Guidelines for assessing the confidentiality of the information contained in the Competent Assessment Report (CAR) and Product Assessment Report (PAR)

Contents

Legal Notice 2
1 Introduction 3
2 Legal framework 3
3 Roles and responsibilities 4
4 General principles for assessing confidentiality requests 7
5 Assessment of specific claim types 12
6 Dissemination on ECHA´s website 16
7 Annex 1: Suggested practical implementation for MSCAs to redact CARs 17
8 Annex 2: Suggested practical implementation for MSCAs to redact PARs 19
9 Annex 3: Practical examples 21

Legal Notice

This document aims to support the Member State Competent Authorities (MSCAs) in assessing the confidentiality of the information in the application dossiers for approval of an active substance or the authorisation of a biocidal product, as part of the evaluation and preparation of the Competent Assessment Report (CAR), active substance renewal (RAR) and Product Assessment Report (PAR). However, users are reminded that the text of the Biocidal Products Regulation (the "BPR")[1] is the only authentic legal reference and that the information in this document does not constitute legal advice. The European Chemicals Agency (ECHA) does not accept any liability with regard to the use that may be made of the information contained in this document.

[1] Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products

1 Introduction

The proper assessment of the confidentiality of the information in the CAR, RAR, and PAR is important to ensure the correct dissemination of information on active substances and biocidal products under the BPR, as required under Article 67 of the BPR. It is also relevant in the context of Regulation (EC) No 1049/2001 ("ATD Regulation")[2] and equivalent national provisions, since the dissemination of the CAR, RAR and PAR will possibly limit the number of access to documents requests.

Two documents on the confidentiality claims check were prepared by ECHA (CA-March14-Doc.7.2.1 and CA-March14-Doc.7.2.2[3]) and presented at the 55th CA meeting. A revised proposal for the assessment of confidentiality claims was agreed in the 56th CA meeting[4].

These guidelines elaborate more in detail on the general principles for assessing confidentiality requests and specific claim types that were already included in the CA document CA March14-Doc.7.2.1 and on their practical application. These guidelines focus primarily on the assessment of confidentiality requests in relation to dissemination of CARs, RARs and PARs.

This document will be reviewed in the light of experience in the first half of 2024.

2 Legal framework

The BPR sets specific rules regarding the confidentiality and electronic public access to certain types of information held by ECHA and the competent authorities.

Information submitted under the BPR shall be either disclosed upon request (Article 66 of the BPR) or made publicly available, free of charge on ECHA's website (Article 67 of the BPR).

In particular, from the date on which the Commission adopts an implementing Regulation providing that an active substance is approved, ECHA shall make publicly available, free of charge, information on the active substance (Art. 67(1) and 67(3) of the BPR). For products, the information shall be made publicly available, free of charge, from the date on which a biocidal product is authorised (Art. 67(2) and 67(4) of the BPR).

Article 66(4) of the BPR foresees the possibility for the applicant to request confidential treatment of the information it has submitted which would otherwise be disseminated under Article 67(3) and (4) of the BPR. This requires the submission of a justification as to why the disclosure of such information would be potentially harmful for its commercial interests or those of any other party concerned. The competent authority assesses the justification and decides on the confidentiality request (acceptance or rejection)[5].

---

[2] Regulation (EC) No 1049/2001 of the European Parliament and the Council regarding public access to European Parliament, Council and Commission documents

[3] CA-March14-Doc.7.2.1 regards the key steps and guidelines and CA-March14-Doc.7.2.2 concerns the separate assessment by ECHA in case of rejection of a request by the MSCA. Both documents are available in CIRCABC at https://circabc.europa.eu/w/browse/af767168-75db-4e3e-8f32-2d53a850d54e.

[4] The document CA-May14-Doc.7.1 presents the possibility for the applicant to request from ECHA a separate second assessment following the rejection of a request by the competent authority. However, up to now ECHA has never received such second assessment requests and the practice is that MSCAs issue decisions on confidentiality requests and communicate them directly to the applicants. The document is available in CIRCABC at https://circabc.europa.eu/w/browse/6890a120-3034-4108-a605-1bd460215b9d.

[5] In case of a rejection of a confidentiality request by the competent authority, the applicant can request to ECHA a separate assessment.

Article 66(2) of the BPR lists the information whose disclosure is normally deemed to undermine the commercial interests of the data submitter and will hence not be made available to the public, unless urgent action is essential to protect human health, animal health, safety or the environment or for other reasons of overriding public interest.

The table below provides an overview of the specific categories of information under the BPR together with the respective criteria for publication.

Category of information	***Reference to the BPR***	***Criteria for publication***
Information that must be always disseminated	Art. 67(1) and (2), Art. 22 of the BPR	The information is made publicly available on ECHA´s website and cannot be claimed confidential.
Information that must be disclosed upon request	Art. 66(3) of the BPR	The information is made publicly available if requested and cannot be claimed confidential.
Information deemed confidential	Art. 66(2) of the BPR	The information is not made publicly available, unless urgent action is essential to protect human health, animal health, safety or the environment or for other reasons of overriding public interest.
Information that must be disseminated, unless claimed confidential with a valid justification	Art. 67(3) and (4) of the BPR	The information is made publicly available on ECHA's website unless it is claimed confidential by applicants with a justification, accepted as valid by the competent authority.

It must be noted that, in case of product authorisation, Article 66(3) of the BPR lists a number of information items to which access shall not in any case be refused, and therefore for which confidentiality does not apply.

3 Roles and responsibilities

3.1 Applicants

Confidentiality requests according to Art. 67(3) and 67(4) of the BPR concern applications submitted under the BPR leading to the approval and renewal of an active substance or the authorisation of a biocidal product, including changes (minor and major), and submitted with a IUCLID dossier[6], as well as information assessed in the context of reviews

[6] In case a IUCLID dossier is not available (i.e. for most applications submitted under the Directive 98/8/EC), applicants can submit confidentiality claims on the information included in the CAR or PAR.

of approval of an active substance under Article 15 of the BPR.

The applicant should make confidentiality requests when submitting the application for approval of an active substance or the authorisation of a biocidal product or when providing additional information in the context of the application.

The confidentiality claims should be made in the IUCLID dossier.

