ECHA
EUROPEAN CHEMICALS AGENCY

Dissemination and Confidentiality under the REACH Regulation

January 2024

ABC

Changes to this document

Version	Changes
11.0	Updated for ECHA CHEM
10.0	
9.0 (May 2023)	Update of outdated links and minor sentence clarifications.
8.0	Information on assigning a Third-party representative in REACH-IT and IUCLID and the new quality check introduced to the validation assistant.
7.0	Simplified confidentiality flags, the new flag option is 'CBI'. Previous option: 'IP' and 'no PA' removed.
6.0 (April 2021)	Updated information on publication of Legal Entity Details and Tonnage band calculation
5.0 (October 2020)	Updated for IUCLID v5.0.0 New section on Expiry of Validity Updated information on the publication and confidentiality of Characterisation parameters of nanoforms
4.0	Updated for IUCLID web interface
3.0	Updated for IUCLID v3.0.0
2.0	Updated for IUCLID v2.0.0
1.0	First version

Disclaimer

This document aims to assist users in complying with their obligations under the REACH Regulation. However, users are reminded that the text of the REACH Regulation is the only authentic legal reference and that the information in this document does not constitute legal advice. Usage of the information remains under the sole responsibility of the user. The European Chemicals Agency does not accept any liability with regard to the use that may be made of the information contained in this document.

Title: Dissemination and Confidentiality under the REACH Regulation

Reference: ECHA-16-B-19-EN
ISBN: 978-92-9495-010-9
Cat. Number: ED-04-16-349-EN-N
DOI: 10.2823/634249
Publ.date: January 2024
Language: EN

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1. Introduction and Legal Basis

1.1. Introduction

In accordance with Articles 119(1) and (2) of the REACH Regulation, the European Chemicals Agency (ECHA) is required to publish information it holds on registered substances (whether on their own, in mixtures or in articles) free of charge on the internet. The information is published on the ECHA Chemicals Database website (ECHA CHEM).

However, in certain cases information can be withheld, if the registrant 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 registrant or any other party concerned. Such justifications are assessed by ECHA in accordance with Article 119(2), and where the justification is accepted as valid by ECHA, the information concerned is not published. Requesting information as confidential may be subject to a fee.

ECHA will publish each submitted dossier separately, based on the confidentiality flags set in that dossier and taking into account any confidentiality claim assessments. Each published dossier will clearly show, where a piece of data is not published.

ECHA will publish per substance a dashboard page to act as the entry point for data on that substance. Substance identity data will be collated from all available sources; therefore unless substance identifiers are requested to be kept confidential in all submissions and in all sources, they will be published. In practice this could mean that if a confidentiality request was accepted on the substance name, the information may still be published if substance identification information is considered public via other public ECHA data sources, such as a notification in the C&L Inventory, in the list of Harmonised Classification & Labelling, or any other regulatory source.

Where urgent action is essential to protect human health, safety or the environment, such as emergency situations, ECHA may disclose information which would normally be considered confidential, in accordance with Article 118(2) of the REACH Regulation.

This manual provides information about the online access to information on chemical substances for which a dossier has been registered under REACH as well as information on the content and assessment of confidentiality requests. Its aim is to help companies to understand:

- what are the steps of the publication process;
- which information is made publicly available on the ECHA Chemical Database website;
- how to make a confidentiality request, prepare a justification and the basic procedure ECHA follows to assess such requests.
- In addition, this document advises industry on how to derive a public name for a substance for which the IUPAC name is requested confidential in accordance with Article 10(a)(xi) of the REACH Regulation, as explained further in Annex 1.

1.2. Legal Basis

Publication of information from Registration Dossiers and the assessment of the confidentiality of information is carried out by ECHA in accordance with Article 119 of REACH, as amended by Article 58(7) of the CLP Regulation:

REACH Article 119(1)

The following information held by the Agency on substances whether on their own, in mixtures or in articles, shall be made publicly available, free of charge, over the Internet in accordance with Article 77(2)(e):

a. without prejudice to paragraph 2(f) and (g) of this Article, the name in the IUPAC nomenclature for substances fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008:
    i. hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F;

    ii. hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10;

    iii. hazard class 4.1;

    iv. hazard class 5.1;

b. if applicable, the name of the substance as given in EINECS;
c. the classification and labelling of the substance;
d. physicochemical data concerning the substance and on pathways and environmental fate;
e. the result of each toxicological and ecotoxicological study;
f. any derived no-effect level (DNEL) or predicted no-effect concentration (PNEC) established in accordance with Annex I;
g. the guidance on safe use provided in accordance with sections 4 and 5 of Annex VI;
h. analytical methods if requested in accordance with Annexes IX or X which make it possible to detect a hazardous substance when discharged into the environment as well as to determine the direct exposure of humans.

REACH Article 119(2)

The following information on substances whether on their own, in mixtures or in articles, shall be made publicly available, free of charge, over the Internet in accordance with Article 77(2)(e) except where a party submitting the information submits a justification in accordance with Article 10(a)(xi), accepted as valid by the Agency, as to why such publication is potentially harmful for the commercial interests of the registrant or any other party concerned:

a. if essential to classification and labelling, the degree of purity of the substance and the identity of impurities and/or additives which are known to be hazardous;
b. the total tonnage band (i.e. 1-10 tonnes, 10-100 tonnes, 100-1000 tonnes or over 1000 tonnes) within which a particular substance has been registered;
c. the study summaries or robust study summaries of the information referred to in paragraph 1(d) and (e);
d. information, other than that listed in paragraph 1, contained in the safety data sheet;
e. the trade name(s) of the substance;
f. subject to Article 24 of Regulation (EC) No 1272/2008, the name in the IUPAC nomenclature for non-phase-in substances referred to in paragraph 1(a) of this Article for a period of six years;
g. subject to Article 24 of Regulation (EC) No 1272/2008, the name in the IUPAC nomenclature for substances referred to in paragraph 1(a) of this Article that are only used as one or more of the following:
    i. as an intermediate;

ii. in scientific research and development;

iii. in product and process orientated research and development.

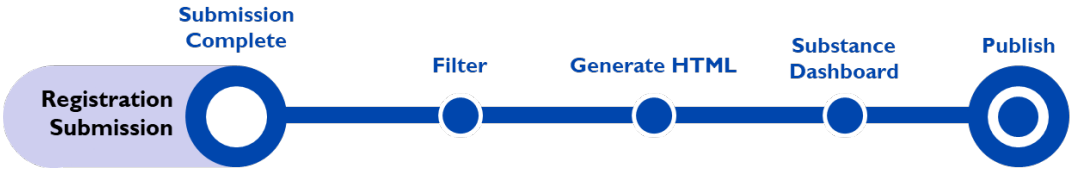
The information listed under REACH Article 119(1) is always published, regardless of whether a registrant attempts to request this information confidential. Hence, any confidentiality requests on this information are disregarded and no fee is incurred. Additionally, the information listed under REACH Article 119(2) is published unless a confidentiality request has been submitted and accepted as valid, and the relevant fee paid if applicable.

2. Publication

2.1. Publication Process

The Publication Process consists of several steps as illustrated in Figure 1 before resulting in the publication of detailed information on chemical substances from REACH Registration Dossiers on the ECHA CHEM website.

Figure 1: The publication process



2.1.1. Submission Complete

The process of publishing information from a registration dossier starts as soon as the submission in REACH-IT is complete and successful. In the case of an initial submission, the registrant is informed of their registration number via the registration decision letter. The completeness of the registration covers the technical completeness check (TCC) and the payment of the registration fee and confidentiality fees (if any). Once a submission is complete, the associated dossier is picked up for publication and enters the publication workflow.

All complete successful submissions are eligible for publication. Publication of the data from a submitted dossier will take place as soon as technically possible after the successful completion of the submission process.

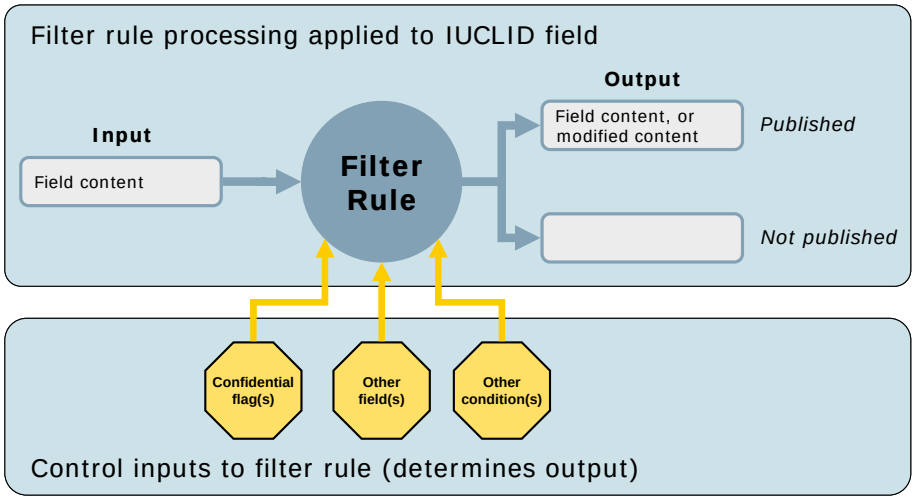
2.1.2. Filtering

The most important step in the publication process is the filtering step in which information not meant to be published is removed from the dossier, along with information flagged or requested to be confidential (Figure 2).

The filtering of registration dossiers is performed applying an IT tool, which has been programmed with Filter Rules. Filter Rules are based on REACH Article 119(1) and (2) and are applied to each field in the IUCLID registration dossier determining whether the field content should be published or not. Dossier filtering is an automated process and it is independent of which text you provide in a certain field, therefore, it is important to review your dossier before submission. If confidential information (e.g. legal entity name) is provided in a field which is set to be published (e.g. the guidance on safe use), **the information will become visible on the internet**.

Information contained in Notifications of New Substances under Directive 67/548/EEC (so called NONS) is published with reduced set of information, as described further in chapter 2.5.

Figure 2: Filter Rules



After the filtering step, the filtered dossiers are processed to create a set of HTML web pages.

2.1.3. Generate HTML

After the filtering step, each filtered dossier is processed to create its set of HTML web pages. This step generates the standard IUCLID table of contents tree, and all relevant pages and data as passed through the filtering step. The HTML generation step will also take into account both the original data provided and the data removed during filtering, to transparently indicate to users whether every single possible element in IUCLID was provided or not, and if it was removed an indication as to why.

2.1.4. Substance Dashboard

Either:

An existing substance dashboard is prepared to accept publication of the HTML version of a dossier, or where relevant:

A substance dashboard is generated and published for the first time, and prepared to accept publication of the HTML version of a dossier.

2.1.5. Publication and ECHA website

Detailed information on chemical substances for which ECHA has received a REACH registration dossier is made available on the ECHA CHEM website. The information is published from all registration dossiers, which have received a registration number; full registrations, registrations of on-site isolated intermediates and registrations of transported isolated intermediates. Information is published from all registrants; joint submission leads, joint submission members, and individual registrants. Since Notifications under Directive 67/548/EEC (NONS) are considered registrations under the REACH regulation, the information from these notifications is also published.

The most recent version of the dossier submitted to ECHA is published and consequently information from a dossier update replaces information from the previous one. Therefore, in case a registrant requests some information confidential, special care should be taken

to ensure that precisely the same confidentiality requests are selected in the updated dossier as were selected in the original submission unless the registrant no longer wishes to request a piece of information confidential, as explained in chapter 3.3.2.

Information on chemicals can be accessed via the ECHA website; information from REACH registrations will be published on the ECHA CHEM website. Note that both websites will operate in parallel during a transition period, while we work to migrate datasets to the ECHA CHEM website. Bear in mind this means that both websites may need to be consulted during this transition period.

In both the ECHA website and ECHA CHEM you can search for a substance by its substance identifier (e.g. substance name, EC/List number or CAS number). Any substance identifier of any kind can be used to find substances. Numerical identifiers such as the EC number or CAS. Registry Number® will tend to give a smaller set of matching results.

2.2. eChemPortal

In addition, ECHA is a key collaborator in the development of **eChemPortal** software and hosting, working in cooperation with the OECD and other international regulatory institutions. eChemPortal provides free public access to information on properties of chemicals, allowing simultaneous searching of reports and datasets by chemical name, number and by chemical property. Direct links to collections of chemical hazard and risk information prepared for government chemical review programmes at national, regional and international levels are obtained. Classification results according to national/regional hazard classification schemes or to the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) are provided when available. In addition, eChemPortal provides also exposure and use information on chemicals.

As part of ECHAs collaboration, the published detailed information on chemicals from REACH registration dossiers is linked to eChemPortal. **NB:** Note that eChemPortal is connected to the legacy REACH registered substance factsheets on the ECHA website, which are frozen as of 19th May 2023. eChemPortal is not yet connected to the new ECHA CHEM data.

2.3. QSAR toolbox

ECHA is also a key contributor to the development of the **QSAR Toolbox** software. The same detailed published data on chemicals from REACH registration dossiers is extracted and processed to populate the scientific data contained in the QSAR Toolbox. All dossier files per substance are processed, and key data is extracted to allow QSAR modelling of chemical properties, using from the combined dossier data the chemical properties such as physicochemical, environmental, ecotoxicological and / or toxicological properties. More information on the QSAR Toolbox is available here: http://echa.europa.eu/support/oecd-qsar-toolbox.

2.4. IUCLID Dissemination preview tool

ECHA has developed a tool to enable registrants to simulate which information from their registration dossiers is likely to be removed before publication over the internet, and which information will be made publicly available.

The IUCLID Dissemination preview tool allows registrants to use it while they are preparing their registration dossiers. The purpose of the tool is to help registrants to prepare dossiers that can be published without revealing business-confidential information, therefore it is strongly recommended to use the tool before submitting the registration dossiers, to simulate which

information from the dossiers is published by ECHA. The tool also produces a report, listing for all information whether it was removed or left in the filtered dossier.

The IUCLID Dissemination preview tool is by default installed with IUCLID 6. For detailed description on how to launch the tool, and how to read its output see the Help system built-in in IUCLID.

2.5. Publication and confidentiality of NONS

Before the REACH regulation entered into force companies notified 'new substances' under Directive 67/548/EEC, the so-called Notifications of New Substances (NONS) Directive. In accordance with REACH Article 24(1), NONS notifications are considered to be registrations under REACH. Therefore, the information contained in NONS is published. Confidentiality requests accepted under Directive 67/548/EEC remain valid under REACH, and no fee is incurred by such requests. In such circumstances, ECHA normally does not follow the regular assessment procedure, however, plausibility checks (such as if the information can be found in public domain) are still performed by ECHA and requests might be rejected on justified grounds.

For the case where confidentiality of the IUPAC name was requested under Directive 67/548, but the IUPAC information in the meantime is already available in the published EC Inventory (http://echa.europa.eu/information-on-chemicals/ec-inventory) or at any other publicly available source, ECHA assumes the request to be expired, unless the registrant provides a full justification that includes a valid reason why the information should still be kept confidential despite of the public availability.

Because:

- NONS were originally submitted with an earlier file format, which has been migrated to the IUCLID format by ECHA
- Many data elements have been added in IUCLID and many additional data completeness requirements were added under REACH
- Some data elements considered public under REACH were not public by default under Directive 67/548/EEC

Therefore NONS registrations are filtered with a more lenient filtering ruleset and will have in general less data published than corresponding REACH registrations.

