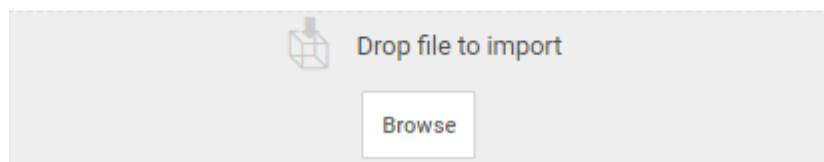
24. Open the dossier. Remember that dossiers are locked for edition and cannot be modified. This can be seen by the presence of a padlock icon representing the dossier header, in the table of contents

and in the top right corner of the screen .

To make the data editable, click on the three dots menu in the top right corner and select the option *Extract to dataset*. This will create an editable dataset from the dossier content (or update the dataset with the information from the dossier in case you already have the corresponding dataset in your IUCLID database).
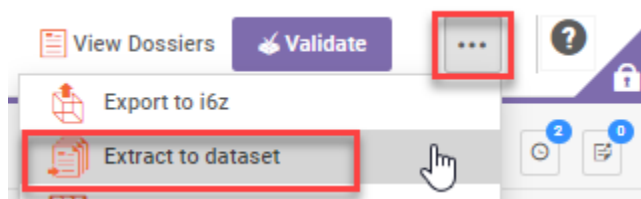
At this stage you will see the list of documents to be extracted. You want to keep the whole content of the dossier, so confirm by clicking *Extract*.

Dataset extraction settings   ✕

Select entities ⌄

☑ 🔒 BPR Summary of product characteristics (SP...	**ADDED**	
☑ 🜋 Disinfection product	**ADDED**	>
☐ 🜂 Iodine		>
☐ glycerol		
☐ trisodium citrate		
☐ water		
☐ propane-1,2-diol		
☐ Iodine		
☐ DB_Company		
☐ AS Manufacturer		
☐ Manufacturer 1		
☑ Winston Ltd	**ADDED**	
☐ Active substance factory		
☐ Product factory		

empty check boxes mean that those entities are already present in your database

🜋 Disinfection product

Table of Contents   Reset to original

BPR Summary of product characteristics (SPC) ⌄

Select documents ⌄

☑ 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
    ☑ ● Disinfection product **ADDED**
  ☑ Family, meta SPC, product
    ☑ ● Product.001 **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**
☑ Other information
  ☑ ● Other information.001 **ADDED**

Extract

Extract dossier to dataset   ✕

✓ Dataset has been extracted successfully
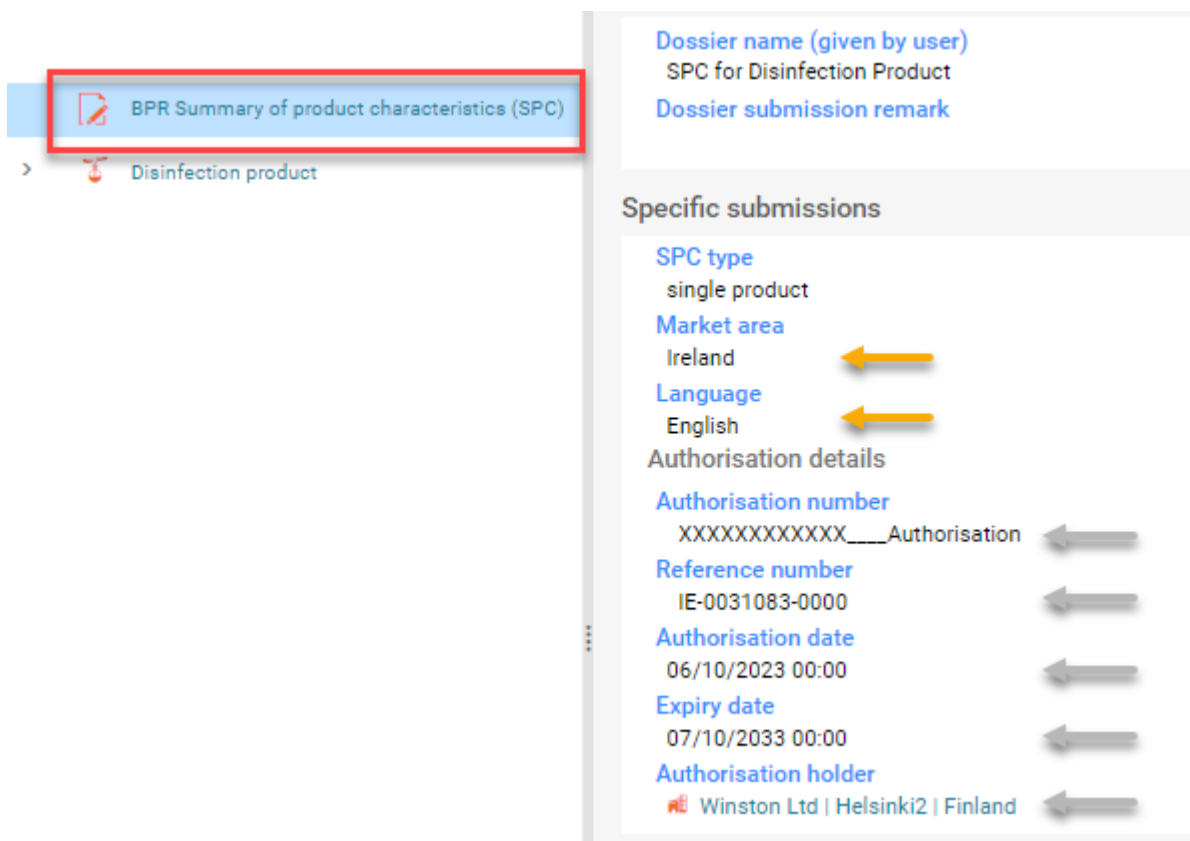
Close   **Open**

Note: You might want to create again an SPC in '.rtf' format to see how the *Authorisation details* are presented in the report.