When making a confidentiality claim, the applicant shall set the confidentiality flag available in the IUCLID dossier next to the information it wishes to claim confidential. The requests need to be accompanied by a detailed justification as to why publication of the information would be potentially harmful to the commercial interest of the applicant or any other party concerned. A mere statement that the information is confidential is not sufficient. These justifications are entered by the applicant in the IUCLID dossier, inside the flag indicating the confidentiality request.

When preparing the application, the applicant shall insert in the confidential part of the dossier the information claimed confidential in the IUCLID dossier and information directly derived from it that may enable deduction of the confidential information.

The applicant has the possibility to update the existing confidentiality claims in the IUCLID dossier and/or submit additional ones, in cases where new information is requested after the initial submission or is taken into account in the final version of the assessment report prepared by the Competent Authority.

3.2 MSCAs

The MSCA responsible for the evaluation of the application[5] (evaluating competent authority [eCA] for active substances and Union authorisations, receiving competent authority for national authorisations, evaluating competent authority for simplified authorisations and reference Member State for mutual recognitions), should assess and decide on the confidentiality requests in the following situations:

1. in parallel with the evaluation and preparation of the draft assessment report. The assessment of the confidentiality requests should be concluded by the time the evaluation is finalized; and
2. after each update of the assessment report (e.g. CAR for active substance approval or PAR Union authorisation application) during the opinion-forming phase (i.e. after the WG and BPC meetings); and
3. before the final CAR or PAR is sent to ECHA for dissemination (at the end of the opinion-forming phase for active substance approval or Union authorisation application[7]) or before the PAR is disseminated (at the end of national and simplified authorisation procedures). MSCAs prepare the redacted final CAR or PAR directly after the BPC meeting and shall submit it according to the timelines indicated in the respective working procedures. Before dissemination of the CAR or PAR, MSCAs can ask the applicant to check that the information accepted as confidential is redacted correctly.
4. The above applies, by analogy, in relation to assessment reports for the active substance renewal (RAR) or review of approval under Article 15 of the BPR, PAR for renewal of a product authorisation and PAR for changes (minor and major). In addition, the eCA should assess any confidentiality requests before information on

[7] For active substance approval and Union authorisation, the timelines for assessing the confidentiality requests and for submitting the CAR and PAR for dissemination are indicated in the respective working procedures, available on ECHA´s website at https://echa.europa.eu/about-us/who-we-are/biocidal-products-committee.

"relevant data" annexed to the RAR is made publicly available in parallel with the publication of the BPC opinion[8].

Assessing the confidentiality requests may require interaction with the applicant, alongside other information requests as part of the evaluation, and the applicant may wish to amend its confidentiality requests or the justification as the assessment proceeds.

The MSCA may invoice the applicant for the assessment of the confidentiality requests in line with the national provisions.

When the assessment of the confidentiality requests is completed, the MSCA[5] shall inform the applicant of the decision via ad hoc communication in R4BP 3 and, in case of rejection (partial or full), indicate the national remedies against the MSCA decision, where available.

3.3 ECHA

Under Art. 67 of the BPR, ECHA is responsible for making certain information publicly available, free of charge. This information is contained in the documents that ECHA disseminates from R4BP 3 under the generated asset with access level "Public". ECHA also disseminates the Summary of Product Characteristics (SPC). The documents are disseminated on ECHA´s website at http://echa.europa.eu/web/guest/information-on-chemicals.

[8] See the document "Relevant Renewal Data under Article 95" (CA-Sept20-Doc.7.1.b, section 4.3).

4 General principles for assessing confidentiality requests

4.1 Locating claims

In order to find confidentiality requests in the original biocide applications submitted via R4BP 3, MSCAs should follow the instructions below:

1. open the IUCLID file using the dossier UUID and generate the 'Confidentiality report'.
2. On top of the page in the IUCLID web user interface click on the three dots, then click on 'Generate Report' and finally select 'Biocidal Products Regulation – Confidentiality Report (Art. 66 of the BPR) [CSV] (Figures 1 and 2).
3. If the dossier contains confidentiality claims, the report lists the items claimed confidential, information allowing easy location of the claims and their justifications (Figure 3).

