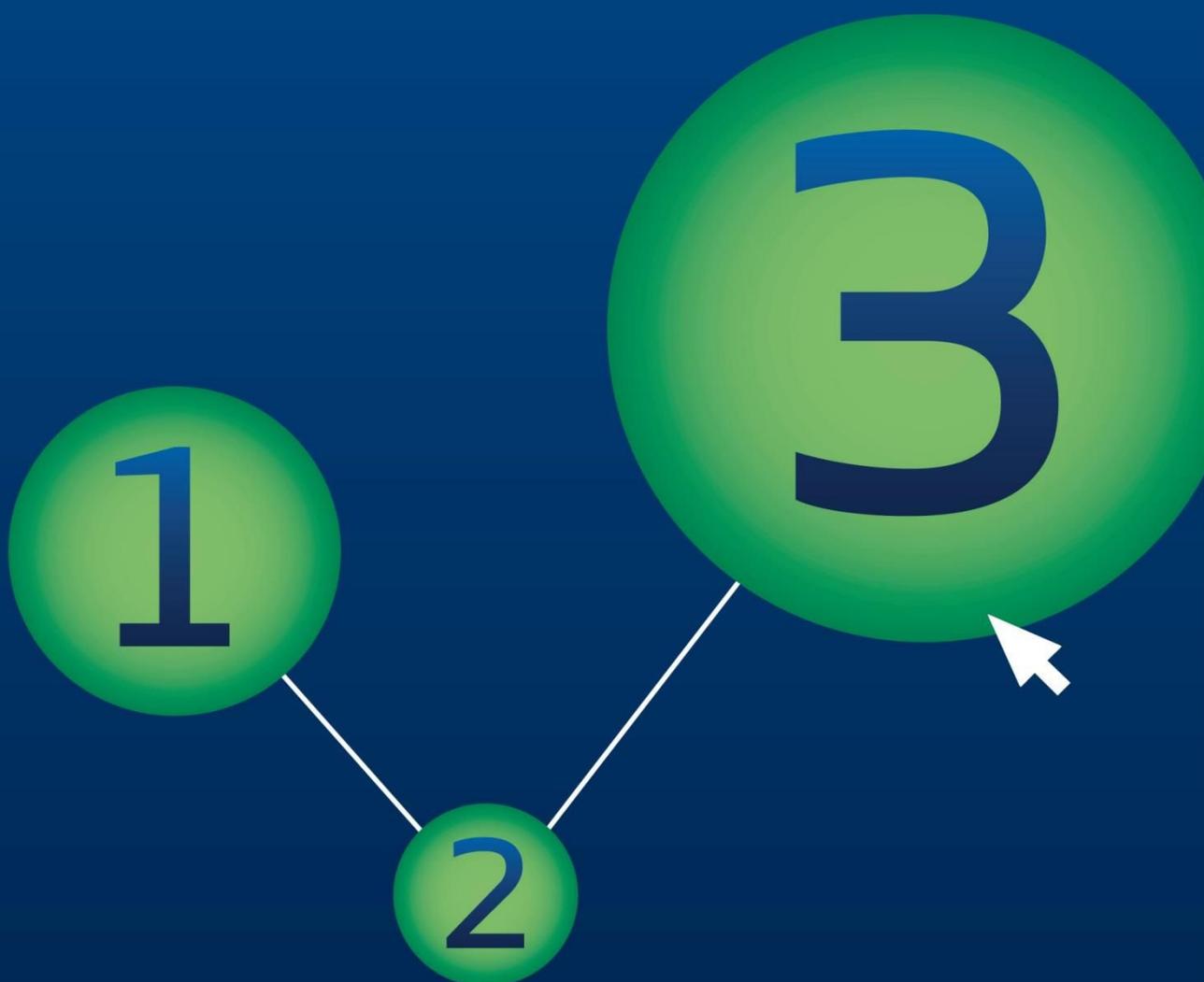


# Biocides Submission Manual

Technical guide: using the SPC Editor



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Version 1.0	First version	October 2014
Version 1.1	Updated to reflect the changes in the BSM series	December 2014
Version 1.2	Screenshots updated and a new chapter included 'Updating an SPC downloaded from R4BP 3'	February 2015

### Technical guide: using the SPC Editor

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## 1. Introduction

### 1.1 Objective

The purpose of this manual is provide guidance on how to upload and submit a summary of product characteristics (SPC) in .xml format for biocidal product authorisation related applications, using the SPC Editor provided by the European Chemicals Agency (ECHA).

Certain application types submitted under the BPR<sup>1</sup> require the inclusion of an SPC. Therefore, the various chapters in this manual aim to describe the different functionalities in the SPC Editor tool, and some general tips when uploading the document via the Register for Biocidal Products (R4BP 3).

## 2. Start using the SPC Editor

The SPC is an integral part of an authorisation decision for certain applications subject to the BPR. To this end, ECHA has provided a standalone tool to aid in the generation of an SPC, the SPC Editor. The SPC Editor can be accessed through the ECHA website at: <https://r4bp.echa.europa.eu/spc/#/home>.

### 2.1 Starting page



The browsers required to run the [SPC Editor](#) are the following:

- Chrome v.35 or above,
- Firefox v.29 or above,
- Internet Explorer 10 or above.

Other browsers or versions may work too, but this is not guaranteed. Although this tool is web based, your data is not. The data you enter and decide to save is only stored in your own file system either on your local disk or on your network drives. The data is never transmitted over the network by this tool. This means, that you are yourself responsible for any data backups, security, etc. the same way as you would be for any other data as per your own organisation`s policies.