25. Open the extracted dataset and make the following changes in the dossier header:

   a) Change *Market area* to *Italy*

   b) Change *Language* to *Italian*

      Note: changing the language in a dossier header is needed for the submission purposes, but also it determines a language in which the SPC report is generated. All the titles, labels and picklists in the report will be translated to the selected language. However, the content of the free text fields will remain in English.

   c) Remove the authorisation details (this information will be added automatically during the authorisation process in R4BP3)

Dossier name (given by user)
SPC for Disinfection Product
Dossier submission remark

Specific submissions

SPC type
single product
Market area
Ireland
Language
English
Authorisation details

Authorisation number
XXXXXXXXXXX____Authorisation
Reference number
IE-0031083-0000
Authorisation date
06/10/2023 00:00
Expiry date
07/10/2033 00:00
Authorisation holder
Winston Ltd | Helsinki2 | Finland
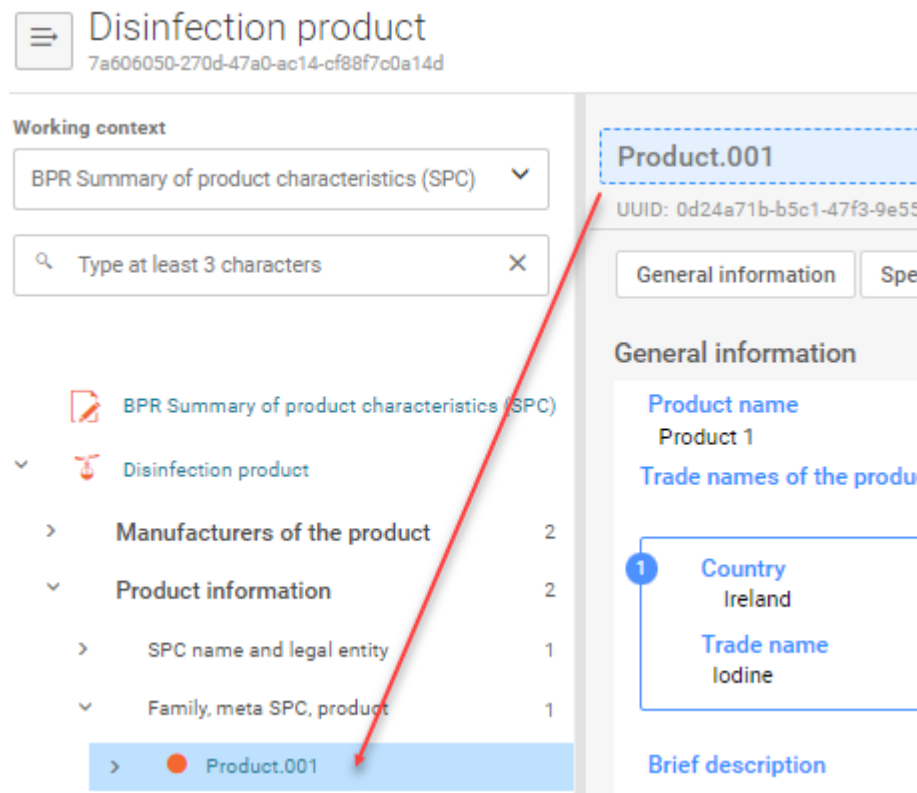
Note: When preparing a dossier for a mutual recognition in sequence <u>do not change</u> the document name displayed in the table of contents (*Product.001* in this example), in the section *Family, meta SPC, product*; it must be identical as in the initial authorisation dossier and it has to be given in English.

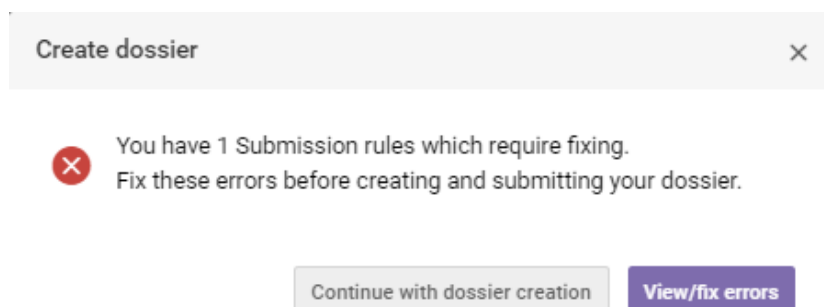The name displayed in the table of contents comes from the editable line on top of each Product document:

Similarly, for families, the documents names (family name, meta SPC names and products names displayed in the table of contents) must be identical and must be written in English.

26. Save your changes and create a new dossier as explained in the part 1 of the exercise. Give a new dossier name, for example *SPC for Disinfection Product (mutual recognition in sequence)*.

Note: If you see the warning message shown below, it means that there are some mistakes or missing data. In this case, please see the part 5 of this exercise.

27. Open the dossier and then export it as explained in the part 1 of the exercise. This is the

file that needs to be submitted to R4BP3 as an NA-MRS based on the Approved NA-APP Asset.