NONS registrations remain entitled to these protections according to Directing 67/548/EEC. However:

2.5.1. Exceptions

When the quantity of the notified substance reaches the next tonnage threshold, and has underdone a **tonnage band update** in accordance with article 24(2), REACH filtering rules apply thereafter to any and all updates of the registration.

Where a NONS registration has been or is updated **containing a testing proposal** requiring a public consultation, REACH filtering rules apply thereafter to any and all updates of the registration.

If your dossier falls into one of these categories, it is thus necessary that you ensure that the dossier is suitable for publication and all necessary confidentiality requests are in place at the time of submission.

2.6. Information published under Article 119 of REACH regulation

2.6.1. General consideration

REACH registration dossiers are submitted to ECHA in the IUCLID format. The following paragraphs summarise which fields from a IUCLID dossier are published.

In cases where different IUCLID fields are suitable for providing certain information, this manual highlights the consequences of these options from the point of view of publication on the internet.

When preparing your own registration dossier take care to ensure that data you wish to keep confidential is flagged as such in every location where it occurs in your dossier. See chapter 3 for details.

When coordinating with other Joint Submission members align your confidentiality requests where necessary, to ensure that data which all members wish to keep confidential is so flagged in each separate members' registration dossiers; confidentiality requests are per registrant, per dossier, and per data element. If a confidentiality request is accepted as valid by ECHA then the information is kept confidential only from the specific registration dossier and the specific data element for which the request is accepted. Thus, there is nothing preventing the data appearing on the ECHA website, from a different location in the same dossier, or from the dossier of another registrant who did not request the data confidential.

2.6.2. General Information (IUCLID section 1)

2.6.2.1. Identification (IUCLID section 1.1)

2.6.2.1.1. EINECS name

The EINECS name of the substance – if one exists –is always published. Additionally, any other data already made public in the EC Inventory, such as the EC and CAS numbers are considered linked to the EINECS name and are also published. This EC Inventory information is always published where an EINECS name exists. The description of the substance provided by the registrant is not published.

A correct listing of the substance name and EC number on the ECHA website depends on a correct definition of the substance name and EC number in the registration dossier, especially for multi-constituent substances. To avoid mistakes when entering the substance identity, the registrants are advised to use the predefined IUCLID “Reference substance” for their substance, by uploading it in section 1.1 Identification. Predefined Reference substances can be obtained:

- from the EC inventory for EINECS substances, available at https://iuclid6.echa.europa.eu/support;
- from http://iuclid.eu/index.php?fuseaction=home.ecinventory&type=public for pre-registered substances without an EINECS number, which were assigned a list number by ECHA; or
- from the IUCLID extract sent to you by ECHA following your inquiry.

2.6.2.1.2. IUPAC Name

Confidentiality Request under Article 119(2)(f) and (g), IUPAC name: see chapter 3 for details.

The IUPAC name of the substance is published unless the registrant has requested its confidentiality. For further information about the conditions for requesting confidentiality and on placing the confidentiality flag on the IUPAC name see chapter 3.5.

Where requested confidential, the IUPAC name also covers the names of the Legal Entity Composition constituents provided in IUCLID section 1.2, to cover the case of multi-constituent substances or reaction masses.

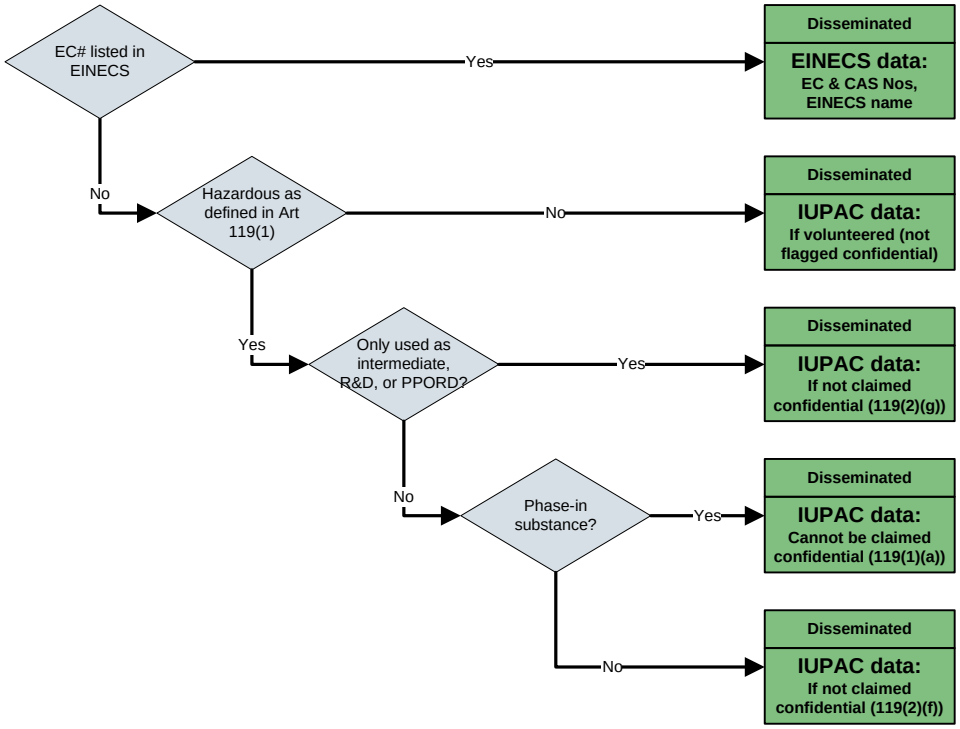
A number of fields related to the IUPAC name, or which can easily be deduced from it, such as the EC information for non-EINECS substances, CAS number, synonyms, molecular formula, molecular weight range, SMILES notation, InChI code and structural formula are considered linked to the IUPAC name. These fields are published only if the IUPAC name is published.

While assessment of a confidentiality request is ongoing, the IUPAC related information is removed from the dossier. In case the confidentiality request is rejected or found inadmissible (see chapter 3.6.6.) the presence of the confidentiality flag on IUPAC name in IUCLID section 1.1 or only in IUCLID section 1.2 on one or more constituents plays an important role in terms of publication of the information on substance constituents:

In both scenarios all IUPAC name information provided in section 1.1 is published. Information on constituents in section 1.2 is maintained as confidential ONLY if the constituents were also flagged confidential. In such case registrants are informed – at the time the IUPAC name request is rejected or found inadmissible – that should they wish to protect any of the constituents, they are advised to place flag(s) on the constituents in IUCLID section 1.2.

In line with the REACH text, for substances which are not listed in EINECS and which are not dangerous, the registrant can choose whether they want the IUPAC name of the substance published or not. For how to proceed with such requests, see chapter 3.6.6.

Figure 3: Flowchart to determine if the IUPAC data of a registered substance could be published



Note that substance identity confidentiality is affected by public data from every legislation and regulatory process handled by ECHA; therefore, if a substance or its IUPAC name is published in any non-confidential source the substance is considered public likewise in the context of REACH registrations.

2.6.2.1.3. Legal Entity Details

Confidentiality Request under Article 119(2)(d), other information in the safety data sheet: see chapter 3 for details.

For manufacturers and importers, the legal entity name is published unless it is requested confidential as it is considered information contained in the safety data sheet.

Only Representatives (ORs) do not necessarily supply the substance and they have the possibility to indicate in section 1.7 of the IUCLID dossier their actual suppliers (importers). The identity of the ORs is published unless requested confidential, or unless suppliers are listed in IUCLID section 1.7 whose identity is not requested confidential.

If the OR chooses to have the supplier's name published instead of their own, the OR has to obtain and attach in IUCLID section 1.7 the agreement by the supplier for the publication of their legal entity name.

In all cases, the fields that are published are the legal entity name and the full address unless the confidentiality request has been accepted. Table 1: Legal Entity publication provides an overview of the data to be published.

The name of a Third Party Representative (TPR), if provided, is not published.

Table 1: Legal Entity publication

Role in Supply Chain	Legal Entity Flag in 1.1	Supplier(s) present in 1.7	Suppliers all flagged as confidential in 1.7	Information published
Manufacturer, Importer	No	NA	NA	Manufacturer / Importer LE name & full address (taken from the REACH-IT account)
Manufacturer, Importer	Yes	NA	NA	[Confidential]
Only representative	No	No	NA	Only representative LE name & full address (taken from the REACH-IT account)
Only representative	No	Yes	Yes	Only representative LE name & full address (taken from the REACH-IT account)
Only representative	No	Yes	No	Only representative (No publishable name)
Only representative	Yes	NA	NA	[Confidential]

2.6.2.1.4. Other substance identifiers

Confidentiality Request under Article 119(2)(e), Trade name: see chapter 3 for details.

Trade name

In case disclosure of the trade name(s) together with the other information available on ECHA's website such as substance properties and/or company information may cause potential harm to

legitimate commercial interests of the registrant, the trade name(s) can be requested to be kept confidential.

Other identifier types

All other identifiers are considered volunteered. These entries, including 'Other' types of identifiers, are published unless they are flagged confidential, with the exception of the CAS name and Alternative name to CLP (not published) and the UN name/number (always published).

2.6.2.1.5. Competent Person responsible for the Safety Data Sheet

In the first version of ECHA CHEM, information on the competent person responsible for the safety data sheet is not published to avoid linking between dossier and company name.

2.6.2.2. Composition (IUCLID section 1.2)

The field 'Type of composition' allows registrants to indicate more precisely the nature of the composition they have provided. The fieldis automatically populated with the value 'legal entity composition of the substance' during migration from IUCLID 5 to IUCLID 6 or by creation of a new section 1.2 composition record. Other composition types available in IUCLID 6 are 'boundary composition of the substance', and 'composition of the substance generated upon use'.

2.6.2.2.1. Legal entity composition

This type of composition is expected to reflect the composition of the registered substance as manufactured or imported by the registrant.

Name

The composition name is published unless there is a confidentiality request on the IUPAC name of the registered substance.

Constituents

The identity of each constituent is published unless there is a confidentiality request on the IUPAC name of the registered substance.

2.6.2.2.2. Boundary composition of the substance and Composition of the substance generated upon use

'Boundary compositions' and 'Composition of the substance generated upon use' is considered volunteered for publication, unless the relevant confidentiality flags are set.

Name

The composition name is published unless there is a constituent in the composition that has been flagged as confidential (either above or within the constituent reference substance).

Constituents

The identity of each constituent is published unless there is a constituent in the composition that has been flagged as confidential (either above or within the constituent reference substance).

2.6.2.2.3. Degree of purity and identity of the dangerous impurities and/or additives

Confidentiality Request under Article 119(2)(a), Degree of Purity or Identity of Impurities: see

chapter 3 for details.

In IUCLID Section 1.2, the degree of purity and the identity of the impurities and additives need to be provided. The registrant needs to indicate for each impurity or additive whether it is considered relevant for the classification and labelling of the substance (i.e. dangerous).

The degree of purity of the substance is published if at least one of the impurities or additives is marked as relevant for the classification and labelling, unless the registrant requested the degree of purity as confidential.

The identity of the impurity or additive is published if the impurity or additive is considered relevant for the classification and labelling of the substance, unless the registrant requested the impurity or additive as confidential.

The precise details of a composition are not published (typical concentration or concentration ranges).

Further, information on the physical state and form of the registered substance constitutes a part of the identification of the substance (previously in IUCLID 5 provided under section 2.1 – GHS). The information on state/form is published.

Other fields in the section 1.2 (e.g. description of composition, justification for deviations) are not published, as detailed in the IUCLID Dissemination preview tool.

2.6.2.2.4. Characterisation of nanoforms

Confidentiality Request under Article 119(2)(d), other information in the safety data sheet: see chapter 3 for details.

When the registered substance covers nanoforms, the characteristics relevant for the nanomaterial are reported in IUCLID section 1.2.

The characterisation parameters of nanoforms are considered to be information contained in the safety data sheet. The information is therefore published, in line with article 119(2)(d) of REACH, unless the registrant requested it confidential and ECHA accepted the request.

The characterisation parameters can be requested confidential separately by using the flags at the top of each header, as detailed in chapter 3.

Table 2: Information made public from the characterisation of nanoforms section in the IUCLID registration dossier

Characterisation of nanoforms IUCLID Composition record	
IUCLID dossier field	**Publication of the information**
Type of information reported	Always published
Name of nanoform	Unless confidential
Name of set of nanoforms	Unless confidential
Justification for reporting set of similar nanoforms	Never published
Attached information	Never published

Cross-reference	
Reason / purpose	Always published
Related information	Always published
Remarks	Never published
Shape	
Shape category	Unless confidential
Shape	Unless confidential
Pure shape	Unless confidential
Typical composition	Unless confidential
Composition range	Unless confidential
Shape description remarks	Never published
Justification for set containing multiple shape categories or shapes	Never published
Particle size distribution and range	
Shape category	Unless confidential
Percentile	Unless confidential
Typical value	Unless confidential
Range	Unless confidential
Percentile remarks	Never published
Typical length	Unless confidential
Range of length	Unless confidential
Typical lateral dimension 1	Unless confidential
Range of lateral dimension 1	Unless confidential
Typical lateral dimension 2	Unless confidential
Range of lateral dimension 2	Unless confidential
Typical aspect ratio	Unless confidential
Range of aspect ratio	Unless confidential
Particle size distribution and range additional information	Unless confidential
Fraction of constituent particles	Unless confidential
Crystallinity	
Structure	Unless confidential
Name	Unless confidential
Pure structure	Unless confidential
Typical composition	Unless confidential
Range (composition)	Unless confidential
Crystal system	Unless confidential
Bravais lattice	Unless confidential
Crystallinity description	Unless confidential
Specific surface area	
Typical specific surface area	Unless confidential
Range of specific surface area	Unless confidential
Typical volume specific surface area	Unless confidential
Range of volume specific surface area	Unless confidential
Skeletal density	Unless confidential

Specific surface area remarks	Never published
Surface functionalisation / treatment	
Surface treatment applied (Yes/No)	Always published
Does the set contain treated and non-surface treated nanoforms? (Yes/No)	Always published
Surface treatment name	Unless confidential
Order	Unless confidential
Surface treatment agent	Unless confidential
Typical weight-by-weight contribution	Never published
Range of weight-by-weight contribution	Never published
Surface treatment remarks	Never published
External layer	Unless confidential
Surface treatment description	Unless confidential
Percentage of coverage of particle surface	Unless confidential
Attached information document	Never published
Attached information remarks	Never published

2.6.2.3. Identifiers (IUCLID section 1.3)

Confidentiality Request under Article 119(2)(d), other information in the safety data sheet: see chapter 3 for details.

REACH Registration Number

The REACH registration number for each registrant is considered to be information contained in the safety data sheet and is therefore published in full unless requested confidential (Confidentiality on the registration number can be requested either in the IUCLID dossier header or in IUCLID section 1.3).

