

IT TOOLS FOR BIOCIDAL PRODUCTS: IUCLID, SPC EDITOR, R4BP3

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Istituto Superiore di Sanità

TOPICS

IUCLID 6

Biocidal Product Dossier

SPC EDITOR an R4BP3

Support

TOPICS

IUCLID 6

Biocidal Product Dossier

SPC EDITOR an R4BP3

Support

IUCLID 6

Main tasks

 Substance	 Mixture / Product	 Template	 Dossier
 Category	 Annotation		






Administration

 User management	 Import	 Bulk export
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Inventories

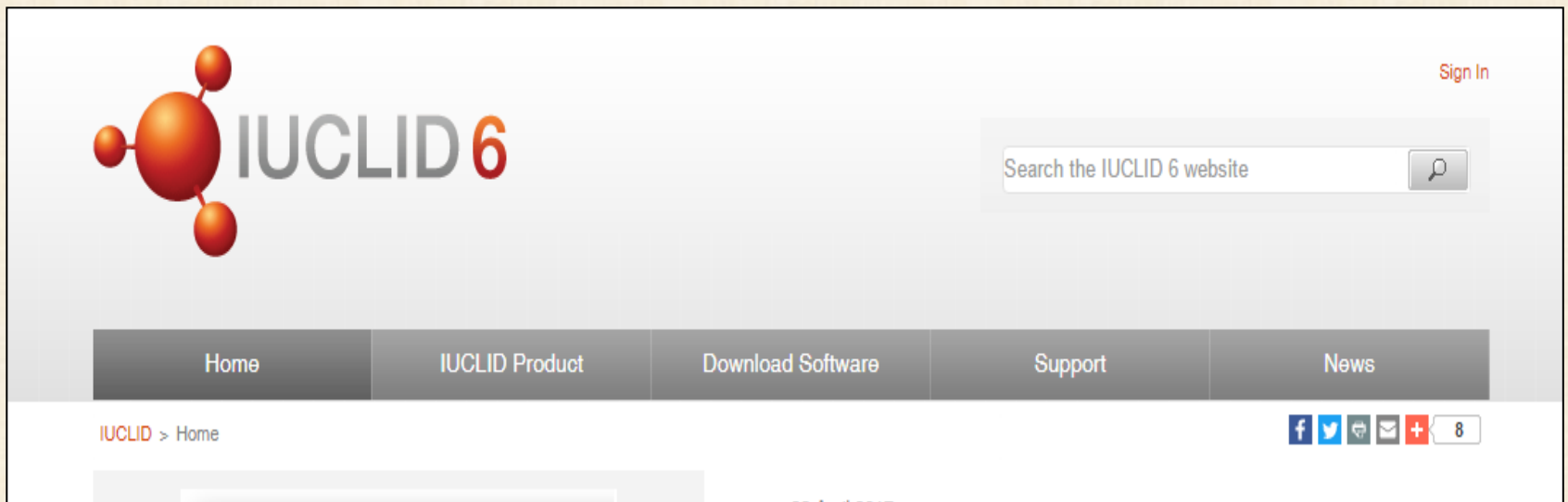
 Legal entity	 Legal entity site	 Reference substance	
 Contacts	 Chemical inventories	 Literature reference	 Test materials

Plugins

 Validation assistant	 Report generator	 Advanced search
 Dissemination preview	 Fee calculator	 Help

IUCLID 6

<https://iuclid6.echa.europa.eu/home>



The screenshot shows the IUCLID 6 website home page. On the left, there is a logo consisting of four orange spheres of varying sizes connected by thin lines, followed by the text "IUCLID 6" in a bold, sans-serif font. In the top right corner, there is a "Sign In" link. Below the logo and search bar, there is a horizontal navigation menu with five items: "Home", "IUCLID Product", "Download Software", "Support", and "News". Below the navigation menu, there is a breadcrumb trail that reads "IUCLID > Home". On the right side of the page, there is a search bar with the placeholder text "Search the IUCLID 6 website" and a magnifying glass icon. Below the search bar, there is a row of social media icons for Facebook, Twitter, LinkedIn, Email, and a plus sign, followed by a notification icon showing the number "8".

IUCLID 6: HOMEPAGE

The screenshot shows the IUCLID 6 homepage with four main sections highlighted by colored boxes:

- Main tasks (red box):** Contains icons for Substance, Mixture / Product, Template, Category, Annotation, and Dossier.
- Administration (purple box):** Contains icons for User management, Import, and Bulk export.
- Inventories (blue box):** Contains icons for Legal entity, Legal entity site, Reference substance, Contacts, Chemical inventories, Literature reference, and Test materials.
- Plugins (green box):** Contains icons for Validation assistant, Report generator, Advanced search, Dissemination preview, Fee calculator, and Help.