Note: You might want to create again an SPC report in '.rtf' format to see how the language changed.

Under this link you can watch the video on how to solve part 3 of the exercise: https://youtu.be/NWBzJ6CGaFU

PART 4: Create an SPC dossier ('.i6z' file) for a biocidal product family

In this part of the exercise, you will prepare an SPC dossier for a biocidal product family. As starting point, we will use the dataset for a single product, prepared in the part 1 of the exercise. We will use the *Clone* functionality to obtain a copy of this dataset.

You can also prepare an SPC for a family from scratch, using the knowledge gained when performing previous parts of the exercise.

28. Go to the *Mixtures* list and make sure that you are looking at the list of editable *Datasets*:
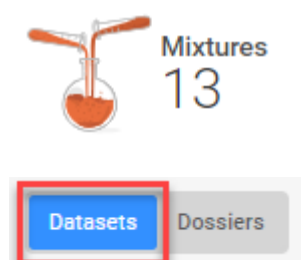
Select the dataset *Disinfection product* prepared in the part 1 of the exercise and select the option *Clone* under the three-dot menu on the right:
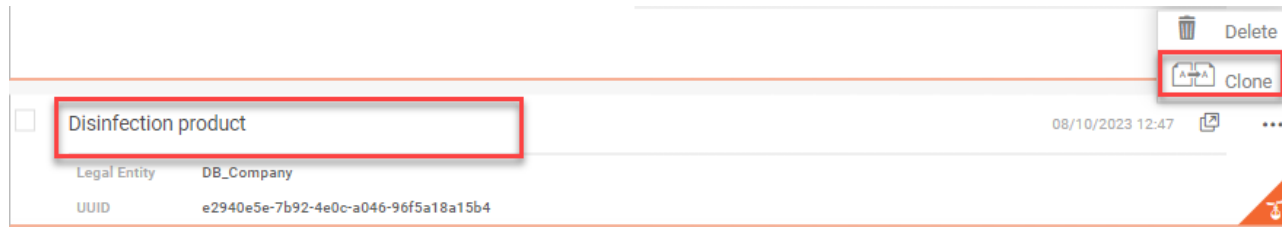
Confirm by clicking *Clone* and open the dataset.
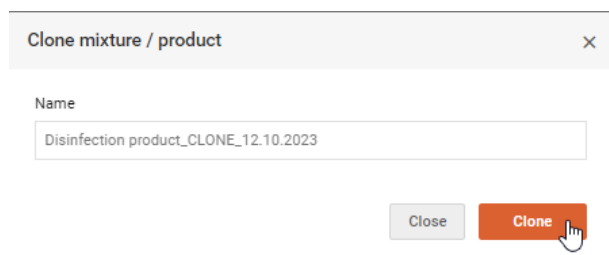
29. Select the working context BPR Summary of product characteristics (SPC). Click *Apply*.
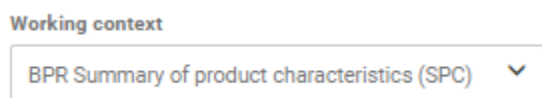
30. Change the name in the field *Family or single product SPC name* to *Family of disinfection products*. Save.

Family or single product SPC name* ⓘ ^
Family of disinfection products

Legal Entity
🔴 DB_Company

31. Open the *Dossier header* and fill in high-level information such as the dossier name of your choice (e.g. SPC for Family of disinfection products), the relevant *SPC type*: *product family*, the *market area (Ireland)*, and the *language (English)*. Save.

Dossier name (given by user)
SPC for Family of disinfection products
Dossier submission remark

Specific submissions

SPC type
product family
Market area
Ireland
Language
English

32. In the navigation tree, open the section *Family, meta SPC, product* under *Product information*. You have here one *Product* document. Click on + to add a *Family* document.

Fill in the fields with example data. Start by editing the default name of the document "*Family or meta SPC.001*" into "F*amily of disinfection products*" so that this is the way it is displayed in the table of contents:

Family or meta SPC.001
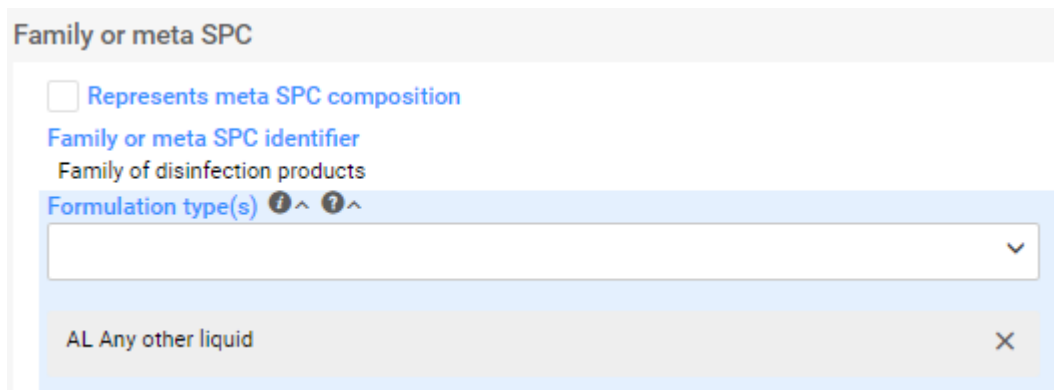
Leave the check box *Represents meta SPC composition* empty, because it is relevant only

to meta SPC documents.

