

New family SPC

9 November 2016

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New version of SPC Editor

2016



**WE
ARE
HERE**

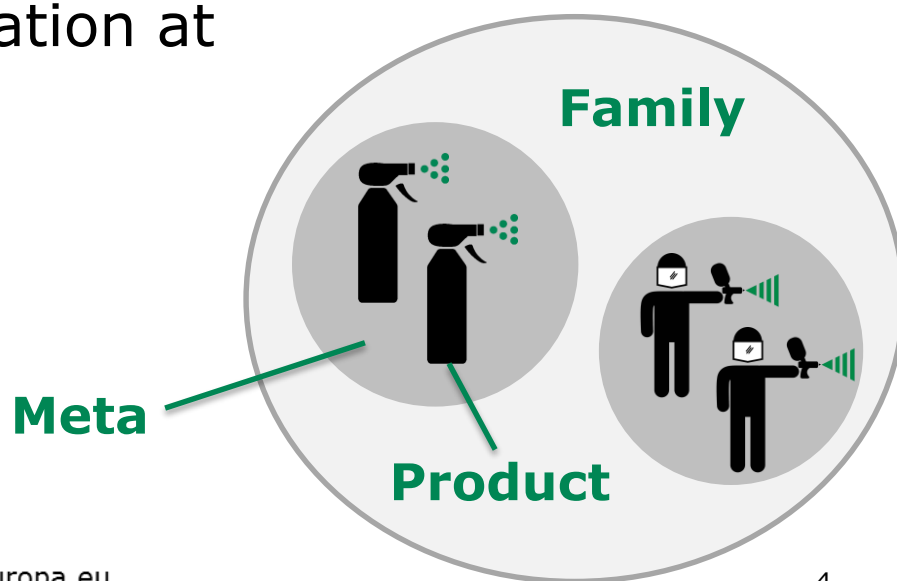
**SPC
editor 2.0**

New features


- Allows you to make **structured product family** applications on three levels
- **Interaction with R4BP 3**
- All existing summaries of product characteristics (SPC) for product families in R4BP 3 **migrated** to the new family structure
- **Improvements in the user interface**

Three levels of information

- 1. Family:** general information that applies to all the products
- 2. Meta:** formulation type, authorised uses, risk management measures and hazard and precautionary statements common to the products
- 3. Product:** specific information at product level



SPC Editor 2.0



SPC Editor

☰
New ▾
Open
Save
Information
PDF Preview ▾
Import XML
Compare with

10 members family European Union English — SPC - family

Expand all
Collapse all

10 members family

Administrative information

Product information

meta SPCs

Meta1

H & P statements

Authorised uses

Use 1

Use 2

Use 3

Use 4

Use 5

Directions for use

Other information

Products

P1

Product type(s)

PT02 - Disinfectants and algaecides not intended for direct application to humans or

PT04 - Food and feed area (Disinfectants) ✕ PT05 - Drinking water (Disinfectants)

Manufacturers of the product

Move up

Move down

Export XML

Import XML

* Name of the manufacturer

BAFS

* Address

Street 1

* Postal code

098765


* City

London

* Country

United Kingdom

SPC from family to single product

 **SPC Editor**

Administrative information

Product information

▼ meta SPCs

▼ meta SPC

Hazard statements

▼ Authorised uses

Use

Directions for use

Other information

Edit name

Duplicate

Apply for a same product

Notify a product

New

Open

Save

Information

Import XML

Compare with

Test

European Union English — SPC - family

Same biocidal product submission combinations

Type of SBP sought	R4BP 3		SPC	
	Case type to use	Reference asset/case to start from	Draft SPC needed	Reference SPC to start from
Family UA	UA-BBP	UA-BBP - case	UA family SPC	UA family SPC
	UA-BBS	UA - asset		
Single UA	UA-BBP	UA-BBP - case	UA single SPC	UA family SPC
	UA-BBS	UA - asset		UA single SPC
	UA-BBP	UA-BBP - case		
	UA-BBS	UA - asset		
Family NA	NA-BBP	UA-BBP - case	NA family SPC	UA family SPC
	NA-BBS	UA - asset		
	NA-BBP	UA-BBP - case		
	NA-BBS	UA - asset		
Single NA	NA-BBP	NA-BBP / NA-MRP - case	NA single SPC	UA family SPC
	NA-BBS	NA - asset		UA single SPC
	NA-BBP	UA-BBP - case		
	NA-BBS	UA - asset		
Family SA	SA-BBP	SA-BBP - case	SA family SPC	SA family SPC
	SA-BBS	SA - asset		
Single SA	SA-BBP	SA-BBP - case	SA single SPC	SA family SPC
	SA-BBS	SA - asset		SA single SPC
	SA-BBP	SA-BBP - case		
	SA-BBS	SA - asset		

Migration – pay attention to...

Duplicated information

- Manufacturers of the product
- Manufacturers of the substance and at meta-SPC level
- Authorised uses
- General instructions for use
- “Other information” contains trade names that used to be in the old family SPC (migrated as free text)

Migration – pay attention to...

