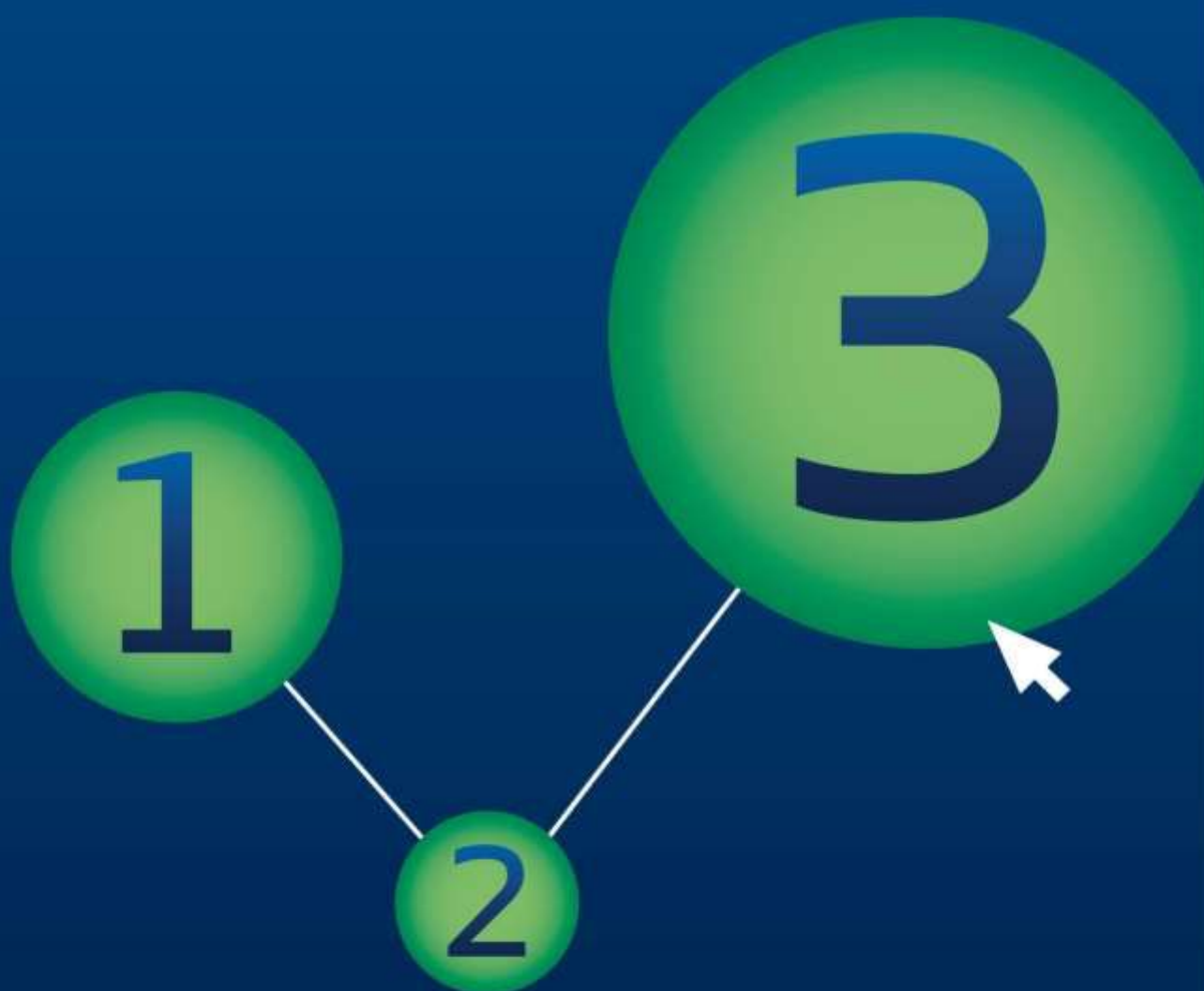


Biocides Submission Manual

Process of confidentiality requests for
biocide applications



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Version 1.0	First version	August 2013
Version 1.1	Title changed to align with the expanded and updated Biocides Submission Manual series.	December 2014

BSM Process of confidentiality requests for biocide applications

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1. Introduction

1.1 Objective

In accordance with Article 67 of the Biocidal Product Regulation¹ (BPR), the European Chemicals Agency (ECHA) is required to publish information it holds on active substances and biocidal products free of charge on the internet. However, in certain cases information can be withheld according to Article 66(4), if the person submitting the information also submits a justification as to why publishing the information could be harmful for their commercial interests or those of any other party concerned.

Such justifications will be assessed by the Authorities (the MSCA or ECHA) in accordance with Article 67(3) and 67(4), and where the justification is accepted as valid, the information concerned will not be published.

This manual is part of the Biocides Submission Manual (BSM) series and should help readers understand:

- The legal basis of the dissemination process
- How to make confidentiality claims in IUCLID in general: how to set the flags and insert a justification
- Which information from the dossier can be claimed confidential for active substances and biocidal products and where to place the flags in IUCLID
- How to draft confidentiality claim justifications.

This manual provides information on the content of confidentiality claims and aims to help those in industry, who are responsible for preparing IUCLID dossiers. Please see [Biocide Submission Manual 'Technical guide: using IUCLID'](#) on the ECHA website for information on preparing a general IUCLID dossier for biocides applications. All the Biocides Submission Manuals can be accessed from the [ECHA website](#).

It should be noted that in cases where urgent action is essential to protect human health, animal health, safety or the environment or for other reasons of overriding public interest, the authorities shall disclose information which would normally be considered confidential, in accordance with Article 66(2).