Indicate *Family of disinfection products* as the *Family identifier*.

Select *Formulation type*: *AL Any other liquid.*
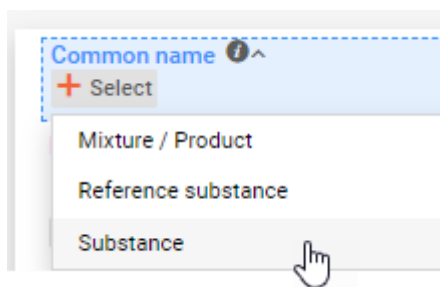
List all relevant components of the family under *Active substances, Substances of concern, Other substances. This is done as follows:*

Click on +*New item* to add the first component which will be the **active substance**. Then fill in the data:

Function: active substance

Content range (%): 1-2 %(w/w)

In the *Common name* field select **Substance**.

Select *Iodine* from the list of substances (you have created this substance in the part 1 of the exercise). Click Save.

Add any remaining components, following the same procedure with one difference. For all components other than the active substance, select **Reference substance** in the *Common name* field after adding a new component.

Here are some example substances that can be added:

- solvent, propane-1,2-diol, EC 200-338-0, 3-6 % (w/w), SoC

- solvent, water, EC 231-791-2, 78-83 % (w/w)

- thickener / thickening agent, trisodium citrate, EC 200-675-3, 0.5-2 % (w/w), SoC

- emulsifier, glycerol, EC 200-289-5, 11-15% (w/w), SoC

Active substances, Substances of concern, Other substances   + New item

1 Function
emulsifier

Content range (%)
11 - 15 % (w/w)

Common Name
glycerol | EC 200-289-5

☑ Substance of concern

☐ Generated in situ

2 Function
thickener / thickening agent

Content range (%)
0.5 - 2 % (w/w)

Common Name
trisodium citrate | EC 200-675-3

☑ Substance of concern

After adding all the components, save.

33. You will need to create a similar document for each *meta SPC*. The most efficient way to do that is to use the function *Copy data from…*

In the top right corner, select the option *Copy data from…* under the three-dot menu:

📋 View Dossiers   🧪 Validate   📄 Create dossier   …   ❓

⬆ Export to i6z

📄 Create document PDF/RTF

📄 Create component PDF/RTF

📑 Generate report

📑 Compare

➕ Clone

🖊 Copy data from …

📑 Bulk operations   ⌄
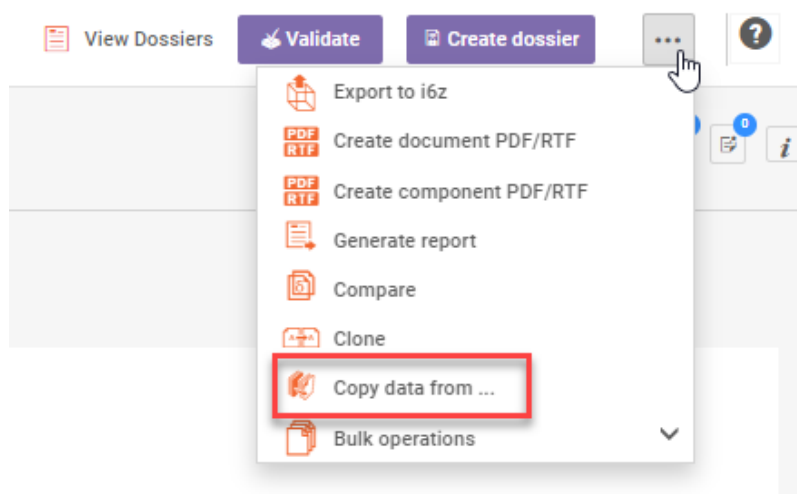
A side window appears. Select the entity type *Mixture* and select *Family of disinfection products*.

Documents that are available in this dataset will be displayed. Deselect all items (click on the main BPR Summary of product characteristics (SPC) box, and then only select *Family of disinfection products* under *Family, meta SPC, product* to be copied and confirm with *Copy*.

After few moments, you will see a copy of the selected document in the table of contents:

It contains all the data you have provided for the family.

34. Open the document and edit it to obtain a document for the meta SPC.

Provide the name to be displayed in the table of contents by replacing "*Family of disinfection products.COPY*" to "*meta SPC 1*":

meta SPC 1

In the document, tick the check box *Represents meta SPC composition* to activate fields relevant only to the meta SPC (scroll down to see these fields at the bottom of the document).

☑ Represents meta SPC composition

For each component, specify the *Content range (%)*, for example:

- solvent, propane-1,2-diol, EC 200-338-0, 2-5 % (w/w), SoC

- solvent, water, EC 231-791-2, 80-82 % (w/w), SoC

- thickener / thickening agent, trisodium citrate, EC 200-675-3, 0.5-1.5 % (w/w), SoC

- emulsifier, glycerol, EC 200-289-5, 12-14% (w/w), SoC

- active substance, Iodine, EC 231-442-4, 1-2 % (w/w)