Once you have gained access to the SPC Editor, you can choose the language to work in on the top right corner (Figure 1). The language that you choose relates to the user interface only, not to the document language. Currently, the language of interface is English. New languages will be available for selection in the future

Start creating an SPC by clicking the 'Start using the SPC Editor!' button (Figure 1).

---

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

**Figure 1: Starting page of the SPC Editor**

**SPC Editor** **ECHA**  
EUROPEAN CHEMICALS AGENCY

[▶ Start using the SPC Editor!](#) English ▾

**Browser requirements**

A fairly modern browser is required to run this application. This means:

- Chrome v.35 or above
- Firefox v.29 or above
- Internet Explorer 10 or above

Other browsers or versions may work too, but this is not guaranteed. Specifically this application will NOT work correctly in IE below version 10.

**Data storage disclaimer**

Although this tool is web based, your data is *NOT*. The data you enter and decide to save is only stored in your own file system either on your local disk or on your network drives. The data is *NEVER* transmitted over the network by this tool.

This means that you are yourself responsible for any data backups, security, etc. the same way as you would be for any other local data as per your own organisation's policies.

Once you are ready to submit your SPC, you will do so via the Register for Biocidal Products (R4BP)

## 2.2 Common features

Clicking on the 'Start using the SPC Editor!' button will direct you to the 'home page' of the SPC Editor. Here you will find four buttons on the top left corner of the screen and six tabs (Figure 2), which are available on all of the SPC Editor pages. The individual features of these buttons are detailed in section 3.1. The six tabs contain different fields in which you can enter data for the SPC. The details of these tabs are discussed in section 3.2.

The green tick icon (✔) at the top of the tabs (Figure 2) indicates sections which you are advised to fill completely, but are not mandatory. The red exclamation icon (⚠) at the top of the tabs (Figure 2) indicates that the respective section is incomplete or incorrectly filled. Although it is not mandatory to fill in the entire draft SPC, if you enter all of the necessary data, the red exclamation icon (⚠) will change to a green tick icon (✔). Mandatory fields are marked with an asterisk (\*).

To create blocks under the different headings, click on the blue '+Add...' button (Figure 2). This will create a block with fields prompting you to provide essential information. You can create as many blocks as needed, however, try not to create excess blocks that are left empty. To delete any unneeded block, hold the cursor over the top of the block to open a taskbar containing the red 'x Delete' button (✖ Delete, Figure 3).

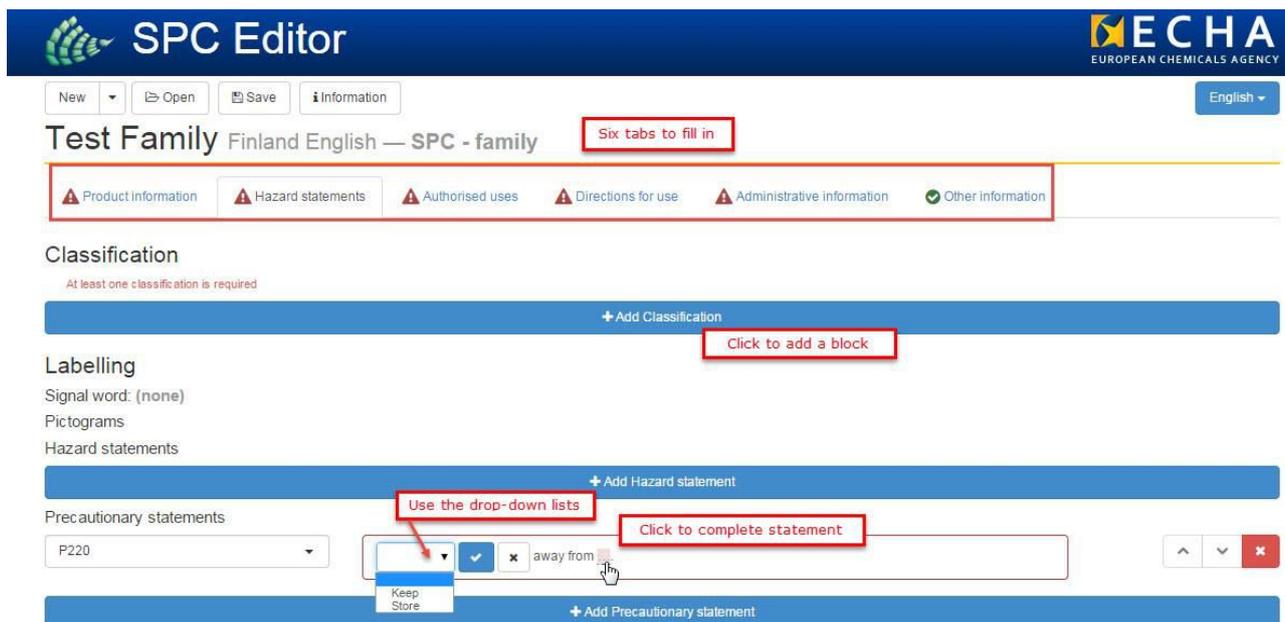
The SPC Editor makes use of two types of fields, either fields with drop-down lists or free text fields (Figure 2). If the field contains a black arrow (▼), clicking on this arrow will open a drop-down list from which you can select the appropriate option. If the appropriate option is not listed, type the relevant text into the field.

For fields with **no** black arrow (▼), please type in all relevant text.

