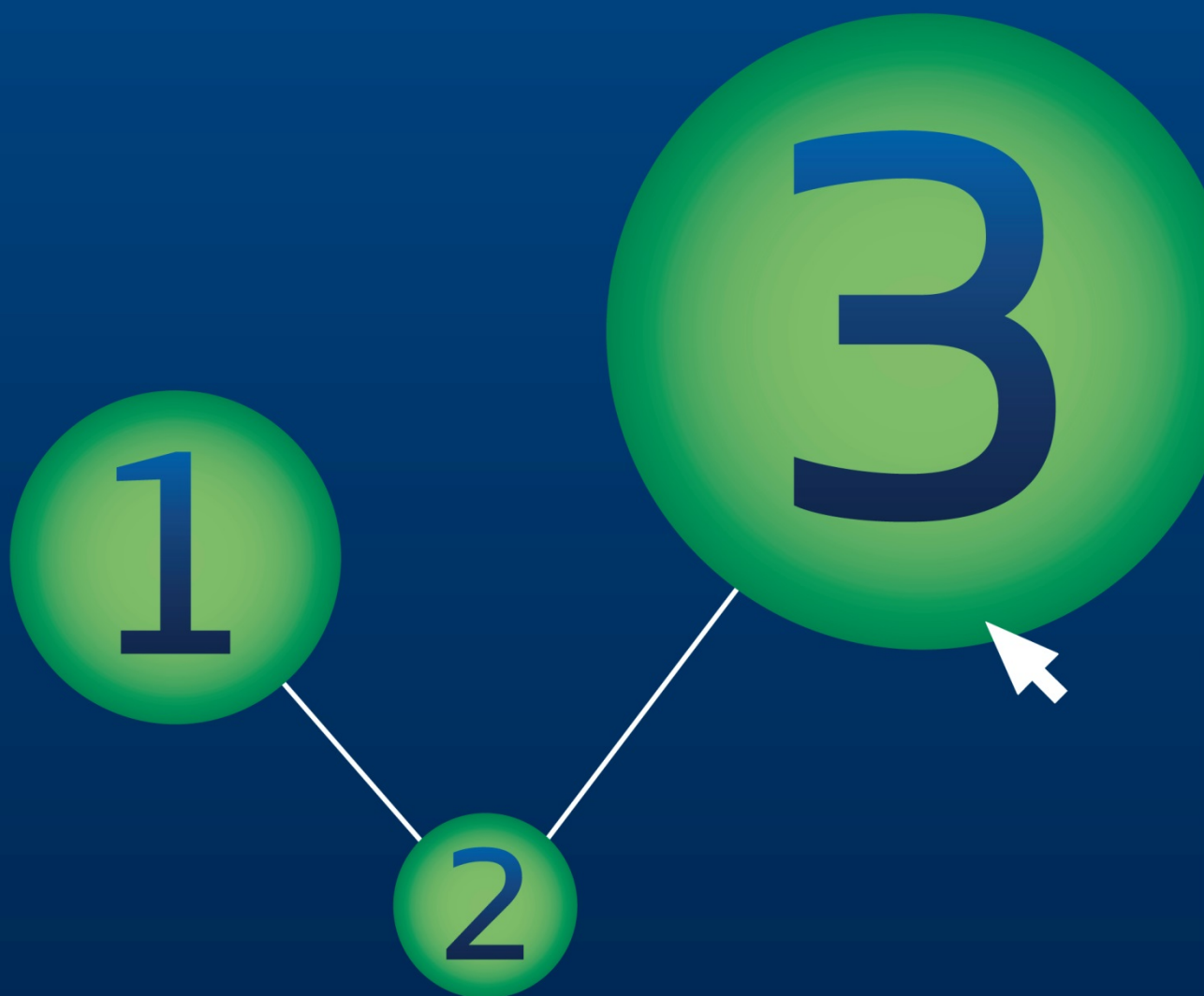


Biocides Submission Manual

Process of dissemination
Part 2: IUCLID sections 5-7



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Introduction

Objective

This manual gives guidance on the online access provided by ECHA to information on active substances approved, and biocidal products authorised, under the Biocidal Products Regulation (BPR) (where the data is in IUCLID). It is aimed at industry, and in particular, at managers and technical experts in companies who are responsible for making sure that comprehensive information is entered in the dossiers.