If you need, you can change the order of the components you have added to the table. Click the option ⠿ under the component number, and drag it to the relevant location:
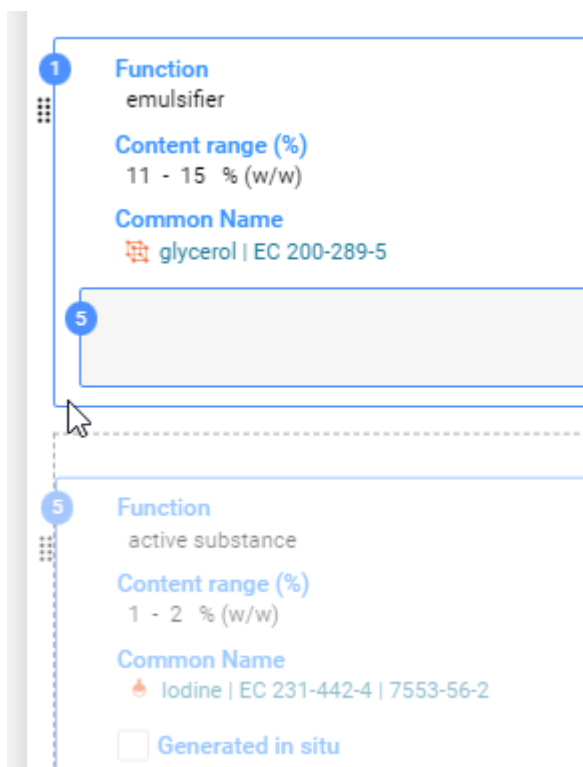
Function
active substance
Content range (%)
1 - 2 % (w/w)
Common Name
🔥 Iodine | EC 231-442-4 | 7553-56-2

The active substance is now displayed as the first component.

35. In the section *Related products* link all the products belonging to this *meta SPC*. Currently, you have just one product recorded.

Select it from the list and click *Select*.

Save.

36. You need to create more products to build the family structure. The most efficient way to do it, is to use the functionality *Copy data from…* and copy the existing product, as many times as needed.
Each created product should be updated with the relevant data (in the same way as you have done for the meta SPC document), and then linked under *Related products* in the relevant meta SPC.
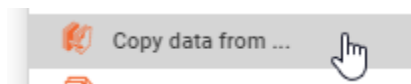
Open the document and edit it to obtain a document for another *product* belonging to the *meta SPC 1*.

Provide the name to be displayed in the table of contents by replacing "Product.001.COPY" to "Product.002":

Change the trade name:

Update the product composition.

Save.

37. Come back to *meta SPC 1* and link the newly created product under *Related products*.
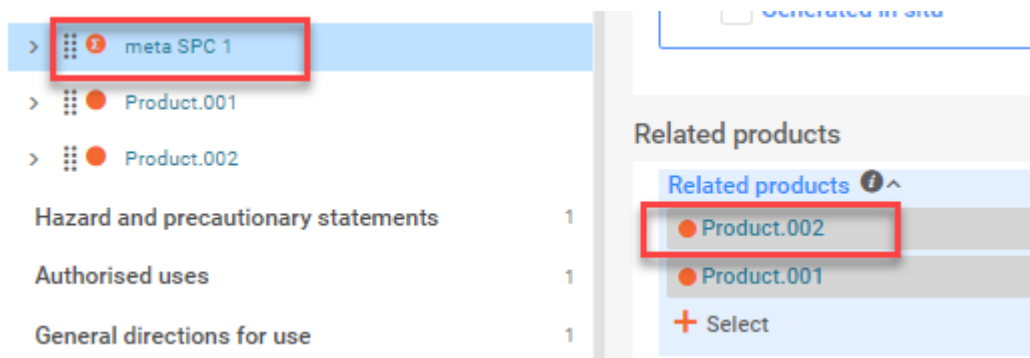
Save.

38. You need to indicate the *Location of manufacturing site* for every created product. For this exercise, the manufacturing site is the same as for the first product.
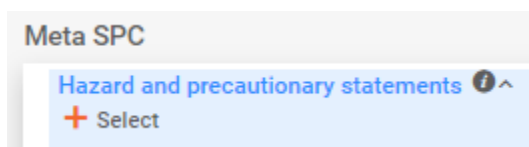Come back to the section *Location of manufacturing site*, and link Product.002 there as well:

Save.

If a product is manufactured in another manufacturing site, you need to create another document *Location of manufacturing site*, as explained in the first part of this exercise instruction.

39. Come back to the document meta SPC 1 to link references to:
   - Hazard and precautionary statements
   - Authorised uses (*more than 1 document can be linked*)
   - General directions for use
   - Other information

To add a reference to the relevant document, click +*Select* to open the side window.

Meta SPC

Hazard and precautionary statements ⓘ ⌄
➕ Select

In the side window, you can choose either to add an existing document, or to create a new one.

Cross Reference

🔍 Type at least 3 characters

BPR Summary of product characteristics (SPC)

Hazard and precautionary statements   ➕ Add new

🔴 Hazard and precautionary statements.001

For this exercise, add the existing documents (created in the part 1 of the exercise), in each field:

Meta SPC

Hazard and precautionary statements
🔴 Hazard and precautionary statements.001
Authorised uses
🔴 Use.001
General directions for use
🔴 General directions for use.001
Other information
🔴 Other information.001

Save.

40. You can edit each added document from here. Click on *Use.001* to open it in a side window and edit the document name.

After saving, the change will appear in the *meta SPC* document.

41. You can add more documents in all the sections, and, when ready, create a dossier or generate an SPC report in '.rtf' format, as explained in part 1 and 2 of the exercise.