MAIN TASKS

Substance

Mixture/Product

Template

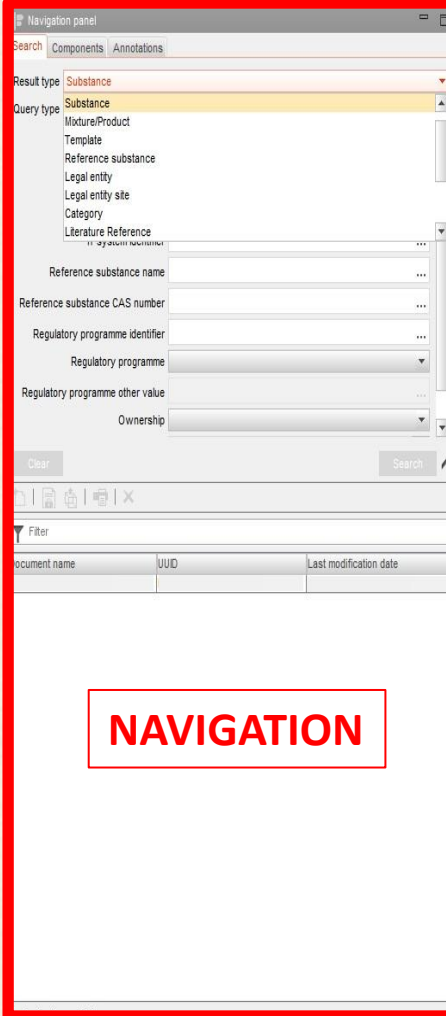
Dossier

Administration Panel

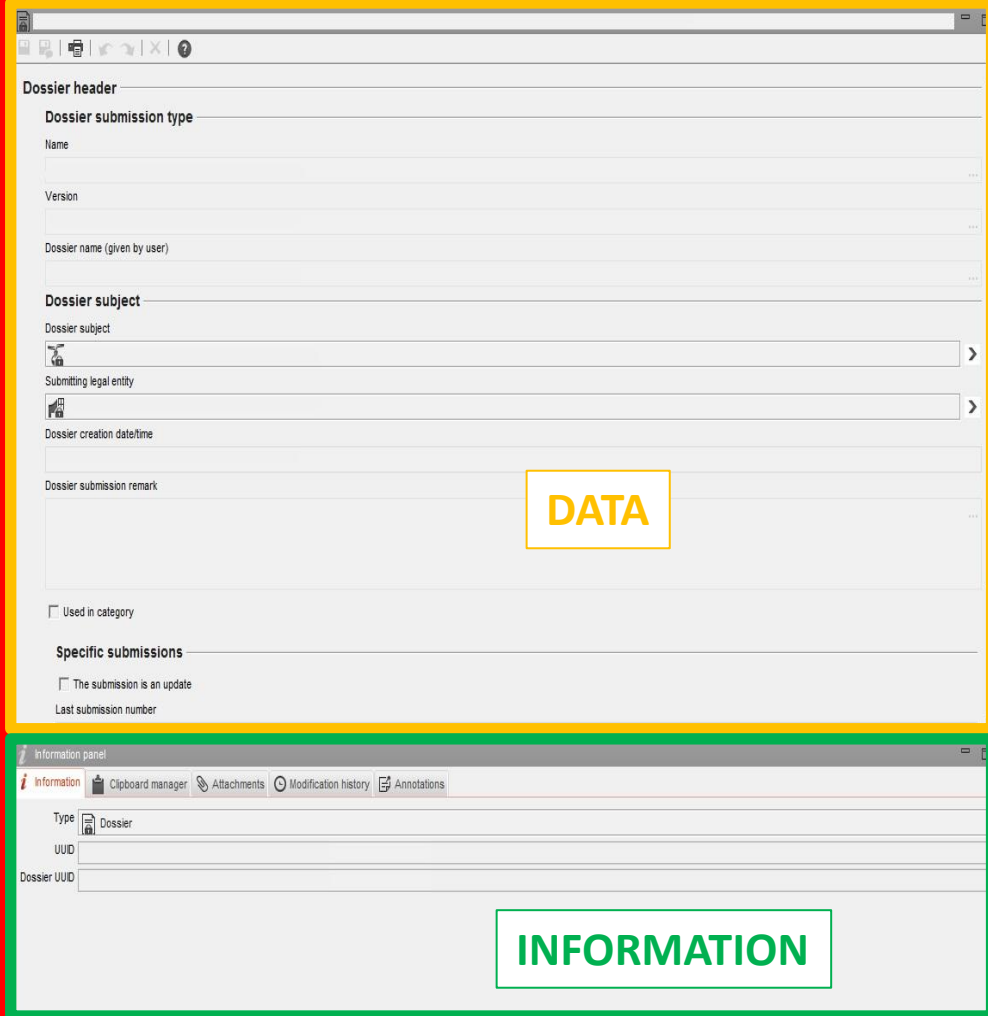
Plugins

Inventories

IUCLID 6: PANELS



The screenshot shows the 'Navigation panel' in IUCLID 6. It features a search bar at the top with tabs for 'Components' and 'Annotations'. Below the search bar, there are several dropdown menus for 'Result type' (set to 'Substance') and 'Query type' (set to 'Substance'). A list of query types is visible, including 'Mixture/Product', 'Template', 'Reference substance', 'Legal entity', 'Legal entity site', 'Category', and 'Literature Reference'. Below the list, there are input fields for 'Reference substance name', 'Reference substance CAS number', 'Regulatory programme identifier', 'Regulatory programme' (a dropdown menu), 'Regulatory programme other value', and 'Ownership'. At the bottom, there is a 'Filter' section with a table showing columns for 'document name', 'UUID', and 'Last modification date'. A red box with the text 'NAVIGATION' is overlaid on the bottom half of the panel.



The screenshot shows the 'Dossier header' and 'Information panel' in IUCLID 6. The 'Dossier header' section includes fields for 'Dossier submission type', 'Name', 'Version', 'Dossier name (given by user)', 'Dossier subject', 'Dossier subject' (with a folder icon), 'Submitting legal entity', 'Dossier creation date/time', and 'Dossier submission remark'. A yellow box with the text 'DATA' is overlaid on the 'Dossier submission remark' field. Below this, there are checkboxes for 'Used in category' and 'The submission is an update', and a field for 'Last submission number'. The 'Information panel' at the bottom shows tabs for 'Information', 'Clipboard manager', 'Attachments', 'Modification history', and 'Annotations'. It displays 'Type' as 'Dossier', 'UUID', and 'Dossier UUID'. A green box with the text 'INFORMATION' is overlaid on the bottom half of the panel.

INVENTORIES

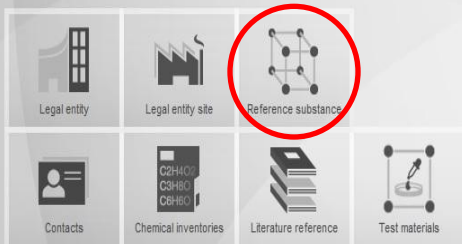
Main tasks



Administration



Inventories

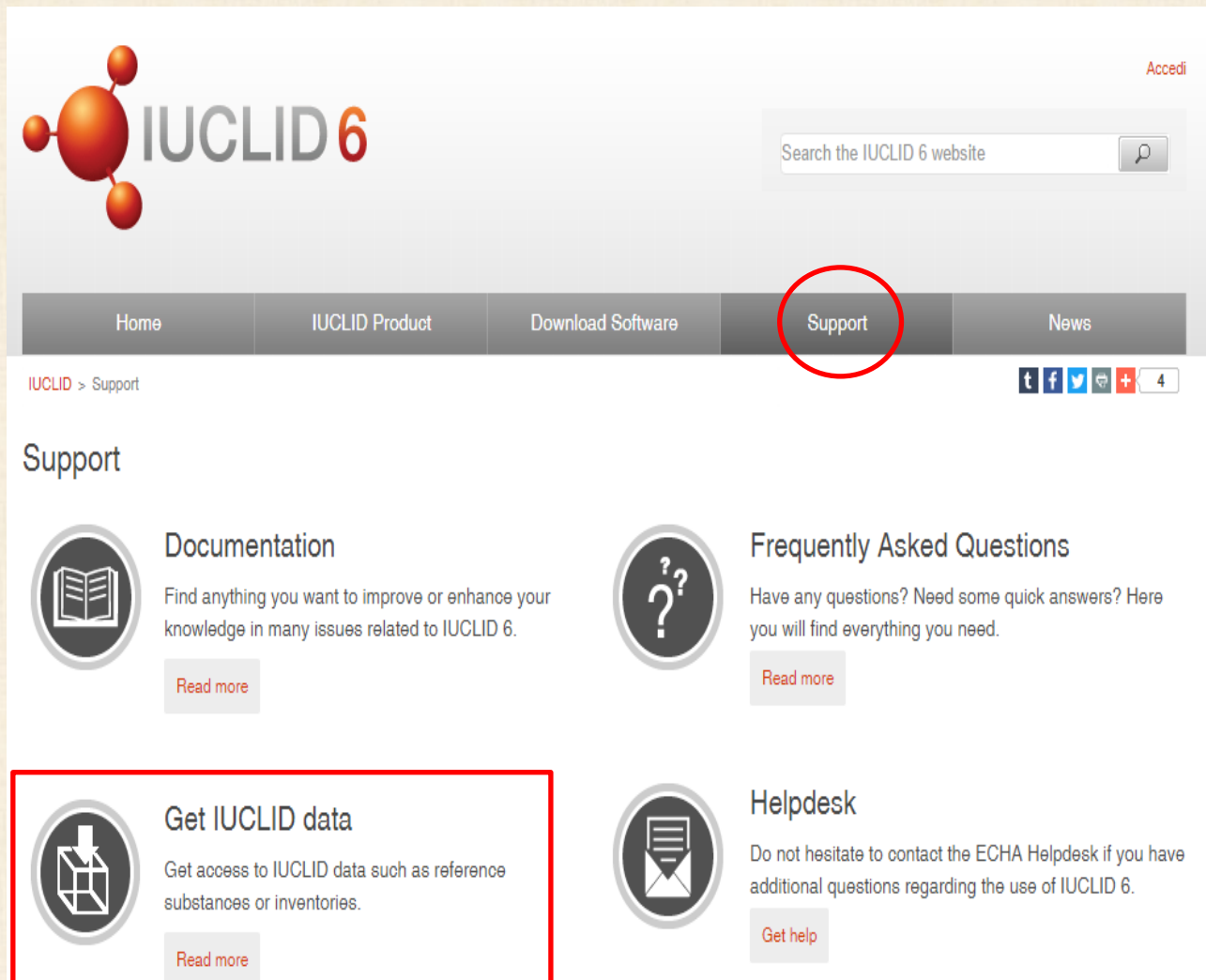


Plugins



REFERENCE SUBSTANCE

<https://iuclid6.echa.europa.eu/it/support>



Accedi

 IUCLID 6

Search the IUCLID 6 website

Home IUCLID Product Download Software **Support** News

IUCLID > Support

t f t + 4


Support



Documentation

Find anything you want to improve or enhance your knowledge in many issues related to IUCLID 6.


[Read more](#)



Frequently Asked Questions

Have any questions? Need some quick answers? Here you will find everything you need.


[Read more](#)



Get IUCLID data

Get access to IUCLID data such as reference substances or inventories.

[Read more](#)



Helpdesk

Do not hesitate to contact the ECHA Helpdesk if you have additional questions regarding the use of IUCLID 6.

[Get help](#)