The REACH registration number is partially published where not requested confidential but where there is a confidentiality request on the legal entity name:

Table 3: Registration Number publication

Regulatory Programme Field	Registration Number Confidential	Legal Entity Confidential	What is published
REACH registration number	No	No	01-0000012345-67-0089
REACH registration number	No	Yes	01-0000012345-67-xxxx
REACH registration number	Yes	NA	[Confidential]
Anything else	NA	NA	-

2.6.2.4. Suppliers (IUCLID section 1.7)

See Legal Entity Details and Table 1: Legal Entity publication above.

2.6.3. Assessment approach (assessment entities) (IUCLID section 1.10)

From the Assessment approach main record, the public description of the approach to fate/hazard assessment is published.

From the specific assessment entity records, the related compositions and endpoint summaries linked, where present, are published.

Remaining information is published unless the assessment entity has been flagged as confidential, or there is a confidentiality request on the IUPAC name of the registered substance, or in the compositions the assessment entity relate to a constituent has been indicated as confidential.

2.6.4. Classification & Labelling and PBT assessment (IUCLID section 2)

2.6.4.1. Globally Harmonised System (GHS) (IUCLID section 2.1)

All the IUCLID fields in section 2.1 GHS are published, as detailed in the IUCLID Dissemination preview, except the substance name in case the registrant has requested the IUPAC name of the registered substance confidential and ECHA accepted the request, or there is a constituent that has been flagged as confidential in a related composition.

2.6.4.2. PBT assessment (IUCLID section 2.3)

Confidentiality Request under Article 119(2)(d), other information in the safety data sheet: see chapter 3 for details.

The information on the PBT/vPvB assessment is considered to be information contained in the safety data sheet. The information is therefore published, unless the registrant requested it confidential and ECHA accepted the request. This includes data from the endpoint study records and the endpoint summary.

The result of the PBT and vPvB assessment can be requested confidential using the flags at the top of each endpoint study record and the flag at the top of the endpoint summary.

From the endpoint summary of the PBT assessment: PBT status, justification and likely routes of exposure are published. From the endpoint study records most fields are published unless requested confidential. The first exception is the reference substance attached to the endpoint study record, which is published unless 1) the PBT endpoint is flagged confidential or 2) a flag is set in the reference substance or 3) the IUPAC name of the registered substance is requested as confidential or 4) a constituent is flagged confidential in a linked composition. The other exception is the remark for the assessed substance, which is not published.

Even if the dossier includes a PBT/vPvB assessment for more than one substance (e.g. for the substance itself and a degradation product), all the relevant endpoint study records are published.

When members of a joint submission include a PBT/vPvB assessment in their dossier, there are multiple PBT assessments available in the published substance dossier.

2.6.5. Manufacture, use and exposure (IUCLID section 3)

Sections 3.2, 3.3, 3.4 and 3.7 are not published. Section 3.7 used to form the sub-section 3.7.2 in IUCLID 5.

2.6.5.1. Use and exposure information (section 3.5)

Confidentiality Request under Article 119(2)(d), other information in the safety data sheet: see chapter 3 for details.

The section on use description is split into sub-sections to capture the lifecycle stage of a substance in a structured way. Each use is reported as a separate record.

Furthermore, each use record contains fields for the related exposure scenario indicated as a tab connected to the relevant use (previously in section 3.7.1 of IUCLID 5). The information on generic exposure potential is also incorporated into the life cycle description (previously in section 3.7.3 of IUCLID 5). Information on uses and certain elements related to exposure scenarios are considered information contained in the safety data sheet. This information is therefore published, unless the registrant requested it confidential and ECHA accepted the request.

Confidentiality can be indicated for the entire use information, in which case also the related exposure scenario is removed from publication. Alternatively, confidentiality can be requested only for the exposure scenario part.

2.6.5.2. Uses advised against (section 3.6)

Confidentiality Request under Article 119(2)(d), other information in the safety data sheet: see chapter 3 for details.

The section on uses advised against is split into sub-sections according to the different life cycle stages. Each use advised against is reported as a separate record.

Information on uses advised against is considered to be information contained in the safety data sheet. This information is therefore published, unless the registrant requested it confidential and ECHA accepted the request.

It is recommended to use the IUCLID dissemination preview tool to simulate how the information on uses is published.

2.6.6. Physical and chemical properties (IUCLID section 4), Environmental fate and pathways (IUCLID section 5), Ecotoxicological information (IUCLID section 6), & Toxicological information (IUCLID section 7)

Confidentiality Request under Article 119(2)(c), study or Robust Study Summaries: see chapter 3 for details.

2.6.6.1. Endpoint Study Records

Fields referring to results are always published as detailed in the IUCLID Dissemination preview, even if the endpoint study record is requested confidential. The IUCLID fields referring to results

contain information such as for example: indication of endpoint addressed, year and report date, test guideline, test results, remarks on results, etc.

Test material and identity of transformation products

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

- there is a confidentiality request on the IUPAC name of the registered substance, or
- the reference substance describing the material itself is flagged confidential, or
- the endpoint study record is flagged confidential.

Justification for type of information

Justification for type of information is always published if it forms part of the third party consultation for endpoint study records indicated as testing proposals.

For other types of information, the field is published unless:

- there is a confidentiality request on the IUPAC name of the registered substance, or
- 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 also 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.

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

> A number of IUCLID fields for Literature references are part of the result. The reference type (e.g. review article or handbook, other company data, etc.) determines which fields of the Literature reference are published, as detailed further in chapter 2.6.12.

2.6.6.2. Endpoint summaries

Certain information on the key values for chemical assessment is always published as detailed in IUCLID Dissemination preview, even if the endpoint summary is requested confidential. These fields include numerical and picklist values which are considered part of the results, the description of the key information, the mode of action analysis and the justification for classification or non-classification. Additional information from endpoint summaries is published if not requested as confidential.

The substances Brief Profiles also display information from the endpoint summaries. The publication of this information enables registrants to further explain their assessment approach and make more transparent the facts they consider relevant for the chemical safety assessment.

2.6.6.3. PNECs (Ecotoxicological Endpoint Summary)

The individual PNEC justifications, the discussion, and the conclusion on classification are not published. Otherwise, all other fields for PNECs in the endpoint study summaries of section 6 of a IUCLID dossier are published as detailed in the IUCLID Dissemination preview.

2.6.6.4. DNELs (Toxicological Endpoint Summary)

The individual DNEL justifications and comments, and the final discussion are not published. Otherwise, all other fields for DNELs in the endpoint study summaries of section 7 of a IUCLID dossier are published as detailed in the IUCLID Dissemination preview, including the assessment factors, most sensitive endpoint and the method used.

2.6.7. Note on (robust) study summaries

According to Article 3(28) of the REACH Regulation, a robust study summary means a detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study minimising the need to consult the full study report.

A study summary means a summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to assess the relevance of the study, according to Article 3(29) of the REACH Regulation.

Fields referring to (robust) study summaries are contained in the IUCLID endpoint study records in sections 4-7. Published endpoint study record fields are detailed in the IUCLID Dissemination preview.

There are fields which are not published, 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 result and a (robust) study summary. These fields are:

- **Confidential details on test material and Specific details on test material used for the study (confidential):** these fields should be used to provide information about the test material, which you consider confidential. Further information can be found in IUCLID.
- **Any other information on materials and methods including tables**: to guarantee the privacy of suppliers of animals and cages, please provide the name of your suppliers here.
- **Overall remarks**.

2.6.8. Analytical methods (IUCLID section 8)

The information to be provided in section 8 Analytical methods upon request by ECHA includes analytical methods if requested in accordance with Annexes IX or X of the REACH Regulation which make possible to detect a hazardous substance when discharged into the environment as well as to determine the direct exposure of humans. If requested by ECHA, then this information is published.

2.6.9. Guidance on safe use (IUCLID section 11)

Section 11 *Guidance on safe* use is published in its entirety.

- Be aware that if you write in this section information you wish to keep confidential, such as the legal entity name or address, **it will become visible over the internet**.
- Please do not write “see CSR” or “see attachment” in the fields of the guidance on safe use section, since the chemical safety report or other attachments are not published.

2.6.10. Assessment reports (IUCLID section 13)

Confidentiality Request under Article 119(2)(d), other information in the safety data sheet: see chapter 3 for details.

If a chemical safety assessment (CSA) was performed then the indication of this is published, including additional information on the parts contained in the chemical safety report (CSR) and the tool used to generate the CSA/CSR, unless requested confidential.

The chemical safety report itself is not published.

2.6.11. Total Tonnage Band

Confidentiality Request under Article 119(2)(b), Total Tonnage Band: see chapter 3 for details.

From the latest published dossier of each full registration, data is extracted for the last year reported, unless the tonnage band has been requested confidential. Data is not extracted from dossiers for intermediate registrations under REACH Articles 17 or 18.

The tonnage data extracted per dossier from section 3.2 of IUCLID is the manufactured + imported tonnage - tonnage directly exported – tonnage immediately used as intermediate.

Per substance, a total tonnage is calculated by summing the data from all full registration dossiers for that substance, except those for which the tonnage band is requested confidential. The exported tonnage, and the tonnage directly used as intermediate, are discounted from the manufactured and/or imported tonnage.

The total tonnage is then converted to a total tonnage band, which is published on the ECHA CHEM website, per substance, in the substance Dashboard > Dossiers > REACH Registrations area.

Example 1:

A substance with full and intermediate registrations, where no dossier has the tonnage band requested confidential. The total tonnage calculated from only the full registration dossiers is: 57 782 tonnes manufactured or imported. The published total tonnage band is then:

≥ 10 000 to < 100 000 tonnes

Example 2:

The same substance as above, but where one dossier has 50 000 tonnes directly exported. The total net tonnage is 7 782 tonnes manufactured or imported. The published total tonnage band is then:

≥ 1 000 to < 10 000 tonnes

Example 3:

The substance as the first, but this time all of the registrants with full registrations have requested their tonnage band confidential. The published total tonnage band is then:

Tonnage data confidential

Example 4:

A substance with one Full registration, which ceased manufacture, and two intermediate registrations which are active. The published total tonnage band is then:

Intermediate use only

Example 5:

A substance with one Full registration, whose registration status is inactive due to ceased manufacture, and two intermediate registrations, whose registration status is inactive due to ceased manufacture. The published total tonnage band is then:

Ceased manufacture

2.6.12. Publication of the Literature references

Table 4: Publication of the literature references outlines the publication of information from the literature references in the endpoint records of sections 4 to 7 of IUCLID. Table 5: Outcome for the publication of literature references' author, title and bibliographic source explains the publication criteria.

Table 4: Publication of the literature references

Reference	Information published
Reference Type	**Always published**
Title	**Published unless protected (see Table 5)**
Author	**Published unless protected (see Table 5)**
Year	**Always published**
Bibliographic source	**Published unless protected (see Table 5)**
Testing facility	**Never published**
Report no.	**Never published**
Study sponsor	**Never published**
Study no.	**Never published**
Report Date	**Always published**
Remarks	**Never published**
Attached documents	**Never published**
Other study identifier(s)	**Never published**
Attachments	**Never published**
Remarks	**Never published**

Table 5: Outcome for the publication of literature references' author, title and bibliographic source

Conditions				Outcome
Confidentiality request on the	**Confidentiality request on**	**Reference Type**	**Testing facility, Report no.,**	**Publication of author / title / bibliographic**

IUPAC name of the registered substance	endpoint record		Study sponsor, Study no.	source
Yes	Does not matter	Does not matter	provided or empty	No
No	Yes	blank “secondary source” “grey material” “study report” “company data”	provided or empty	No
No	Yes	“publication” “review article or handbook”	empty	Yes
No	No	“study report” “company data”	provided or empty	No
No	No	Does not matter	at least one of these provided	No
No	No	“publication” “review article or handbook” blank “secondary source” “grey material”	empty	Yes

The literature references’ author, title and bibliographic source are not published if the IUPAC name of the registered substance is requested confidential because the name of the substance is often included in the title of a reference. This is to be noted if ECHA rejects a confidentiality request on the IUPAC name.

3. Confidentiality Requests

3.1. Introduction

The IUCLID template allows registrants to set confidentiality request flags on information covered by REACH Article 119(2). For information that a registrant wishes to keep confidential, a confidentiality request must be submitted to ECHA.

For confidentiality requests relating to information covered by REACH Article 119(2) a fee is incurred and the request must be accompanied by a full justification. In such cases, the request is upheld only where the appropriate fee is paid, and the justification is accepted as valid by ECHA.

The fees for requesting information confidential depend on the item for which confidentiality is requested, the company size of the manufacturer or importer, and whether the registration is part of a joint submission or not.

Information listed in REACH Article 119(1) is published and confidentiality requests on this information are disregarded, and no fee is incurred.

Information that is not specifically covered by REACH Articles 119(1) or (2), if not flagged confidential, is considered to be volunteered for publication e.g. safety data sheet information for substances that do not require a safety data sheet (legal entity name, registration number etc.).

3.2. Information on Public Names

Following the entry into force on 01 December 2010 of the amendments to REACH by Article 58 of the CLP Regulation (Regulation (EC) No 1272/2008), a public name must be provided where the IUPAC name is requested confidential under Article 119(2)(f) or (g). ECHA can only consider a confidentiality request for the IUPAC name admissible and accept the request as valid if an adequate public name, and if applicable, a valid justification as to why two or three levels of masking are necessary, is provided. For guidelines on how to derive an adequate public name, see Annex 1 of this manual.

3.3. Confidentiality Requests in Joint Submissions and Dossier updates

3.3.1. Joint Submissions

If there is only one registrant of the substance, the registrant can make confidentiality requests according to their individual needs. For a joint submission, it is strongly recommended that all registrants involved in the submission engage in discussions with each other, and in particular with their lead registrant, to decide on which information shall be requested confidential by all registrants, since ECHA publishes dossiers in an aggregated form.

For information that is available in the dossiers of all the registrants of a joint submission (such as the IUPAC name of the substance), if they wish to request it confidential, all of the registrants involved should make a confidentiality request on this information.

Where the information is not provided in a member dossiers, only in the lead dossier on behalf of all the members of the joint submission (e.g. a study summary), only the lead registrant is required to set a confidentiality request in the dossier.

3.3.2. Dossier updates

When a dossier is updated, registrants should consider if they want to keep the previous confidentiality requests, in particular the confidentiality request on the tonnage band, which is entered at the dossier creation step, and is otherwise not available in the IUCLID substance dataset.

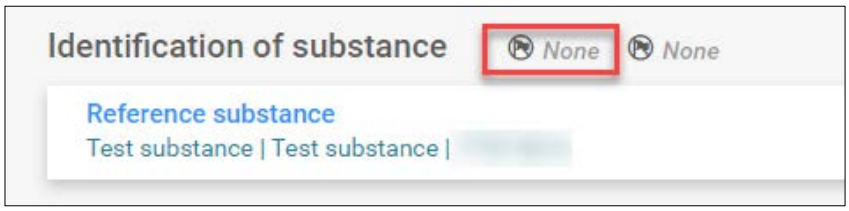
If the information is no longer wished to be kept confidential, the relevant flag should not be selected (for the tonnage band) or be removed. If additional information is wished to be requested confidential, the relevant additional confidentiality flag(s) should be selected. No fee is incurred for previously submitted requests – additional fee is incurred only if the registrant requests additional information falling under REACH Article 119(2) as confidential.