    Note: to generate an SPC report in '.rtf' format you need to select the relevant type of report, in that case:


Under this link you can watch the video on how to solve part 4 of the exercise:
https://youtu.be/Y9feVgPmVd8

PART 5: Correct errors in an SPC dataset to successfully create and submit an SPC dossier (validation assistant)

The purpose of this exercise it to help you to understand the Validation Assistant available in IUCLID. We have prepared a dossier which contains some errors. Your task is to extract this dossier to a dataset, identify these mistakes, correct them and create a valid SPC dossier.

42. Import the dossier (*IND_part5_dossier_for_validation.i6z*). It is available among the training material to be downloaded from the IUCLID website. This dossier contains test data relevant to a family. For this exercise we have used a limited number of documents in the dossier: one family, one meta SPC, two products.

    Import a dossier and open it.
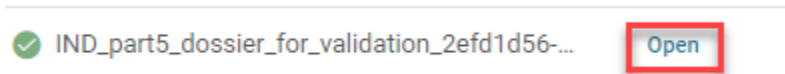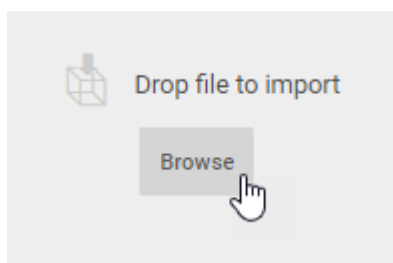
    Extract dataset from the imported dossier, as explained in part 3 of the exercise instruction.
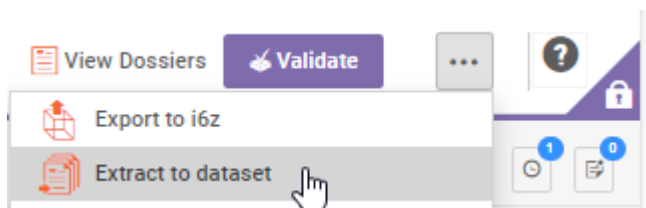
43. Once the extract is completed, open the extracted dataset, and click the button *Validate* on the top right corner.
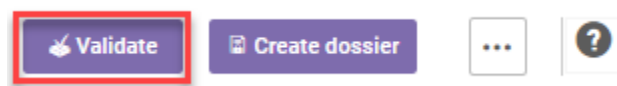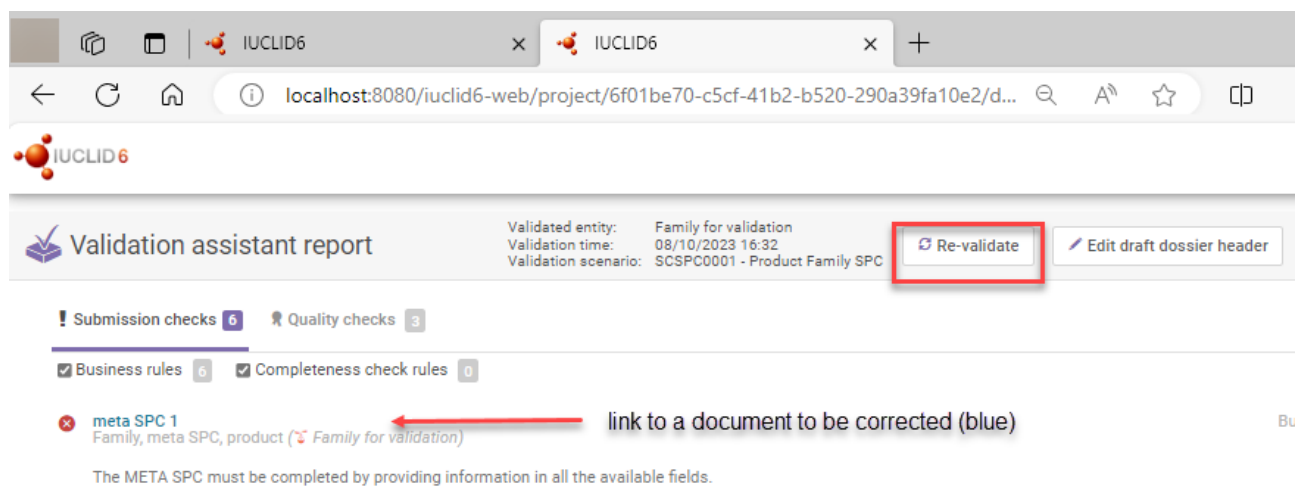

    The dossier header is first displayed. Make sure that *SPC type* is correct: *product family* (the validation is different for a single product and for a family).

    Confirm with *Validate*. You will see a list of rules that failing because of deficiencies in the data recorded.

    The list of rule failures opens in a new tab, and it provides the direct link to the document to be corrected, if such document exists. If there is no document available yet, it must be created first.

    After each correction, save, and you can click on *Re-validate* to verify that your action was
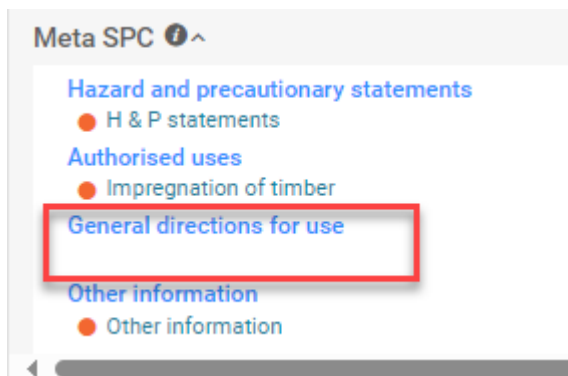
successful.