Biocides Submission Manuals

This manual is part of the Biocides Submission Manual (BSM) series concerning technical guides, application instructions and process manuals and also includes:

Technical guides:

Using IUCLID, which describes how to prepare a general IUCLID dossier, giving you details on the different functionalities in IUCLID, as well as explaining the different sections contained within a dossier.

Using R4BP 3, which describes how to create user accounts in R4BP 3 through ECHA Accounts and gives a detailed description of the various functionalities of the system.

Using the SPC Editor, which describes how to prepare a summary of the product characteristics (SPC) required for certain application types.

Application instructions:

Application instruction manuals give guidance on how to submit applications concerning various processes concerning active substance approvals and biocidal product authorisations.

- **Active substances**
- **National authorisations**
- **Simplified authorisations**
- **Union authorisations**
- **Technical equivalence and chemical similarity**

Process manuals:

Invoicing in R4BP 3, which describes the general information related to invoices and credit notes issued by ECHA following the submission of an application.

Confidentiality requests for biocide applications, which describes how to make confidentiality claims in IUCLID and which dossier information can be claimed confidential.



All of the Biocides Submission Manuals, including the technical guides, application instructions and related processes can be found from the [‘ECHA website’](#).

Article 67 of the Biocidal Products Regulation (BPR)

Article 67 of the Biocidal Products Regulation (BPR) stipulates that the European Chemicals Agency (ECHA) shall publish certain information it holds on approved biocidal active substances and authorised biocidal products free of charge over the internet. This information is published on the ECHA website, in the section 'Information on Chemicals'.

However, in certain cases information can be withheld, if the applicant submitting the information also indicates they wish to keep the information confidential, and submits a justification as to why publishing the information would be potentially harmful to the commercial interests of the applicant or any other party concerned. Relevant authority will then assess such justifications in accordance with Article 67(3) and (4), and where the justification is accepted, the information concerned will not be published. Claiming information confidential may be subject to a fee.

Where urgent action is essential to protect human health, safety or the environment, such as emergency situations, ECHA may disclose additional information, in accordance with Article 66(2). This will not happen in an automated way, and is therefore not covered in this manual.

This manual provides information about the online access to information on active substances approved, and biocidal products authorised, under the BPR.¹ The document will help readers to understand:

- what are the steps in the dissemination process; and
- which information will be made publicly available on the ECHA website.

The manual presents what ECHA directly publishes from the IUCLID dossiers and it does not cover information from other documents such as SPCs², assessment reports, etc.

Because of technical progress with IUCLID and the Dissemination portal, this manual will be regularly updated. We recommend that you check our website regularly to make sure that you have the most recent version of the document.

In addition to this manual, a specific dissemination preview will be made available for applicants in the near future. This tool will enable applicants to verify – when preparing a dossier in IUCLID – which information will be published on the ECHA website, as explained further below (see [Dissemination preview for IUCLID](#)).

The Dissemination portal

Web address

Information on chemicals can be accessed through the ECHA website; detailed information on approved active substances or authorised biocidal products can be accessed through the ECHA website following the below paths:

Active substances: ECHA Website > Information on Chemicals > Biocidal Active

¹ The dissemination obligations under Article 67 of the BPR also apply to information on active substances and biocidal products where the approval/authorisation application was submitted under the Biocidal Products Directive (BPD) (Directive 98/8/EC). The process for doing so is different to that described in this manual due to the use of IUCLID for the BPR dossiers.

² The information contained in the SPC associated with the authorisation of a biocidal product will be published on the ECHA website. It is the responsibility of the authorisation holder and Member State competent authority to make sure that this document does not contain confidential information.

Substances: <http://echa.europa.eu/information-on-chemicals/biocidal-active-substances>

Biocidal products: ECHA Website > Information on Chemicals > Biocidal Products:

<http://echa.europa.eu/information-on-chemicals/biocidal-products>

Searching in the portal

Before you can begin to search for active substances and/or biocidal products in the Dissemination portal, you have to acknowledge that you have taken note of the Legal Notice explaining the nature of the information, the right to use the information, and possible limits to the right to use the information.

You can search for an active substance in the portal by its name, EC number, CAS number, type, biocide ID and approval information.

A biocidal product can be searched by its name, asset number, product-type and name, EC number or CAS number, approval ID of its active substance as well as by authorisation data.

A list of all the active substances or biocidal products in the database can be obtained by searching without entering any search criteria.

Search results can be reordered by clicking on the individual column headers.