The most recent version of the dossier is the version, which is published by ECHA, and the confidentiality requests in this version are taken into account to determine which information to publish on the ECHA website. If a registrant omits confidentiality requests from a dossier update, this may result in information initially requested confidential being made public.

3.4. Making confidentiality requests

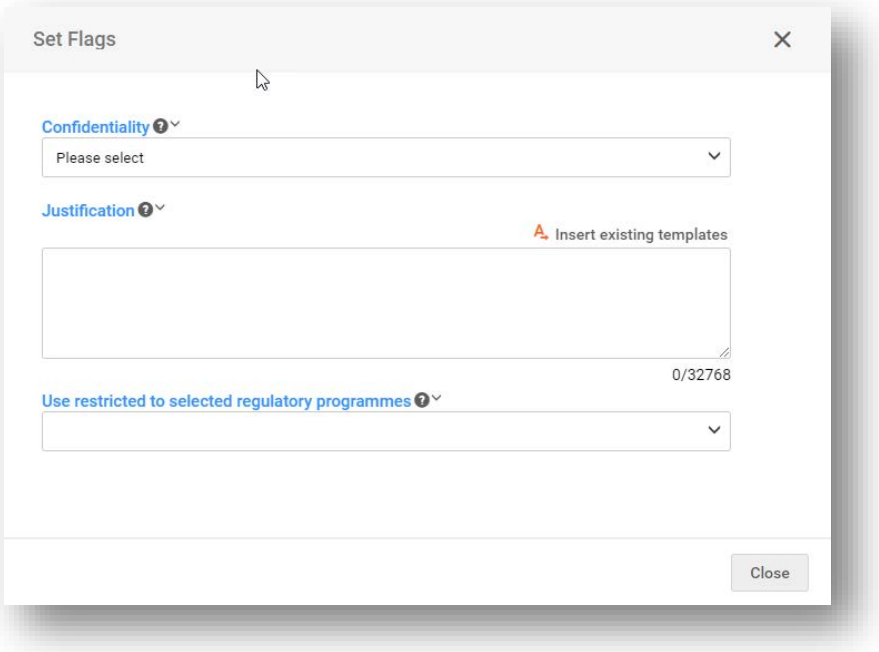
Where confidentiality can be requested in a IUCLID 6 dataset, there is a field for a confidentiality flag.

Figure 4: Example of an Unset Confidentiality Request Flag in IUCLID



To set a confidentiality flag, click on the flag icon, which opens the ‘set flags’ window.

Figure 5: Opening window in IUCLID to set a confidentiality flag

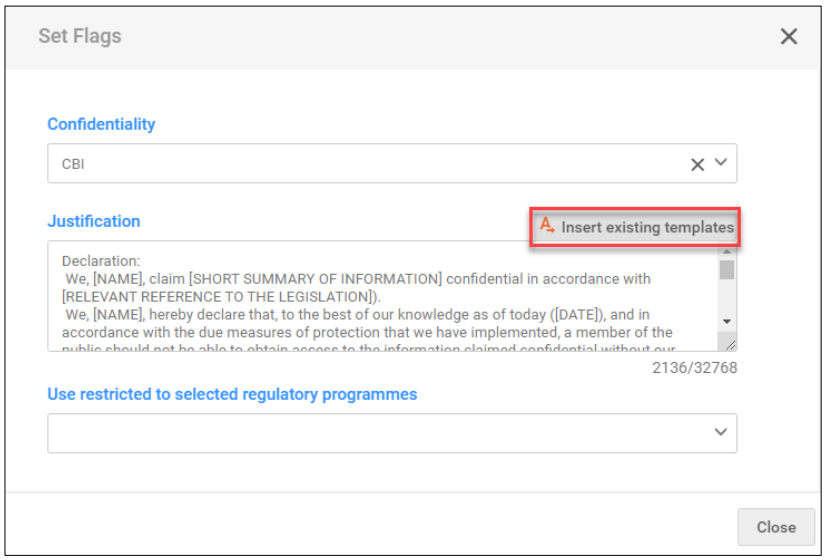


To set a confidentiality flag, click on the blank field under *confidentiality*. To request the information as confidential, you must select 'CBI-[confidential business information]'.

Enter the justification in the justification text box. For information falling under REACH Article 119(2) it is strongly recommended to use the justification template described in this document. This ensures that the justification contains all the necessary information to be assessed by ECHA.

Click on 'insert existing templates' to add the justification template and edit it. Make sure to delete irrelevant parts for the specific request type, e.g. delete the public name section if the request is not on the IUPAC name of the substance.

Figure 6: Justification template to be edited to fit the confidentiality request



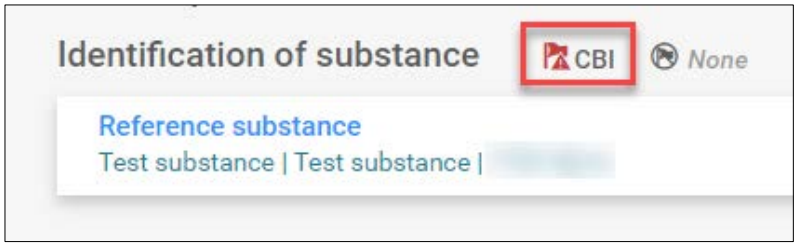
A justification may also be provided as an attachment, however, ensure that all the required elements are present. See chapter 3.7 for full instructions on justifications.

For information, not falling under REACH Article 119(2) it is suggested to enter a simple sentence as a justification next to the selected confidentiality flag, 'CBI-[confidential business information]'.

If confidentiality is flagged, the justification box cannot be empty, some text must be entered for requests in accordance with Article 119(2), otherwise the dossier is not accepted for processing by REACH-IT (i.e. business rule failure).

Once the confidentiality flag is selected on the 'set flags' window, the flag icon turns to red, and a warning triangle appears as well.

Figure 7: Example of a Set Confidentiality Request Flag



Once the confidentiality flag has been set, the information is regarded as having been requested confidential.

Within the 'set flag' window, it is possible to select if the use is restricted to selected regulatory programmes. This information does not affect requests for confidentiality.

In some cases, multiple flags are available in IUCLID to request confidentiality on the same information, see chapter 3.5.

3.5. Article 119(2) Confidentiality Request flags and fees

The table below lists for each request under Article 119(2) where the flag should be placed to request the information confidential. If a flag refers to information covered by REACH Article 119(2) a fee is incurred in accordance with Annex IV of the Fee Regulation, and the dossier containing the request is invoiced and processed accordingly. If a flag refers to information not covered by REACH Article 119(2), no fee is incurred.

Under the Fee Regulation, reduced fees are applicable for Medium, Small and Micro Enterprises, and for members of Joint submissions. A list of all IUCLID flags relating to information covered by REACH Article 119(2) along with the range of the potential fee is as follows:

Table 6: Confidentiality Request Flags and Fees for Information Covered by REACH Article 119(2)

Information Requested Confidential	Legal Basis	Fee	Location(s) of Confidentiality Flag(s) in IUCLID	Comment
If essential to classification & labelling, the degree of purity and identity of impurities or additives which are known to be hazardous	REACH Article 119(2)(a)	€183 to €4892	In Section 1.2 Degree of Purity is flagged and the checkbox 'this impurity/ additive is considered relevant for the classification and labelling of the substance' is selected for at least one Impurity/ Additive within the same composition. Impurity is flagged next to the Reference Substance and the checkbox 'this impurity is considered relevant for the classification and labelling of the substance' is selected for the same Impurity AND / OR Impurity is flagged inside a linked Reference Substance (either or both of the 'Reference	One single fee is calculated regardless of how many or which of the above flags in relation to a particular piece of information are selected. The fee is only calculated if the type of composition is 'legal entity composition'.

			Substance information' and 'Molecular and Structural Information' are flagged) and the checkbox 'this impurity is considered relevant for the classification and labelling of the substance' is selected for the same Impurity. Additive is flagged next to the Reference Substance and the checkbox 'this additive is considered relevant for the classification and labelling of the substance' is selected for the same Additive AND / OR Additive is flagged inside a linked Reference Substance (either or both of the 'Reference Substance information' and 'Molecular and Structural Information' are flagged) and the checkbox 'this additive is considered relevant for the classification and labelling of the substance' is selected for the same Additive.	
Tonnage Band	REACH Article 119(2)(b)	€61 to €1631	Dossier Header: Checkbox "Confidentiality claim on tonnage band" is selected and the dossier template is standard	No fee for tonnage band requests in dossiers for intermediates in accordance with article 17 or 18.
Study summary or robust study summary	REACH Article 119(2)(c)	€183 to €4892	Sections 4 – 7: Each study summary or robust study summary flagged confidential. NB: A study summary or robust study summary within the meaning of REACH Art 119(2)(c) is referred to as an "Endpoint Study Record" in IUCLID.	A separate fee is calculated for each (robust) study summary requested confidential.
Other information in the Safety Data Sheet – Life cycle description and Uses advised against	REACH Article 119(2)(d)	€122 to €3261 *	Sections 3.5.1 - 3.5.5: Confidentiality requests on any Identified Use. Sections 3.6.1 - 3.6.4: Confidentiality requests on any Use Advised against. Several records can be created on both uses and uses advised against and each of them can be requested as confidential separately.	* One single fee is calculated no matter how many flags in relation to request types falling under Art. 119(2)(d) are selected. The fee is invoiced for dossiers other than On-Site Isolated Intermediates (OSII) that require a Safety Data Sheet according to REACH Art. 31(1).
Other information in the Safety Data Sheet – Registration number	REACH Article 119(2)(d)	€122 to €3261 *	For initial submissions and dossier updates: Dossier header: Checkbox "Confidentiality claim on registration number" is selected. For dossier updates: Flag in Section 1.3 on "Regulatory programme identifiers" when "REACH registration number" is selected as programme identifier.	* One single fee is calculated regardless how many flags in relation to request types falling under Art. 119(2)(d) are selected. The fee is invoiced for dossiers other than On-Site Isolated Intermediates (OSII) that require a Safety Data Sheet according to REACH Art. 31(1).
Other information in the Safety Data Sheet – Legal entity information	REACH Article 119(2)(d)	€122 to €3261 *	Section 1.1: Flag next to Legal entity.	* One single fee is calculated no matter how many flags in relation to request types falling under Art. 119(2)(d) are selected. The fee is invoiced for dossiers other than On-Site Isolated Intermediates

				(OSII) that require a Safety Data Sheet according to REACH Art. 31(1).
Other information in the Safety Data Sheet – PBT assessment	REACH Article 119(2)(d)	€122 to €3261 *	Section 2.3: flag on the endpoint summary or Section 2.3: flag on each endpoint study record	* One single fee is calculated no matter how many flags in relation to request types falling under Art. 119(2)(d) are selected. The fee is invoiced for dossiers that require a Safety Data Sheet according to REACH Art. 31(1) and that require a chemical safety report (CSR).
Other information in the Safety Data Sheet – Exposure scenarios	REACH Article 119(2)(d)	€122 to €3261 *	Section 3.5.1 – 3.5.6: Confidentiality can be requested within the same record where the use is encoded: Contributing scenario for the environment (related to workers activities) Contributing scenario for the environment (related to consumer activities) Contributing scenario for the workers Contributing scenario for the consumers	* One single fee is calculated no matter how many flags in relation to request types falling under Art. 119(2)(d) are selected. The fee is invoiced for dossiers that require a Safety Data Sheet according to REACH Art. 31(1) and that require a chemical safety report (CSR).
Other information in the Safety Data Sheet – whether a Chemical Safety Assessment was performed	REACH Article 119(2)(d)	€122 to €3261*	Section 13.1: flag in section 13.1 and a file is attached to the field “Chemical safety report (CSR)”.	* One single fee is calculated no matter how many flags in relation to request types falling under Art. 119(2)(d) are selected. The fee is invoiced for dossiers that require a Safety Data Sheet according to REACH Art. 31(1) and that require a chemical safety report (CSR).
Other information in the Safety Data Sheet – article Service Life and Article Service Life advised against	REACH Article 119(2)(d)	€122 to €3261 *	Sections 3.5.6 and 3.6.5: Confidentiality requests on the Article Service Life and Article Service Life advised against.	* One single fee is calculated no matter how many flags in relation to request types falling under Art. 119(2)(d) are selected. The fee is invoiced for dossiers that require a Safety Data Sheet according to REACH Art. 31(1) and that require a chemical safety report (CSR).
Other information in the Safety Data Sheet – characterisation parameters of nanoforms	REACH Article 119(2)(d)	€122 to €3261 *	Sections 1.2: Flag on the Characterisation parameters of nanoforms: • Nanoform name; • Nanoform set; • Shape; • Particle size distribution and range; • Crystallinity; • Specific surface area;	* One single fee is calculated no matter how many flags in relation to request types falling under Art. 119(2)(d) are selected. The fee is invoiced for dossiers other than On-Site Isolated Intermediates

			• Surface functionalisation / treatment	(OSII) that require a Safety Data Sheet according to REACH Art. 31(1).
Trade name(s) of the substance	REACH Article 119(2)(e)	€61 to €1631	Section 1.1: Flag in table 'Other substance identifiers' if there is a confidentiality flag in a row with Name Type 'Trade name'.	One single fee is calculated for any trade name(s) requested.
IUPAC Name of non-phase in substances which are hazardous in one of the hazard classes listed in Article 119(1)(a)	REACH Article 119(2)(f)	€61 to €1631	Section 1.1: Flag next to the Reference Substance (preferred way of indicating a confidentiality request on the IUPAC name) Flags inside a linked Reference Substance (one or both flags: Reference Substance information; Molecular and Structural Information) Section 1.2: Constituents: Flag next to Reference Substance (preferred way of indicating a confidentiality concern on the identity of a constituent of a multi-constituent substance or UVCB. This flag is useful when confidentiality requests on the IUPAC name of the registered substance are inadmissible. Constituents / Reference Substances: Flags inside a linked Reference Substance (one or both flags: Reference Substance information; Molecular and Structural Information)	One single fee is calculated no matter how many flags from the list are selected. In addition, a fee is applicable only if (i) the substance is indicated as a non-phase-in substance, (ii) fulfils the criteria for any of the hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008 and (iii) it concerns a 'legal entity composition'. This request is only valid for a period of 6 years.
IUPAC Name of substances used as intermediates, and / or in scientific research, and / or in product and process oriented research and development if hazardous in one of the hazard classes listed in Article 119(1)(a)	REACH Article 119(2)(g)	€61 to €1631	Section 1.1: Flag next to the Reference Substance (preferred way of indicating a confidentiality request on the IUPAC name) Flags inside a linked Reference Substance (one or both flags: Reference Substance information; Molecular and Structural Information) Section 1.2: Constituents: Flag next to Reference Substance (preferred way of indicating a confidentiality concern on the identity of a constituent of a multi-constituent substance or UVCB. This flag is useful when confidentiality requests on the IUPAC name of the registered substance are inadmissible. Constituents / Reference Substances: Flags inside a linked Reference Substance (one or both flags: Reference Substance information; Molecular and Structural Information)	One single fee is calculated no matter how many flags from the list are selected. In addition, a fee is applicable only if (i) the substance fulfils the criteria for any of the hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008, (ii) it is indicated in the dossier that the substance is only used as an intermediate, in scientific research, or in product process oriented research and development and (iii) it concerns a 'legal entity composition'.