Note: Try to perform the correction yourself, following the error messages displayed. In case of difficulties, detailed instructions start on the next page.

Solution to part 5:

1)

Click the blue link. The META SPC must be completed by providing information in all the available fields.
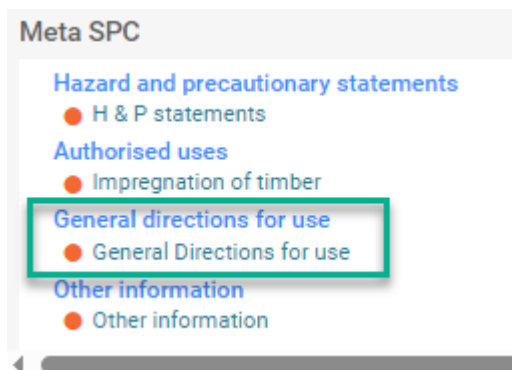
You can see that a reference to *General directions for use* is missing.

Click this field, link the relevant document, and **Save**:

Re-validate.

2)

meta SPC 1
Family, meta SPC, product Composition, (1)(Family for validation)

The values under the Content range (%) in the META SPC must be within the ranges of the Family SPC composition.

meta SPC 1
Family, meta SPC, product Composition, (3)(Family for validation)

The values under the Content range (%) in the META SPC must be within the ranges of the Family SPC composition.

Click the blue link (you can see that both errors are in the same document, meta SPC 1). The values under the Content range (%) in the META SPC must be within the ranges of the Family SPC composition.

Check the ranges for the family in the first tab, in section *Family, meta SPC, product*, in document *Family for validation*:

tebuconazole	0.5-1.5 % (w/w)
propiconazole	0.5-1.5 % (w/w)
ethanol	98.5-99.5 % (w/w)

Compare them to the ranges indicated for the meta SPC

The values for tebuconalzole and ethanol are incorrect:

Correct them according to the ranges indicated for the family and **save**.

Re-validate.

3)

Click the blue link. For each Biocidal Product, the specific composition must be provided, which means that, for each component, common name, function and Content (%) or Content range (%) must be provided.

The message requires a check of component number 1:

For this component, the *Function* is not specified.

Add *Function*, close and **save**.

Re-validate.

Whenever a correction is made, the validation assistant checks once again all the documents. Therefore, as we have corrected *Content range (%)* in the meta SPC, and the *Function*, new errors appeared as now the *Content (%)* of the components in the products are not in line with the corrected *Content range (%)* in the meta SPC.

4)

❌ **Product 1**
Family, meta SPC, product Components, (1)(⚑ *Family for validation*)

The value/s under the Content (%) in the biocidal product/s must be within the ranges of the META SPC composition.

❌ **Product 2**
Family, meta SPC, product Components, (1)(⚑ *Family for validation*)

The value/s under the Content (%) in the biocidal product/s must be within the ranges of the META SPC composition.

❌ **Product 2**
Family, meta SPC, product Components, (2)(⚑ *Family for validation*)

The value/s under the Content (%) in the biocidal product/s must be within the ranges of the META SPC composition.

Products 1 and 2 belong to the same meta SPC, so you can correct them using the same ranges as reference value. You can check them in the first tab, in section *Family, meta SPC, product*, in document *meta SPC 1*:

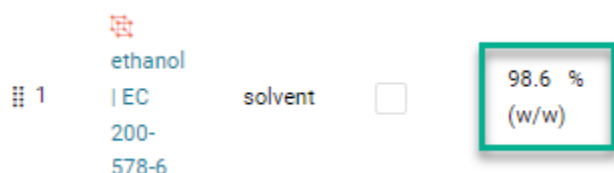|	
tebuconazole	0.5-1.5 % (w/w)
propiconazole	0.5-1.5 % (w/w)
ethanol	98.5-99.5 % (w/w)

Click the first blue link, to Product 1.

The value for component 1, ethanol, is incorrect:

Provide a value within the meta SPC range, close and **save**:

Click the second blue link, to Product 2.

The values for component 1, ethanol and 2, tebuconazole, are incorrect:

Provide a value within the meta SPC range, close and **save**:

Re-validate.

5)

❌ Location of manufacturing sites (🌿 *Family for validation*)

   At least one complete 'Location of Manufacturing site' must be provided indicating full contact details in the Site Document.

❌ Manufacturers of the product (🌿 *Family for validation*)