ECHA has also developed InfoCards and Brief Profiles for substances where details on the substance classification, uses and exposure and scientific properties are summarised and aggregated. Whilst currently they are primarily based on the data submitted in REACH registrations, they also include data from other sources, including the C&L Inventory, other REACH regulatory processes, and data from the BPR and PIC regulation.

Intellectual property rights

You should use the information available in the Dissemination portal with care. Reproduction and use or further distribution of the information is subject to copyright laws and may require the permission of the owner of that information.

Data protection periods apply to data submitted for the purposes of the BPD or of the BPR. Remember that in line with Article 59(1) of the BPR, the competent authorities may not use that data for the benefit of a subsequent applicant unless it has a letter of access or the data protection periods have expired.

The data protection periods are set in Article 60 of the BPR (*"Protection of Data held by competent authorities or the Agency"*) and Article 95(5) of the BPR (*"Transitional measures concerning access to the active substance dossier"*).

The Dissemination process

When is the information published?

For active substances, the process of disseminating information from an application dossier starts as soon as the European Commission has adopted an Implementing Regulation providing that the active substance is approved.

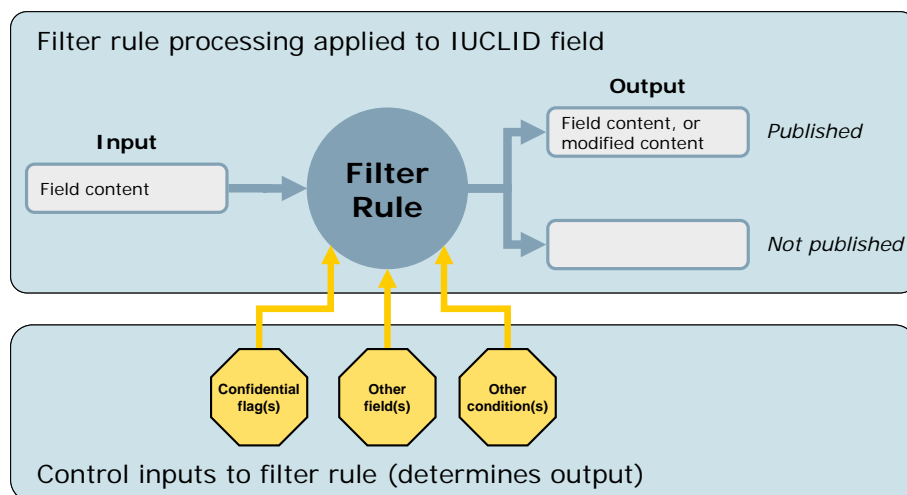
For biocidal products, the dissemination process starts from the date a biocidal product is authorised.

At this point, the associated dossier – which by now only contains confidentiality requests upheld by the relevant authority – is prepared for dissemination, as described below:

Filtering

The most important step in the dissemination process of the IUCLID information is the filtering step in which information not meant to be published is removed from the dossier, along with information flagged or claimed to be confidential (Figure 1).

Figure 1: Filter rules



The filtering of IUCLID dossiers is performed by an IT tool which has been programmed with Filter rules. Filter Rules are based on the Article 67 of the BPR and are applied to each field in the IUCLID dossier determining whether the field content should be published or not. After the filtering step is completed, the filtered dossier will contain only the information from the fields that is to be published.

Dossier filtering (the removal of information not to be published) is an automated process and is independent of which text you provide in a certain field. Please review your dossier before you submit it, to make sure the correct content is provided. If you provide confidential information in a field which is set to be published (e.g. the guidance on safe use), **the information will become visible on the internet.**

In this manual (consisting of four separate parts), you can see the filter rule that applies for all IUCLID 6 fields from the *BPR Active substance information* and *BPR Biocidal product authorisation* templates. The filter rules are explained in the [legend](#).

The other BPR templates for the substances (substances of concern and non-active substances) and representative biocidal products are currently not covered in this manual. Further information on how this information will be published will be made available in due time.

Publication

ECHA disseminates information at substance/product level. All documents and information from a IUCLID dossier will be linked to other relevant substance data identifiers. After the filtering step, the dossier is processed to create a set of html web pages. A batch of these web pages is regularly published on the ECHA website. As part of the same step, the relevant data and metadata are published to allow the search results to be searched and filtered.