2. Dissemination Process

2.1 Legal Basis

Dissemination of information from dossiers and the assessment of the confidentiality of information will be carried out in accordance with Article 67 of the BPR:

"BPR Article 67 – Electronic Public Access:

1. *From the date on which an active substance is approved, the following up-to-date information held by the Agency or the Commission on active substances shall be made publicly and easily available free of charge:*

¹ [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

- a) *where available, the ISO name and the name in the International Union of Pure and Applied Chemistry (IUPAC) nomenclature;*
 - b) *if applicable, the name as given in the European Inventory of Existing Commercial Chemical Substances;*
 - c) *the classification and labelling, including whether the active substance meets any of the criteria set out in Article 5(1);*
 - d) *physicochemical endpoints and data on pathways and environmental fate and behaviour;*
 - e) *the result of each toxicological and ecotoxicological study;*
 - f) *acceptable exposure level or predicted no-effect concentration established in accordance with Annex VI;*
 - g) *the guidance on safe use provided in accordance with Annexes II and III;*
 - h) *analytical methods referred to under Sections 5.2 and 5.3 of Title 1, and Section 4.2 of Title 2 of Annex II.*
2. *From the date on which a biocidal product is authorised, the Agency shall make publicly and easily available free of charge the following up-to-date information:*
 - a) *the terms and conditions of the authorisation;*
 - b) *the summary of the biocidal product characteristics; and*
 - c) *analytical methods referred to under Sections 5.2 and 5.3 of Title 1, and Section 5.2 of Title 2 of Annex III.*
3. *From the date on which an active substance is approved, the Agency shall, except where the data supplier submits a justification in accordance with Article 66(4) accepted as valid by the Authority or the Agency as to why such publication is potentially harmful for its commercial interests or any other party concerned, make publicly available, free of charge, the following up-to-date information on active substances:*
 - a) *if essential to classification and labelling, the degree of purity of the substance and the identity of impurities and/or additives of active substances which are known to be hazardous;*
 - b) *the study summaries or robust study summaries of studies submitted to support the approval of the active substance;*
 - c) *information, other than that listed in paragraph 1 of this Article, contained in the safety data sheet;*
 - d) *the trade name(s) of the substance;*
 - e) *the assessment report.*
4. *From the date on which a biocidal product is authorised, the Agency shall, except where the data supplier submits a justification in accordance with Article 66(4) accepted as valid by the Authority or the Agency as to why such publication is potentially harmful for its commercial interests or any other party concerned, make publicly available, free of charge, the following up-to date information:*
 - a) *study summaries, or robust study summaries, of studies submitted to support the biocidal product authorisation; and*
 - b) *the assessment report."*



All of the information listed under Article 67(1) and 67(2) will always be disseminated on the Dissemination Portal, regardless whether an applicant attempts to claim this information confidential.



All the information listed under Article 67(3) and 67(4) will also be disseminated, **unless** a confidentiality claim has been submitted and accepted as valid, and the relevant fee paid if applicable.

2.2 ECHA Website

Information on active substances, biocidal products, and active substance suppliers can be accessed and searched via the ECHA website, by selecting "Information on Chemicals", or by entering the following address:

<http://echa.europa.eu/web/guest/information-on-chemicals/>

Alternatively, one can search for a substance via the "Search for Chemicals" box on the top right of the ECHA home page. If the substance searched for has been approved as an active substance, the search results will include a link to the disseminated biocides dossier for that substance.

3. Confidentiality Claims

3.1 Introduction

The IUCLID dossier template allows applicants to set confidentiality claim flags on certain information. For information that an applicant wishes to keep confidential, a confidentiality claim must be submitted to ECHA.

Such claims are submitted by setting the confidentiality flag(s) next to the information in the IUCLID dossier, accompanied by a justification as to why publishing the information would be potentially harmful for the commercial interests of the applicant or any other party concerned.

It is important to note that in case of confidentiality claims relating to information covered by BPR Article 67(3) and 67(4), a fee may be incurred. In such cases the confidentiality claim will be upheld only where the appropriate fee is paid (if applicable) and the justification is accepted as valid by the Authority.



Information listed in BPR Article 67(1) and 67(2) will be disseminated, therefore confidentiality claims on this information will be disregarded.

3.2 How to make confidentiality claims in IUCLID

Step 1: Determine the information you would like to 'flag' as confidential

Next to each piece of information in the IUCLID 5 substance dataset is a confidentiality claim flag. These fields are set to not confidential as a default (Figure 1).

Figure 1: Example of a confidentiality flag (unclaimed) in the IUCLID dataset


Endpoint study record: Methods of detection and identification.001

Detail level: all fields

Administrative Data | Data source | Materials and methods

Results and discussions | Overall remarks, attachments | Applicant's summary and conclusion

Administrative Data

 Purpose flag: key study ☐ robust study summary ☐ used in

Data waiving: ☐ ☐

Justification for data waiving:

Study result type: experimental result ☐ Study period:

Reliability: 1 (reliable without restriction) ☐

Rationale for reliability incl. deficiencies:

Step 2: Mark the information as confidential



Click on a confidentiality claim flag () , and a 'Set flags' pop-up window appears (Figure 2).