Figure 1: How to run the report generator – step 1

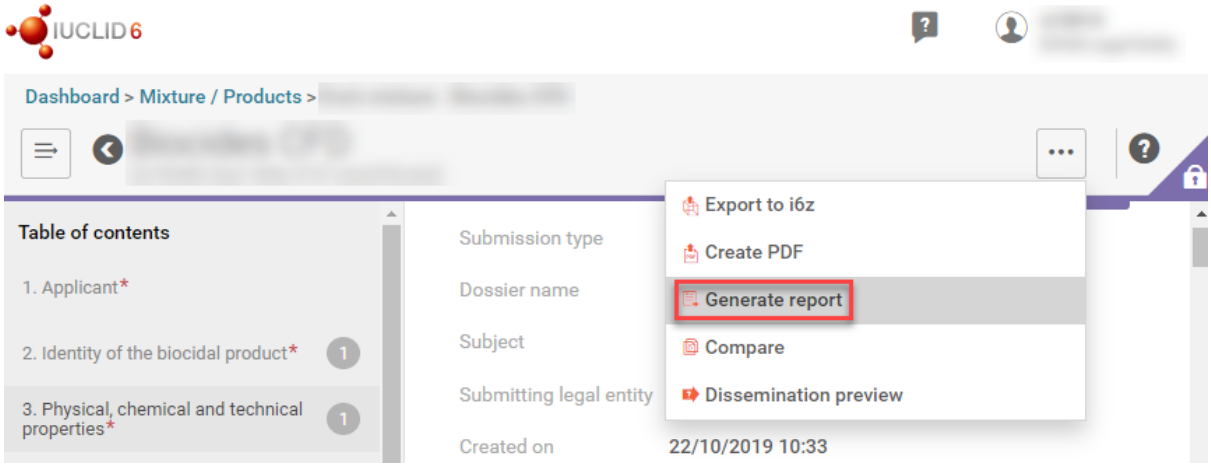


Figure 2: How to run the report generator – step 2

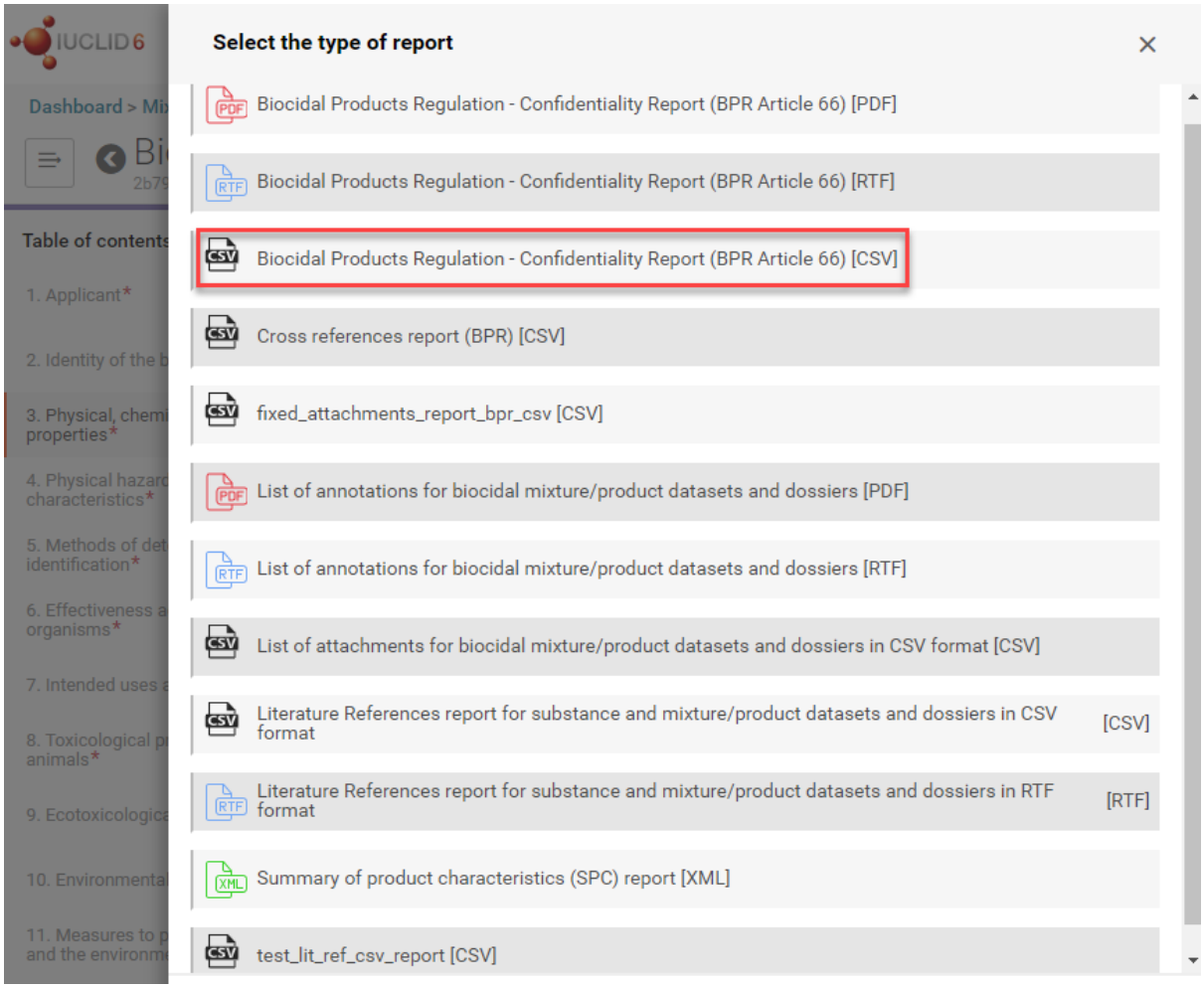


Figure 3: Generated report in IUCLID

No.	Section in IUCL	Type	Item	Name	Section UUID	Justification	Accept/Do Not Acce	Decision based on c	ECHA's assessment
	3.4.2.1	Product	Light	Effects of Temperature. Accelerated Storage Test	IUCS-	Confidentiality is clain			
	3.4.2.1	Product	Light	Effects of Temperature. Accelerated Storage Test	IUCS-	Confidentiality is clain			
	3.4.2.1	Product	Light	Effects of Temperature. Accelerated Storage Test	IUCS-	Confidentiality is clain			
	3.4.2.1	Product	Light	Effects of Temperature. Accelerated Storage Test	IUCS-	Confidentiality is clain			
	3.4.2.1	Product	Light	Effects of temperature. Accelerated Storage Test.	IUCS-	Confidentiality is clain			
	3.4.2.1	Product	Light	Effects of temperature. Accelerated Storage Test.	IUCS-	Confidentiality is clain			
	3.4.2.1	Product	Light	Effects of temperature. Accelerated Storage Test.	IUCS-	Confidentiality is clain			
	3.4.2.1	Product	Light	Effects of temperature. Accelerated Storage Test.	IUCS-	Confidentiality is clain			

4.2 Assessment of the justification

A valid justification demonstrates the existence of a commercial interest worthy of protection which could potentially be harmed if the information concerned is disclosed.

The justification should be properly reasoned rather than being generic statements. For example, the requester shall explain how the disclosure of the information claimed confidential would reveal or allow deduction of certain (manufacturing, compositional, product, strategic or other) information to competitors or clients, which is currently not known to them, leading them to undertake certain actions that could cause commercial harm to the applicant or a third party.

Some examples of valid lines of argumentation can be found in section 5 "Assessment of specific claim types", based on cases under the BPR and justifications for confidentiality

requests received by ECHA under REACH, adapted to the biocides context where necessary. These examples are not exhaustive.

In addition to these type-specific justifications, the applicant can refer to a secrecy agreement in its justification. In case the justification explains that the applicant has a secrecy agreement or non-disclosure agreement with the data-holder, some evidence of the actual existence of such an agreement needs to be provided by the applicant (e.g. declaration that such an agreement exists or extract from the agreement describing the relevant clauses preventing disclosure) to be accepted as a valid justification.

4.3 Invalid justifications

Below some examples of invalid justifications can be found, based on justifications for confidentiality requests received by ECHA under REACH. These examples are not an exhaustive list.