Dissemination preview for IUCLID

ECHA is developing a IUCLID plugin to enable applicants to simulate which information from their IUCLID dossier will be removed during filtering, and which information will be made publicly available over the internet. The Dissemination preview will allow applicants to use it while they are preparing their BPR dossier in IUCLID. The purpose of the tool is to help applicants to prepare dossiers that can be published without revealing confidential business information. More information on the tool will be available on the ECHA website in due time.

Confidentiality

The IUCLID template allows applicants to set confidentiality request flags on information covered by Article 67(3) and (4) of the BPR. For information that an applicant wishes to keep confidential, a confidentiality request must be justified and the request will only be implemented if it is upheld by the relevant authority. For guidance on confidentiality claims, please see the Biocides Submission Manual on the Process of confidentiality requests for biocide applications.³

³ http://echa.europa.eu/documents/10162/14938692/bsm_10_confidentiality_requests_en.pdf

Process of dissemination, Part 2: IUCLID sections 5-7







In this manual, you can find the filter rule – illustrated with screenshots – for every field in sections 5, 6 and 7 of the IUCLID 6 dossier. The filter rule automatically determines if the content of the field is published on the ECHA website or not.

The legend on the next page briefly explains the different filter rules.

Unless otherwise stated, the rules of the section refer to the active substance template.

To allow for easy navigation, the sections in this manual use the same numbering as the sections in IUCLID in the appropriate BPR view. For information on the other sections of the IUCLID dossier, please consult the relevant part of the manual (the manual is divided into four parts, each dealing with separate groups of IUCLID sections).

Legend

	<p>Is always automatically published.</p> <ul style="list-style-type: none"> This rule concerns information listed in Article 67(1) and (2).
	<p>Is not automatically published.</p> <ul style="list-style-type: none"> This rule concerns information normally deemed to undermine the protection of the commercial interests of the persons concerned, or information which does not relate to the hazard and safe use of the substance.
	<p>Is automatically published unless confidentiality has been claimed on this section.</p> <ul style="list-style-type: none"> This rule concerns information listed in Article 67(3) and (4).
	<p>Fields that are always automatically published in the active substance dossier can be claimed confidential in the biocidal product dossier. Confidentiality flags and indication of endpoint addressed will be published.</p> <ul style="list-style-type: none"> This rule concerns information listed in Article 67(4).
	<p>The bibliographic references author, title, and source are published according to the following rule, with the most important criteria listed first:</p> <ul style="list-style-type: none"> are not published if the endpoint record is claimed confidential, unless the reference type is publication, review article or handbook; are not published if the reference type is study report or company data; are not published if at least one of following is provided: testing lab, report number, owner company or study number.
	<p>This information will be published from other source (e.g. SPC, R4BP) and not from the IUCLID dossier.</p>

Any confidentiality claim must be justified and the claim will only be implemented if it is upheld by the relevant authority. Justifications for claiming the confidentiality are not published.

Note to the legend

Field with a link

Fields containing a link to a record or information do not carry a filter rule as information they contain is published according to the individual filter rules set within the given record or information to which they refer.

Test material and identity of transformation products – conditioned filter rule

The test material and the identity of transformation products will be published unless:

- the reference substance describing the material itself is flagged confidential, or
- the endpoint study record is flagged confidential.

Justification for type of information – conditioned filter rule

Justification for type of information will be published unless:

- the reference substances linked to the endpoint study record have been flagged confidential, or
- the endpoint study record is flagged confidential.


For read-across, the information is not published if the study record in the related information is flagged confidential, or the test material reference substance in the related information is flagged confidential.

(Robust) study summary data

Fields referring to (robust) study summary data will only be published if the endpoint study record is not requested confidential.






5. Methods of detection and identification *(also in Biocidal Product)*

Administrative data ^





Link to relevant study record(s) ^

Study name / type


 Add...  Delete  Move up  Move down  Go to link target


Description of key information ^





Additional information ^





Administrative data ^

Endpoint
 ... Remarks

Type of information
 ... Other ... Remarks

Adequacy of study
 ...
 Robust study summary
 Used for classification
 Used for SDS

Study period

Reliability
 ... Other

Rationale for reliability incl. deficiencies
 ... Other ... Remarks

Data waiving

Justification for data waiving

Justification for type of information

Attached justification

Attached justification	Reason / purpose
<input type="text" value="N"/>	<input type="text" value="N"/>

+ Add... Edit... Delete Move up Move down

Cross-reference

Reason / purpose	Related information	Remarks
<input type="text" value="A"/>	<input type="text" value="A"/>	<input type="text" value="N"/>