Figure 2: The 'Set flags' pop-up window

Set flags

These flags can be used to mark a record or a field for the purpose of potentially excluding it from an export file, a dossier or other report. Verify the default settings (no flags set = all data are considered as public and relevant to all regulatory programmes) or select the appropriate level of confidentiality or of restriction to specific regulatory programmes

Confidentiality

1. ☐ 2. ☐ 

Justification:  

Use restricted to selected regulatory programmes

☐ EU: BPD or EU: BPR - Biocidal Products Directive 98/8/EC or Biocidal Products Regulation 528/2012/EC

☐ EU: CLP - Classification, Labelling and Packaging

☐ EU: PPP - Plant Protection Products Directive 91/414/EEC

☐ EU: REACH - Registration, Evaluation and Authorisation of Chemicals

☐ CA: CEPA - Existing Substances Program under CEPA

☐ CA: PCPA - Pest Control Products Act

☐ JP: CSCL - Chemical Substances Control Law

☐ OECD - Cooperative Chemicals Assessment Programme

☐ US: EPA HPVC - HPV Chemical Challenge Programme


☐ US: FIFRA - Federal Insecticide, Fungicide, and Rodenticide Act

☐ US: TSCA - Toxic Substances Control Act

☐ other:

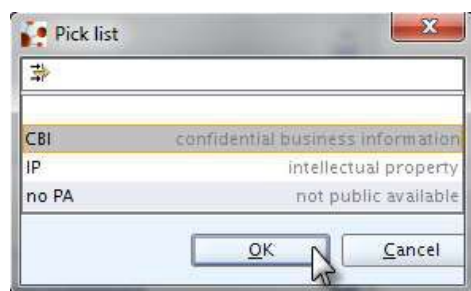
3.

Step 3: Select the type of confidentiality claim


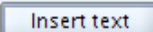
To claim the information confidential this confidentiality flag must be set to 'CBI' (confidential business information), 'IP' (intellectual property), or 'no PA' (not public available). To make your selection, click on the Confidentiality Dropdown arrow next to the 'Confidentiality' text box to select from the pick list and then click 'OK' () (Figure 3).

There is no difference in the treatment of confidentiality claims flagged 'CBI', 'IP' or 'no PA'. The selected type is simply for the information of the applicant – each type will be processed in an identical manner by the Authority.

Figure 3: Pick list containing the types of confidentiality claims available in IUCLID

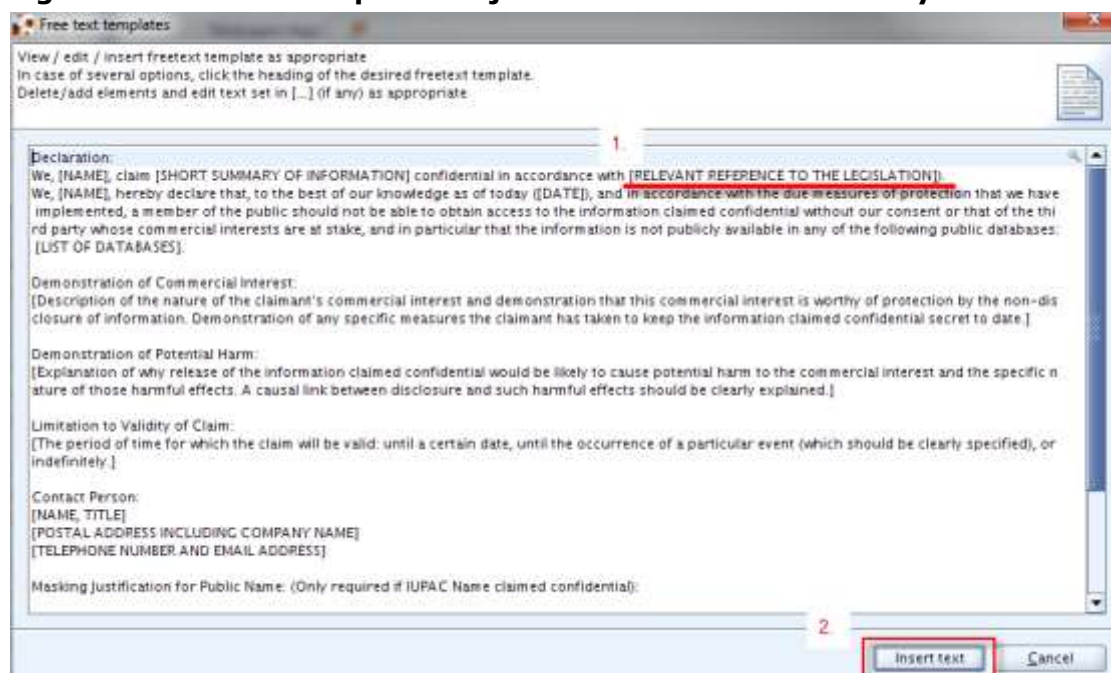


Step 4: Include your justification

To complete the claim enter appropriate text into the justification text box for every confidentiality claim flagged. Click on the justification button (, Figure 2) to open the 'Free text templates' to add a sample justification to the free text field (Figure 4). It is strongly recommended that the template provided should be completed for each individual confidentiality claim. When using this feature in IUCLID, adapt the justification accordingly, making sure to input the specifics of the claim by deleting the generic text supplied in capitals and enclosed by square brackets. For example, delete [RELEVANT REFERENCE TO THE LEGISLATION] and input the relevant legislation reference (Figure 4). Then click on 'Insert text' () to insert the text to the confidentiality claim box.

It is also recommended to use the justification template described in this document. This will ensure that the justification contains all the necessary information to be assessed by the Authority.

Figure 4: Free text template for justification of confidentiality claims



Step 5: Select relevant regulatory programmes (optional)

You can then select any regulatory programmes from the list provided, that may be relevant to your claim. If you select 'other' from the list then you must input the relevant regulatory programme in the adjacent free text field (Figure 5).

The confidentiality request will be detected even if the box is unticked.