Confidentiality requests on the IUPAC name can be placed either in IUCLID Section 1.1 and/or 1.2. Although the publication tool makes no distinction whether a confidentiality request is set above or inside the reference substance, confidentiality flags should be set preferably ABOVE the reference substance, rather than INSIDE. This increases the visibility of the confidentiality request for staff assessing or working on the dossier.

The precise fees incurred for requesting the above information confidential, along with all other REACH related fees are available in the Annexes to Commission Regulation (EC) No 340/2008 (the Fee Regulation) at http://www.echa.europa.eu/web/guest/regulations/reach/legislation

(implementing legislation section).

3.6. Rationales for requesting information confidential under Article 119(2) and factors taken into account

3.6.1. Requests under Article 119(2)(a) – Degree of Purity or Identity of Impurities

Rationale for requesting the information confidential:

Disclosure of the degree of purity may have an effect on the competitive environment by giving competitors a direction for their research efforts. The identity of impurities (if identified by IUPAC name) may reveal details about the respective production process – including purification methods – or (if certain impurities are not present) may allow the determination of which production process has not been applied. Interest in keeping the identity of additives confidential may be based on their relevance to the function of the substance.

Table 7: Factors taken into account when requesting the information confidential under Article 119(2)(a)

Supporting Factors	Non-Supporting Factors
A risk to potentially suffer harm to the commercial interests is normally deemed to exist where confidentiality is requested by companies, in particular SMEs, operating in innovative niche markets, where the commercial existence of these operators would be at peril if the information were disclosed.	A higher number of registrations with a similar degree of purity normally means that effects on competition are lower.

For the publication rules see the corresponding paragraphs in Section 2.5 of this manual.

3.6.2. Requests under Article 119(2)(b) - Total Tonnage Band

Rationale for requesting the information confidential:

The exact volume in which a substance is manufactured / imported by a registrant is always confidential. However, if the market can be considered as relatively small (i.e. small number of competitors) a registrant may also have an interest not to disclose the tonnage band in which the substance is manufactured / imported, as this may give an indication to competitors to the size of the market for the substance, which would be otherwise unknown. Other competitors in the global market may also get access to tonnage information in the European market.

Table 8: Factors taken into account when requesting the information confidential under Article 119(2)(b)

Supporting Factors	Non-Supporting Factors
Small number of competitors (e.g. only two or three registrants within a joint submission where only one requests the tonnage confidential).	The possibility of potential harm associated with the disclosure of the total tonnage band is increasingly unlikely the more members are in a joint submission.
Tonnage band requested confidential is relatively precise (i.e. higher interest for confidential treatment if 1-10 tonnes, than if 100-1000 tonnes).	

As requests on the tonnage information are made by each registrant in the individual part of the registration dossier (and not for the joint submission as a whole), requests on the tonnage band are assessed by ECHA on their individual merit. This means that ECHA assesses whether the registrant requesting the tonnage information confidential can demonstrate that disclosure of the tonnage information could cause potential harm to their or a third party's commercial interest.

For the publication rules see the corresponding paragraphs in Section 2.5 of this manual.

3.6.3. Request under Article 119(2) (c) - Study or Robust Study Summaries

Rationale for requesting the information confidential:

Conducting studies constitutes a substantive financial investment by registrants. Further concerns may be based on the argument that publication of the information may lead to conflicts with existing intellectual property rights / licences granted by third parties.

Table 9: Factors taken into account when requesting the information confidential under Article 119(2)(c)

Supporting Factors	Non-Supporting Factors
Significant financial investment for the company concerned in relation to its turnover (e.g. if study has been conducted by an SME)	Testing proposal present on same endpoint (need for public consultation)
Clear conflict with existing intellectual property rights	Published study
Limited relevance of study summary for interpretation of result	High relevance of study summary for interpretation of result
	Study submitted in the framework of a registration at least 12 years previously

For the publication rules see the corresponding paragraphs in Section 2.5 of this manual.

3.6.4. Requests under Article 119(2)(d) – other information in the safety data sheet

Rationale for requesting the information confidential:

The information on the legal entity, the REACH registration number, uses, uses advised against, exposure scenarios, PBT/vPvB assessment, article service life, article service life advised against, indication on whether a chemical safety assessment was performed and the characterisation parameters of nanoforms is considered to be information contained in the safety data sheet which may contain data intended only for the direct customer, such as detailed indications regarding use. In some cases, disclosure of the information may also reveal links between registrants and his distributors or downstream users.

Table 10: Factors taken into account when requesting the information confidential under Article 119(2)(d)

Uses (Life cycle description)

Supporting Factors	Non-Supporting Factors
All registrants are requesting the information on the same uses confidential.	The use is already published on the ECHA website as it is a common use and other registrants did not request it confidential.
Uses related to scientific R&D or PPORD	General nature of description of use (e.g. no information on use, concentration and frequency of application)

Legal entity

Supporting Factors	Non-Supporting Factors
The registrant has appointed a third-party representative for data sharing purposes. [1]	Registrant is directly supplying the substance in a non-complex supply chain.
Registrant is not acting as a direct supplier (e.g. in case of toll manufacturing)	

Registration number

Supporting Factors	Non-Supporting Factors
The registration number is not fully available throughout the supply chain (e.g. distributors make use of the possibility to omit the last 4 digits on the safety data sheet).	Registration number is fully available on the safety data sheet throughout the supply chain

Exposure scenarios, PBT/vPvB assessment, indication on whether a Chemical Safety Assessment was performed, Article service life

Supporting Factors	Non-Supporting Factors
The information requested confidential in the registration dossier is not fully available throughout the supply chain.	Information requested confidential in the registration dossier is available throughout the supply chain and does not reveal business secrets.

For the publication rules see the corresponding paragraphs in Section 2.5 of this manual.

3.6.5. Requests under Article 119(2)(e) – Trade Name(s)

Rationale for requesting the information confidential:

Disclosure of the trade name together with the substance properties and/or company information may reveal market dealings between manufacturers / importers and their customers, in particular in combination with other information published on the ECHA website.

[1] In order to take this factor into account, you need to appoint the third-party representative (TPR) in REACH-IT, in both the Co-Registrants page and the Joint submission page. If you appoint a TPR only in IUCLID, the name of the registrant remains visible to your co-registrants in REACH-IT. To highlight this, we introduced a 'Quality check' (QLT230) that warns you when you run the validation assistant. This warning is to inform you that there are further tasks to be taken care of in REACH-IT. You can find further information on the ECHA website on how to appoint a TPR. A Q&A is available at https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/ids/1768.

Table 11: Factors taken into account when requesting the information confidential under Article 119(2)(e)

Supporting Factors	Non-Supporting Factors
Smaller markets, where links between the registrants and his distributors or downstream users could be easily established.	As trade names are generally public, harm through disclosure can normally not be established unless the registrant can demonstrate that disclosure of the trade name together with the other information available on ECHA's website may cause potential harm to his legitimate commercial interests.

For the publication rules see the corresponding paragraphs in Section 2.5 of this manual.

3.6.6. Requests under Article 119(2)(f) or (g) – IUPAC Name

Rationale for requesting the information confidential:

The rationale for making confidentiality requests on the IUPAC name lies mainly with the fact that the IUPAC name contains information on the chemical structure of a substance, from which competitors may receive valuable knowledge of a registrant's products.

Where the IUPAC name is requested confidential, a **public name must be provided** for publication. ECHA can only consider a confidentiality request for the IUPAC name admissible and accept the request as valid if an adequate public name, and if applicable, a valid justification as to why two or three levels of masking are necessary, is provided. A public name should be derived from the IUPAC name following the guidelines provided in Annex 1 of this manual – How to derive a Public Name for a substance for use under the REACH Regulation.

The transitional phase-in scheme of registering known substances ended on 31 May 2018, nonetheless the phase-in status of a substance is still relevant and must be declared if confidentiality is requested on the name of a non-phase-in substance.

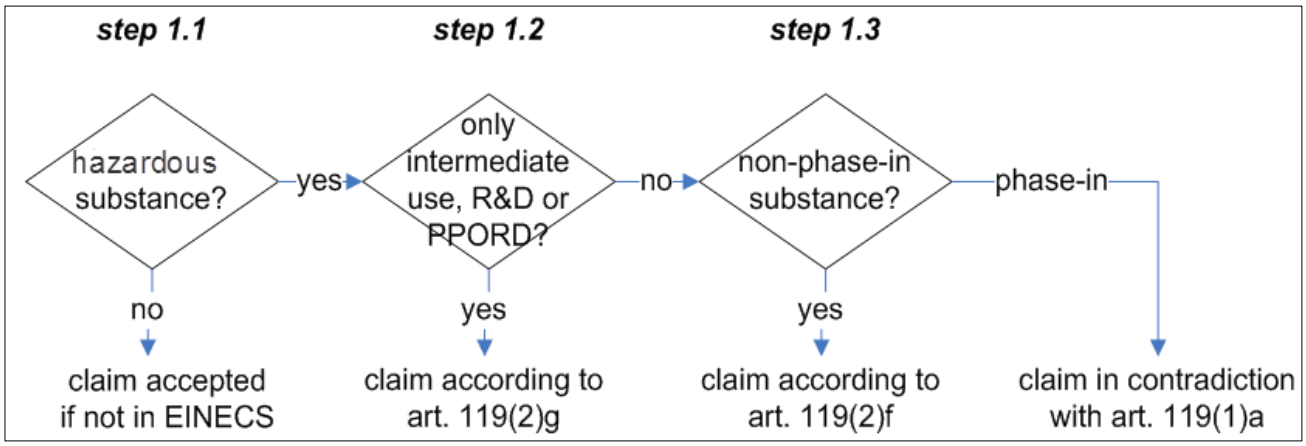
A substance is defined as phase-in if it meets at least one of the following criteria:

- It is listed in the European Inventory of Existing Commercial Chemical Substances (EINECS). [Substances with EC number starting with 2 or 3 are listed on EINECS.]
- It was manufactured/ imported in a Member State, but not placed on the market by the manufacturer or importer, between 1 June 1992 and 31 May 2007, provided that you have documentary evidence of this.
- It was placed on the market in a Member State before 1 June 2007 by the manufacturer or importer and it qualifies as 'no-longer polymer' (NLP), provided that you have documentary evidence of this. [Substances with EC number starting with 5 are NLP.]

Otherwise, your substance is a non-phase-in substance.

Regarding confidentiality flags on the IUPAC name ECHA distinguishes four cases:

Figure 8: Confidentiality of IUPAC name



a. Non-Hazardous substances (step 1.1.)

There are no provisions in REACH requiring publication of the name of substances, which are not classified in one of the hazard classes referred to in Article 119(1)(a) and not listed in EINECS. For these cases, the IUPAC name is published unless flagged confidential. In such case, ECHA does not incur a fee and a detailed justification does not need to be provided.

b. Requests on IUPAC name according to Article 119(2)(g) (step 1.2)

Confidentiality requests made on substances, which are classified in one of the hazard classes, referred to in Article 119(1)(a) and are used ONLY as an intermediate, in scientific research and development, in product and process orientated research and development fall within the scope of Article 119(2)(g) and can be kept confidential for an indefinite period.

ECHA checks the use as an intermediate (1) from the dossier template or (2) from the relevant uses section in IUCLID 3.5. It is important to note that ECHA may re-assess the validity of the request if ECHA has indications at a later stage that the substance has incorrectly been identified as an intermediate.

- Registrants can submit a PPORD dossier, which is not subject to publication when only uses for scientific research and development or product and process orientated research and development are relevant.
- When use in PPORD is submitted in a standard registration dossier, it should be clearly indicated in the Uses section (3.5) of IUCLID.

Since manufacturers and importers of polymers must submit a standard registration to ECHA for the monomer substance(s) the use “intermediate for polymer production” is not considered as “intermediate use” within the meaning of Article 119(2)(g).

c. Requests on IUPAC name according to Article 119(2)(f) (step 1.3)

Confidentiality requests made on substances, which are classified in one of the hazard classes, referred to in Article 119(1)(a) and are non-phase-in, fall within the scope of Article 119(2)(f) and can be kept confidential for a limited period of 6 years.

d. Inadmissible requests according to Article 119(1)(a)

Confidentiality requests made on the IUPAC name are considered as inadmissible if they neither fall in the scope of Article 119(2)(f) nor (g). E.g. if a hazardous substance is classified in one of the hazard classes listed in Article 119(1)(a) and has been registered as a phase-in substance, the conditions set out in Article 119(2)(f) are not fulfilled. When additionally the use information

provided in the registration dossier for such a substance indicates that the uses go beyond the sole use as an intermediate and/or in scientific research and development and/or in product and process orientated research and development, the conditions set out in Article 119(2)(g) are not fulfilled either.

Such substances fall in the scope of Article 119(1)(a), therefore the IUPAC name must be published on the ECHA website.

For details on how to set confidentiality flags on IUPAC name, see chapter 3.5 and for publication rules see chapter 2.5 of this manual.

Table 12: Factors taken into account when requesting the information confidential under Article 119(2)(f) and (g)

Supporting Factors	Non-Supporting Factors
A risk to potentially suffer harm to the commercial interests is normally deemed to exist where confidentiality on the IUPAC name is requested by companies, in particular SMEs, operating in innovative niche markets, where the commercial existence of these operators is at peril if the name was disclosed.	Existence of testing proposal in the dossier (public consultation needed): In particular, if testing proposals are contained in dossiers for phase-in substances, third parties are likely to hold information, which could be relevant. For non-phase in substances, usually only the registrant would hold the relevant information, and disclosure of the IUPAC name would bring less added value in this respect.
Higher need for protection in case of scientific R&D or PPORD. (PPORD dossiers are not publication at all.)	Determinations made under Article 24 of the CLP Regulation.

3.7. Confidentiality Request Justification

In general, the following points should be addressed in a confidentiality request:

- Statement explaining that this information point is requested confidential in accordance with article 119(2)(a), (b), (c), (d), (e), (f), or (g) of REACH
- Generic statement on the nature of the information requested confidential (to be used as the introduction to each request)
- Demonstration of the commercial interest / value worthy of protection – see case-by-case factors below
- Potential harm caused by the disclosure: potential impact on business (e.g. positive advantage to competitors). It is important to highlight the link and direct causality between the disclosure and the impact on business: see case-by-case factors in chapter 3.6.

For information, falling under REACH Article 119(1), any confidentiality request justification is disregarded, as such information is always published.

For information falling under REACH Article 119(2), confidentiality request justifications are recommended to be structured as below.

Justifications as to why disclosure of information listed in Article 119(2) may be potentially harmful to a registrant'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.

In line with the jurisprudence of the European Court of Justice regarding the definition of what may constitute confidential material and the definition of undisclosed information in Article 39(2) of the World Trade Organisation's Trade-Related Aspects of Intellectual Property Rights (TRIPS)

Agreement, a number of common principles can be derived. Thus, ECHA's understanding of what constitutes confidential information is based on the following elements:

- Only a limited number of people must know the information, i.e. it must not be in the public domain or general knowledge in the industry. Typically, the registrant or third party would have undertaken specific measures to keep the information secret.
- Requests must be properly reasoned rather than using a simple statement.
- The existence of a commercial interest must be demonstrated, i.e. the information must have some commercial value or legitimate commercial interests need to be at stake.
- Disclosure of the information must potentially harm a registrant's or a third party's commercial interests and there must be a causal link between publication of the information and the potential harm.