   At least one complete 'Manufacturer of the product' must be provided indicating full address details in the Legal Entity Document.
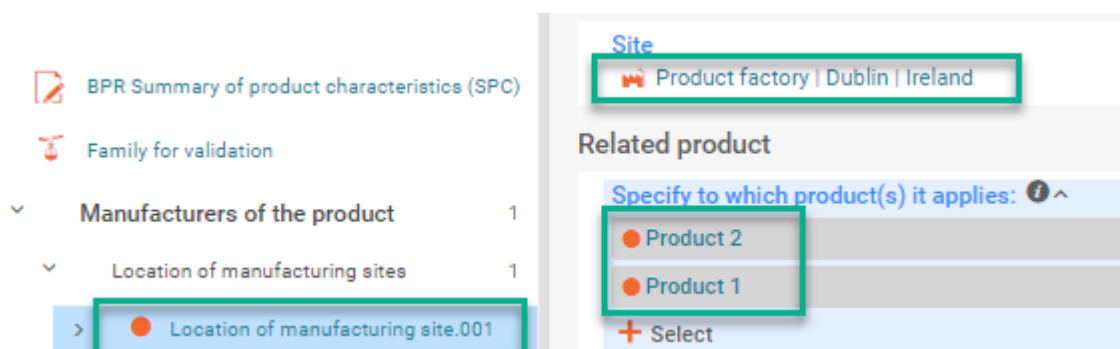
There are no links to IUCLID documents provided together with the error messages, which means that the documents themselves are missing.
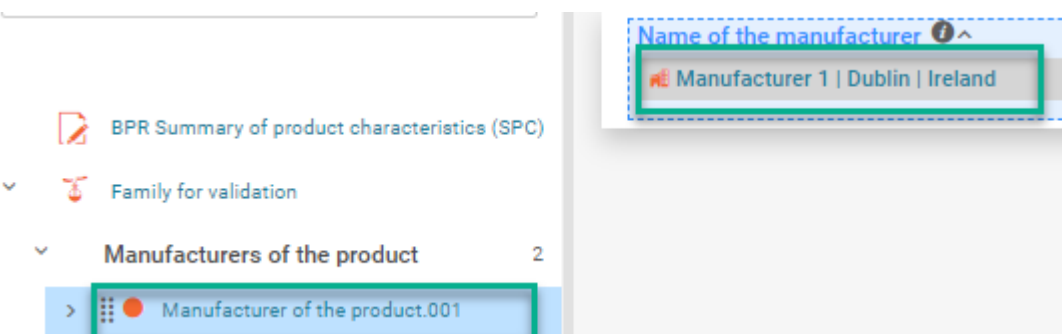

You need to add *Location of manufacturing site* in the relevant section and fill the relevant data. Please, check in part 1 of the exercise to see how to record the information.

You need to add *Manufacturer of the product* in the relevant section and fill the relevant data. Please, check in part 1 of the exercise to see how to record the information.


The Legal entity that has been referenced as representing the *Manufacturer of the product*, must be the same as the Legal entity that is referenced by the *Manufacturing site* to ensure that the Site location matches the manufacturer.

Re-validate.

The validation report does not display any remaining errors as all previous ones have been corrected. However, it is important to remember that the quality of a data is the full

responsibility of the applicant. The Validation assistant only provides support to the extent of the specified rules.
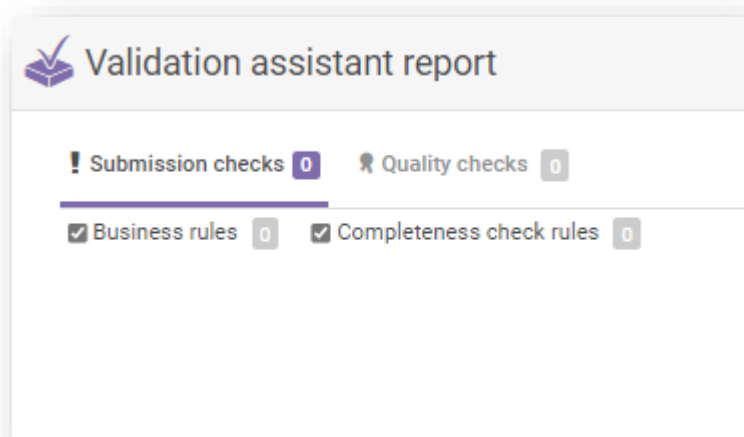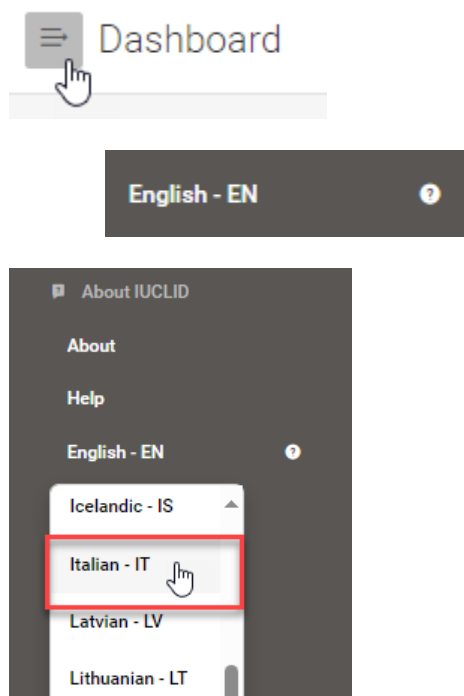

Under this link you can watch the video on how to solve part 5 of the exercise:
https://youtu.be/ZpHU33eeJvg

Appendix:

There is another feature in IUCLID that might be useful for you, a possibility to display a user interface in a selected language. This feature might help in translation of the relevant parts of a dataset/dossier. It is activated from the Dashboard:

Change of the language in the Dashbord determines the language of the interface, picklists. It does not translate the content of the fields provided by the user.

Some examples:

Table of contents:

Picklist:

Uso autorizzato

Tipo/i di prodotto ⓘ ∧ ⓘ ∧

☐ **Select/Deselect all**

☐ Tipo di prodotto 1: Igiene umana-[biocidi]

☐ Tipo di prodotto 2: Disinfettanti e alghicidi non destinati all'applicazione diretta sull'uomo o su animali

☑ Tipo di prodotto 3: Igiene veterinaria-[biocidi]

☐ Tipo di prodotto 4: Settore dell'alimentazione umana e animale-[biocidi]

☐ Tipo di prodotto 5: Acqua potabile-[biocidi]

END OF THE EXERCISE PERFORMED IN IUCLID