Figure 5: Selecting relevant regulatory programmes

These flags can be used to mark a record or a field for the purpose of potentially excluding it from an export file, a dossier or other report. Verify the default settings (no flags set = all data are considered as public and relevant to all regulatory programmes) or select the appropriate level of confidentiality or of restriction to specific regulatory programmes

Confidentiality

CBI

Justification

Declaration:
We, the Company, claim short summary of information confidential in accordance with relevant reference to the legislation. We, the Company, hereby declare that, to the best of our knowledge as of today, and in accordance with the due measures of

Use restricted to selected regulatory programmes

☒ EU: BPD or EU: BPR – Biocidal Products Directive 98/8/EC or Biocidal Products Regulation 528/2012/EC

☐ EU: CLP – Classification, Labelling and Packaging

☐ EU: PPP – Plant Protection Products Directive 91/414/EEC

☐ EU: REACH – Registration, Evaluation and Authorisation of Chemicals

☐ CA: CEPA – Existing Substances Program under CEPA

☐ CA: PCPA – Pest Control Products Act

☐ JP: CSCL – Chemical Substances Control Law

☐ OECD – Cooperative Chemicals Assessment Programme

☐ US: EPA HPVC – HPV Chemical Challenge Programme

☐ US: FIFRA – Federal Insecticide, Fungicide, and Rodenticide Act

☐ US: TSCA – Toxic Substances Control Act

☒ other: Relevant regulatory programme

OK Cancel

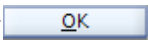
To complete the claim, click the 'OK' () button (Figure 5). Note the flag should be shaded to indicate that it is set, and the text entered in the justification text box should be visible (Figure 6).

Figure 6: Example of a set confidentiality flag in the IUCLID dataset

Endpoint study record: Methods of detection and identification 001

Detail level: Administrative Data Data source Materials and methods

all fields: Results and discussions Overall remarks, attachments Applicant's summary and conclusion

Administrative Data

[CBI: Demonstration of Com...]

Purpose flag: key study ☐ robust study summary ☐ used for clai

Data waiving:

Justification for data waiving:

Study result type: experimental result Study period:

Reliability: 1 (reliable without restriction)

Rationale for reliability Incl. deficiencies:

Data source:

Once the confidentiality flag next to a piece of information has been set, the information is

regarded as having been claimed confidential.

3.3 Confidentiality Claim Flags for active substances - Article 67(3)

The list below describes for each claim under article 67(3) where the flags should be placed in the IUCLID active substance dataset to claim the information confidential.



A fee may be issued by the Authority, and the dossier containing the claim may be invoiced and processed accordingly.

3.3.1 Degree of purity and the identity of hazardous impurities and/or additives - Article 67(3)(a)

- **Section 2.9: Degree of Purity** - To make a confidentiality claim in this section, set the flag below Degree of Purity if at least one of the tickboxes "this impurity/additive is considered relevant for the classification and labelling of the substance" is ticked (Figure 7 and 8).

Figure 7: Confidentiality flag on the Degree of Purity

Degree of purity

[CBI]

88 94 % (w/w)

Figure 8: At least one of the impurities or additives is considered relevant – tickbox is ticked

☒ this impurity is considered relevant for the classification and labelling of the substance


☒ this additive is considered relevant for the classification and labelling of the substance


- **Section 2.9: Impurities** – To make a confidentiality claim in this section, set the flag below Impurities for each impurity where the tickbox "this impurity is considered relevant for the classification and labelling of the substance" is ticked (Figure 9).

Figure 9: Confidentiality flag on the Impurity

Impurities

< 0.05 Impurity 1

 [CBI]

Reference substance  Impurity 1

EC number EC name

CAS number CAS name

IUPAC name

Typical concentration < 0.05

Concentration range < 0.05 % (w/w)

Remarks


☒ this impurity is considered relevant for the classification and labelling of the substance


- **Section 2.9: Additives** - To make a confidentiality claim in this section, set the flag below Additives for each additive where the tickbox "this additive is considered relevant for the classification and labelling of the substance" is ticked (Figure 10).

Figure 10: Confidentiality flag on the Additive

Additives

ca. 1 % (v/v) Additive 1

 [CBI]

Reference substance  Additive 1

EC number EC name

CAS number CAS name

IUPAC name

Function

Typical concentration ca. 1 % (v/v)

Concentration range ca. 0 ca. 2 % (v/v)

Remarks Additive

☒ this additive is considered relevant for the classification and labelling of the substance



Make sure that the tickbox referring to the classification and labelling is ticked for each impurity and additive where needed. A claim on an impurity or additive will only be assessed if the tickbox is ticked.



The degree of purity can be claimed confidential separately from the impurities and/or additives. A claim on the degree of purity will only be assessed if at least one impurity or additive is considered relevant for the classification and labelling and the relevant tickbox is ticked.

Dissemination aspects:

Impurities and additives that are not considered relevant for the classification and labelling (i.e. the tickbox is not ticked) will not be disseminated, so there is no need to claim this information confidential from the dissemination point of view.

If none of the impurities or additives are considered relevant for the classification and labelling (i.e. none of the tickboxes are ticked), the degree of purity will not be disseminated, so there is no need to claim this information confidential from the dissemination point of view.

3.3.2 Study summary or robust study summary - Article 67(3)(b)

- **Sections 3, 4, 6, 8, 9 and 10: Study summary or robust study summary** – To make a confidentiality claim in this section, double-click on the specific endpoint(s) marked with green dot(s) (Figure 11) to get the endpoint study record window open, where the flag can be set below Administrative Data (Figure 12).

You need to set flag(s) for each endpoint study record intended to be claimed confidential.

Figure 11: Opening the endpoint study record window for setting the flag

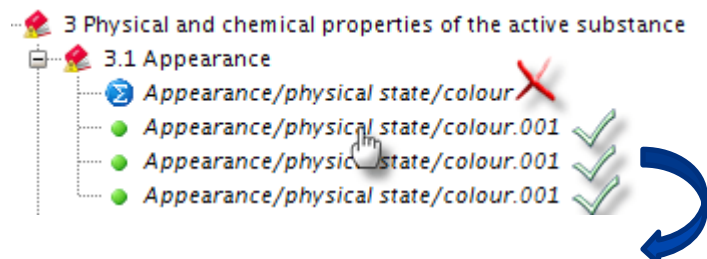


Figure 12: Confidentiality flag on the endpoint study record

Administrative Data	
<input checked="" type="checkbox"/> [CBI]	
Purpose flag	key study <input type="checkbox"/> robust study summary
Data waiving	
Justification for data waiving	
Study result type	experimental result <input type="checkbox"/> Study period
Reliability	1 (reliable without restriction) <input type="checkbox"/>
Rationale for reliability incl. deficiencies	



For a confidentiality claim on a study summary or robust study summary, the flag should be placed in the "Endpoint study record" (marked with a green dot ●). Flags placed in the "Endpoint summary" (marked with a blue sigma Σ) will not be assessed. See Figure 11.