These principles should be reflected in a confidentiality request justification for ECHA to accept it as valid. Verification of whether all essential elements are present in a case and whether a request can be accepted as valid is performed by ECHA, as described in chapter 3.8.

As explained above, ECHA searches for certain elements in a confidentiality request justification on information falling under REACH Article 119(2). While all of the required elements described below should be present in a justification, the justification should not be a detailed essay or market study. The suggested guideline would be two to three sentences per element (below), and a maximum of one A4 page in total for the justification.

For information not falling under REACH Article 119(1) or (2), it is suggested to enter a simple sentence as a justification next to the selected confidentiality flag, 'CBI-[confidential business information]'.

3.7.1. Elements to be present in the justifications in general

ECHA assesses confidentiality requests made on information covered by REACH Article 119(2) solely on what is present in the confidentiality request justifications. Thus, it is important that justifications contain all the required elements and are well reasoned.

Table 13: Required elements for confidentiality request justifications

Required Elements	Description
Declaration that the information (in the form requested confidential) is not in the public domain or general knowledge in the industry with the registrant's permission	Confirmation that (to the registrant's best knowledge) a member of the public should not be able to obtain access to the information without the consent of the registrant or the third party whose commercial interests are at stake and that the information is not available in any of a pre-determined list of publicly available databases (See chapter 3.8). If a public authority made a determination as to the confidentiality of the information, the registrant should indicate the name of the authority, the reference no. of the decision/statement and briefly state the conclusion.
Demonstration that the registrant has a commercial interest worthy of protection for non-disclosure of the information	Description of the nature of commercial interest in non-disclosure (e.g. the information is a business or trade secret, confidential intellectual property, etc.) and why the registrant thinks this interest is worthy of protection. Description of the specific measures the registrant has taken to safeguard the confidentiality of the information and indication whether these measures will continue in the future.
Demonstration that disclosure of the information would cause potential harm to the commercial interest of	For each category of information requested as confidential, the registrant should explain with specificity why release of the information is likely to cause harm to his commercial interest. The specific nature of those harmful effects, and the causal

the registrant or a third party	relationship between disclosure and such harmful effects should be explained. The description should be clear, transparent and persuasive.

Table 14: Optional elements for confidentiality request justifications

Optional Elements	Description
Limitation to validity of the request	The registrant should specify the period of time for which the request is valid: until a certain date, until the occurrence of a particular event (which must be clearly specified), or permanently.
Contact person	The registrant should provide the contact details (a name, email address and phone number at a minimum) of a responsible person that may be contacted by ECHA if further clarifications are needed.

Table 15: Additional element required for IUPAC name confidentiality request justifications

Additional Required Element (IUPAC Name Requests Only)	Description
Details of the elements of the IUPAC name masked to derive the public name, and justifications for masking if two- or three-level masking is used	As described in Annex 1 of this manual: "How to derive a Public Name for a substance for use under the REACH Regulation", a coherent system for deriving public names for substances is needed to increase the usefulness of the publication of substance-specific information by ECHA on its website. To this end, each IUPAC name confidentiality request must be accompanied by a suitable public name, derived from the IUPAC name in accordance with Annex 1. Details of what is masked should be described, and if two- or three-level masking is used then each level must be accompanied by a justification of why the masking is necessary.

The absence of any of the required elements for requesting confidentiality leads to the rejection of the confidentiality request when it is assessed by ECHA – see chapter 3.8: Assessment of Confidentiality Requests by ECHA.

3.7.2. Additional Elements to substantiate a request

Depending on the nature of the information requested confidential, additional elements may be added in order to explain how disclosure of information would affect the registrant's financial or competitive position, or how competitors could make use of the information. For example:

- For requests concerning the chemical name or trade name – a brief description of the relevant information regarding the market sector and concerned product(s), and an indication of the impact of disclosing the chemical name or trade name.
- For requests concerning information on the tonnage band – a brief description of the relevant information regarding the market sector and concerned product(s), and the approximate size of the market (number of competitors).
- For requests concerning information in the safety data sheet – an outline of why the information can only be made available to the registrant's direct customers.
- For requests in which the justification is based on intellectual property rights – an explanation of the legal implications of publication of the information for the registrant, i.e. whether publication would undermine the protection warranted by the right in question or would likely interfere with contractual relations or other negotiations being conducted by the person providing the information, or on whose behalf it is provided. Where contractual relations are invoked, extracts or detailed descriptions of these arrangements should be provided.

In the case of all the elements the descriptions provided should be clear and transparent, and any reasoning should be simple, logical, and easy to follow.

3.8. Assessment of the Confidentiality Request by ECHA

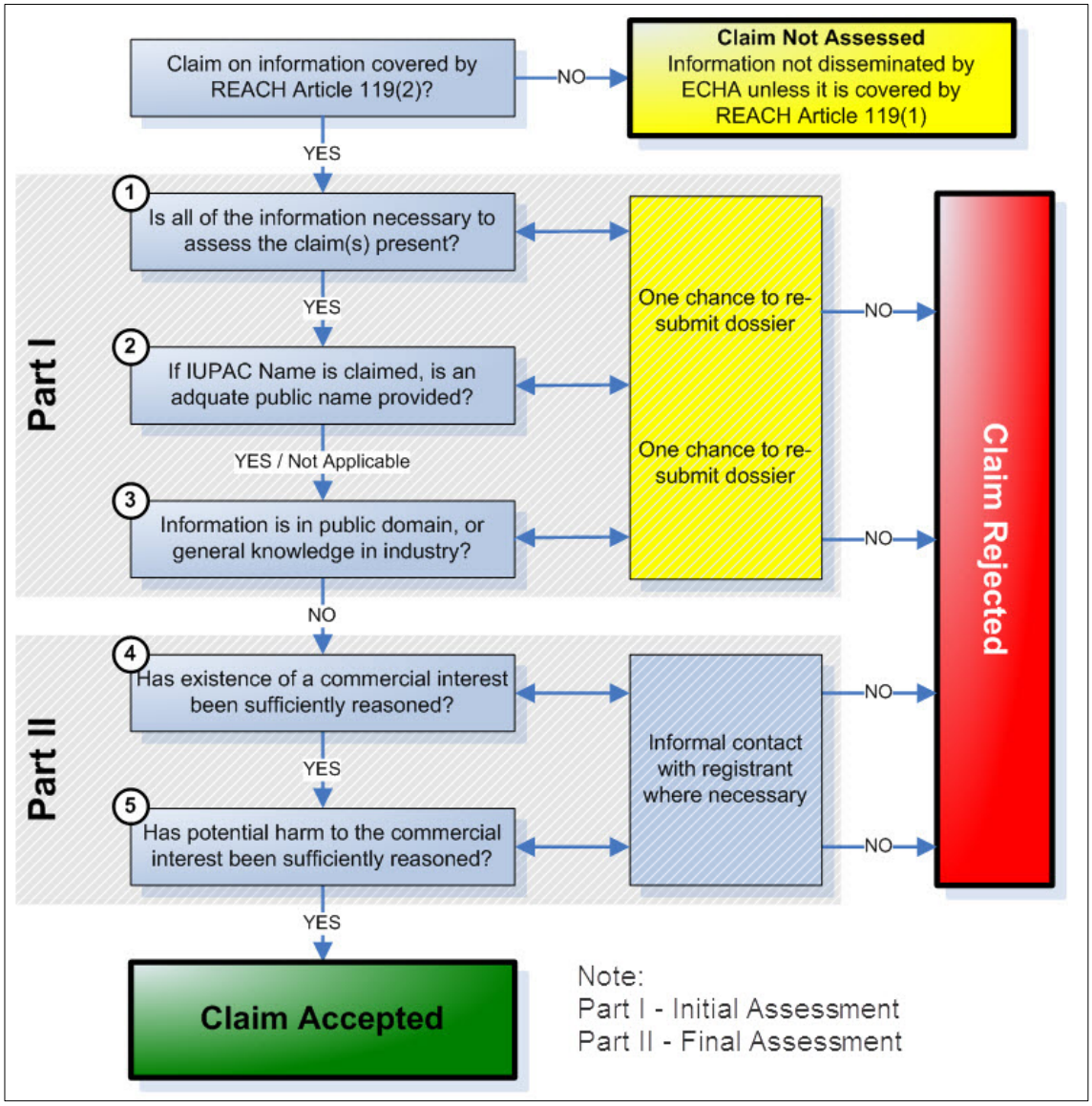
3.8.1. Assessment procedure

An important objective of REACH is to ensure that EU citizens have access to information about chemicals to which they may be exposed to, in order to allow them to make informed decisions about their use of chemicals. Thus, the intention of the legislators drafting REACH was that by default there is an interest of the public to have access to the type of information listed in Article 119(2). For this reason, confidentiality requests on this information are only accepted where a registrant can clearly reason the existence of a commercial interest and show that the disclosure of information is potentially harmful to this interest. It is ECHA's task to assess the confidentiality request justifications in this light.

The assessment of confidentiality requests is not part of the dossier evaluation or compliance check. All confidentiality requests on information covered by REACH Article 119(2) that are submitted to ECHA are assessed in all registration dossiers.

ECHA uses the following 5-step workflow to assess confidentiality request justifications:

Figure 9: Flowchart of standardised confidentiality request assessment process



Before starting the assessment workflow, each confidentiality request is examined to see if it relates to information covered by REACH Article 119(1) and 119(2). If the information requested confidential does not fall under REACH Articles 119(1) nor (2), then the claim is not assessed and the information concerned is not published. If the information requested confidential falls under REACH Article 119(1), the request is disregarded, and the information is published on the ECHA website.

In the workflow itself, ECHA carries out an initial assessment of the request. In this step, it is established whether the request meets the precise criteria of the particular subsection of Article 119(2) under which confidentiality is requested – 119(2)(a), (b), (c), (d), (e), (f), or (g). If the IUPAC name is requested confidential, it is checked whether an adequate public name, and if two- or three-level masking are used that an appropriate justification is provided. Next, it is checked that the information requested confidential is not in the public domain, using the below listed databases. During the initial assessment, ECHA also highlights to the registrant any other deficiencies that are likely to lead to a rejection of the request (e.g. if the reasoning provided by

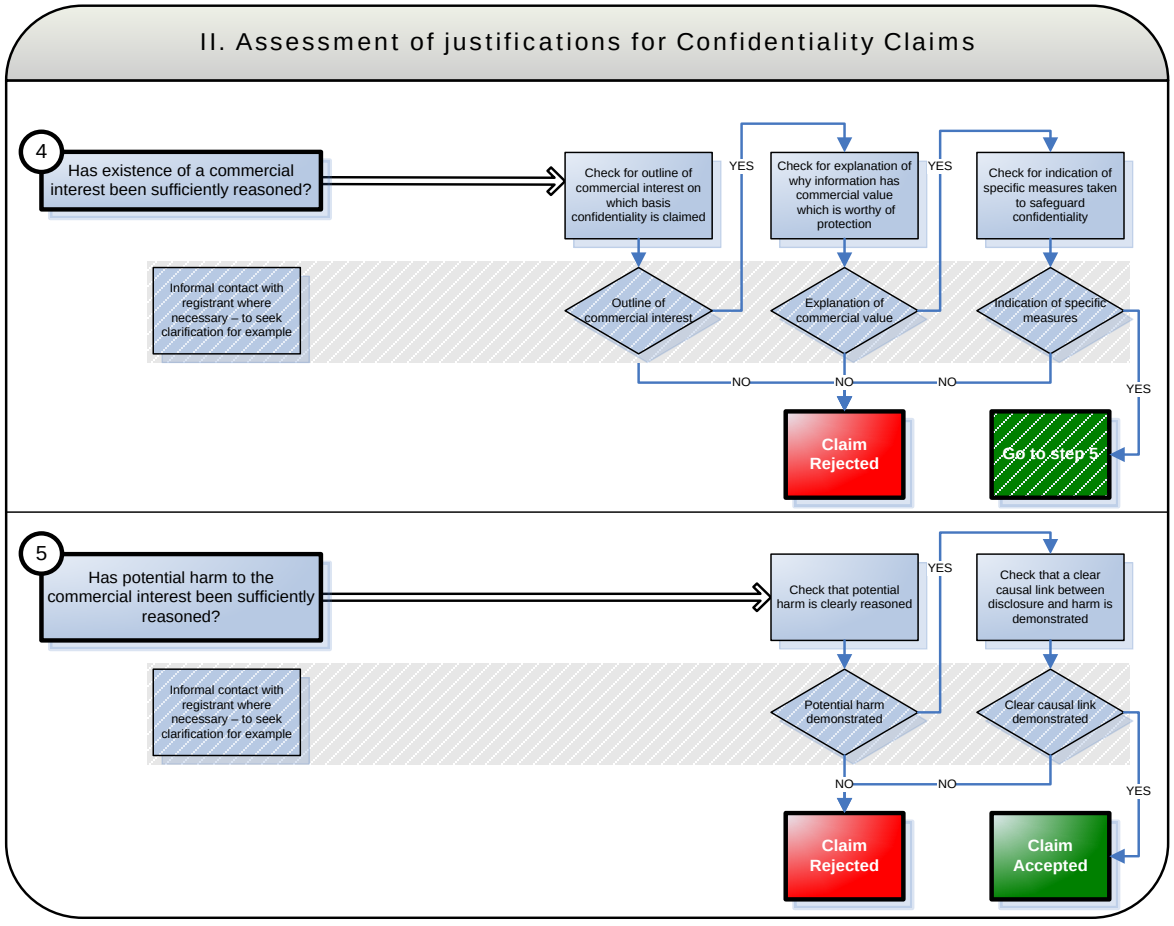
the registrant is not sufficient to justify that disclosure of the information may cause harm to the commercial interest). Following this initial assessment, ECHA gives registrants one chance to update the justification and provide any missing/additional elements.

In a second step, ECHA takes into account any potential updates and clarifications made to the justification and carries out a final assessment of the justification. During this assessment, ECHA verifies the following:

- the existence of a commercial interest worthy of protection by the non-disclosure of information is demonstrated in a well-reasoned manner and;
- the potential harm to this commercial interest if the information is disclosed is explained, also a clear causal link between disclosure and any harmful effects is clearly demonstrated.

The assessment of pre-conditions - in Part I above – varies, depending on which subsection of Article 119(2) the request is made on. The assessment of confidentiality request justifications usually follows the same standard workflow:

Figure 10: Workflow for Assessment of Justifications for Confidentiality Requests



3.8.2. List of Databases

The databases, which may be used by ECHA during the assessment of confidentiality requests (REACH Article 119(2)) whether the information requested confidential is in the public domain are the following:

- eChemPortal: http://www.echemportal.org/ (Participating databases: ACToR , CCR , CESAR, CHRIP, GHS-J, HSDB, HSNO CCID, INCHEM, JECDB, OECD HPV, OECD SIDS IUCLID, UK CCRMP Outputs, US EPA IRIS, US EPA SRS)
- Chemical Safety Information from Intergovernmental Organizations (INCHEM): http://www.inchem.org/
- GESTIS-Stoffdatenbank: http://www.dguv.de/ifa/de/gestis/stoffdb/index.jsp
- Institut national de recherche et de sécurité (fiches toxicologiques): http://www.inrs.fr
- NITE - Chemical Risk Information Platform (CHRIP): http://www.safe.nite.go.jp/english/db.html
- Toxnet: http://toxnet.nlm.nih.gov/ (Participating databases: HSDB, TOXLINE, CCRIS, DART, GENETOX, IRIS, ITER, LactMed, Multi-Database, TRI, Haz-Map, Household Products, TOXMAP)

3.8.3. Contact with the registrant

ECHA may be in contact with the registrant during the assessment of confidentiality requests. If, after an initial assessment, the confidentiality request is considered insufficient, the registrant has one opportunity to re-submit their dossier and add additional elements to the justification. ECHA contacts the registrant via REACH-IT to outline the grounds on which the justification was found to be insufficient.