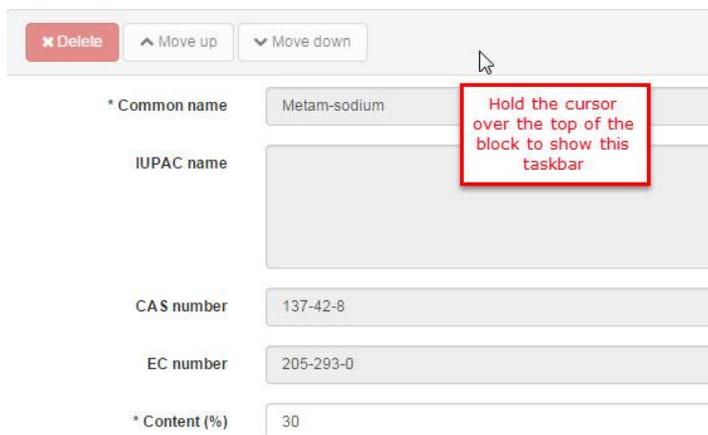


Some options selected from a drop-down list require you to fill in a blank denoted by three dots (...) by typing the correct words, or making a selection from a list of options (Figure 2).

**Figure 2: Common features in the SPC Editor**



**Figure 3: Individual taskbar per block**



### 3. Creating a new SPC

An SPC can be prepared for:

- **A single product:** An individual biocidal product with a specifically defined composition.
- **A product family:** A biocidal product family with composition defined as ranges.
- **A product in family:** A biocidal product family member with a specifically defined composition which falls within the composition ranges of the family it belongs to.

The following sections will guide you through the various functionalities of the SPC Editor and how to use them to create your SPC documents.

## 3.1 Taskbar buttons

### 3.1.1 'New' button

Clicking the 'New' button will automatically open a new standalone i.e. single product SPC, with empty fields for you to fill in. Clicking the black arrow next to the 'New' button gives you several alternative options. Information on the alternative options is given below.



Some options associated with the 'New' button will not become active until an SPC has been created and saved. Only after creating and saving the SPC can you then modify the content of the SPC.

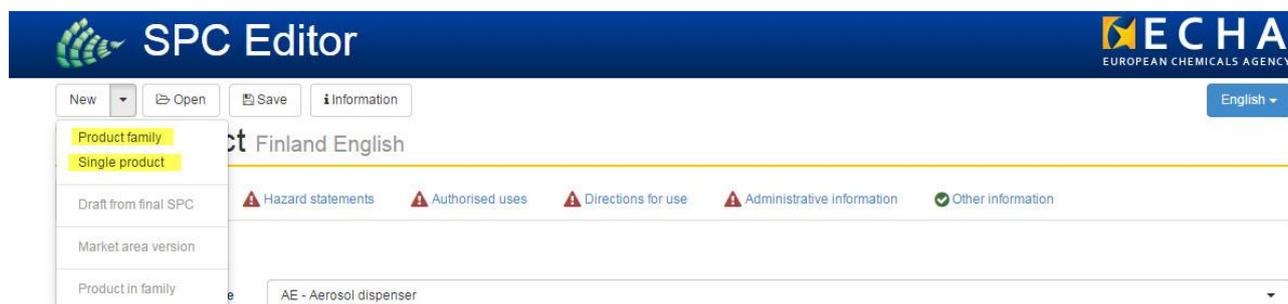
#### Step 1) SPC for single product or product family

Choose 'single product', if you want to create an SPC for a single product (Figure 4).

Choose 'Product family', if you want to create an SPC for a product family (Figure 4). You can then create individual family member SPCs at a later stage (refer to step 3) of this section).

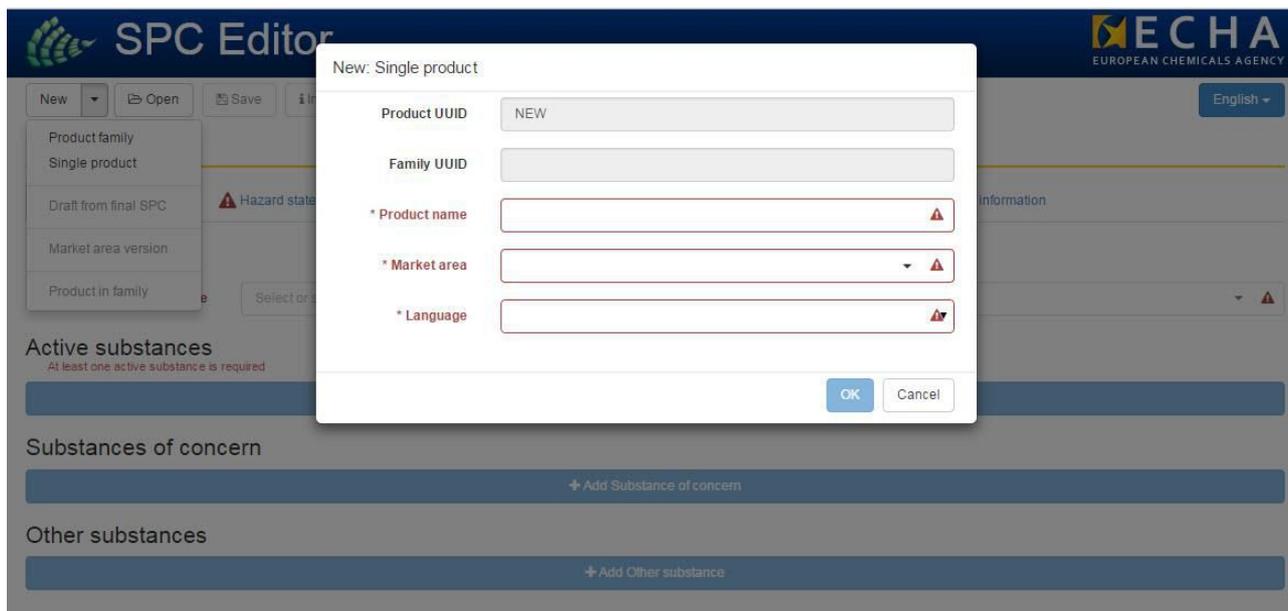
The key difference between a family SPC and a single product or family member SPC is that the content percentage of any substance is indicated as a range, for components in a family SPC, or a specific value, for components in a single product or member SPC.