Mini (template) SPC

- If there are family cases or assets without any member, the system added one meta level and one 'empty' product in the converted family SPC
- In these scenarios, you or the evaluating competent authority will need to add all the relevant information for the product in the third level of the SPC (appears empty after the migration)
- For assets, the evaluating competent authority will need to use an XX-AAT (asset amendment case type)

Migration – pay attention to...

Finalising the migration

- In any case, for the migration to be finalised for all open cases, the evaluating competent authority will have to download the family SPC and upload it as part of the final SPC
- In the evaluation step, the evaluating competent authority needs to download the existing family SPC (evaluate it) and then upload it to finalise the migration

Improvements in the user interface

- SPC family structure
- SPC master language

Case SPC document tab

Application for national authorisation (NA-APP): BC-KG016394-47

Case status: In Progress
Evaluating authority: MSCA-Cyprus
Submission date: 17/06/2016
Completed on: -
Dossier UUID: dd54e1c3-c67d-4565-847a-68830d5e19cd

Product information

Family name: Lena_123
Product type(s): 15, 20, 19, 1
Active substance(s):

- Chlorocresol
- Boric oxide

Case owner details

Company name: elenk
Company UUID: ECHA-7bc94251-11c9-4c85-a85d-2067c028191b

SPC documents

Dossiers

Company details

Events history

Documents

Financial management

Related cases



Case master language

Submission for application for national authorisation (NA-APP)

Upload SPC

Please upload below your SPC (summary of product characteristics) file that is required for your application.

*Please upload the necessary SPC file(s)

	BE-Belgium		HR-Croatia		CY-Cyprus		DK-Denmark
	<input type="radio"/> el	<input type="radio"/> fr	<input type="radio"/> de	<input type="radio"/> fr	<input checked="" type="radio"/> el	<input type="radio"/>	
Samsung	<input type="button" value="Browse"/>	<input type="button" value="Upload All"/>	<input type="button" value="Cancel All"/>	<input type="button" value="Browse"/>	<input type="button" value="Upload All"/>	<input type="button" value="Cancel All"/>	

+ Browse ↗ Upload All ⌂ Cancel All

File names should not contain special characters ?

← Previous Cancel

Evaluate & Decide TASK-859811

Task details

Task name: Evaluate & Decide
 Task number: TASK-859811
 Created on: 05/03/2015 Status: Claimed
 Claimed by: Manager Cyprus DNA 1 Claimed on: 01/09/2016

Due date: 04/03/2016

Task history

Complete Save Assign Release Close

Task actions

Decision number: NAP-D-1027523-37-00/F
 Temporary asset number: CY-0006222-0000

Please select one of the following allowed actions based on your decision:

Approve application

Set the validity period of the authorisation:

*Valid from:

*Expiry date:

Provide a reference number for the asset that will be created:

Other reference number:

*Please upload the necessary SPC file(s)

	CY-Cyprus
	<input checked="" type="radio"/> en
Generated product name	<input type="text"/>

+ Browse ↗ Upload All ⌂ Cancel All

- A master SPC identifies the SPC used as a reference to determine what **key information** of your application will be **displayed in R4BP 3**
- When you upload one or more translated SPCs, **you need to define what SPC should be considered as the master SPC**. If only one SPC is provided, you need to select that value

Supporting material

SPC Editor

Since 3 December 2014, with the release of **R4BP version 3.2**, a new format for the summary of the product characteristics (SPC) has been mandatory for all companies wishing to apply for product authorisations.*

In order to support companies in preparing their applications for authorisation of biocidal products, either on a national or European level, an online application called **SPC Editor** has been prepared by ECHA. The tool is fully compatible with R4BP 3.

Applicants can use this tool to create SPC for single products, product families and members of the family. Applicants will be able to generate either new documents or amend existing ones. For example, applicants can create a new SPC for an additional member in a product family starting from an existing SPC prepared for another member of the same family.

Authorities will also use the tool to amend and finalise the SPC while granting an authorisation.

Additionally, an updated **Report Generator plug-in for IUCLID** is available at the IUCLID website. The plug-in is compatible with IUCLID version 5.6 and can be used to generate a draft SPC for single product authorisations. The relevant information available in the biocidal product file in IUCLID is automatically extracted into a format which is fully compatible with the SPC Editor.

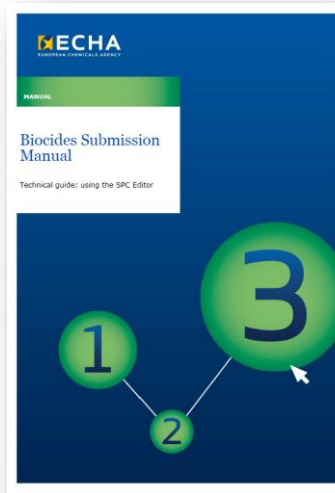
The new structure of the SPC will make data dissemination easier and, in the long run, could support the comparative assessment of different products.

* with the exception of application for products' renewal.

SPC Editor



SPC Editor manual



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