Once the initial assessment has been completed and ECHA has begun its final assessment, ECHA may engage in informal contact with the registrant to seek clarification of certain elements of the confidentiality request justification.

To allow ECHA to engage in informal contact with a registrant during assessment of the confidentiality request justification, the contact details of a designated person (a name, email address and phone number at a minimum) should be included in the justification, as shown in the confidentiality request justification template (see Annex 2). Registrants are advised to check regularly their tasks in REACH-IT to be able to react to any communications from ECHA concerning their confidentiality requests, within the set deadlines.

3.8.4. Expiry of validity

The validity of a confidentiality request on the IUPAC name of a non-phase-in substance is 6 years. This date is calculated from the reference date, i.e. the date when the registration number was assigned and is indicated in the decision on the confidentiality request sent to the registrant.

For any other confidentiality requests, the default validity period is indefinite. If a registrant requests a specific validity date, ECHA grants the validity until that date.

After the confidentiality request has passed its validity date, it is considered expired and ECHA publishes the information on its website.

The information requested as confidential may in certain cases be published earlier than the validity date of the confidentiality request. This can happen when the same information is submitted by a different source, without a confidentiality request e.g. from another registration,

or where the confidentiality request already expired. In this situation, we are not in the position to inform the registrant who was granted a longer validity date.

3.8.5. Administrative review of a confidentiality request decision

Based on Article 118(3) of the REACH Regulation, the Management Board decision 17/2008 establishes remedies for reviewing partial or full rejection of confidentiality claims. The Decision establishing this process is available at:

https://echa.europa.eu/documents/10162/17208/final_mb_17_2008_decision_on_review_of_rejection_of_confidentiality_claims_en.pdf/7336dc05-4a8e-483b-95f3-31b7f5f4d11d

In brief, this Decision describes the arrangements under which the registrants may seek redress in a situation where ECHA partially or wholly rejected a request for confidentiality made in their registration dossier.

The registrant is notified of the decision where ECHA partially or wholly rejects a confidentiality request. The registrant then has two months from the notification of the decision in REACH-IT to request a review by the Agency. The information requested confidential is not published during this time.

To initiate a review of ECHA's decision, the registrant must submit a request for review in writing, clearly stating the grounds on which the review is requested, and any supporting information that substantiates those grounds. The request must be made by filling out the web-form, "Submission of request for review of a partial or full rejection of confidentiality request(s)" pursuant to Article 118(3) of REACH Regulation available at https://comments.echa.europa.eu/comments_cms/RequestForReview.aspx

If you do not wish to use the web form, alternatively you can use standard mail:

By mail: European Chemicals Agency (ECHA)

Executive Director

P.O. Box 400

FI-00121 Helsinki

A decision on the review is taken within two months from the date of receipt of the request, and is notified to the registrant in writing via REACH-IT. Should the registrant disagree with the decision, they have the right to bring an action before the General Court of the Court of Justice of the European Union or, if appropriate, to lodge a complaint with the European Ombudsman.

The information requested confidential is not published during the period of the review.

3.9. Presence of Confidentiality Requests

For transparency reasons, the locations where information covered by REACH Article 119(2) has been requested confidential are indicated in the published dossiers. The information where the presence of a confidentiality request is indicated:

- 119(2)(a) Degree of purity, identity of impurities and / or additives if essential for classification & labelling
- 119(2)(b) The total tonnage band
- 119(2)(c) Study summaries or robust study summaries

- 119(2)(d) Information contained in the safety data sheet
  - Legal entity
  - Registration number
  - PBT assessment outcome
  - Indication whether chemical safety assessment was performed
  - Characterisation parameters of nanoforms
- 119(2)(e) Trade name(s)
- 119(2)(f) or (g) IUPAC name

> The presence of a confidentiality request is NOT indicated for uses in sections 3.5 or 3.6. In such cases, the existence of a use, rather than the use itself may be the information, which is to be kept confidential. Thus, the presence of a confidentiality request cannot be indicated, as this would infer the presence of a use.

Annex 1. How to derive a Public name for a substance for use under the REACH Regulation

1. Introduction

A coherent system for deriving public names for substances is needed to increase the usefulness of the publication of substance-specific information by ECHA on its website, in particular in the context of:

- Publication of information from registrations according to Article 119 of the REACH Regulation[2]
- Publication of testing proposals according to Article 40(2) of the REACH Regulation

This document advises industry on how to derive a public name for a substance for which the IUPAC name[3] is requested as confidential[4] within a registration dossier in accordance with Article 10(a)(xi) of the REACH Regulation.

This manual does not cover inorganic substances.

2. Principles and purpose of Public names for Substances in the context of REACH

The underlying principle of a 'public name' (sometimes referred to as a 'masked name', 'generic name' or 'disguised name') is that the chemical identity of the substance is revealed to the maximum extent possible, but without disclosing trade secrets or other confidential information that would potentially harm the commercial interests of the registrant or any other party concerned. It should be noted that ECHA publishes information on substances on its website in accordance with the principles set out in Article 119. For example, this includes trade names, which have not been requested as confidential.

One of the characteristics of a suitable public name is such that it should permit a scientist to gain sufficient knowledge of the chemical structure as to allow understanding of the intrinsic properties. It is often also necessary to make professional judgements based on knowledge of similar substances having similar properties due to the same or similar chemical groups and substructures of the published substance. Hence the public name must allow interested parties to do this; otherwise, a key purpose of the provisions in REACH, which provide for communication of information on substances, would be compromised. In the particular case of a public call for scientifically valid data on a registered substance in the context of the evaluation of a testing proposal, if the public name does not provide adequate information on the chemical structure the effectiveness of the public consultation would be compromised.

If the IUPAC name of the substance is successfully requested as confidential, then this name and the structural information of that substance is not made publicly available. If no other non-confidential substance identifier is available (e.g. an EINECS name), a public name is published.

This manual provides rules for registrants on how to generate a public name for most substances. In some aspects it may not be fully comprehensive and therefore registrants and ECHA need to use their professional judgement. The manual will be updated on the basis of experience in generating public names.

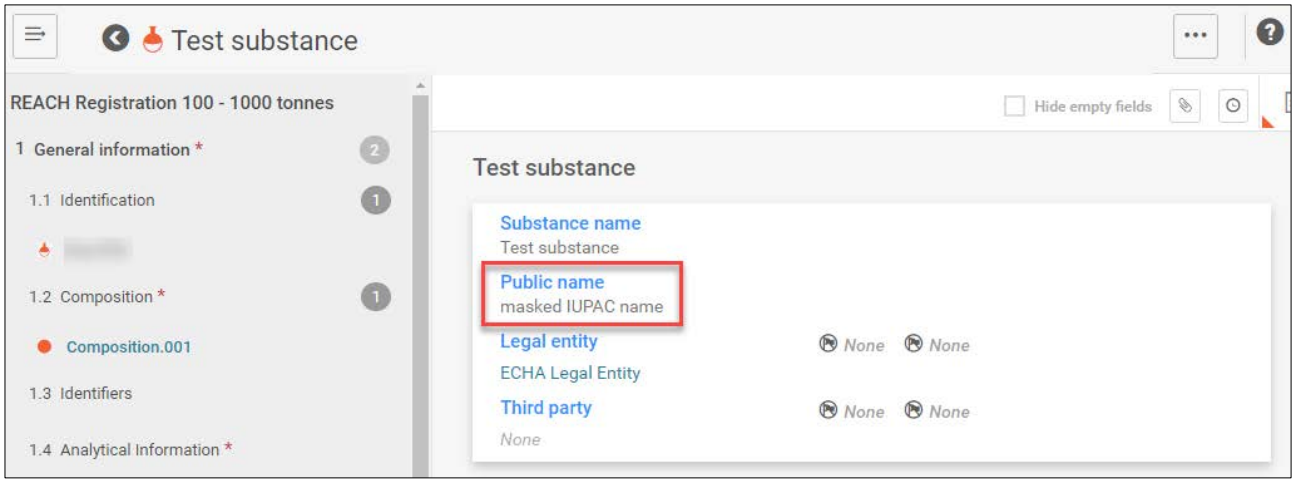
[2] Regulation (EC) No 1907/2006 OJ L 396, 30.12.2006, p. 1 and Corrigendum L136/3 29.5.2007, Corrigendum OJ LL141/22, 31.5.2008, p.22, Corrigendum L 143/55, 3.6.2008, p.1 and Corrigendum OJ L 36, 5.2.2009, p. 84 and Amendments
[3] The IUPAC name is the chemical name in accordance with the nomenclature of the **I**nternational **U**nion of **P**ure and **A**pplied **C**hemistry
[4] How to make a confidentiality request on the IUPAC name in accordance with Article 119(2)(f) or (g) of the REACH Regulation is described in chapter 3 of this manual

3. Where to include the public name?

If the registrant makes a confidentiality request on the IUPAC name, they are required to provide an appropriate public name (masked name) for ECHA to use for publication purposes. In the absence of an adequate public name, a confidentiality request on the IUPAC name cannot be accepted by ECHA. Registrants are requested to include the public name in their registration dossier in the 'public name' field of IUCLID.

When a registrant creates a substance following the steps as indicated by IUCLID they arrive at the substance identification screen where they can include the masked name in the public name field as indicated in the next screen shot.

Figure 11: Location of the public name field in IUCLID



If the IUPAC name is requested as confidential, the justification for the confidentiality request also need to include a masking justification for the public name. In case of one level masking, this can be a simple statement on what is masked in the public name. In case of two or three levels of masking also a valid well-reasoned justification of why the second/third level masking is necessary is required (see example in Annex 2). Absence of any of these elements leads to a rejection of the confidentiality request and publication of the IUPAC name.

If a confidentiality request on the IUPAC name has been accepted by ECHA, no structural information is published. This includes the composition of the substance, hence information on the individual constituents.

4. Advice on how to mask IUPAC names for Substances

The system to derive a public name from the IUPAC name has been developed by ECHA for use under REACH. The approach is based on the well-established concept of 'masked names' used in the Canadian version of the US EPA scheme, and we are grateful for the assistance from Environment Canada in their experience with operating a similar scheme for public names.

The system allows different elements of the chemical name to be 'masked' in order to conceal the full description of different parts of the chemical structure. The rules presented below describe how to derive a public name for publication by illustrating the masking of various structural elements from the IUPAC name with a single level of masking. The use of these rules in combination is considered multiple masking. Two to three levels of masking may be permitted

if the registrant provides an acceptable justification for each level of masking.

The system provides guidance to Manufacturers, Importers and Only Representatives wishing to request the IUPAC name as confidential when submitting a registration dossier in accordance with Article 10, 17 or 18 of the REACH Regulation.

There are inherent differences between naming well-defined substances with a definite chemical structure and naming UVCB substances for which in most cases a structural diagram cannot be depicted. Each of these possibilities is addressed separately.

4.1. Well-defined substances

Substances of well-defined chemical composition are named according to the main constituent(s). These are mono-constituent or multi-constituent substances. A mono-constituent substance is named by the main constituent using the IUPAC nomenclature rules[5]. A multi-constituent substance is named as a reaction mass of the main constituents of the substance with the generic format: “Reaction mass of [IUPAC name of main constituent 1 and IUPAC name of main constituent 2 and IUPAC name of main constituent 3]”. It should be noted that only main constituents typically >10% contribute to the name. More information on the different types is given in section 4.2 of the Guidance document for identification and naming of substances under REACH.[6]

The name of well-defined substances usually discloses the following structural information:

- the identity of the parent structure (i.e. a chain of carbon atoms, a ring system, or a coordinated metal);
- the identity, number, and position of chemical group(s) that are attached to the parent structure(s) or to other chemical groups;
- the identity and number of counter ions (for salts);
- the stereo-chemistry.

Public names may be created for well-defined substances by masking structurally-descriptive fragments of the IUPAC name. One degree of masking can be applied without providing a justification. Multiple masking (two to three levels) may be permitted if the registrant provides an acceptable justification for each additional level of masking. The rules for the different types of masking are given below.

The IUPAC name of a well-defined substance is masked taking into account the following:

- the locant(s) that indicate(s) the position(s) of a specific chemical group;
- the multiplicative prefixes that specify the number of a given chemical group (e.g. di-, tri-, and/or tetramethyl);
- the identity (but not position and number) of a given chemical group (e.g. sulfonyl);
- the identity of a given parent structure, (e.g. a chain or ring system);
- the locant(s) of substituent chemical group(s) for a given parent structure.

4.1.1. Masking options

One option is to mask one parent group (or multiple occurrences of the same parent group).

An alternative option (but not in addition to the first) is to mask one other structural element. This covers masking of:

- the locant with or without multiplicative prefixes;

[5] http://www.acdlabs.com/iupac/nomenclature/
[6] http://guidance.echa.europa.eu/docs/guidance_document/substance_id_en.pdf

- the identity of a chemical group;
- the cation or anion;
- the stereochemistry.

4.1.2. Parent Masking

A parent structure that is in general a chain of carbon atoms with either single, double or triple bonds, or a ring system with one or more fused rings may be masked by using one of the following masking terms:

- alkane or alkyl (e.g. to mask octadecane or octadecanyl);
- alkene or alkenyl (e.g. to mask ethene or ethenyl);
- alkyne or alkynyl (e.g. to mask acetylene* or ethynyl, propyne or 1-propynyl / 2-propynyl);
- arene or aryl (e.g. to mask benzene, or phenyl);
- alicycle or alicyclic (e.g. to mask cyclohexane or cyclohexyl, cyclohexene or cyclohexenyl);
- polycycle or polycyclic (e.g. to mask naphthalene or naphthyl, spiroundecane or spiroundecanyl);
- heteromonocycle or heteromonocyclic (e.g. to mask thiophene or thienyl, morpholine or morpholinyl);
- heteropolycycle or heteropolycyclic (e.g. to mask quinoline or quinolyl, xanthene or xanthenyl).

It should be noted that for some substances the trivial name is preferred and retained by IUPAC.

- Only one such parent group or multiple occurrences of the same parent group should be masked.
- Masking of (an) additional parent group(s) is considered multiple masking and needs to be justified by the registrant. ECHA may refuse to accept multiple masking if the justification cannot be considered as valid.

4.1.3. Substituent Masking

In cases where (a) functional group(s) is/are attached to the parent structure(s) or to other chemical groups, the IUPAC name may be masked by using the following masking terms:

- halo or halide (e.g. to mask fluoro, chloro, or fluoride, chloride);
- *substituted* is used for substituents where no generic name can be established e.g. amino, hydroxy, oxo;
- *stereo-isomer(s) of* is used for isomers where the specific stereochemistry should not be revealed (e.g. to mask *cis*- and *trans*- or R- and S-isomer(s)).