**Figure 4: A single product versus a product family**



Once you have selected whether you want to create a single product or a family SPC, the 'New:' window will automatically appear (Figure 5). This window prompts you to enter the product/family name. Then choose the market area you intend the product to be marketed in and the language you wish the document to be created in, from the drop-down lists. Please note that the language selected here will only determine the language used for the options in the drop-down lists, it will not change the interface language or translate any typed text.

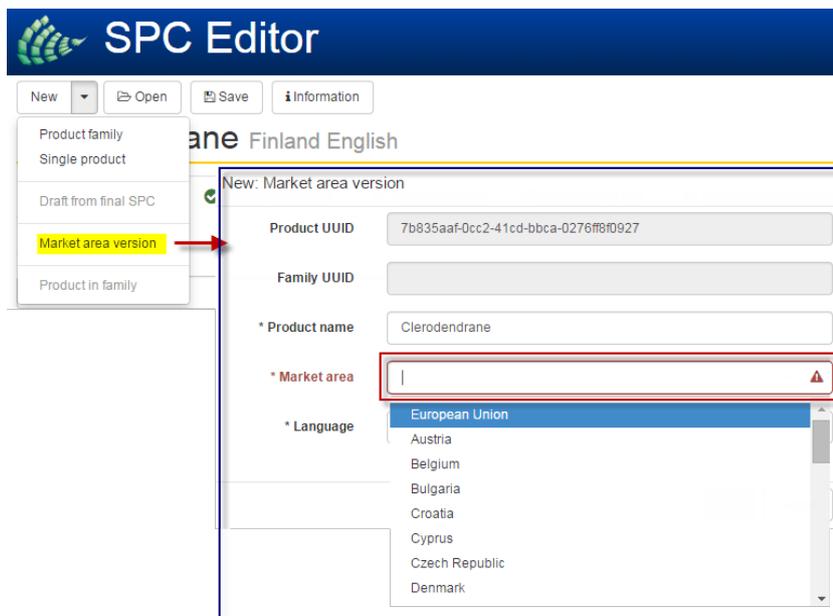
**Figure 5: 'New:...' window**



**Step 2) Market area**

A previously created SPC file can be generated into a market area version by clicking on the 'Market area version' option and then selecting the desired market area (Figure 6). The resulting SPC will have content identical to, or a subset of, the previously created SPC file. This option is intended for SPCs that concern the same product but are to be placed in different market areas, e.g. for mutual recognition cases.

**Figure 6: Changing the market area version**



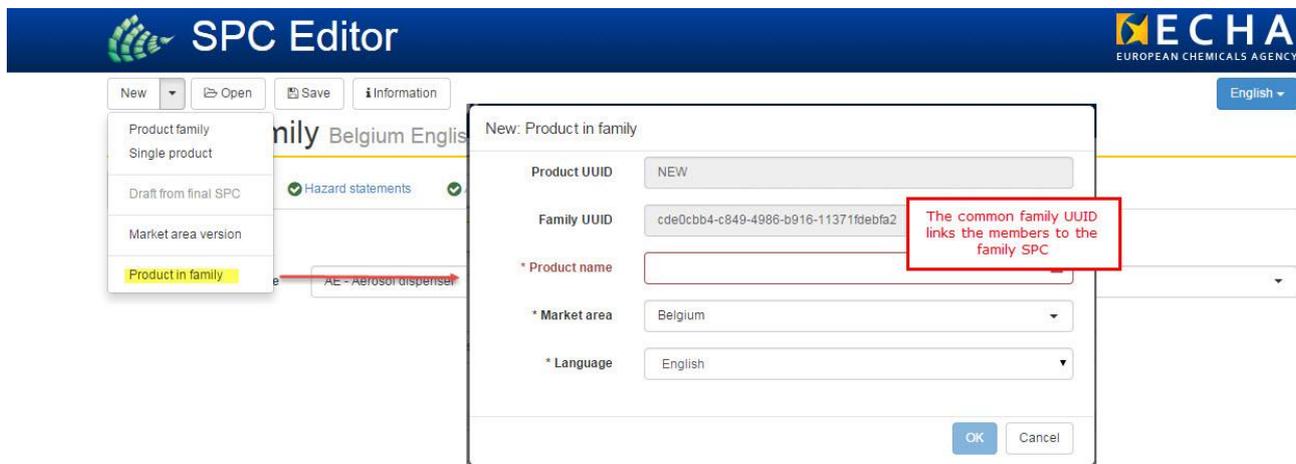
### Step 3) Product in family

As explained in step 1) of this section, you can create an SPC for a single product or for a product family. If you create a family SPC you can add family members by selecting the 'Product in family' option (Figure 7). Clicking this option will create a family member SPC, connected to the family by the family UUID (See section 3.1.4).



You should submit the family SPC when applying for a family authorisation in R4BP 3, and the member SPC when submitting a 'Notification of product in product family' in R4BP 3.