TOPICS

IUCLID 6

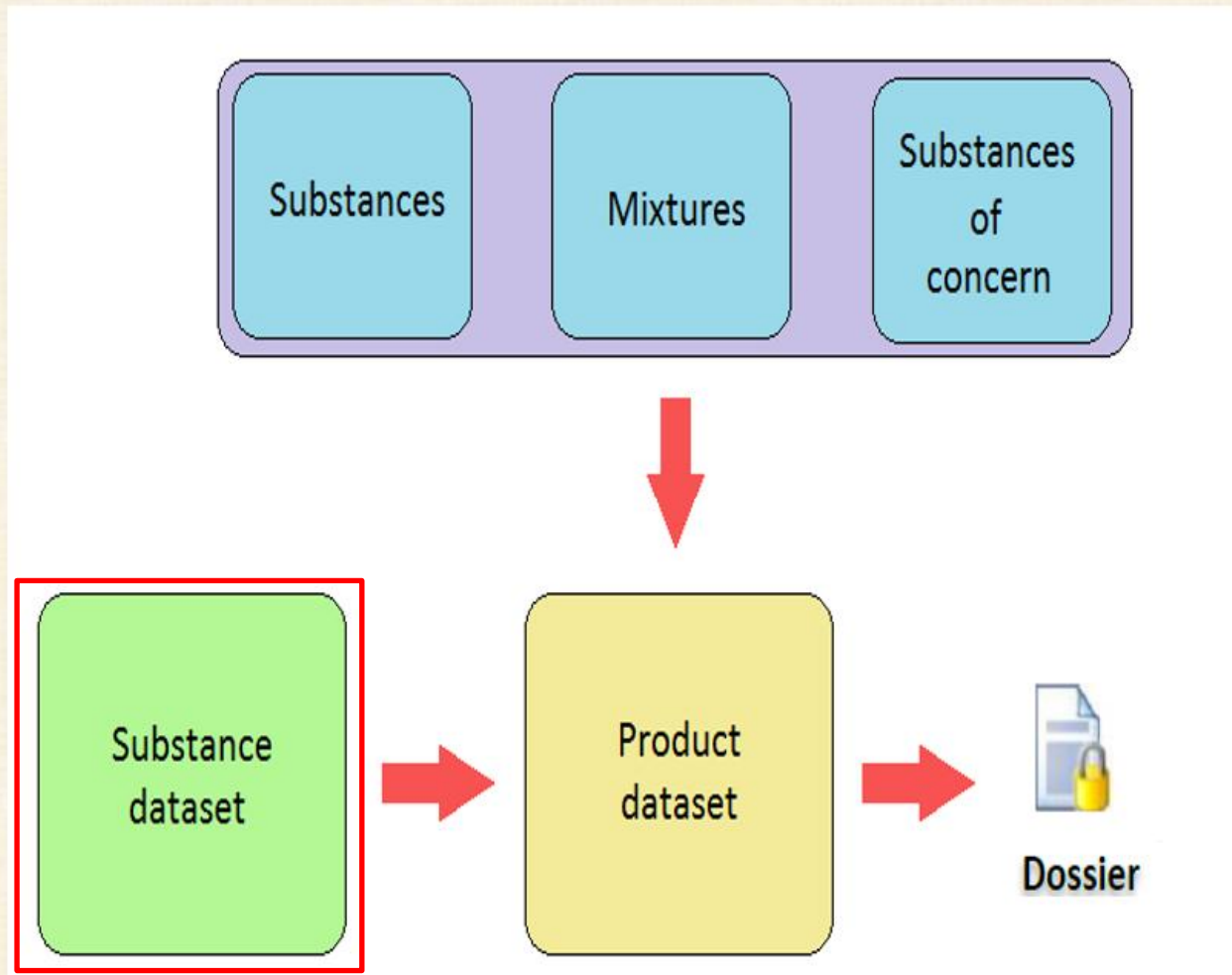
Biocidal Product Dossier

SPC EDITOR an R4BP3

Support

BIOCIDAL PRODUCT DOSSIER

NEW SUBSTANCE



BIOCIDAL PRODUCT DOSSIER

NEW SUBSTANCE

Main tasks

Substance

Mixture / Product

Template

Category

Annotation

Dossier

Substance

Substance

Substance

Substance

New

New

Inventories

Legal entity

Legal entity site

Reference substance

Contacts

Chemical inventories

Literature reference

Test materials

Plugins

Validation assistant

Report generator

Advanced search
















Dissemination preview

Fee calculator

Help

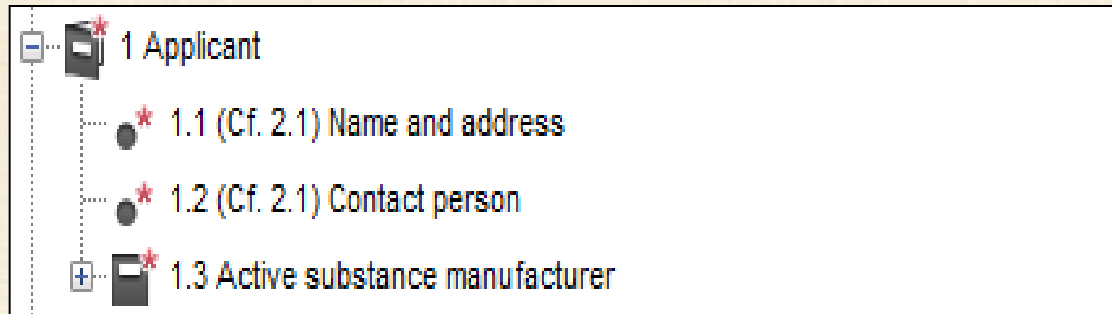
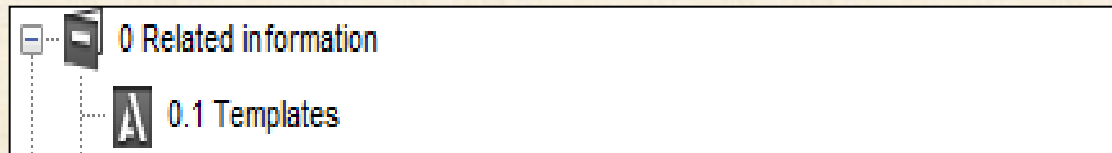
BIOCIDAL PRODUCT DOSSIER

NEW SUBSTANCE

		0 Related information
		1 Applicant
		2 Identity of the active substance
		3 Physical and chemical properties
		4 Physical hazards and respective characteristics
		5 Methods of detection and identification
		6 Effectiveness against target organisms
		7 Intended uses and exposure
		8 Toxicological profile for humans and animals
		9 Ecotoxicological studies
		10 Environmental fate and behaviour
		11 Measures to protect humans, animals and the environment
		12 Classification & Labelling
		13 Summary and evaluation



















BIOCIDAL PRODUCT DOSSIER

NEW SUBSTANCE



BIOCIDAL PRODUCT DOSSIER

NEW SUBSTANCE

	 *	2 Identity of the active substance
	 *	2.1 Common name and synonyms
		* 2.2 (Cf. 2.1) Chemical name (IUPAC and CA nomenclature or other international chemical name(s))
	 *	2.3 Manufacturer's development code number(s)
		* 2.4 (Cf. 2.1) CAS number plus EC, INDEX and CIPAC numbers
		* 2.5 (Cf. 2.1) Molecular and structural formula (including SMILES notation)
		* 2.6 (Cf. 2.1) Information on optical activity and full details of any isomeric composition
		* 2.7 (Cf. 2.1) Molar mass
	 *	2.8 Method of manufacture (syntheses pathway) of the active substance
	 *	2.9 Specification on purity of the active substance as manufactured
		* 2.10 (Cf. 2.9) The identity of any impurities and additives
		* 2.11 (Cf. 5) Analytical profile of at least five representative batches
		* 2.12 (Cf. 2.1) The origin of the natural active substance or the precursor(s) of the active substance


























BIOCIDAL PRODUCT DOSSIER

NEW SUBSTANCE

		3 Physical and chemical properties
		3.1 Appearance
		3.2 Melting point / freezing point
		3.3 Acidity, alkalinity
		3.4 Boiling point
		3.5 Relative density
		3.6 Absorption spectral data (UV/VIS, IR, NMR) and a mass spectrum, molar extinction at relevant wavelengths
		3.7 Vapour pressure and Henry's law constant
		3.8 Surface tension
		3.9 Water solubility
		3.10 Partition coefficient (n-octanol/water) and its pH dependency
		3.11 Thermal stability, identity of breakdown products
		3.12 Reactivity towards container material
		3.13 Dissociation constant
		3.14 Granulometry
		3.15 Viscosity
		3.16 Solubility in organic solvents, including effect of temperature on solubility
		3.17 Stability in organic solvents used in biocidal products and identity of relevant breakdown products
		3.18 Additional physico-chemical properties of nanomaterials










BIOCIDAL PRODUCT DOSSIER









NEW SUBSTANCE

  *	4 Physical hazards and respective characteristics
  *	4.1 Explosiveness
  *	4.2 Flammability
 *	4.3 (Cf. 4.2) Flammable aerosols
  *	4.4 Oxidising properties
 *	4.5 Gases under pressure
 *	4.6 (Cf. 4.2) Flammable liquids
 *	4.7 (Cf. 4.2) Flammable solids
 *	4.8 Self-reactive substances and mixtures
 *	4.9 (Cf. 4.17) Pyrophoric liquids
 *	4.10 (Cf. 4.17) Pyrophoric solids
 *	4.11 (Cf. 4.17) Self-heating substances and mixtures
 *	4.12 (Cf. 4.17) Substances and mixtures which in contact with water emit flammable gases
 *	4.13 (Cf. 4.4) Oxidising liquids
 *	4.14 (Cf. 4.4) Oxidising solids
 *	4.15 Organic peroxides
 *	4.16 Corrosive to metals
  *	4.17 Additional physical indicators for hazards
  *	5 Methods of detection and identification

BIOCIDAL PRODUCT DOSSIER

NEW SUBSTANCE

-   **6 Effectiveness against target organisms**
-  **6.1 Function and mode of control**
 -  **6.2 (Cf. 6.1) Representative organism(s) to be controlled and products, organisms or objects to be protected**
 -  **6.3 (Cf. 6.1) Effects on representative target organism(s)**
 -  **6.4 (Cf. 2.3 of the BPR Active substance application (representative product)) Likely concentration at which the active substance**
 -  **6.5 (Cf. 6.1) Mode of action (including time delay)**
 -  **6.6 Efficacy data to support these claims on biocidal products and on treated articles**
 -  **6.7 (Cf. 6.6) Any known limitations on efficacy**