- The justification is an unsubstantiated statement. It only states that the information is confidential or sensitive, or that the applicant does not wish it to be disseminated, e.g.
    - Publication on the internet would be detrimental to our business
    - Confidential due to business sensitive information
    - Protection of knowhow against competitors
- The justification is insufficiently reasoned. It vaguely hints that disclosure of the information could reveal certain information, but too little information is provided to make the justification acceptable or it is not possible to follow the applicant's reasoning.
- The justification does not address the (type of) information claimed confidential.
- The justification consists only in stating that data is protected or that competitor could misuse information made publicly available Confidentiality and data protection are different notions and are governed by different legal provisions. Protected data are not necessarily confidential. Only limited information is expected to be eligible for confidentiality. See also paragraph 5 below (Assessment of specific claim types, Study summaries or robust study summaries of studies submitted to support the biocidal product authorisation).

In addition, in case of product authorisation, Article 66(3) of the BPR lists a number of information items to which access shall not in any case be refused, and therefore for which confidentiality does not apply.

4.4 Public domain search

Since as a general principle, information can only be of confidential character as long as it is not already publicly available, additionally, it is advisable to verify that the information is not found in the public domain.

A search shall be conducted on public databases of other authorities (e.g. United States Environmental Protection Agency [US-EPA]), on the company´s or consortium´s website(s), or via a general internet search.

When using public search engines, it is very important that the search is performed without releasing the confidential information itself. Never use information claimed confidential to perform the search!

4.5 Overall conclusion

The confidentiality request is acceptable

If the justification is judged to be sufficiently reasoned and the information is not found in the public domain, the confidentiality request is accepted by the MSCA[5] and the information is not disseminated.

The confidentiality request is not acceptable: request further information

It might happen that no justifications are present in the dossier, as applicants may have unintentionally set a flag in their IUCLID database, or may not be aware that justification is necessary. In this case, it should be clarified with the applicant if a confidentiality request was intended. If a justification is present but it is not sufficiently reasoned and/or the information is found in the public domain, the confidentiality request cannot be accepted as such. In this case, it is also recommended for the MSCA to interact with the applicant.

The options to be offered to the applicant are to withdraw the request or to provide further justification. The applicant should be informed that its current confidentiality request will not be accepted as such and that it has the possibility to update its justification within a certain time and further justify the request and/or refute the availability in the public domain. Alternatively, if the confidentiality request is no longer relevant, the applicant can withdraw it.

It is recommended that the MSCA and the applicant interact via R4BP 3.

The MSCA can inform the applicant via an ad-hoc communication with Topic "Confidentiality requests" and Subject "Report of the confidentiality request". It is important to set a deadline in the message, so the applicant can reply via R4BP 3[9].

Second assessment of the confidentiality request

A second assessment of the confidentiality request should be performed by the MSCA[5] after the deadline for submission of further information has passed. The criteria for the second assessment are the same as for the initial assessment. Therefore, if the applicant does not submit any further information within the given deadline, the claim should be rejected.

If the applicant submits an updated justification and all the identified shortcomings have been addressed and the justifications are considered valid, the confidentiality request should be accepted, otherwise it should be rejected.

If the applicant withdraws the confidentiality request, no second assessment is needed.

The time to perform the assessment of the confidentiality request should be taken into account to avoid delaying the dissemination of the information.

4.6 Inform the applicant of the outcome of the assessment

When the assessment of the confidentiality requests is concluded, the applicant shall be informed by the MSCA[5] of the outcome via ad hoc communication in R4BP 3.

[9] For more information, consult the latest version of the manual for authority users "How to run BPR processes with R4BP 3 in Member State competent authorities" available in S-CIRCABC at https://webgate.ec.europa.eu/s-circabc/w/browse/21143482-68ca-4a30-8b06-4bb8b33547f1

4.7 Reflect the outcome of the assessment in the CAR/PAR

The assessment of the confidentiality claims should be reflected in the final public CAR or PAR. The same approach should be followed by analogy for the assessment report concerning renewal of active substances, product authorisations and changes (minor and major) to a product authorisation.

The assessment and decision on the confidentiality requests is an integral part of the evaluation. The public version of the CAR or PAR shall reflect the outcome of the MSCA's decision on the confidentiality requests. MSCAs include in the confidential annex information deemed confidential (Art. 66(2) of the BPR) and information for which confidentiality claims have been accepted (Art. 67(3) and (4) of the BPR).

MSCAs prepare the following versions of the CAR and PAR:

CAR: versions to be prepared at the end of the opinion-forming phase of active substance approval

- Final CAR including the confidential annex (non public version): information deemed confidential is visible. The confidential annex contains all the confidential information (information deemed confidential (Art. 66(2) of the BPR) and information for which confidentiality claims have been accepted (Art. 67(3) of the BPR).
- Public CAR or Public Assessment Report (AR) for Review Programme dossiers[10]: this consist in the final CAR where information deemed confidential is redacted, and does not contain the confidential annex. The public CAR or AR is disseminated on ECHA´s website.

PAR: versions to be prepared at the end of national and simplified authorisation procedures and at the end of the opinion-forming phase of Union authorisation applications

- Final PAR (non public version): information deemed confidential is visible.
- Public PAR: information deemed confidential is redacted. The public PAR is disseminated on ECHA´s website.
- Final PAR – confidential annex and/or confidential annex accessible to MSCAs only: the confidential annex contains all the confidential information (information deemed confidential (Art. 66(2) of the BPR) and information for which confidentiality claims have been accepted (Art. 67(4) of the BPR). The confidential annex accessible to MSCAs only contains confidential information that can not be accessible to the applicant.

[10] The "Working procedure for active substance approval" describes the structure of the CAR and the documents to be provided by the evaluating Competent Authority in the old format, as used under the Biocidal Products Directive (Directive 98/8/EC, BPD), and in the new format as agreed by the BPC.

5 Assessment of specific claim types

In this section, some examples of valid lines of argumentation can be found, based on experience of justifications for confidentiality requests received by ECHA under REACH, adapted to the biocides context where necessary. Examples are organised by type of confidentiality request. These examples are not exhaustive. Member States must make a case-by-case assessment.

As mentioned under section 4.2 "Assessment of the justification", in addition to these type-specific justifications, the applicant can refer to a secrecy agreement in its justification. In case the justification explains that the applicant has a secrecy agreement or non-disclosure agreement with the data-holder, some evidence of the actual existence of such an agreement needs to be provided by the applicant (e.g. declaration that such an agreement exists or extract from the agreement describing the relevant clauses preventing disclosure) to be accepted as a valid justification.