**Figure 7: Adding member products to a product family**



#### 3.1.2 'Open' button

You can open and edit an existing SPC that respects the defined SPC xml schema, using the 'Open' button (Figure 8). Clicking 'Open' will open a window that allows you to browse your local IT environment to locate saved SPC files. If you are required to edit i.e. update a previously submitted SPC, please refer to Chapter 5 for more details.



Only SPC files that respect the defined SPC xml schema will open correctly in the SPC Editor

**Figure 8: The 'Open' button**



### 3.1.3 'Save' button

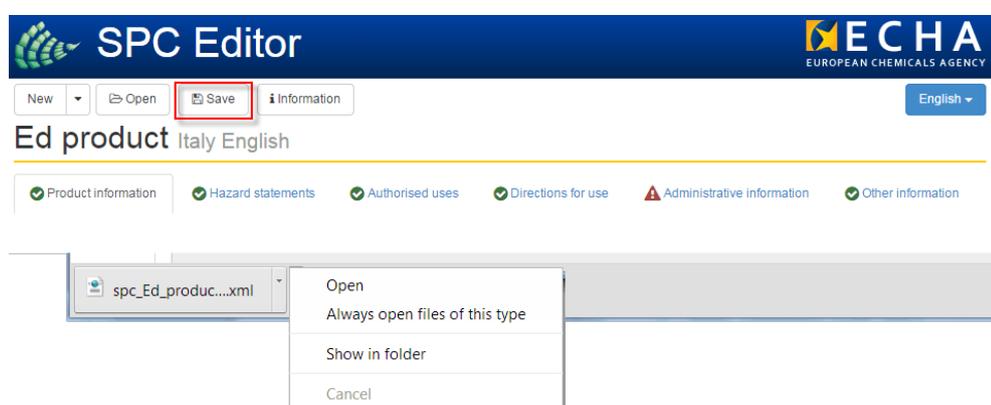
Clicking the 'Save' button (Figure 9) will allow you to save the SPC in your local IT environment (How to save your file depends on the browser you are using). Figure 9 demonstrates how to save your file when using the latest version of Google Chrome.



Check your browser settings to ensure that you are prompted as to where you save your SPC xml file, otherwise the file will go to your default folder.

Please note that the name of the document (naming conventions) is created automatically, incorporating the language and market area, but you can rename it.

**Figure 9: Save button**

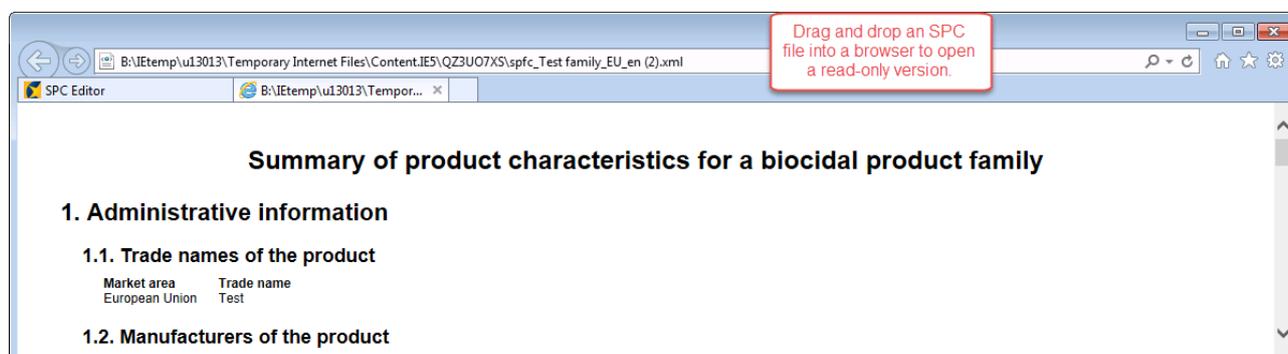


Clicking 'Open' will open a read-only version of the SPC in a new browser tab (Figure 10). If you wish to print this version, refer to Chapter 4 for more details.



Dragging and dropping an SPC file made using the SPC Editor, into a browser tab automatically opens a read-only version of the SPC (Figure 10).