-   **7 Intended uses and exposure**
-  **7.1 Field(s) of use envisaged for biocidal products and treated articles**
 -  **7.2 (Cf. 7.1) Product type(s)**
 -  **7.3 (Cf. 7.1) Details description of the intended use pattern(s)**
 -  **7.4 (Cf. 7.1) Users e.g. industrial, trained professional, professional or general public (non-professional)**
 -  **7.5 Likely tonnage to be placed on the market**
 -  **7.6 (Cf. 7.1) Exposure data in conformity with Annex VI to this Regulation**

BIOCIDAL PRODUCT DOSSIER

NEW SUBSTANCE

	8 Toxicological profile for humans and animals
	8.1 Irritation
	8.2 (Cf. 8.1.2) Eye irritation
	8.3 Sensitisation
	8.4 (Cf. 8.3.2) Respiratory sensitisation
	8.5 Genetic toxicity in vivo / in vitro
	8.6 (Cf. 8.5.5) In vivo genotoxicity study in mammalian cells
	8.7 Acute Toxicity
	8.8 Toxicokinetics and metabolism studies in mammals
	8.9 Repeated dose toxicity
	8.10 Reproductive toxicity
	8.11 Carcinogenicity
	8.12 Relevant health data, observations and treatments
	8.13 Additional studies
	8.14 Studies related to the exposure of humans to the active substance
	8.15 Toxic effects on livestock and pets
	8.16 Food and feeding stuffs studies including for food-producing animals and their products
	8.17 Tests to assess toxic effects of metabolites from treated plants

BIOCIDAL PRODUCT DOSSIER


NEW SUBSTANCE


[-]	[+]	[*]	9 Ecotoxicological studies
		[Σ]	Ecotoxicological Information-copy
[+]	[+]	[*]	9.1 Toxicity to aquatic organisms
[+]			9.2 Terrestrial toxicity, initial tests
[+]			9.3 Terrestrial tests, long term
[+]			9.4 Effects on birds
[+]			9.5 Effects on arthropods
			9.6 Bioconcentration terrestrial
		[●]	9.7 (Cf.9.6) Bioaccumulation: terrestrial
			9.8 Effects on other non-target, non-aquatic organisms
[+]			9.9 Effects on mammals
			9.10 Identification of endocrine activity

[-]	[+]	[*]	10 Environmental fate and behaviour
[+]	[+]	[*]	10.1 Fate and behaviour in water and sediment
[+]			10.2 Fate and behaviour in soil
[+]	[+]	[*]	10.3 Fate and behaviour in air
			10.4 Additional information on environmental fate and behaviour
		[●]	10.5 (Cf. 8.16.4) Definition of residues
			10.6 Monitoring: Identification of all degradation products (>10%) in the studies on degradation in soil, water and sediments



BIOCIDAL PRODUCT DOSSIER


NEW SUBSTANCE



 11 Measures to protect humans, animals and the environment

 12 Classification & Labelling

  12.1 GHS

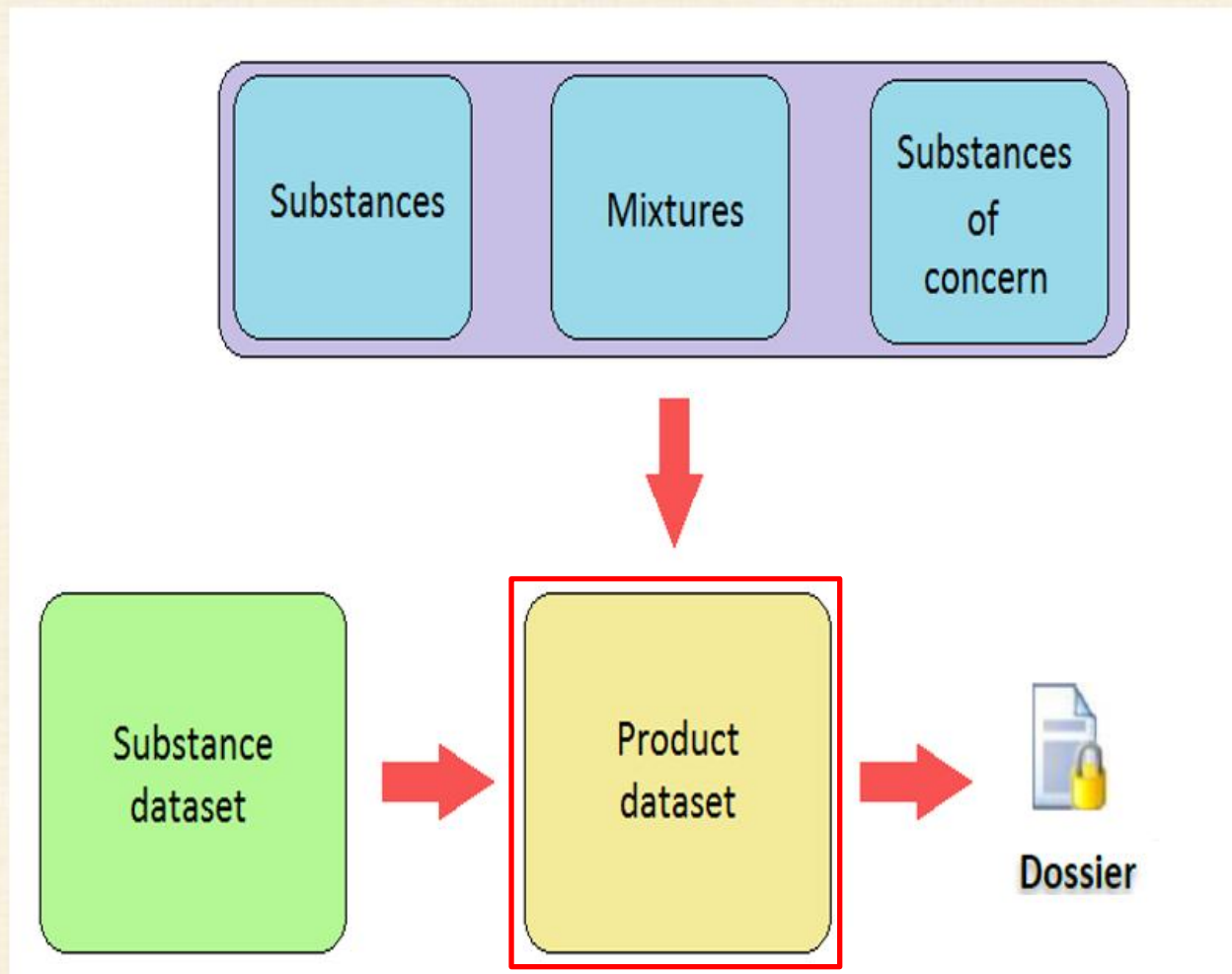
  12.2 DSD - DPD

 13 Summary and evaluation

  13.1 PBT Assessment

BIOCIDAL PRODUCT DOSSIER

NEW PRODUCT



BIOCIDAL PRODUCT DOSSIER

NEW PRODUCT

Main tasks

- Substance
- Mixture / Product**
- Template
- Category
- Annotation
- Dossier

Administration

- User management
- Import
- Bulk export

Inventories

- Legal entity
- Legal entity site
- Reference substance
- Contacts
- Chemical inventories
- Literature reference
- Test materials

Plugins

- Validation assistant
- Report generator
- Advanced search
- Classification preview
- Fee calculator
- Help

BPR Biocidal product authorisation

Text filter

- + 0 Related information
- + 1 Applicant
- + 2 Identity of the biocidal product
- + 3 Physical, chemical and technical properties
- + 4 Physical hazards and respective characteristics
- + 5 Methods of detection and identification
- + 6 Effectiveness against target organisms
- + 7 Intended uses and exposure
- + 8 Toxicological profile for humans and animals
- + 9 Ecotoxicological studies
- + 10 Environmental fate and behaviour
- + 11 Measures to protect humans, animals and the environment
- + 12 Classification & Labelling
- + 13 Summary and evaluation

- 2 Identity of the biocidal product
 - + 2.1 Trade name or proposed trade name
 - + 2.2 Manufacturer's development code and number of the biocidal product
 - + 2.3 Biocidal product composition
 - 2.4 (Cf. 2.3) Formulation type and nature of the biocidal product

- 2 Identity of the active substance
 - + 2.1 Common name and synonyms
 - 2.2 (Cf. 2.1) Chemical name (IUPAC and CA nomenclature or other international chemical name(s))
 - + 2.3 Manufacturer's development code number(s)
 - 2.4 (Cf. 2.1) CAS number plus EC, INDEX and CIPAC numbers
 - 2.5 (Cf. 2.1) Molecular and structural formula (including SMILES notation)
 - 2.6 (Cf. 2.1) Information on optical activity and full details of any isomeric composition
 - 2.7 (Cf. 2.1) Molar mass
 - + 2.8 Method of manufacture (syntheses pathway) of the active substance
 - + 2.9 Specification on purity of the active substance as manufactured
 - 2.10 (Cf. 2.9) The identity of any impurities and additives
 - 2.11 (Cf. 5) Analytical profile of at least five representative batches
 - 2.12 (Cf. 2.1) The origin of the natural active substance or the precursor(s) of the active substance