Dissemination aspects:

When a (robust) study summary is claimed confidential, ECHA still disseminates the results of the studies in accordance with Article 67(1)(d) and (e), except "Efficacy data" in IUCLID section 6.

"Results" include the numerical values and the information needed to put it into context, such as for example: study result type, year and report date, test guideline, test animal species, strain and sex, route of administration, test results, remarks on results, etc. Details of which fields in the endpoint study record refer to the results and which refer to the (robust) study summaries can be found in the technical annexes of the '[REACH Data Submission Manual 15 – Dissemination](#)'

In each endpoint study record, there are three same fields which are not disseminated and which can be used for communicating to the authorities any information which is considered to be always confidential or which falls otherwise outside of the scope of a (robust) study summary. These fields are: (1) Confidential test material, (2) Any other information on materials and methods including tables, and (3) Overall remarks.

Note that the IUCLID field for the name of the test lab is not disseminated, but for biocides dossiers the owner company of the reported study will be disseminated.

The "endpoint summary" of section 8 (Adverse effect level (AELs)) and section 9 (Predicted No Effect Concentration (PNECs)) are disseminated; other "endpoint summaries" will not be disseminated, so there is no need to claim this information confidential from the dissemination point of view.

3.3.3 Other information in the safety data sheet - Article 67(3)(c)

If the substance does not require a safety data sheet in accordance with Article 31 of REACH² (by virtue of Article 70 of the BPR):

- these confidentiality claims will not be assessed;
- in the absence of a confidentiality claim the information will be disseminated.

- **Section 1.3: Active substance manufacturer** – To make a confidentiality claim in this section, set the flag below manufacturer.

You need to set flag(s) for each manufacturer intended to be claimed confidential.

Figure 13: Opening the active substance manufacturer section for setting the flag

² [Regulation \(EC\) No 1907/2006](#) of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

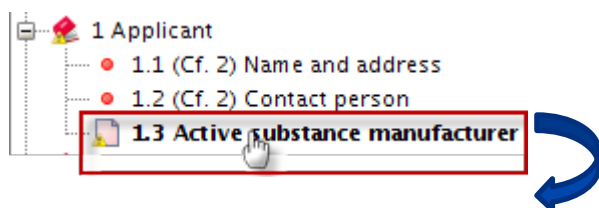
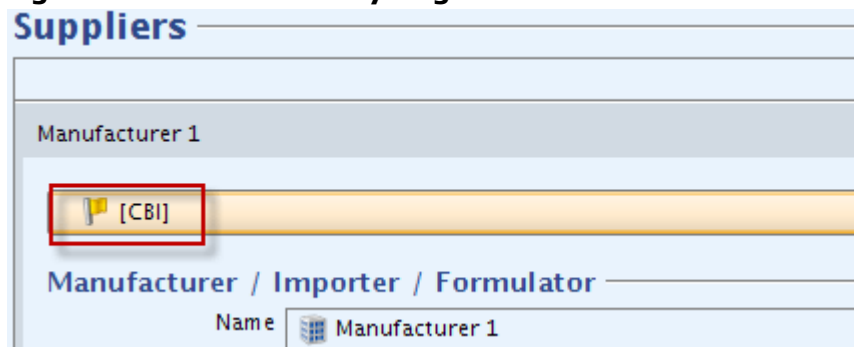


Figure 14: Confidentiality flag on the active substance manufacturer



Note that when the active substance is included in a biocidal product, as of the date of the authorisation of the biocidal product, information on the biocidal product will be disseminated on the ECHA website, including the manufacturers of the active substances, as part of the Summary of Product Characteristics.

- **Section 7.1: Field(s) of use envisaged for biocidal products and treated articles**
 - To make a confidentiality claim in this section, double-click on the specific endpoint(s) marked with green dot (●) (Figure 15) to get the field(s) of use window open, where the flag can be set below Administrative Data (Figure 16).

Figure 15: Opening the field(s) of use window for setting the flag

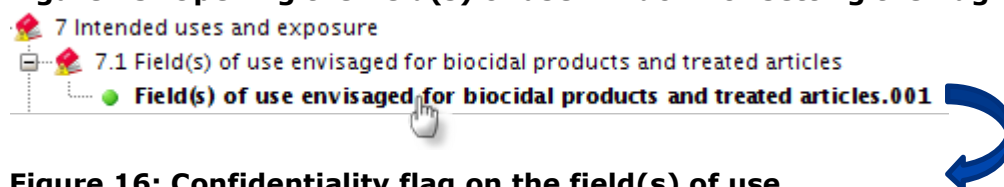
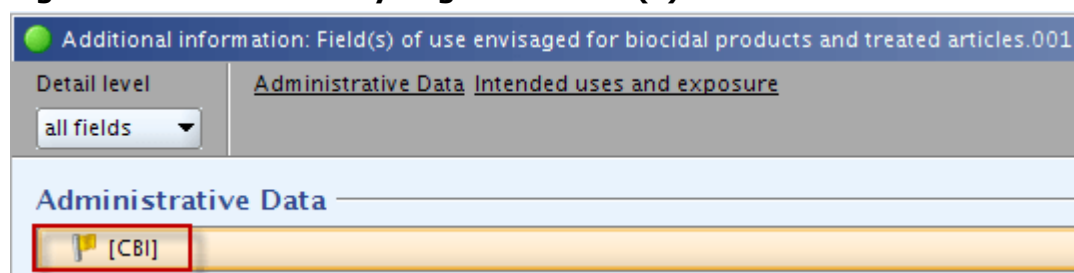


Figure 16: Confidentiality flag on the field(s) of use



Note – Data for “Field(s) of uses...” need to be entered by creating a new endpoint study record in this section. For more information, consult [Biocide Submission Manual 'Technical guide: using IUCLID'](#).