Degree of purity and identity of hazardous impurities/additives of active substances (Art. 67(3)(a) of the BPR)

Identity of hazardous impurities, additives, and the degree of purity of the active substance have to be claimed confidential separately. The confidentiality claim will be assessed only if the hazardous impurities and additives are considered relevant for the classification and labelling. Indeed, hazardous impurities and additives that are not considered relevant for the classification and labelling will not be disseminated.

Examples of potentially valid lines of argumentation in the justification would state that disclosure would reveal or allow deducing:

- Sourcing information (e.g. sourcing location or strategy of the raw materials);
- Manufacturing information (e.g. a specific production technology or synthesis route).

In such cases, potential harm could be caused by the fact that competitors could compete for the raw material or competitors could reproduce the production technology. In cases when there is only one source of the active substance supporting the product type(s), it is possible to directly link the quality and information to the applicant. An example of a valid justification is provided below:

> *We claim the Degree of Purity and Identity of Impurities of Active Substance Name confidential in accordance with Art 67 (3)(a) of the BPR.*
>
> *We hereby declare that, to the best of our knowledge as of today (01 January 2014), 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 a third party whose commercial interests are at stake, and in particular that the information is not publicly available in any of the public databases (list).*
>
> *We have sourced supplies of plant-based raw materials from an area of the Mato Grosso do Sul region of Brazil, building up relationships with suppliers over many years. In combination with purification technology developed in-house, this gives our active substance a much higher degree of purity compared to our competitors, which is the unique selling point for our product.*
>
> *Our product has a purity higher than that possible with commonly known production technologies, and contains particular impurities arising from raw materials used. Thus, dissemination of the degree of purity or identity of impurities*

will reveal to our competitors our technology lead and / or the location from which our raw materials are sourced. This would allow our competitors to attempt to buy up our raw materials at source, or begin to attempt to copy our novel production technology, thereby harming our market position and commercial interest.

Study summaries and robust study summaries of studies submitted to support the approval of the active substance (Art. 67(3)(b) of the BPR)

Examples of potentially valid lines of argumentation in the justification would state that disclosure would reveal or allow deducing:

- R&D related information (e.g. elements of the technological process);
- Specific test methodology.

In such cases, potential harm could be caused by the fact that competitors could reproduce technology or methodology or by the loss of competitive advantage.

The justifications can be very different depending on the type of study performed.

A justification focusing on concerns about theft of the data when disseminated, and use of the data (in other parts of the world) without compensation for the testing costs is not considered acceptable.

When assessing the justification of the confidentiality request, it is important to keep in mind that other companies will need to obtain a Letter of Access in order to use the unpublished studies in their own applications, referred to in the application in question (Article 59 of the BPR). In other words, dissemination on ECHA´s website does not mean that other companies could simply use that information for their own BPR applications.

The concern that others could use information made publicly available for the purpose of applications under the BPR, or other regulatory regimes, as such, is not deemed to be a commercial interest "worthy of protection" to justify a confidentiality request on the robust study summary. This concern could apply indistinctively for any applicant and any information to be made publicly available on ECHA's website in accordance with Art. 67 of the BPR. However, the EU legislator, by introducing the principle that certain information is to be made available to the general public (unless exceptional circumstances justify a derogation), has explicitly accepted this risk.

Additionally, a justification referring to the results of toxicological and ecotoxicological studies or to other information which is to be disseminated by ECHA (see next) is not considered acceptable.

Information contained in the safety data sheet for the active substance (Art. 67(3)(c) of the BPR)

ECHA has to make publicly available over the internet the information which is contained in the safety data sheet, and which is not already disseminated under other provisions of the BPR, unless the applicant successfully claims confidentiality. This does not apply to information which is to be always disseminated under other provisions of the BPR. Since a copy of the safety data sheet of the active substance is not part of the data submitted as part of the application, it has been determined which information has to be listed in both the safety data sheet and the active substance application. This information, if not already disseminated for other reasons (in accordance with Art. 67 of the BPR), is considered "safety data sheet information".

It includes (1) the name of the active substance manufacturer, (2) the use, and (3) the results of the PBT (Persistent, Bioaccumulative and Toxic chemicals) and vPvB (very

Persistent and very Bioaccumulative) assessment.

Name of the active substance manufacturer(s)

N.B.: When the active substance is included in a biocidal product, as of the date of the authorisation of the biocidal product, the name and address of the active substance manufacturer(s) will be disseminated on ECHA's website, as part of the Summary of Product Characteristics (Article 67(2)(b) of the BPR). MSCA's decisions accepting the confidentiality claim in the context of AS approval applications should therefore refer to the limited validity of the claim accordingly.

Examples of potentially valid lines of argumentation in the justification would state that disclosure would reveal or allow deduction of:

- Manufacturing information (e.g. a specific manufacturing technology);
- Product information (e.g. envisaged use of the active substance);
- Market information (e.g. the competitive structure of the market);
- Company strategic information (e.g. the production concept of the company or the applicant´s role in the supply chain).

In such cases, potential harm could be caused by the fact that competitors could copy some elements of the company strategy or could identify growing market opportunities.

Uses

N.B.: When the active substance is included in a biocidal product, as of the date of the authorisation of the biocidal product, the product-type, authorised uses and categories of users will be disseminated on ECHA's website, as part of the Summary of Product Characteristics (Article 67(2)(b) of the BPR). MSCA's decisions accepting the confindentiality claim which are issued prior to the authorisation of the biocidal product should therefore refer to the limited validity of the claim accordingly.

In general, an acceptable justification explains that disclosure of the uses would for example reveal or allow deduction of certain use-related information to competitors or clients, which is currently not known to them, allowing them to undertake certain actions that would cause commercial harm to the applicant.

ECHA cannot advise on valid lines of argumentation for the use, since the experiences under REACH pertain mainly to the existence of specific unknown uses, whereas under the BPR the substance is known to be used as an active substance in a biocidal product.