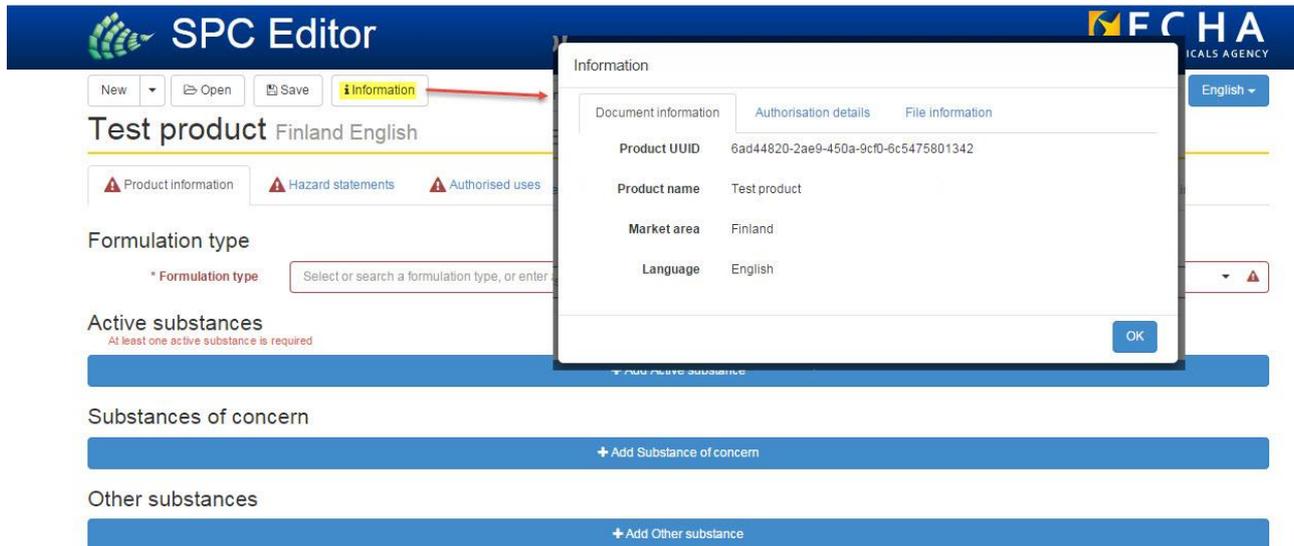
**Figure 10: Read-only SPC version**



### 3.1.4 'Information' button

Clicking the 'Information' button will open the 'Information' window (Figure 11). The 'Information' window contains several tabs with general information concerning the product authorisation.

**Figure 11: Information tab**



The '**Document information**' tab gives the:

- Product (or family) UUID; this is the unique identifier created by the SPC Editor system to identify the product when it is encountered in multiple SPCs (e.g. different market area or language versions).
- Product (or family) name; name defined by the user for the product being authorised (i.e. to identify the product in a simpler form than the UUID). This cannot be changed after creation in order to maintain data integrity.
- Market area; the country in which the product is authorised or you are seeking authorisation in. This can be the European Union, for Union level authorisations.
- Language; the language of the document content. This may differ to the language of the SPC Editor user interface.



Note that the product name is not to be confused with the trade name.

The '**Authorisation details**' tab (Figure 11) is a read-only tab containing any available authorisation details. The authorisation details (e.g. number and dates) will be automatically entered into the SPC when the relevant authorising authority uploads the final SPC and completes the product authorisation in R4BP 3.

The '**File information**' tab initially gives a proposed file name automatically generated based on the name of the substance, as well as the market area and language you selected. The file name is linked to the name the SPC is saved under; the user can therefore alter this at any stage.

## 3.2 Home page tabs

If you correctly complete all fields in each tab, the red exclamation icon (⚠) will change to a green tick icon (✔), indicating the SPC is complete.



An industry user is expected to submit a draft SPC, therefore the field validations are more of a guide to indicate to the user what information might still be missing. The SPC Editor will allow the user to save an SPC even if all the fields are not completed.

### 3.2.1 'Product information' tab

The 'Product information' tab includes information on the substance components of the product, (e.g. the active substance).

Start by choosing the 'Formulation type' (Figure 12) from the drop-down list. Then click on the blue '+ Add...' strip to enter details of any 'Active substances', 'Substances of concerns' and 'other substances' that are present in the product (Figure 12).

The Biocidal Active Substance (BAS) number can be found in the list of approved active substances published on the ECHA website. If the relevant active substance is not listed here, please contact the [ECHA Helpdesk](#) (on the contact form, select IT tools, 'I am using R4BP 3' so your query can be processed more efficiently).



If you do not know the BAS number; in the field 'BAS number', you can search for the substance by typing the common name, CAS number or EC number. The BAS number will then be found automatically if listed.



Selecting the correct BAS number from the drop-down list will automatically fill in other available data, e.g. common name, CAS number, etc. **Note** that you must type in the Content (%); this will be a range if filling in an SPC for a product family.

If a value higher than 100 is inserted into the 'Content (%)' field, the value will be highlighted red as incorrect (Figure 12).



When filling in the substance components 'Content (%)' for a family member SPC, they must lie within the range specified in the related family SPC.

**Figure 12: 'Product information' tab**

If the product contains any 'Substance of concern' or 'Other substances' (i.e. non-active substances), enter relevant details by creating a block using the '+ Add...' button. Select the function of the substance from the drop-down list, or add free text if the correct function is not listed, into the 'Function' field. Fill in the other free text fields, mandatory fields are highlighted in red and preceded by an asterisk (\*).

### 3.2.2 'Hazard statements' tab

The 'Hazard statement'<sup>2</sup> tab includes information on the classification and labelling of the product.

You can add a 'Classification', 'Hazard statements' and 'Precautionary statements' from the drop-down lists once a block is created (Figure 13).



Some of the statements require additional input after their selection. A selection may require you to fill in a blank denoted by three dots (...) by typing the correct words, or making a selection from a list of options (Figure 13).

<sup>2</sup> For micro-organisms, indicate the need for the biocidal product to carry the biohazard sign specified in Annex II to Directive 2000/54/EC (Biological Agents at Work).

**Figure 13: 'Hazard statements' tab**

SPC Editor

ECHEA  
EUROPEAN CHEMICALS AGENCY

New Open Save Information English

Test product Finland English

Product information Hazard statements Authorised uses Directions for use Administrative information Other information

Classification

+ Add Classification

Labelling

Signal word: (none)

Pictograms

Hazard statements

+ Add Hazard statement

Precautionary statements

P220 Keep away from Complete the statement

+ Add Precautionary statement

### 3.2.3 'Authorised uses' tab

The 'Authorised uses' tab includes details about the target organism, application methods, packaging and directions for use.