Note that when the active substance is included in a biocidal product, as of the date of the authorisation of the biocidal product, information on the biocidal product will be disseminated on the ECHA website, including the product-type,

authorised uses and categories of users, as part of the Summary of Product Characteristics.

- **Section 13: PBT Assessment** – To make a confidentiality claim in this section, double-click on the specific endpoint(s) marked with green dot (●) (Figure 17) to get the PBT assessment window open, where the flag can be set below Administrative Data (Figure 18).

You need to set flag(s) for each PBT assessment intended to be claimed confidential.

Figure 17: Opening the PBT assessment window for setting the flag

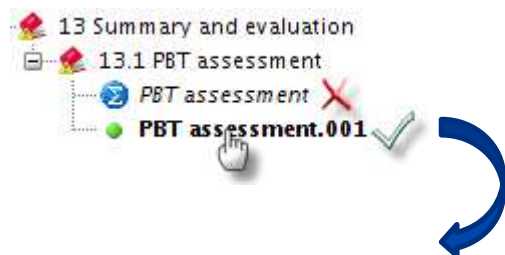
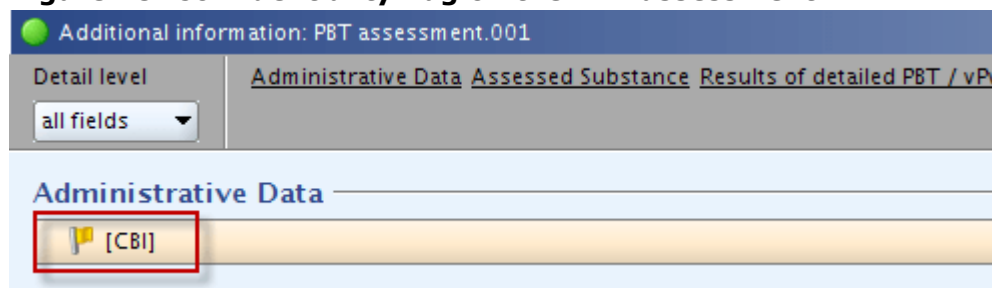


Figure 18: Confidentiality flag on the PBT assessment



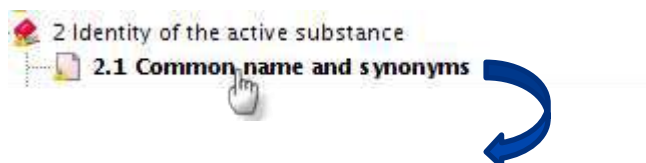
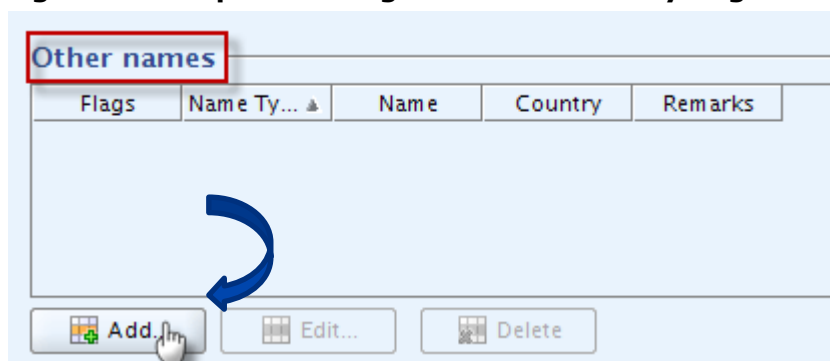
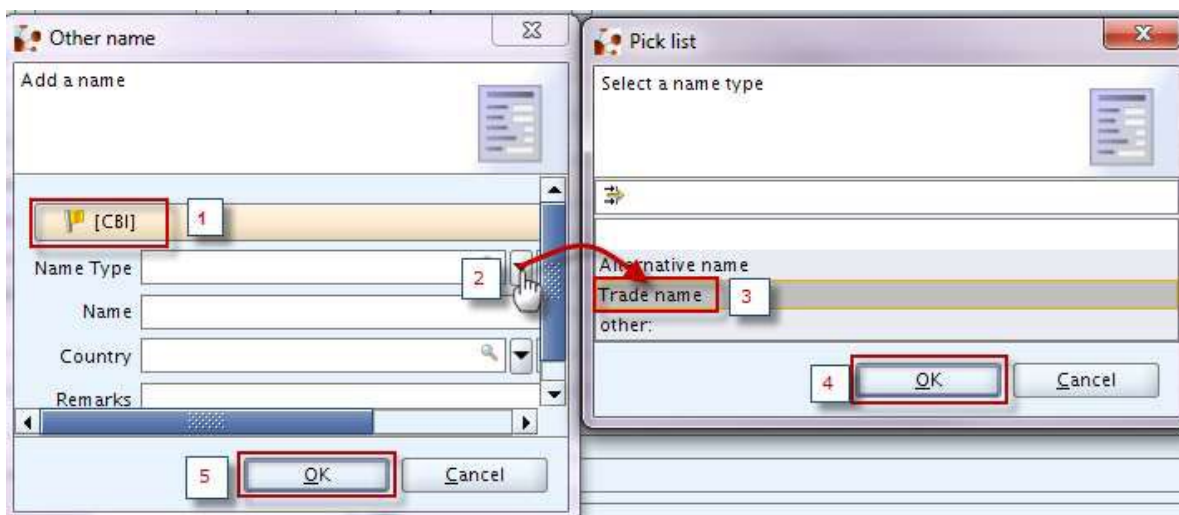
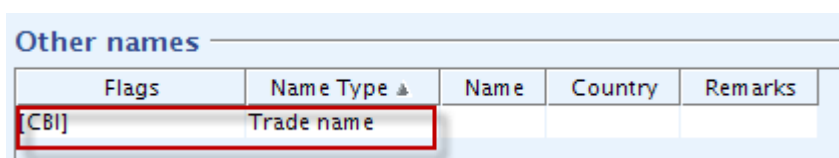
For a confidentiality claim on the PBT assessment, the flag should be placed in the "Endpoint study record" (marked with a green dot ●). Flags placed in the "Endpoint summary" (marked with blue sigma ⚡) will not be assessed. See Figure 17.