PBT and vPvB assessment

The meeting of the PBT and vPvB criteria cannot be claimed as confidential. However, confidentiality claims can be made on the PBT or vPvB assessment. In general, an acceptable justification explains that disclosure of the PBT or vPvB assessment would, for example, reveal certain assessment-related information to competitors or clients, allowing them to undertake certain actions that would cause commercial harm to the applicant.

ECHA cannot advise on valid lines of argumentation for the PBT or vPvB assessment, since to date no such confidentiality requests have been accepted under REACH.

A mere statement that the PBT/vPvB assessment is of commercial interest is not sufficient to demonstrate that disclosure of the PBT/vPvB assessment will lead to harm of the commercial interest. The applicant needs to explain in detail the causal relationship between the disclosure on ECHA´s website of the PBT/vPvB assessment (i.e. in the entries

for persistence, bioaccumulation or toxicity in the IUCLID dossier) and the harmful effects of this disclosure. The justification should describe in detail that such harmful effects cannot occur from any Safety Data Sheet(s) circulating in the supply chain in relation to this active substance or, in the alternative, that the applicant has taken measures for the information to remain limited to its supply chain.

Trade name(s) of the active substance (Art. 67(3)(d) of the BPR)

Examples of potentially valid lines of argumentation in the justification would state that disclosure would reveal or allow deduction of:

- The composition/purity of the substance behind the trade name;
- Which different trade names are behind the same substance.

In such cases, potential harm could be caused by the fact that competitors could identify growing market opportunities.

Assessment report on the active substance (Art. 67(3)(e) of the BPR)

A confidentiality request on the CAR does not apply to the CAR in its entirety, but to certain elements of it, excluding the information referred to in Article 67(1). Only limited information is expected to be eligible for confidentiality.

For a confidentiality request on the CAR, the applicant should clearly indicate in the CAR which specific elements of the CAR are claimed confidential, and each element should be justified. The confidential elements are presented in a confidential annex to the CAR.

The information claimed confidential in the CAR should correspond to information claimed confidential in the IUCLID dossier (i.e. information itself or information directly derived from it that may enable deduction of the confidential information).

If confidentiality is accepted, the MSCA must ensure that those elements are not present in the redacted non-confidential version of the CAR which will be disseminated on ECHA´s website.

While evaluating a claim on the CAR, the assessor should consider the whole IUCLID dossier.

Study summaries or robust study summaries of studies submitted to support the biocidal product authorisation (Art. 67(4)(a) of the BPR)

The same applies as for confidentiality claims on (robust) study summaries submitted to support the active substance approval. Therefore, justifications explaining the potential harm to the commercial interest if the information is disseminated, could be acceptable.

Assessment report on the biocidal product (Art. 67(4)(b) of the BPR)

The same applies as for confidentiality claims on the assessment reports for an active substance approval.

As an example of invalid justification, before the publication of the PAR on ECHA´s website, the applicant required to remove a part of the text prepared by the competent authority related to the assessment and conclusion reached on the residues study. The applicant claimed that these paragraphs are considered as part of their intellectual properties that have been developed only for this dossier, and do not fall under the core data set usually

presented for biocidal product dossiers. These arguments, waivers and studies (particularly residues study) clearly present an added value for allowing the placing on the market of this product compared to other products, which can thus be considered as part of their commercial interest.

This is not a valid justification, since the reference to a copyright on the study is not sufficient to demonstrate commercial harm stemming from the dissemination. In addition, a compilation of objective data can neither, as such, reveal the content of commercial strategy or future choices as regards the strategies of the applicant nor can it be regarded as information particular to that undertaking which would reveal its expertise.

6 Dissemination on ECHA´s website

Under Art. 67 of the BPR, ECHA is responsible for making certain information publicly available, free of charge.

ECHA currently does not disseminate the IUCLID data from application dossiers for approval of an active substance or the authorisation of a biocidal product. ECHA only disseminates documents provided through R4BP 3 that are marked with the access level "Public" under the generated asset.

The BPR foresees that, for active substances, dissemination (i.e. publication on ECHA´s website), will take place when the Commission adopts the approval decision. The redacted version of the assessment report will be published on ECHA´s website, as well as the BPC opinion. For transparency reasons, the assessment report and the BPC opinion are disseminated also for non-approved active substances.

By analogy, ECHA disseminates on its website the redacted version of the RAR from the date in which the Commission adopts the renewal decision. ECHA also disseminates information on "relevant data" in parallel with the publication of the BPC opinion to facilitate the implementation of Article 95(7) of the BPR by Article 95 listed companies[8].

For biocidal products, the BPR foresees that dissemination will take place as from the date of authorisation of the biocidal product. The redacted version of the PAR will be published on ECHA´s website. Furthermore, the summary of the biocidal product characteristics (SPC), the terms and conditions of the authorisation and the BPC opinion (for biocidal products authorised via Union authorisation) will be published.

This applies, by analogy, to PARs for renewal of a product authorisation or to PARs for minor and major changes and the revised SPC referred to in Article 13(5) of the Changes Regulation (Regulation (EU) No 354/2013).

The information will be published on ECHA´s website, and can be accessed and searched by selecting "Information on Chemicals" from the ECHA home page, 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.

7 Annex 1: Suggested practical implementation for MSCAs to redact CARs

Some practical examples of redaction of the CAR are provided in Annex 3.

7.1 Redaction of the CAR or AR (for Review Programme dossiers)

- Redact the information in the final documents as detailed in the following section and create the "Public CAR" or "Public AR" in pdf format.
- Verify that text which appears to be redacted has indeed been redacted, and is not only highlighted in black. Redacted text cannot be copied into another document, whereas text highlighted in black will become readable if copied into, for example, a Doc document.
- **Do not** remove the redacted information or replace it by XXXX text.

The instructions above refer to the parts of the CAR that are not already included in the confidential annex.