Substance

- 13 Summary and evaluation
 - + 13.1 PBT Assessment

Product

- 13 Summary and evaluation
 - Σ Summary and evaluation

BIOCIDAL PRODUCT COMPOSITION

IUCLID 5

BPR Biocidal product authorisation

- 0 Related information
- 1 Applicant
- 2 Identity of the biocidal product
 - 2.1 Trade name or proposed trade name
 - 2.2 Manufacturer's development code and number of the biocidal product
 - 2.3 Biocidal product composition**
 - Biocidal product composition.001
 - 2.4 (Cf. 2.3) Formulation type and nature of the biocidal product
- 3 Physical, chemical and technical properties
- 4 Physical hazards and respective characteristics

ENDPOINT STUDY RECORD

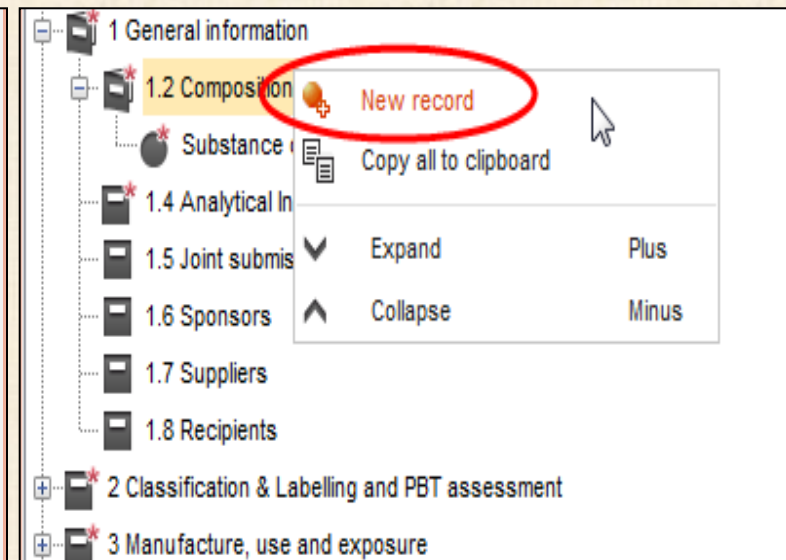
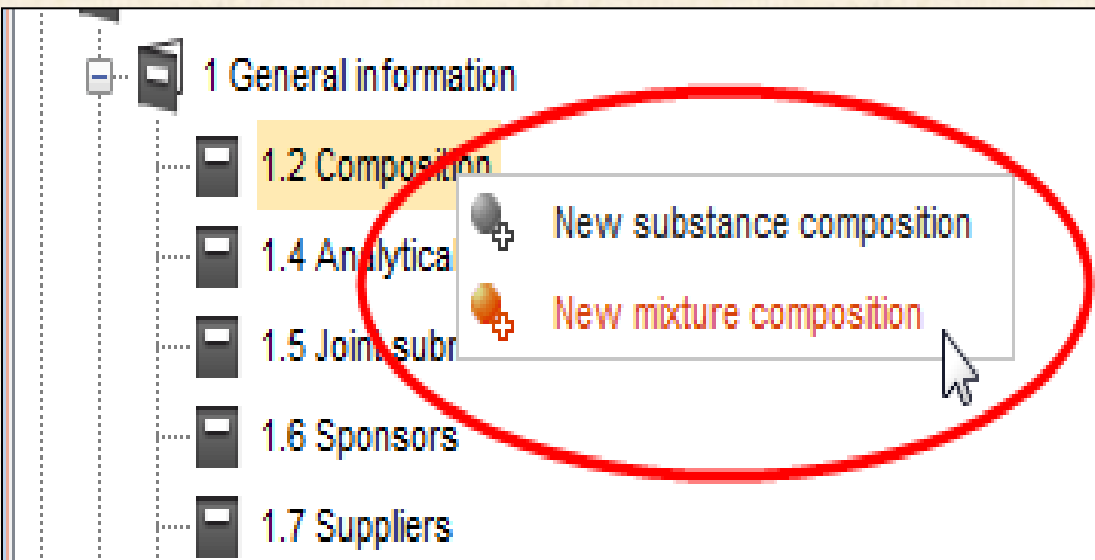
BPR Biocidal product authorisation

- 0 Related information
- 1 Applicant
- 2 Identity of the biocidal product
 - 2.1 Trade name or proposed trade name
 - 2.2 Manufacturer's development code and number of the biocidal product
 - 2.3 Biocidal product composition**
 - Family composition
 - Product X
 - Product Y
 - Product Z
 - 2.4 (Cf. 2.3) Formulation type and nature of the biocidal product
 - 3 Physical, chemical and technical properties
 - 4 Physical hazards and respective characteristics

ENDPOINT STUDY SUMMARY

BIOCIDAL PRODUCT COMPOSITION


IUCLID 6



RECORD

BIOCIDAL PRODUCT COMPOSITION

Administrative data



Mixture/product name
Mix_1 ...

Brief description
...

Formulation type
▼ VP Vapour releasing product (X)

Components

	▼	▲	+		
substance1	▼	▲	+		X
substance2	▼	▲	+		X

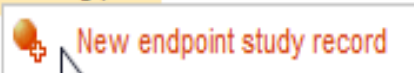
Impurities

	▼	▲	+
	▼	▲	+

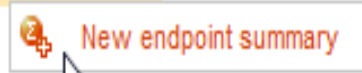
Additives

	▼	▲	+		
	▼	▲	+		X

A Physico-chemical properties

- 1 Appearance / physical state / colour
- 2 Melting point / freezing point
- 3 Boiling point 
- 4 Density
- 5 Particle size distribution (Granulometry)

4 Physical and chemical properties

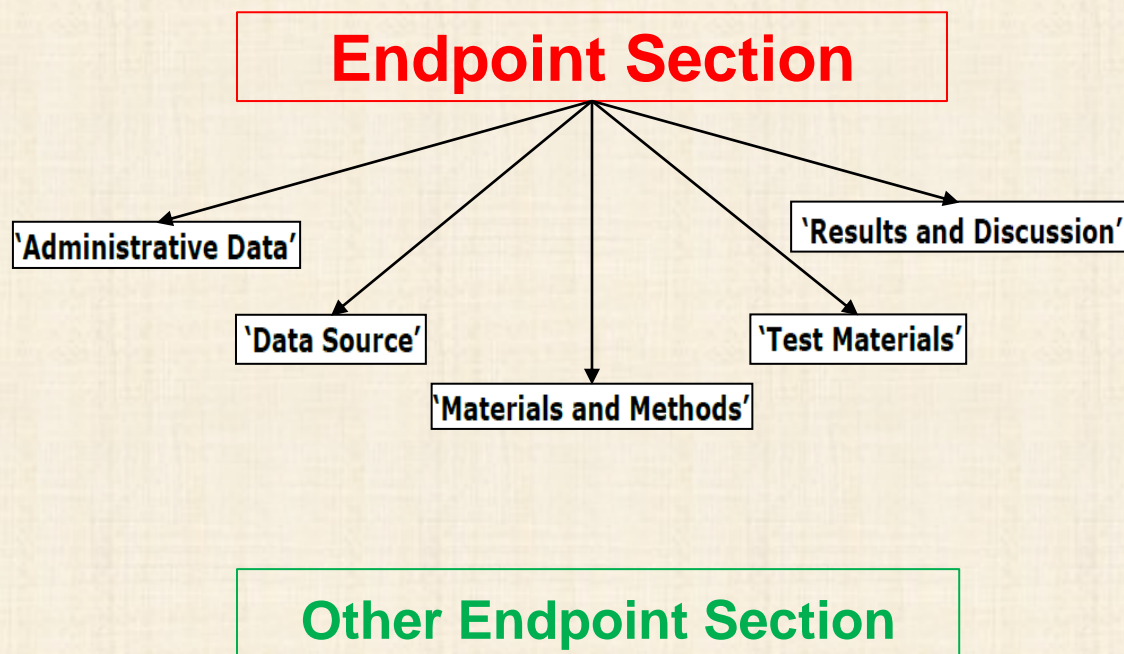
- 4.1 Appearance / physical state / colour
- 4.2 Melting point / freezing point
- 4.3 Boiling point 
- 4.4 Density
- 4.5 Particle size distribution (Granulometry)