Fill in as many of the fields as possible. You can type text into the free-text fields e.g. 'Title for use', make selections from the drop-down lists (▼) e.g. 'Product type', or select the appropriate tick boxes e.g. 'Field of use' (Figure 14).

The details of target organisms, application methods, and packaging can be entered by first creating relevant blocks (Figure 14).



You can enter details about more than one use by creating a new block for each use. This is achieved by clicking '+Add Use' at the top of the page (Figure 14).

**Figure 14: 'Authorised uses' tab**

The screenshot displays the 'Authorised uses' tab in the SPC Editor. The interface includes a header with the SPC Editor logo and ECHA logo. Below the header, there are navigation tabs: Product information, Hazard statements, Authorised uses (selected), Directions for use, Administrative information, and Other information. The 'Authorised uses' tab shows a form for 'Use #1'. The form contains the following fields and sections:

- Title for use:** A text input field.
- Product type:** A dropdown menu with 'PT01 - Human hygiene (Disinfectants)' selected. A red callout box points to this dropdown with the text: 'When present use the arrow to open the drop-down list, or enter free text'.
- Where relevant, an exact description of the authorised use:** A large text area.
- Field of use:** Radio buttons for 'Indoor' (checked), 'Outdoor', and 'Other'.
- Field of use description:** A text input field.
- User categories:** Checkboxes for 'Industrial', 'Trained professional', 'Professional', and 'General public (non-professional)'.
- Target organisms:** A section with a red note 'At least one target organism is required' and a '+ Add Target organism' button.
- Application methods:** A section with a red note 'At least one application method is required' and a '+ Add Application method' button. A red callout box points to this button with the text: 'Create a block to input relevant data'.
- Packagings:** A section with a red note 'At least one packaging is required' and a '+ Add Packaging' button.

At the bottom of the form, there is a section for 'Directions for use'.

### 3.2.4 'Direction for use' tab

The 'Directions for use'<sup>3</sup> tab contains only free text fields giving explicit details on how to use the product (Figure 15). Type in all relevant text under the correct heading (e.g. 'Instructions for use', 'Risk mitigation measure', etc.).

<sup>3</sup> Describe the necessary instructions for use (e.g. the period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product, or the next recommended access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance; etc.).

**Figure 15: 'Directions for use' tab**

SPC Editor

ECHA  
EUROPEAN CHEMICALS AGENCY

New Open Save Information English

Test product Finland English

Product information Hazard statements Authorised uses **Directions for use** Administrative information Other information

General directions for use

\* Instructions for use

\* Risk mitigation measures

\* Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

\* Instructions for safe disposal of the product and its packaging

\* Conditions of storage and shelf-life of the product under normal conditions of storage

### 3.2.5 'Administrative information' tab

The 'Administrative information' tab includes the trade name of the product in the market area, and details on the manufacturers of the product and the manufacturers of the active substance.

Start by selecting the market area you are seeking authorisation in, from the drop-down list at the top of the page (Figure 16). Then type in the 'Trade name'<sup>4</sup> of the product.

Fill in the other free text fields and then choose the country in which the manufactures are located in from the drop-down lists.



When entering information about the substance manufacturer, you must first select the substance you are detailing in the 'Substance name' field using the drop-down list. This list will contain any substance you included in the 'Product information' tab.

<sup>4</sup> In case a product has more than one trade name, all trade names should be provided in this section.

**Figure 16: 'Administrative information' tab**

The screenshot displays the 'Administrative information' tab in the SPC Editor. At the top, the ECHA logo and 'SPC Editor' are visible. Below the header, there are navigation buttons: 'New', 'Open', 'Save', and 'Information'. The main title is 'Test product' with language options 'Finland' and 'English'. A horizontal menu contains tabs for 'Product information', 'Hazard statements', 'Authorised uses', 'Directions for use', 'Administrative information' (highlighted), and 'Other information'. The 'Administrative information' section is titled 'Trade names of the product'. It features a 'Market area' dropdown menu with a list of countries including European Union, Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, and Denmark. A text input field contains 'Test product' and a 'Delete' button. Below this is a '+ Add Trade name' button. The section contains several input fields for 'Name of the product', 'Postal code', 'City', and 'Country', each with a warning icon.

In sections 'manufacturers of the product' and 'manufacturers of the substance' there is a functionality (see Figure 17) which allows the users to import and export .xml files containing the administrative information related to the manufacturers. These .xml files, once saved, can then be used to avoid retyping information in SPC files when the same manufacturer is used for other products.

**Figure 17: 'Exporting and importing administrative information'**

Manufacturers of the product

\* Address

\* Postal code

\* City

\* Country

Location of manufacturing sites

\* Address

\* Postal code

\* City

\* Country

Manufacturers of the substance

\* Substance name

### 3.2.6 'Other information' tab

Enter any additional information into the free-text field under the 'Other information' tab (Figure 18).

**Figure 18: 'Other information' tab**


**SPC Editor**


Test product Finland English

Other information

## 3.3 Editing commands

In certain free text fields, you will be able to edit the text to different font sizes (H4, H5, H6) and/or use bold, italics or underline functionalities. In addition, you can use a bullet type system of a series of points or numbers (Figure 19).

**Figure 19: Edit tool bar**

## 4. Printing an SPC

Once you have saved an SPC .xml file, you can print the SPC by dragging-and-dropping the file into a browser window. The SPC file should open in an easy to read format (Figure 20).

You can then use the browsers' print function to print the SPC. The browser print options are accessed by clicking Ctrl+P or right-clicking on the window and selecting 'Print' from the pop-up list (Figure 20).