7.2 Information that must be disseminated (NEVER BLANK)

Art. 67(1) and (2) of the BPR

Information regarding the active substance

- ✓ The ISO name and the IUPAC name (Art. 67(1)(a) of the BPR)
- ✓ EINECS name (Art. 67(1)(b) of the BPR)
- ✓ Classification and labelling, including information if the active substance meets any of the criteria in Art. 5(1) of the BPR, (Art. 67(1)(c) of the BPR)
- ✓ Physicochemical endpoints and data on pathways and environmental fate and behaviour (Art. 67(1)(d) of the BPR)
- ✓ The results of toxicological and ecotoxicological studies (Art. 67(1)(e) of the BPR)
- ✓ Acceptable exposure level (AEL) or predicted no-effect concentration (PNEC) established in accordance with Annex VI of the BPR, (Art. 67(1)(f) of the BPR)
- ✓ Guidance on safe use provided in accordance with Annex II and III of the BPR, (Art. 67(1)(g) of the BPR)
- ✓ Analytical methods referred to under Sections 5.2 and 5.3 of Title 1, and Section 4.2 of Title 2 of Annex II of the BPR (Art. 67(1)(h) of the BPR)

7.3 Information deemed confidential (ALWAYS BLANK)

- ✗ Names and addresses of persons involved in testing on vertebrates (Art. 66(2)(d) of the BPR)[11]
- ✗ Any other personal data, including authors of unpublished non-vertebrate studies (Art. 5(1) of Regulation (EU) 2018/1725)
- ✗ Details of the full composition of a biocidal product (Art. 66(2)(a) of the BPR)
- ✗ The precise tonnage of the active substance (Art. 66(2)(b) of the BPR)
- ✗ Links between a manufacturer of an active substance and the person responsible for the placing of a biocidal product on the market or between the person responsible for the placing of a biocidal product on the market and the distributors of the product (Art. 66(2)(c) of the BPR)
- ❖ **Unless** an urgent action is essential to protect human health, animal health, safety or the environment or for other reasons of overriding public interest.
- ❖ **Unless** it is already publicly available information.

7.4 Information that must be disseminated unless claimed confidential with a valid justification (BLANK IN CASE OF VALID JUSTIFICATION ONLY)

Art. 67(3) and (4) of the BPR

Information regarding the active substance

- ✓ 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 (Art. 67(3)(a) of the BPR)
- ✓ Study summaries or robust study summaries of studies submitted to support the approval of the active substance (Art. 67(3)(b) of the BPR)
- ✓ Other information contained in the safety data sheet (Art. 67(3)(c) of the BPR)
- ✓ Trade name(s) of the substance (Art. 67(3)(d) of the BPR)
- ✓ Assessment report (Art. 67(3)(e) of the BPR)

[11] This refers to authors of the studies and testing laboratories.

8 Annex 2: Suggested practical implementation for MSCAs to redact PARs

Some practical examples of redaction of the PAR are provided in Annex 3.

8.1 Redaction of the PAR

- Redact the information in the PAR as detailed in the following section and create the "Redacted final PAR" file in pdf format.
- Verify that text which appears to be redacted has indeed been redacted, and is not only highlighted in black. Redacted text cannot be copied into another document, whereas text highlighted in black will become readable if copied into, for example, a Doc document.
- **Do not** remove the redacted information or replace it by XXXX text.

The instructions above refer to the parts of the PAR that are not already included in the confidential annex.

8.2 Information that must be disseminated (NEVER BLANK)

Art. 67(1) and (2) of the BPR

Information regarding the active substance

- ✓ The ISO name and the IUPAC name (Art. 67(1)(a) of the BPR)
- ✓ EINECS name (Art. 67(1)(b) of the BPR)
- ✓ Classification and labelling, including information if the active substance meets any of the criteria in Art. 5(1) of the BPR (Art. 67(1)(c) of the BPR)
- ✓ Physicochemical endpoints and data on pathways and environmental fate and behaviour (Art. 67(1)(d) of the BPR)
- ✓ The results of toxicological and ecotoxicological studies (Art. 67(1)(e) of the BPR)
- ✓ Acceptable exposure level (AEL) or predicted no-effect concentration (PNEC) established in accordance with Annex VI of the BPR, (Art. 67(1)(f) of the BPR)
- ✓ Guidance on safe use provided in accordance with Annex II and III of the BPR, (Art. 67(1)(g) of the BPR)
- ✓ Analytical methods referred to under Sections 5.2 and 5.3 of Title 1, and Section 4.2 of Title 2 of Annex II of the BPR (Art. 67(1)(h) of the BPR)

Information regarding the biocidal product

- ✓ Terms and conditions of the product authorisation (Art. 67(2)(a) and Art. 22 of the BPR)
- ✓ Summary of the biocidal product characteristics (SPC) (Art. 67(2)(b) and Art. 22 of the BPR)
- ✓ Analytical methods referred to under Sections 5.2 and 5.3 of Title 1, and Section 5.2 of Title 2 of Annex III of the BPR (Art. 67(2)(c) of the BPR)

8.3 Information deemed confidential (ALWAYS BLANK)

Art. 66(2) of the BPR

- ✗ Names and addresses of persons involved in testing on vertebrates (Art. 66(2)(d) of the BPR)
- ✗ Any other personal data, including authors of unpublished non-vertebrate studies (Art. 5(1) of Regulation (EU) 2018/1725)
- ❖ **Unless** it is already publicly available information
- ✗ Details of the full composition of a biocidal product (Art. 66(2)(a) of the BPR)
- ✗ The precise tonnage of the active substance or biocidal product (Art. 66(2)(b) of the BPR)
- ✗ Links between a manufacturer of an active substance and the person responsible for the placing of a biocidal product on the market or between the person responsible for the placing of a biocidal product on the market and the distributors of the product (Art. 66(2)(c) of the BPR)
- ❖ **Unless** an urgent action is essential to protect human health, animal health, safety or the environment or for other reasons of overriding public interest.

8.4 Information that must be disseminated unless claimed confidential with a valid justification (BLANK IN CASE OF VALID JUSTIFICATION ONLY)

Art. 67(3) and (4) of the BPR

Information regarding the active substance that can be contained in the PAR

- ✓ 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 (Art. 67(3)(a) of the BPR)
- ✓ Study summaries or robust study summaries of studies submitted to support the approval of the active substance (Art. 67(3)(b) of the BPR)
- ✓ Other information contained in the safety data sheet (Art. 67(3)(c) of the BPR)
- ✓ Trade name(s) of the substance (Art. 67(3)(d) of the BPR)
- ✓ Assessment report (Art. 67(3)(e) of the BPR)

Information regarding the biocidal product

- ✓ Study summaries, or robust study summaries, of studies submitted to support the biocidal product authorisation (Art. 67(4)(a) of the BPR)
- ✓ Assessment report (Art. 67(4)(b) of the BPR)

9 Annex 3: Practical examples

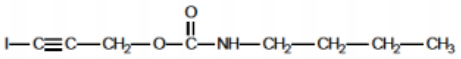
The examples are organised by specific categories of information under the BPR. These examples are not exhaustive.