ENDPOINT SECTIONS

BPR Biocidal product authorisation

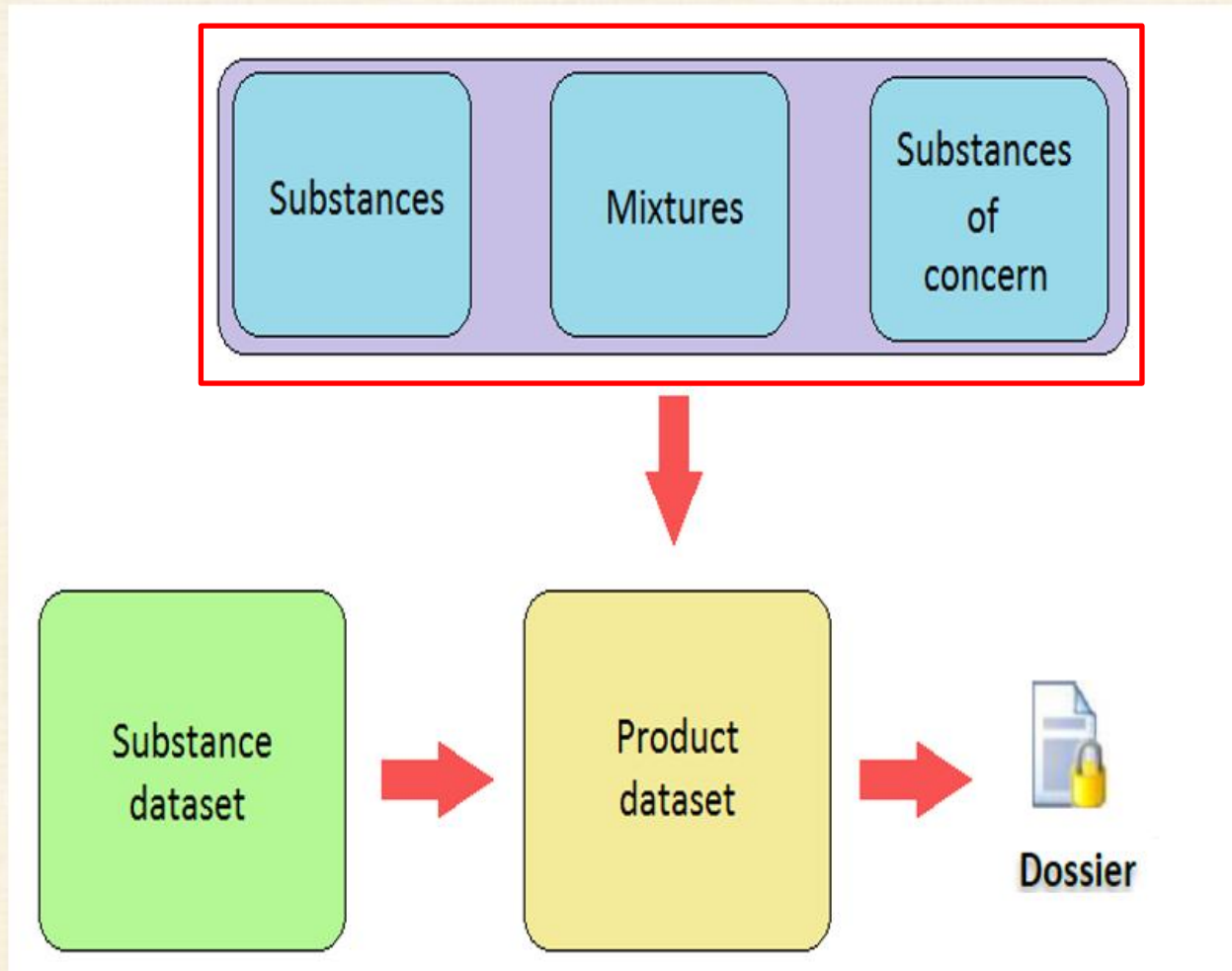
Text filter

- 0 Related information
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- 12 Classification & Labelling
- 13 Summary and evaluation



BIOCIDAL PRODUCT DOSSIER

OTHER INFORMATION



TOPICS

IUCLID 6

Biocidal Product Dossier

SPC EDITOR an R4BP3

Support

APPLICATION FOR A NATIONAL AUTHORISATION

Competent Authority

'CONTACT PERSON'

Details of the application (eg. fees)

DOSSIER (in IUCLID format)

SPC (SPC editor)

SPC EDITOR



ECHA
EUROPEAN CHEMICALS AGENCY

Ricerca la pagina web dell'ECHA

Ricerca avanzata

L'Agenzia | Regolamenti | **Trattamento delle sostanze chimiche problematiche** | Informazioni sulle sostanze chimiche | Le sostanze chimiche nella vostra vita | Assistenza

ECHA > Assistenza > Strumenti per la presentazione dei fascicoli > SPC Editor

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

- BSM Technical guide: using SPC [EN](PDF)
- Addendum to the technical guide [EN](PDF)

Dossier submission tools

- IUCLID

Guida

- Introduzione
- Supporto Q&A
- Metodi di sperimentazione e alternative
- Webinar
- Strumenti per la presentazione dei fascicoli
 - Manuals
 - REACH-IT

<https://echa.europa.eu/it/support/dossier-submission-tools/spc-editor>

SPC EDITOR

 Start using the SPC Editor!

English ▾

Browser requirements


The SPC editor has been optimised for:

- Internet Explorer 10 and higher on a Microsoft Windows platform
- Mozilla Firefox 29 and higher on a Microsoft Windows platform
- Google Chrome 35 and higher on a Microsoft Windows platform

The use of no supported browsers might reduce SPC editor functionalities and cause application errors. Therefore, we advise all SPC editor users to use the above mentioned browsers.

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.

Therefore, use the  Save button to store the SPC editor content on your local hard drive.

Once you are ready to submit your SPC, you will do so via the Register for Biocidal Products (R4BP 3).

SPC EDITOR

The screenshot displays the SPC Editor web application interface. At the top, there is a dark blue header with the SPC Editor logo on the left, the text "SPC Editor" in the center, and a language dropdown menu set to "English" on the right. Below the header is a white navigation bar containing buttons for "New", "Open", "Save", "Information", "PDF Preview", "Import XML", "Compare with", and "SPC version convertor".

The main content area is divided into a left sidebar and a main workspace. The sidebar, titled "Expand all" and "Collapse all", contains a tree view of sections: "Prodotto" (expanded), "Product information" (selected), "H & P statements", "Authorised uses", "Use", "Directions for use", "Administrative information", and "Other information". Each section has a status indicator (warning or checkmark) and a right-pointing arrow.

The main workspace displays the "Prodotto Italy Italian" section. It features a "Formulation type" field with a dropdown menu containing the text "Select or search a formulation type, or enter a custom value." Below this are three sections for adding substances: "Active substances" (with a red warning "At least one active substance is required"), "Substances of concern", and "Other substances". Each of these sections has a blue button with a plus sign and the text "+ Add [substance type]".

R4BP3

You are company1 on behalf of Geo Biocides

Submit application for:

- AS-ACC - Inclusion in the Article 95 (active substance suppliers) list
- AS-APP - Approval of active substance
- AS-RNL - Renewal of active substance
- CC-APP - Classification of a change to
- NA-APP - National authorisation**
- NA-BBP - National authorisation of sa

⚠ BEFORE YOU SUBMIT:

- Before you submit your application, please consult the submission requirements and supporting documents to make sure your application contains all the requirements for an application (Regulation 528/2012). You can find more information in:

[Guidance documents](#)

[Biocides Submission Manuals](#)

- Please contact the [ECHA Helpdesk](#) if you have any questions regarding the submission process.

Resubmission for application for national authorisation (NA-APP)

Your next steps

Submission number BC-LG009487-38/3

Note that receipt of this message does not guarantee that your application is accepted for processing. Verification of the format must first be completed by R4BP 3, therefore it is important that you follow the advice below in case further action (such as a resubmission) is required from you.

- If your application is in the correct format you will receive a message in your R4BP 3 message tab with further instructions. If your **application is not in the correct format you will receive a task item with instructions on how to resubmit a new one.** Please pay attention to the resubmission deadline.
- Monitor your application progress in the "Events History" tab under the case details page.

If you need to contact the ECHA Helpdesk regarding your application please provide the submission number.

RESUBMIT INFORMATION

Resubmit information

TASK-1568513

Task details

Task name: Resubmit information
Task number: TASK-1568513
Created on: 17/11/2014 Claimed
Status: Claimed
Claimed by: One Tester
Claimed on: 17/11/2014
Due date: 01/12/2014
Task history:

Associated case

Case number: [BC-LG009487-38](#)
Case type: Application for national authorisation
Product name: Leg_Single_v.1.1.1
Evaluating authority: MSCA-Germany

Communication number: NAP-C-1074595-24-00/F

Submission details

You may open the submission details screen below to see the information submitted during the previous submission.

Submission number: [BC-LG009487-38/2](#)

Requested information

Please read the following requested information regarding your submitted information and upload any relevant one

Topic: Format Checks

Subject: Resubmission requested [NAP-C-1074595-24-00/F]

Content:

Your application has failed the format check due to an invalid or missing IUCLID dossier and/or supporting document. Please see below this message the list of failed business rules and instructions on how to correct them. The failure message indicates whether the error was found in the supporting document and/or in the IUCLID dossier.