+ Add... Edit... Delete Move up Move down Go to link target

Data source ^

Reference

Title	Author	Reference t...	Year	Bibliographi...	Testing labo...	Report no.	Company o...	Company st...	Report date	Remarks
<input type="text" value="B"/>	<input type="text" value="B"/>	<input type="text" value="A"/>	<input type="text" value="A"/>	<input type="text" value="B"/>	<input type="text" value="N"/>	<input type="text" value="N"/>	<input type="text" value="A"/>	<input type="text" value="N"/>	<input type="text" value="A"/>	<input type="text" value="N"/>

+ Add... Delete Move up Move down Go to link target

Data access
 ... Other ... Remarks

Data protection claimed
 ... Remarks

Background ^

Background information

A
...

Materials and methods ^

Test guideline

Qualifier	Guideline	Version / remarks	Deviations
A	A	A	A

+ Add...
✎ Edit...
✕ Delete
↑ Move up
↓ Move down

Principles of method if other than guideline

A | ✕
 ▼

GLP compliance

A
Remarks N

Other quality assurance

A
Other A Remarks N

Matrix / medium

A

Test material ^

Test material information

A
> 🔗 ✕

Specific details on test material used for the study

A | ✕
 ▼

Principles of analytical methods ^

Instrument / detector

A

Details on analytical method

A | ✕
 ▼

Enforcement method (if applicable) ^

Instrument / detector for enforcement method

A

Details on enforcement method

A | ✕
 ▼

Confirmatory method (if applicable) ^

Instrument / detector for confirmatory method

A

Details on confirmatory method

A
...

Any other information on materials and methods incl. tables ^

Normal Aharoni 8 A B I U | | | 1 2 = | A

N

Results and discussion ^

Recovery results and characteristics of analytical method ^

Recovery results
A X
A ...

Characteristics of analytical method
A X
A ...

Results using enforcement method (if applicable) ^

Recovery results (enforcement method)
A X
A ...

Characteristics of enforcement method
A X
A ...

Independent laboratory validation (if applicable) ^

Independent laboratory validation
A ...

Any other information on results incl. tables ^

Normal Aharoni 8 A B I U | | | 1 2 = | A

A

Overall remarks, attachments ^

Overall remarks

Normal Aharoni 8 A B I U [List icons]

N

Attached background material

Attached document	Remarks
N	N

+ Add... Edit... Delete Move up Move down

Attached full study report

N

+ Add... Open Properties Delete Move up Move down

Illustration (picture/graph)

N

Zoom Load Delete

Applicant's summary and conclusion ^

Conclusions

A ...


Executive summary

Normal Aharoni 8 A B I U [List icons]


A

6. Effectiveness against target organisms (*also in Biocidal Product*)

Administrative data ^

 A


Description of key information ^




Normal Aharoni 8 A B I U | | | | 1 2 | | | | |

 C

Additional information ^



Normal Aharoni 8 A B I U | | | | 1 2 | | | | |

 C

6.1 Function and mode of control *(also in Biocidal Product)*

Administrative data ^

Endpoint **A** ... Remarks **N** ...

Type of information **C** ... Other **C** ... Remarks **N** ...

Adequacy of study **C** ...

Robust study summary **N**

Used for classification **N**

Used for SDS **N**

Study period **C** ...

Reliability **C** ... Other **C** ...

Rationale for reliability incl. deficiencies **C** ... Other **C** ... Remarks **N** ...

Data waiving **C** ...

Justification for data waiving **C** ...

Justification for type of information **A** | X **C** ...

Attached justification	Reason / purpose
N	N

+ Add... Edit... Delete Move up Move down

Reason / purpose	Related information	Remarks
C	C	N

+ Add... Edit... Delete Move up Move down Go to link target

General information ^

Background information **C** ...

Pest / target organisms to be controlled ^

Target organisms

Scientific name	Common name	Developmental stage
C	C	C

Products, organisms or objects to be protected / under study ^

Organisms (to be protected) or treated materials

C ...

Information on intended use and application ^

Function addressed

C

Product type

C ... Other C ...

Field of use envisaged / User

C ...

Information on application of biocidal product ^

Method of application

C

Details on application

A₁ | X

C ...

General information on effectiveness ^

Effects on target organisms

C ...

Mode of action

C ... Other C ... Remarks N ...

Details on mode of action

A₁ | X

C ...