Dissemination aspects:

The endpoint summary of the PBT assessment will be entirely disseminated under article 67(1)(c), since it contains the summary of whether the active substance meets the criteria for being PBT or vPvB, which is one of the exclusion criteria set out in Article 5(1).

3.3.4 The trade name(s) of the substance - Article 67(3)(d)

- **Section 2.1: Trade name** – To make a confidentiality claim in this section, set the flag in the table "Other names" by clicking on "Add" tab. Select the Name Type 'Trade name' and set the flag as indicated in Figure 19-21.

Figure 19: Step 1 – setting the confidentiality flag on the Trade name**Figure 20: Step 2 - setting the confidentiality flag on the Trade name****Figure 21: Step 3 - setting the confidentiality flag on the Trade name****Figure 22: Confidentiality flag on the Trade name**

3.3.5 The assessment report - Article 67(3)(e)

- **Section 13: Assessment report** – To make a confidentiality claim in this section, set the flag below Administrative Data (Figure 24).

Figure 23: Opening the Assessment Report “endpoint summary” for setting the flag

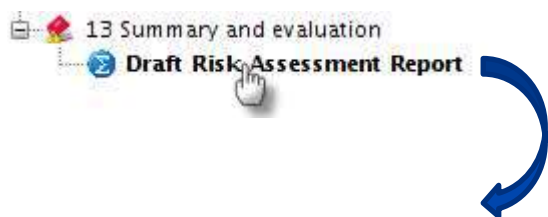
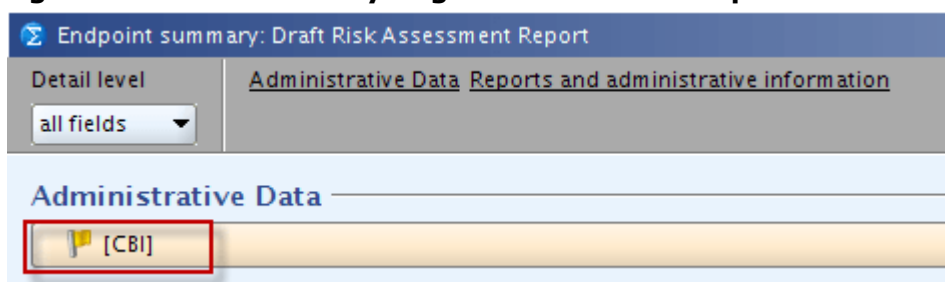


Figure 24: Confidentiality flag on Assessment Report



A confidentiality claim does not apply to the Draft Assessment (Doc II) in its entirety, but to certain elements in the Draft Assessment.



Applicants are advised to seek further information concerning how to indicate the confidential elements within/annexed to the Draft Assessment from the MSCA who will be assessing the confidentiality claim and preparing the Assessment Report and Conclusions.



A Draft Risk Assessment Report can be added in the IUCLID dossier by creating a new endpoint summary record in this section. For more information, please consult the [‘Biocide Submission Manual Technical guide: using IUCLID’](#).

Dissemination aspects:

The assessment report will be disseminated from R4BP 3, where the final (non-confidential) version is stored.

3.4 Confidentiality Claim Flags for biocidal products - Article 67(4)

The list below describes for each claim under article 67(4) where the flags should be placed in the IUCLID biocidal product dataset to claim the information confidential.



A fee may be issued by the Authority and the dossier containing the claim may be invoiced and processed accordingly.

3.4.1 Study summary or robust study summary - Article 67(4)(a)

- **Sections 3, 4, 6, 8, 9 and 10: Study summary or robust study summary** – To make a confidentiality claim in this section, double-click on the specific endpoint(s) marked with green dot (●) (Figure 25) to get the endpoint study record window open, where the flag can be set below Administrative Data (Figure 26).

You need to set flag(s) for each endpoint study record intended to be claimed confidential.

Figure 25: Opening the endpoint study record window for setting the flag

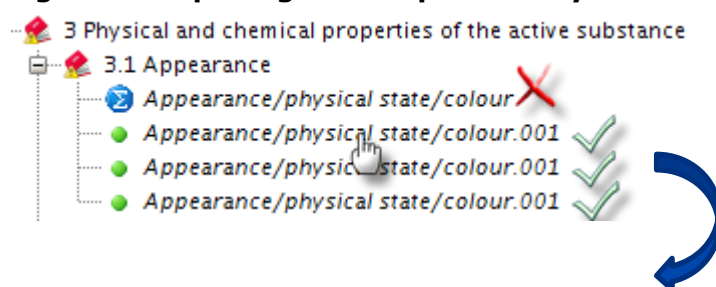













Figure 26: Confidentiality flag on the endpoint study record

Administrative Data	
 [CBI]	
Purpose flag	key study   <input type="checkbox"/> robust study summary
Data waiving	 
Justification for data waiving	
Study result type	experimental result     Study period
Reliability	1 (reliable without restriction)  
Rationale for reliability incl. deficiencies	



For a confidentiality claim on a study summary or robust study summary, the flag should be placed in the "Endpoint study record" (marked with a green dot ●). Flags placed in the "Endpoint summary" (marked with blue sigma ⚡) will not be assessed. See Figure 25.