Please correct the business rule failures and resubmit the necessary files using this resubmission task as outlined below. Note the due date for this task.

If the IUCLID dossier was considered invalid or missing, then you need to submit a valid IUCLID dossier.

If the supporting document was considered invalid or missing, then you need to submit a valid supporting document. In case your previous submission included a IUCLID dossier that was considered valid, then due to technical constraints, you need to upload the same dossier file again in addition to the supporting document.

Further information on the requirements for different application types can be found on the ECHA website at <http://echa.europa.eu/web/guest/support/dossier-submission-tools/r4bp>.

Failed Business Rules	
Rule number	Error message
BRB0020	Your IUCLID dossier was created from a dataset other than a Mixture/Product dataset. Please, create a new dossier in IUCLID using a Mixture/Product dataset. These issues are explained in the biocides submission manual relevant to your application type.

REPLY TO COMMUNICATION

Reply to communication

1601026 TASK-

Task details

Task name: Reply to communication
Task number: TASK-1601026
Created on: 18/11/2014
Status: Claimed
Claimed by: One Tester
Claimed on: 18/11/2014
Due date: 20/11/2014
Task history:

Associated case

Case number: BC-WD009675-34
Case type: Application for national authorisation
Product name: Generated product name
Evaluating authority: MSCA-Finland

Communication number: NAP-C-1075502-43-00/F

Communication request details

Please read the following communication request and reply accordingly in the task actions area.

From: Agency To: Test Company One
Topic: Validation Sent on: 18/11/2014
Subject: Reply to communication - test
Content: Dear Sir/Madam,
Please find attached documentation related to case NA-APP and recorded under Case number BC-WD009675-34.
Regards.

Attachments:

Task actions

Please reply to the authority request by either upload the requested file, and/or a reply note.

Reply note:

No file(s) found. Please choose a file to upload.

File names should not contain special characters:

*Security check:

Enter the characters shown above:

MUTUAL RECOGNITION

ECHA
EUROPEAN CHEMICALS AGENCY

TASKS MESSAGES **CASES** ASSETS NEW APPLICATION

You are [companyAmanager_test](#) on behalf of **Company A (GR)**

Search for cases

Case number:

Product name:

Case type: **NA-APP - Application for national authorisation**

Common name (AS):

Case status: Please select

- AN-AAT - Amendment of active substance in Annex I (COM initiated)
- AN-APP - Inclusion of active substance in Annex I
- AS-AAT - Amendment of active substance
- AS-ACC - Inclusion in the Article 95 (active substance suppliers) list
- AS-APP - Application for approval of active substance
- AS-EVA - Active substance evaluation under Directive 98/8/EC (Participant)
- AS-NAS - Active substance evaluation

Submission date from:

Evaluating authority type:

Evaluating country:

Search Clear

My cases list

Case number	Product/Substance name
BC-VB000021-73	dakoktono

Application for national authorisation (NA-APP): BC-VB000021-73

Case status: In Progress

Evaluating authority: MSCA-Cyprus

Submission date: 17/06/2014

Completed on: -

Product information

Product name: dakoktono

Trade names:

Product type(s): 14, 16

Active substance(s):

Create new case Download as PDF

NA-MRP - Mutual recognition in parallel

SPC documents Delegation Dossiers Company details Events history Documents Financial management Related cases

R4BP3

ECHA
EUROPEAN CHEMICALS AGENCY

Welcome, m

TASKS **MESSAGES** **CASES** **ASSETS**

R4BP News

New release of R4BP went live on 14.06.2017 (user manuals available) 14/06/2017 13:52

My tasks

Task name	Product/Substance name	Active substances	Due date	Case type
No task found based on your search criteria. Please change the criteria and try again				

[See all my tasks here](#)

Messages

From	Topic: Subject	Product/Substance name
------	----------------	------------------------

[See all messages here](#)

My group tasks

Task name	Product/Substance name	Active substances	Task status	Case type
-----------	------------------------	-------------------	-------------	-----------



[See all group tasks here](#)

GOOD TO KNOW:

- Asset** - In the R4BP 3 context, an asset is a regulatory decision on an application (with a unique asset number) related to either an active substance (e.g. a decision on technical equivalence or the Article 95 list) or a biocidal product (e.g. a national authorisation or a Union authorisation).
- Case** - A case relates to an application and is created after the successful submission of an application (with a unique case number) in R4BP 3 by the Industry users. It includes all the steps in the application process which lead to the creation of, or update of, an asset (the regulatory decision). The purpose of a case is to manage and view the progress of the submission by both the Industry and Authority users.
- Event** - An event is a step whereby information is submitted that is needed in the handling / processing of an application. Examples include the submission of an application, the submission of additional information on the request of the authorities, fee payment, and the communication of a decision.
- Task** - A working item that is created and assigned to specific user groups (Industry or Authority users). A task is created in order to perform and complete certain actions (e.g. request for additional information) that are required from the user. These requests are completed through task items within a defined time period. The task is identified by the task name and is related to a particular case number.

R4BP3

Search or filter cases

Case number:	<input type="text"/>	Case type:	Please select ▾
Case status:	In Progress ▾	Looking for:	Please select ▾
Dossier UUID:	<input type="text"/>	Family name:	<input type="text"/>
Evaluating authority:	MSCA ▾	Product name:	<input type="text"/>
Evaluating country:	Italy ▾	Trade name:	<input type="text"/>
Company UUID:	<input type="text"/>	Active substance:	<input type="text"/>
Submission date from:	<input type="text"/> 	Product type:	Please select ▾
To:	<input type="text"/> 		
<input type="button" value="Search"/> <input type="button" value="Clear"/>		<input type="button" value="Export (.xls)"/> <small>*Please select one or more of the filters above in order to find case(s).</small>	

Case list

Case number ↕	Product/Substance name ↕	Active substances	Case type ↕	Submission date ▾	Case status ↕
---------------	--------------------------	-------------------	-------------	-------------------	---------------

R4BP3

Welcome, m

Application for national authorisation (NA-APP)

Actions...

Case status: **In Progress**
Evaluating authority: **MSCA-Italy**
Submission date:
Completed on:
Dossier UUID:

Product information
Product name:
Trade name(s):
Product type(s):
Active substance(s):

Case owner details
Company name:
Company UUID:

- SPC documents
- Dossiers
- Company details
- Events history
- Documents
- Financial management
- Related cases

IT-Italy

it (**Master**)

download to PDF

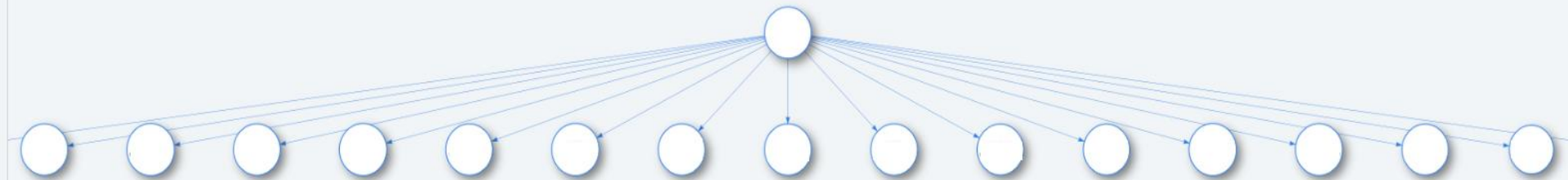
download in XML

R4BP3

Create new case ?

SPC documents Related assets Related cases Documents **Relation diagram**

- The diagram represents the relations between the current case or asset and other cases and assets.
- Squares represent cases while circles represent assets. Inside squares and circles you may find the case/asset numbers. Above the numbers you may find the case type for cases or the originating case type for assets.
- The current case/asset square/circle is highlighted by default in the diagram. Clicking on any other square or circle will open in a new tab the corresponding case or asset details.
- The arrows in the diagram are solid when the target of the relation is an asset, while they are dotted when the target of the relation is a case.
- If a circle with an asset number does not contain any case type inside it means that the asset is migrated without any associated originating case type.
- If a circle's border is dotted it means that this asset is a family member and it is shown in the diagram because it is the context asset of a case (in the case details diagram) or the causing asset (in the asset details diagram).
- If the label of a circle (asset) is not bold that means that the current user does not have access to the asset details page of that asset (due to the asset being transferred).



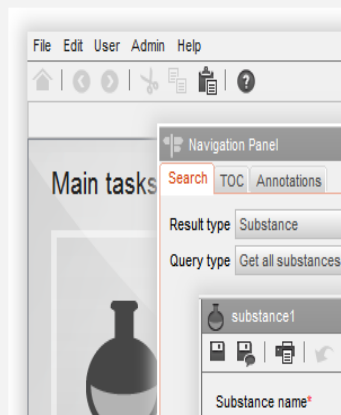
TOPICS

IUCLID 6

Biocidal Product Dossier

SPC EDITOR an R4BP3

Support



IUCLID 6 plays a central role in the IT environments of all organisations that manage scientific data on chemicals in a regulatory context, for example under the OECD HPV, EU Biocides and EU REACH.