(Possible) Occurrence of resistance

C ...

Management strategies to avoid resistance

C ...

Any other known limitations and management strategies

C ...

6.6 Efficacy data to support these claims on biocidal products and on treated articles *(also in Biocidal Product under 6.7 Efficacy data to support these claims)*

Administrative data ^

Endpoint **A** Remarks **N**

Type of information **C** Other **C** Remarks **N**

Adequacy of study **C**

Robust study summary **N**

Used for classification **N**

Used for SDS **N**

Study period **C**

Reliability **C** Other **C**

Rationale for reliability incl. deficiencies **C** Other **C** Remarks **N**

Data waiving **C**

Justification for data waiving **C**

Justification for type of information **C**

Attached justification

Attached justification	Reason / purpose
N	N

+ Add... Edit... Delete Move up Move down

Cross-reference

Reason / purpose	Related information	Remarks
C	C	N

+ Add... Edit... Delete Move up Move down Go to link target

Data source ^

Reference

Title	Author	Reference t...	Year	Bibliographi...	Testing labo...	Report no.	Company o...	Company st...	Report date	Remarks
C	C	C	C	C	N	N	C		C	

+ Add... Delete Move up Move down Go to link target

Data access

N ... Other **N** ... Remarks **N** ...

Data protection claimed

N ... Remarks **N** ...

Basic information ^

Background information

C ...

Objective / label claim(s) addressed

C ...

Source of information / type of study(ies)

C

Materials and methods ^

Test guideline

Qualifier	Guideline	Version / remarks	Deviations
C	C	C	C

Principles of method if other than guideline

A | **X**

C ...

GLP compliance

C ... Remarks **N** ...

Compliance with quality standards

C ... Remarks **N** ...

Test material ^

Test material information

> 🔗 ✕

Specific details on test material used for the study

A | **X**

C ...

Formulation type

C ... Other **C** ... Remarks **N** ...

Analytical monitoring

C ... Remarks **N** ...

Details on sampling and analytical methods

C ...

7. Intended uses and exposure

7.1 Field(s) of use envisaged for biocidal products and treated articles

Administrative data ^

A

Intended uses and exposure ^

For a biocidal product family, specify to which biocidal product(s) it applies:

C

+ Add...
X Delete
↑ Move up
↓ Move down
> Go to link target

Product type

C

Use(s) pattern

Use Number	Use Name	Field of use	User	Estimated Ora...	Estimated Der...	Estimated Inh...	Estimated Tot...	External Expo...	External Expo...
C	C	C	C	C	C	C	C	C	C

+ Add...
✎ Edit...
X Delete
↑ Move up
↓ Move down

Detailed description of uses including in treated articles

C

Remarks

N

7.1 Biocidal Product – Field(s) of use envisaged for biocidal products and treated articles

Administrative data ^

A

Intended uses and exposure ^

For a biocidal product family, specify to which biocidal product(s) it applies:

N

+ Add...
✕ Delete
↑ Move up
↓ Move down
➤ Go to link target

Product type

O

Use(s) pattern

Use Number	Use Name	Field of use	User	Estimated Ora...	Estimated Der...	Estimated Inh...	Estimated Tot...	External Expo...	External Expo...
O	O	O	O	N	N	N	N	N	N

+ Add...
✎ Edit...
✕ Delete
↑ Move up
↓ Move down

Detailed description of uses including in treated articles


C
...

Remarks

N
...

7.5 Likely tonnage to be placed on the market (*also in Biocidal Product*)






Administrative data ^

 **N**

Likely tonnage to be placed on the market ^

Likely tonnage to be put on the market (tonnes / year)

Product type	Year	Tonnage placed on the market (t)	Remarks
N	N	N	N

 Add...  Edit...  Delete  Move up  Move down

7.6 Biocidal Product – Method of application and a description of this method

Administrative data ^

A

Directions for use ^

Reference use

0

+ Add...
✕ Delete
↑ Move up
↓ Move down
➤ Go to link target

Method of application

0

Detailed description of method of application

0
...

Application dose and final concentration of active substance and biocidal product in treated article or system

Dilution (%)	Application dose	Final concentration of active ...	Final concentration of biocidal...	Remarks
0	0	0	0	0

+ Add...
✎ Edit...
✕ Delete
↑ Move up
↓ Move down

Application aim

0

Number and timing of applications

0
...

Proposed instruction for use

0
...

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