Dissemination aspects:

In each endpoint study record, there are three same fields which are not disseminated and which can be used for communicating to the authorities any information which is considered to be always confidential or which falls otherwise outside of the scope of a (robust) study summary. These fields are: (1) Confidential test material, (2) Any other information on materials and methods including tables, and (3) Overall remarks.

Contrary to the dissemination of active substances, when a (robust) study summary for a biocidal product is claimed confidential, ECHA does not disseminate any information from the endpoint study record, including the results of the studies.

"Endpoint summaries" (⚡) will not be disseminated, so there is no need to claim this

information confidential from the dissemination point of view.

3.4.2 The assessment report - Article 67(4) (b)

- **Section 13: Assessment report** – To make a confidentiality claim in this section, set the flag below Administrative Data (Figure 28).

Figure 27: Opening the Assessment Report “endpoint summary” for setting the flag

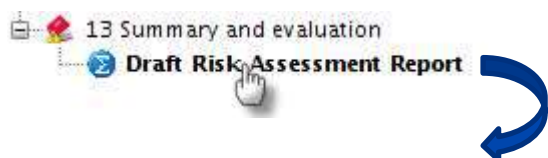
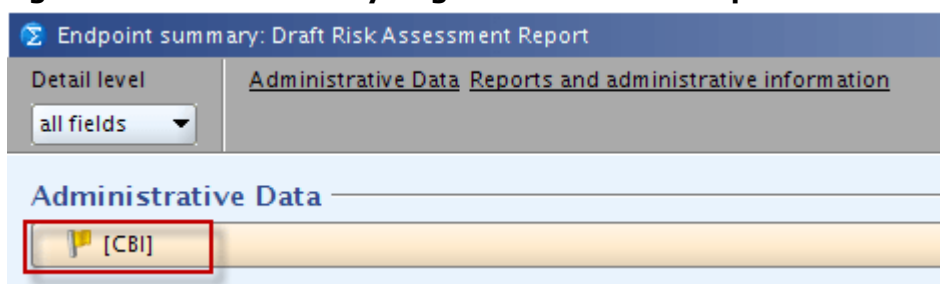


Figure 28: Confidentiality flag on Assessment Report



A confidentiality claim does not apply to the Draft Assessment (Doc II) in its entirety, but to certain elements in the Draft Assessment.



Applicants are advised to seek further information concerning how to indicate the confidential elements within/annexed to the Draft Assessment from the MSCA who will be assessing the confidentiality claim and preparing the Assessment Report and Conclusions.



Note – Draft Risk Assessment Report can be added in the IUCLID dossier by creating a new endpoint summary record in this section. For more information, please consult the Biocides [Biocide Submission Manual 'Technical guide: using IUCLID'](#).

Dissemination aspects:

The assessment report will be disseminated from R4BP 3, where the final (non-confidential) version is stored.

4. Confidentiality claim justifications

As referred above, in accordance with Article 67 of the Biocidal Product Regulation (BPR), certain information can be withheld from publication on the ECHA website according to Article 66(4), if the applicant submitting the information also 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.

The justifications will be assessed by the Authority in accordance with Article 67(3) and (4), and where the justification is accepted as valid, the information concerned will not be published.

For more information about the required elements of justifications, contact the Authority.

Justifications as to why disclosure of information listed in Article 67(3) and (4) may be potentially harmful to an applicant's commercial interests cannot be limited to a simple statement of the fact that the information is a business secret. Rather, other grounds for the confidential character of the information must be provided.

4.1 Required and optional elements for justifications

4.1.1 Required Elements

- Declaration that the information (in the form claimed confidential) is not in the public domain or general knowledge in the industry with the applicant's permission.
- Demonstration that the applicant has a commercial interest worthy of protection for non-disclosure of the information.
- Demonstration that disclosure of the information would cause potential harm to the commercial interest of the applicant or a third party.

4.1.2 Optional (but recommended) elements

- Limitation to validity of the claim, if applicable.
- Details of a contact person.

4.2 Recommended confidentiality claim justification template

--- **Company Letterhead** ---

(Template copied to company headed document)

Declaration:

We, [Applicants name], claim [Insert short summary of information] confidential in accordance with BPR 67 (3) or/and (4) [Insert relevant sub section].

We, [Applicants name], hereby declare that, to the best of our knowledge as of today ([Date]), and in accordance with the due measures of protection that we have implemented, a member of the public should not be able to obtain access to the information claimed confidential without our consent or that of the third party whose commercial interests are at stake, and in particular that the information (in the form claimed confidential) is not publicly available in any of the following public databases: [Insert databases].

Demonstration of Commercial Interest:

Description of the nature of the applicant's commercial interest and demonstration that this commercial interest is worthy of protection by the non-disclosure of information. Demonstration of the specific measures the applicant has taken to keep the information claimed confidential secret to date.

Demonstration of Potential Harm:

Explanation of why release of the information claimed confidential would be likely to cause potential harm to the commercial interest and the specific nature of those harmful effects. A causal link between disclosure and such harmful effects should be clearly explained.

Limitation to Validity of Claim:

The period of time for which the claim will be valid: until a certain date, until the occurrence of a particular event (which should be clearly specified), or indefinitely.

Contact Person

Name and contact details of a designated person to deal with any queries which may arise during the assessment by the Authority of the confidentiality claim justification.

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