9.1 Examples of information that must be disseminated

9.1.1 ISO name and name in the International Union of Pure and Applied Chemistry (IUPAC)

According to Art. 67(1)(a) of the BPR, where available, the ISO name and the name in the IUPAC shall be made publicly and easily available.

2.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	IPBC, 3-Iodo-2-propynyl butyl carbamate
IUPAC or EC name	3-Iodo-2-propynyl butyl carbamate
EC number	259-627-5
CAS number	55406-53-6
Index number in Annex VI of CLP	616-212-00-7
Minimum purity / content	980 g/kg
Structural formula	

9.1.2 Acceptable exposure level or predicted no-effect concentration

According to Art. 67(1)(f) of the BPR, the acceptable exposure level or predicted no-effect concentration established in accordance with Annex VI of the BPR shall be made publicly and easily available.

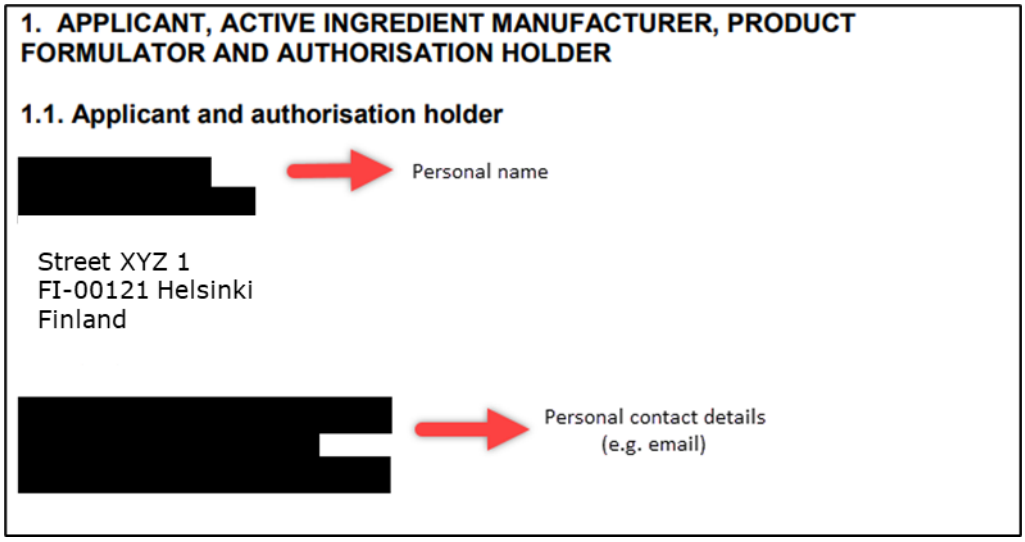
PNEC values used for risk characterisation			
	Iodine (I_2)	**Iodate (IO_3^-)**	**Iodide (I^-)**
$PNEC_{STP}$ (µg iodine/L)	2900	-	-
$PNEC_{surface\ water}$ (µg iodine/L)	0.59	58.5	0.83
$PNEC_{sediment}$ (mg iodine/kg wwt)	Covered by surface water		
$PNEC_{soil}$ (mg iodine /kg wwt)	0.0118	0.304	0.0043

9.2 Examples of information deemed confidential

9.2.1 Personal data

The processing of personal data by EU Institutions, bodies and agencies is governed by Regulation (EU) 2018/1725. According to Article 5(1) of that Regulation the processing of personal data shall be lawful only if and to the extent that at least one of the conditions indicated therein applies. It is considered that none of the conditions referred to by that provision would apply in the context of dissemination under Article 67 of the BPR, unless otherwise demonstrated. Therefore, personal data which is not already publicly available should be redacted by default in the documents to be disseminated.

Personal name and personal contact details of the applicant



Names and addresses of persons involved in testing on vertebrates

According to Art. 66(2)(d) of the BPR, disclosure of information relating to names and adresses of persons involved in testing on vertebrates shall normally be deemed to undermine the protection of the privacy or safety of the persons concerned.

List of studies for the biocidal product

Author(s)	Year Report date	Reference No. *(Annex III requirement)*/IUCLID Section No.	IUCLID Document name	Title. Report No.	Type of publication	Source (where different from company) Study sponsor	GLP (Yes/No)	Data Protection Claimed (Yes/No)
[redacted]	2021	Annex III – 6.7 / IUCLID 6.7	6.7-1_ 2021_Trial 1	Efficacy evaluation of Product A against roof rat (*Rattus rattus* L.) 2021.XYZ.1	Report	Laboratories XYZ	Y	Y
[redacted]	2021	Annex III – 6.7 / IUCLID 6.7	6.7-2_2021_Trial 2	Efficacy evaluation of Product A against roof rat (*Rattus rattus* Berk.) 2021.XYZ.2	Report	Laboratories XYZ	Y	Y

9.2.2 Precise tonnage information

According to Art. 66(2)(b) of the BPR, the disclosure of the precise tonnage of the active substance or biocidal product manufactured or made available on the market shall normally be deemed to undermine the protection of the commercial interests of the persons concerned.

Calculation of PEC_{stp} and $PEC_{surface\ water}$

		[redacted] Tonnage approach	Consumption approach		
Parameters	Nomenclature	[redacted]	Value	Unit	Origin
Effluent discharge rate of STP	EFFLUENT T_{stp}	[redacted]	2000000	L	Default
Concentration in untreated wastewater	$Clocal_{inf}$	[redacted]	1.38	mg/l	Output

9.2.3 Details of the full composition of the product

According to Art. 66(2)(a) of the BPR, the disclosure of the information related to the details of the full composition of the product is deemed to undermine the protection of the commercial interests of the authorisation holder.

In this example, the name of the wrapping component which forms part of the product has been blanked.

Composition and formulation

The capsule suspension Product A contains the active substance Margosa Extract.

The active substance is encapsulated in a wrapping component ([redacted]) which is intended to crack open during use of the treated articles (household textiles, feathers or down) thereby releasing the active substance.