- Industry stakeholders
- EU Member States
- The European Chemicals Agency (ECHA)
- And any other interested parties

IUCLID is the essential tool for any organisation or individual that needs to record, store, submit, and exchange data on chemical substances in the format of the OECD [Harmonised Templates](#).

28 April 2017

IUCLID 6 version 1.3.0 is available

A new service release for IUCLID is available. It brings improvements and bug fixes, but also three new features: a PNEC calculator, re-use of the dossier header and the Report manager.

24 March 2017

IUCLID 5 website closure

The IUCLID 5 website will be shut down permanently from 30th of March 2017 onwards. The relevant content has been transferred to the IUCLID 6 website. Before the closure, IUCLID 5 website users are invited to download any additional information they may need.

22 March 2017

REACH study results are published

REACH study results is a collection of non-confidential substance data that was submitted to ECHA under the REACH regulation. It is now available to download free of charge from this website.

27 February 2017

IUCLID 6 Desktop available for Mac OS X

31 January 2017

IUCLID 6 version 1.2.0 is available

A new service release for IUCLID is available. It brings improvements, bug fixes but also three new features: IUCLID hyperlinks, a DNEL calculator and a public API.

[More news...](#)



10/11/2016 - Press release

ECHA proposes nine substances for authorisation

Nine substances of very high concern (SVHCs) are recommended to be added to the REACH Authorisation List. They have been prioritised from the Candidate List because of their high volume and widespread uses, which may pose a threat to human health, or may be used to replace other substances already on the Authorisation List.

Due to a technical maintenance, **ECHA website** will be unavailable on **Monday, 21 November at 18:00 - 20:00 (Helsinki time)**.



ECHA apologises for any inconvenience caused.

News

17/11/2016 - News item

November Newsletter online

The November issue of the ECHA Newsletter gives you an overview on ECHA's plans to meet the 2020 sustainable development goals, what IUCLID as a cloud service means and explains why some substances have harmonised classification and labelling.

16/11/2016 - News alert

Last call to pre-register your low volume chemicals

To benefit from the extended deadline for registering existing, low volume chemicals by the last REACH registration deadline, you need to have pre-registered your substance with ECHA. If you manufacture or import a substance for the first time at or above 1 to 100 tonnes per year, and your substance is not a known carcinogen, mutagen or toxic to reproduction, you can still pre-register within six months of starting the activity, and at the latest by 31 May 2017 – one year before the deadline.

16/11/2016 - News alert

Updated interactive Guide on safety data sheets and exposure scenarios available

The Guide helps suppliers and recipients of safety data sheets to compile and understand substance and use information.

14/11/2016 - News item

Forum launches major project on classification and labelling of mixtures

The Forum for Exchange of Information on Enforcement (Forum) has agreed to launch a project on classification and labelling of mixtures and SDSs.

11/11/2016 - News item

Search for Chemicals

Advanced search



I have read and I accept the legal notice

REACH 2018



> REACH-IT



> IUCLID 6



> CHESAR



> R4BP 3



> SPC Editor



> ePIC



> QSAR Toolbox



> Poison Centres

SOURCES

REGULATION

<https://echa.europa.eu/it/regulations/biocidal-products-regulation>

GUIDANCE DOCUMENTS

<https://echa.europa.eu/it/guidance-documents/guidance-on-biocides-legislation>


PRATICAL GUIDES

<https://echa.europa.eu/it/practical-guides/bpr-practical-guides>

SUPPORT

<https://echa.europa.eu/it/support/dossier-submission-tools/r4bp/submit-applications-for-national-authorisation>

<https://iuclid6.echa.europa.eu/it/support>



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Sei in: Home > Temi e professioni > Dispositivi medici e altri prodotti > Biocidi e presidi medico-chirurgici > Biocidi > Help desk

Help desk

Lo scopo principale dell'help desk è di dare supporto alle aziende titolari di prodotti biocidi in ambito regolatorio e tecnico, a seguito dell'entrata in vigore del Regolamento sui biocidi (BPR, regolamento (UE) n. 528/2012), concernente l'immissione sul mercato e l'uso di biocidi e di materiali o di articoli trattati utilizzati per la tutela dell'uomo e degli animali per combattere organismi nocivi, quali batteri o insetti, mediante l'azione di principi attivi contenuti nel prodotto biocida.

L'help desk nazionale si propone di sostenere le imprese, sia a rispettare i nuovi adempimenti su queste sostanze, sia a comprendere il cambiamento delle procedure e le opportunità applicative conseguenti all'entrata in vigore del Regolamento sui biocidi (ai sensi dell'articolo 81 del Regolamento 528/2012 sui biocidi).

Le Autorità Competenti sono il primo punto di contatto per le industrie con sede nell'Unione europea e nello Spazio economico europeo. (È importante ricordare che il regolamento sui biocidi non è stato ancora inserito nell'accordo sullo Spazio economico europeo).

Che tipo di consulenza fornisce l'help desk nazionale?

Questo help-desk fornisce chiarimenti sul Regolamento Biocidi, informazioni su come presentare la domanda per l'autorizzazione di un prodotto biocida, chiarimenti sugli aspetti regolatori e tecnici dei biocidi ed anche la normativa inerente i biocidi stessi. Offre anche una consulenza sulle responsabilità cui le industrie possono essere soggette ai sensi di tali regolamenti.

Perché contattare il servizio di help desk ?

Gli help-desk delle Autorità Competenti sono il primo punto di contatto per tutti i soggetti che desiderano ricevere una consulenza sul Regolamento Biocidi.

Come contattare l'help desk

E' possibile inviare una domanda al servizio di help desk e chiedere pareri in merito all'attuazione del Regolamento Biocidi e al periodo transitorio.

I temi di questa sezione sono a cura di: Direzione generale dei dispositivi medici e del servizio farmaceutico

Web editing: Deborah De Crinto

Servizi online

- > Biocidi
- > Presidi medico-chirurgici
- > Pubblicità sanitaria

Vai direttamente a

- > FAQ - Biocidi e presidi medico-chirurgici
- > Biocidi - Help desk
- > Tariffe biocidi
- > Tariffe PMC
- > Tabella prodotti biocidi autorizzati
- > Lista consolidata dei principi attivi in revisione
- > Elenco delle officine autorizzate a produrre presidi medico-chirurgici

L'organigramma
del Ministero della Salute

http://www.salute.gov.it/portale/temi/p2_6.jsp?lingua=italiano&id=3823&area=biocidi&menu=biocidi



Centro Nazionale Sostanze Chimiche prodotti Cosmetici e protezione del Consumatore

Responsabile: Rosa Draisci



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[Home](#) > [Chimica e salute](#) > [Prodotti chimici](#) > **Biocidi**

Cosa sono i biocidi

Il periodo di transizione

Il processo di revisione delle sostanze attive

Autorizzazione e ruolo del CNSC

Ruolo dell'ECHA

Pubblicazioni ISS sui biocidi e PMC

Attività del Centro

Chimica e salute

Sostanze chimiche

Prodotti chimici

Biocidi

Fitosanitari

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PMC

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Economia circolare

Nanomateriali

Normativa

<https://cnscc.iss.it>

facebook

E-mail o telefono Password

Resta collegato Hai dimenticato la password?

European Chemicals Agency
 è su Facebook.
 Per connetterti con European Chemicals Agency, iscriviti subito a Facebook.

 **European Chemicals Agency**
 Organizzazione governativa

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PERSONE ▸

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 954 "Mi piace"
 105 visite

INFORMAZIONI ▸

- The European Chemicals Agency (ECHA) is an Agency of the European Union which works for the safe use of chemicals.
- <http://echa.europa.eu/>

APPLICAZIONI

 Twitter

 YouTube

 **European Chemicals Agency**
 16 h · 🌐

On this day in Chemistry: Pierre and Marie Curie exchanged wedding vows in 1885. From 1896 until Pierre's death in 1906, the two physicists worked together researching radioactivity. In 1898, they discovered the elements polonium (Po) and radium (Ra). <http://www.rsc.org/.../collections/chemistry-calendar/july-26...>

Visualizza traduzione



December 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31

July 26 - On This Day in Chemistry | RSC

 Cerca su Twitter



ECHA
 @EU_ECHA

European Chemicals Agency works for the safe use of chemicals. ECHA is a regulatory agency of the European Union. RTs should not be considered as endorsements.

Helsinki
echa.europa.eu
 Iscritto a Luglio 2011

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 **ECHA** @EU_ECHA · 24 lug
 Preparing to register a chemical before 2018? Get moving! #REACH2018



<https://www.youtube.com/user/EUchemicals>

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FOR YOUR ATTENTION**