If the browser doesn't show the easy to read layout you may need to refresh the browsers cache by erasing the complete history.

**Figure 20: Printing an SPC**

Open in a new window to see the easy to read format

### Summary of product characteristics for a biocidal product

- Administrative information
  - Trade names of the product
 

Market area	Trade name
European Union	Test
  - Manufacturers of the product
 

Name of the manufacturer	Test
Address of the manufacturer	TestTestFinland
Location of manufacturing sites	TestTestFinland
  - Manufacturer(s) of the active substance(s)
 

Name of the manufacturer	Test
Address of the manufacturer	TestTestFinland
Location of manufacturing sites	TestTestFinland
- Product composition and formulation
  - Qualitative and quantitative information on the composition of the product
 

BAS number	EC number	CAS number	Common name	IUPAC name	Function	Content (%)
1328	205-293-0	137-42-8	Metam-sodium		Active Substance	25

AL - Any other liquid
- Authorised use(s)
 

Use #1 4 Test	Product type
	PT01 - Human hygiene (Disinfectants)

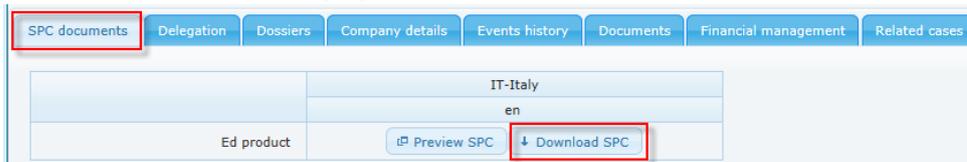
Print...

## 5. Updating an SPC from R4BP 3

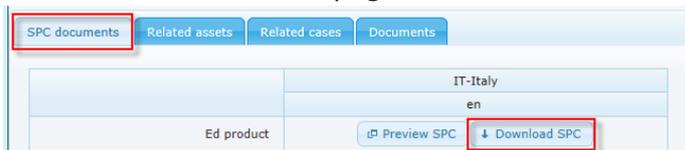
It may be that you are required to re-submit an updated SPC, e.g. where applications for a change on request is made, or, for instance, where an authority asks you for further information. In such cases, you should use the latest available version of the previously submitted SPC, which can be found in R4BP 3. The process of downloading a previously submitted SPC from R4BP 3 has been outlined in [BSM Technical guide: using R4BP 3](#) from the 'SPC documents' sub-tab located in the relevant case details (Figure 21a) or asset details (Figure 21b).

**Figure 21: Locating the SPC from R4BP 3**

a) From the case’s details page

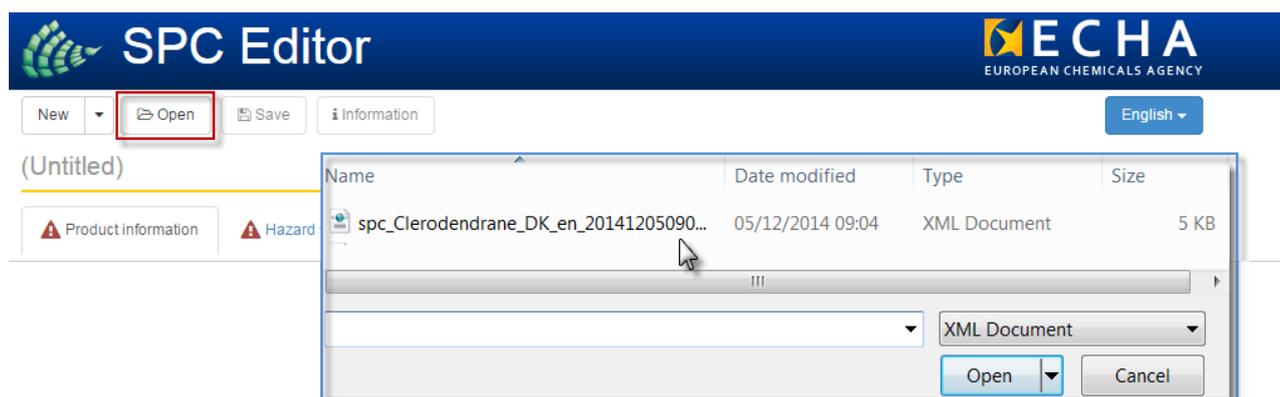


b) From the asset’s details page



Once the SPC has been downloaded to your computer, you can go to the SPC Editor home page and select 'open' (  Open ) to locate the relevant file and open it in order for you make the necessary edits (Figure 22). This file can be saved and updated as many times as needed though do take note that the new name of the saved document is created automatically. When you are sure all of the necessary changes have been made, the file can be uploaded in R4BP 3.

**Figure 22: Opening an SPC downloaded from R4BP 3**



The product (or family) UUID of the updated SPC must match the UUID of the originally submitted version.

## 6. Tips when including your SPC in an application

Once the SPC has been created and saved on your local IT environment you can upload it as part of an application through R4BP 3 where required.

The SPC is largely identified by the product or family UUID number assigned to it so take extra care to ensure the correct SPC is ready to upload in your application. The R4BP 3 wizard will display an error message if there is conflicting information in the uploaded SPC and the details entered into the application form.

**Some tips to bear in mind may include:**

- Ensure the market area selected in the application wizard matches the market area in the SPC.
- Ensure you upload the correct type of SPC (i.e. single, family or member).
- Ensure you use the correct SPC as defined by the product or family UUID when submitting multiple SPCs
- When uploading an SPC following a change or renewal of an existing authorisation, the product or family UUID must match with that of the product or family reference SPC.

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