If there is more than one of the same chemical group, then the addition of the prefix ‘poly’ should be considered:

- polyamino (e.g. to mask diamino) or polyhydroxy (e.g. to mask trihydroxy).

- In case of organometallic substances and organo coordinated metal complexes the organic moiety can be masked according to the rules as described in this manual. However, the metal atom should not be masked in the chemical name.

In case of organic salts, only alkali and alkaline earth metals can be masked.

- alkali metal, e.g. sodium, potassium;
- earth alkali metal, e.g. calcium, magnesium.

It is possible to mask the organic part of a given salt using the rules outlined in this manual.

- Masking of individual parts of a functional group should generally be avoided as this may result in potentially misleading name changes e.g. oxygen in a carboxyl or amide group should not be masked, as this would result in renaming the groups as substituted alcohol and substituted amine respectively, which are different substances from their precursors.

- Only one such substituent or multiple occurrences of the same substituent should be masked.
- Masking of (an) additional substituent(s) is considered multiple masking and needs to be justified by the registrant. ECHA may refuse to accept multiple masking if the justification cannot be considered as valid.

- This manual does not cover inorganic substances.

Multi-constituent substances can be masked by applying the rules to the name of each constituent of the substance as described in this manual, hence:

Reaction mass of [*masked* IUPAC name of main constituent 1] and [*masked* IUPAC name of main constituent 2] and [*masked* IUPAC name of main constituent 3]

A **list of examples** of masked names is given in the chapter 8 of this Annex. These examples are merely used for illustrative purposes and are of substances already published elsewhere. They cover a relatively broad range of both substance type and masking possibilities.

4.2. UVCB Substances

UVCB substances are substances of Unknown or Variable composition, Complex reaction products or Biological materials, which cannot be sufficiently identified by their chemical composition because:

- the number of constituents is relatively large and/or;
- the composition is, to a significant part, unknown and/or;
- the variability of the composition is relatively large or poorly predictable.

Therefore, UVCB substances in contrast to well-defined substances are named by a combination of source and process.

In general, UVCB substances are named as “Reaction products of [names of the starting materials]” and these names should be given in the English language using the IUPAC nomenclature. For these cases where the UVCB name includes elements in IUPAC nomenclature, the masking rules in this manual can be applied.

4.2.1. UVCB sub-types

Among the UVCB substances there are four UVCB sub-types for which the naming convention employed is dependent upon whether the source is biological or not and whether the process is a synthesis or a refinement. Substances derived from biological sources are named according to their genus, species, family and process, whereas those derived from chemical sources are described by their starting materials and the process. For these UVCB sub-types masking of the name is not recommended as these substances are by definition not well-defined. Relevant details that may be commercially sensitive are likely to be included in the description of the

process of the individual UVCB sub-type. However, it should be noted that such information is not published unless already published on EINECS[7].

4.2.2. Specific types of UVCB substances

For other types of UCVB substances which have more specified variability, namely substances with variation in the carbon-chain lengths, substances from oil (petroleum) or oil like sources (e.g. coal) and enzymes, individual naming conventions are used.

More information regarding the different UVCB sub-types and specific types of UVCB substances is given in section 4.3 UVCB substances of the Guidance document for identification and naming of substances under REACH and CLP available at:
http://www.echa.europa.eu/web/guest/guidance-documents/guidance-on-reach.

4.2.2.1. Substances with variation in the carbon-chain length

Substances with variation in the carbon-chain length, e.g. paraffins and olefins are substances either derived from natural fats or oils or produced synthetically. They are systematically named using alkyl, functionality and/or salt descriptor(s).

The **alkyl descriptor** C x-y describes the number of carbon atoms in the carbon-chain length(s) of the alkyl group(s), e.g. C8-12 corresponding to the carbon numbers C8, C9, C10, C11 and C12.

The **functionality descriptor** identifies the functional group of the substance, e.g. amine, ammonium, carboxylic acid.

The **salt descriptor** identifies the cation / anion of any salt, e.g. sodium (Na+), potassium (K+) / carbonate (CO32-), chloride (Cl-).

> In general, the alkyl descriptor C x-y refers to saturated, linear alkyl chains comprising all chain length from x to y. If the carbon chain is branched and/or unsaturated and/or only even numbered this needs to be indicated in the name.

More details on the naming convention can be found in section 4.3.2.1 of the Guidance document for identification and naming of substances under REACH.

4.2.2.2. Substances obtained from oil or oil like sources

Substances from oil sources (petroleum) can be obtained through various different processes, e.g. distillation, gasification, cracking, and are usually named by the stream source, the refinery process and general composition or characteristics. If the substance contains aliphatic and/or aromatic and/or cyclic hydrocarbons and has a boiling range, this information is included in the description. The same approach is applied for substances from oil like sources. As this specific type of UVCB substance is very complex, variable and of partly undefined composition, masking of the name may not be appropriate in all cases. It should be noted that information provided in the description of this specific UVCB type is not published unless already published on EINECS[8].

4.2.2.3. Enzymes

Enzymes are named according to the IUBMB nomenclature conventions[9]. The IUBMB

[7] European Inventory of Existing Chemical Substances
[8] European Inventory of Existing Chemical Substances
[9] http://www.chem.qmul.ac.uk/iupac/jcbn/index.html#6

classification system provides a unique four-digit number for each enzyme type and catalytic function. The name of the enzyme as well as the IUBMB number (i.e. the Enzyme Commission Number (EC number)) is used for the identification of a specific enzyme. Enzymes names are masked by disguising the fourth digit of the IUBMB number. Some examples are illustrated in chapter 7.2.1 of this Annex.

5. Justifying the Use of Additional Masking

The rules presented in this document describe the masking of various structural elements from the IUPAC name in order to derive a public name with a single level of masking. There may be specific circumstances where additional levels of masking are justified. The examples provided in Annex I illustrate one level masking as well as some instances of two-level masking (also indicated as double masking). A maximum of three levels may be permitted; one level may be used without justification, however each subsequent level (2nd and 3rd level) must be accompanied by a valid justification. The reasons why more than one level of masking is necessary shall be clearly stated and explained by the registrant. A template for confidentiality request justifications is provided in chapter 6 of this Annex.

- For confidentiality requests on the IUPAC name under REACH Article 119(2)(f) or (g), in addition to a valid justification of the potential harm of disclosure to the commercial interest, a public name must be provided, otherwise the request cannot be accepted by ECHA.

When making a confidentiality request on the IUPAC name also details of the masking performed should be included together with justifications for two and three-level masking where relevant, as outlined in the confidentiality requests justification template, see Annex 2 and the template included in IUCLID.

- ECHA can only consider a confidentiality request for the IUPAC name admissible and accept it as valid, if an adequate public name, and if applicable, a valid justification as to why two or three levels of masking are necessary, is provided.
- Absence of any other mandatory elements for requesting confidentiality also leads to a rejection of the confidentiality request on the IUPAC name. (see further details in chapter 3 of this manual)

An example template is provided in Annex 2, which illustrates where and how to include the respective masking justifications for the IUPAC name in the standard confidentiality request template.

6. Further information

IUPAC Nomenclature of Organic Chemistry

https://pubs.rsc.org/en/content/ebook/978-0-85404-182-4
http://www.acdlabs.com/iupac/nomenclature/

IUPAC nomenclature of Inorganic Chemistry

http://old.iupac.org/publications/books/rbook/Red_Book_2005.pdf
http://old.iupac.org/publications/books/author/connelly.html

IUBMB nomenclature conventions

https://www.qmul.ac.uk/sbcs/iubmb/iubmb.html
https://www.qmul.ac.uk/sbcs/iubmb/enzyme/

Guidance document for identification and naming of substances under REACH and CLP

https://echa.europa.eu/guidance-documents/guidance-on-reach

7. Examples of Substances

7.1. Well-Defined Substances

7.1.1. Mono-constituent substances

Example 1

Fully Defined Name

N-(3,5-dichloro-4-ethyl-2-hydroxyphenyl)-2-(3-pentadecylphenoxy)butanamide

Figure 12: Structural formula – Example 1

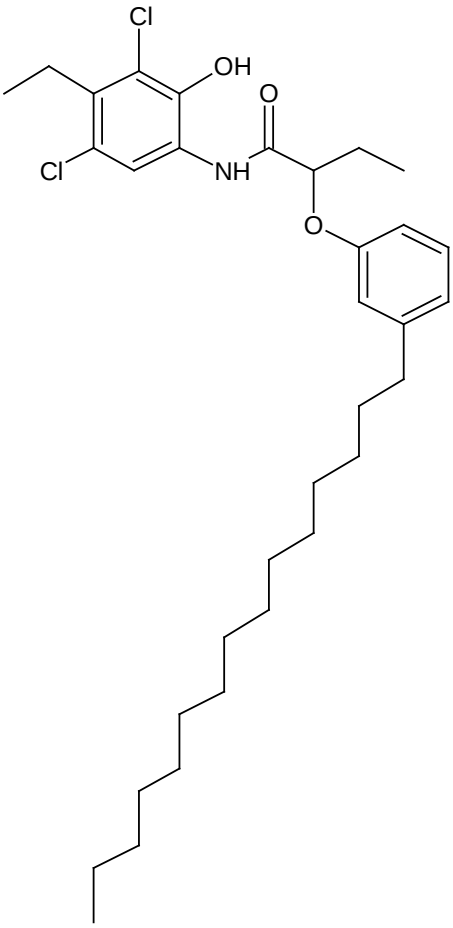


Table 16: Single masking of mono-constituent substances – Example 1

Single Masking	Acceptable Masked Name
Number of chlorine atoms	**N-(polychloro-4-ethyl-2-hydroxyphenyl)-2-(3-pentadecylphenoxy)butanamide**
Chlorine atoms	**N-(3,5-dihalo-4-ethyl-2-hydroxyphenyl)-2-(3-pentadecylphenoxy)butanamide**

Hydroxyl group	**N-(3,5-dichloro-4-ethyl-2-*substituted*phenyl)-2-(3-pentadecylphenoxy)butanamide**
Ethyl group	**N-(3,5-dichloro-4-alkyl-2-hydroxyphenyl)-2-(3-pentadecylphenoxy)butanamide**
Pentadecyl group	**N-(3,5-dichloro-4-ethyl-2-hydroxyphenyl)-2-(3-alkylphenoxy)butanamide**
Butane parent	**N-(3,5-dichloro-4-ethyl-2-hydroxyphenyl)-2-(3-pentadecylphenoxy)alkanamide**

Table 17: Double masking of mono-constituent substances – Example 1

Double Masking	Acceptable Masked Name
Butane parent (plus parent locant)	**N-(3,5-dichloro-4-ethyl-2-hydroxyphenyl)-(3-pentadecylphenoxy)alkanamide**

Example 2

Fully Defined Name

N,N-Dimethyl-3-{[4-(methylamino)-9,10-dioxo-9,10-dihydroanthracen-1-yl]amino}-N-propylpropan-1-aminium bromide

Figure 13: Structural formula – Example 2

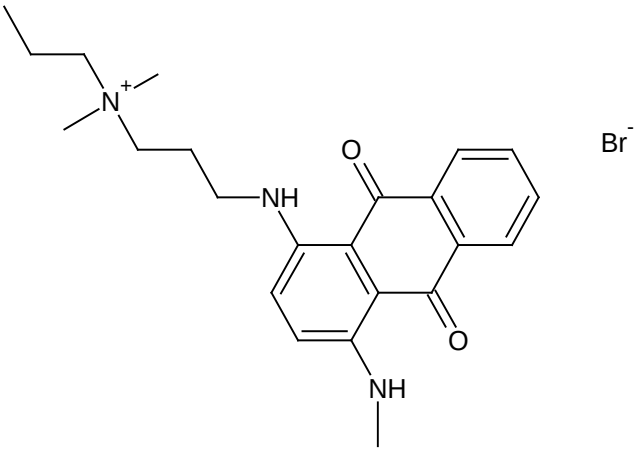


Table 18: Single masking of mono-constituent substances – Example 2

Single Masking	Acceptable Masked Name
Bromine anion	**N,N-Dimethyl-3-{[4-(methylamino)-9,10-dioxo-9,10-dihydroanthracen-1-yl]amino}-N-propylpropan-1-aminium salt**
Oxo groups	**N,N-Dimethyl-3-{[4-(methylamino)-9,10-di*substituted*-9,10-dihydroanthracen-1-yl]amino}-N-propylpropan-1-aminium bromide**
Methyl groups	**N,N-Dialkyl-3-{[4-(methylamino)-9,10-dioxo-9,10-dihydroanthracen-1-yl]amino}-N-propylpropan-1-aminium bromide**
Propyl group	**N,N-Dimethyl-3-{[4-(methylamino)-9,10-dioxo-9,10-dihydroanthracen-1-yl]amino}-N-alkylpropan-1-aminium bromide**
Propane parent	**N,N-Dimethyl-3-{[4-(methylamino)-9,10-dioxo-9,10-dihydroanthracen-1-yl]amino}-N-propylalkan-1-aminium bromide**
Anthracene parent	**N,N-Dimethyl-3-{[4-(methylamino)-9,10-dioxo-9,10-dihydrocarbopolycycl-1-yl]amino}-N-propylpropan-1-aminium bromide**

Table 19: Double masking of mono-constituent substances – Example 2

Double Masking	Acceptable Masked Name
Anthracene parent (plus parent locants)	**N,N-Dimethyl-3-{[(methylamino)-dioxo-dihydro-carbopolycyclyl]amino}-N-propylpropan-1-aminium bromide**
Propane parent (plus parent locants)	**Dimethyl{[4-(methylamino)-9,10-dioxo-9,10-dihydroanthracen-1-yl]amino}propylalkanaminium bromide**

Example 3

Fully Defined Name

3-ethoxy-1,1,1,2,3,4,4,5,5,6,6,6-dodecafluoro-2-(trifluoromethyl)hexane

Figure 14: Structural formula – Example 3

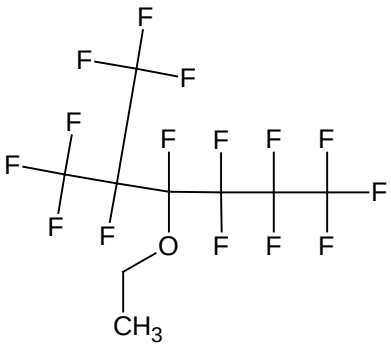


Table 20: Single masking of mono-constituent substances – Example 3

Single Masking	Acceptable Masked Name
Number of fluorine atoms	**3-ethoxy-polyfluoro-2-(polyfluoromethyl)hexane**
Fluorine atoms	**3-ethoxy-1,1,1,2,3,4,4,5,5,6,6,6-dodecahalo-2-(trihalomethyl)hexane**
Ethoxy group	**3-(alkoxy)-1,1,1,2,3,4,4,5,5,6,6,6-dodecafluoro-2-(trifluoromethyl)hexane**
Hexane parent	**3-ethoxy-1,1,1,2,3,4,4,5,5,6,6,6-dodecafluoro-2-(trifluoromethyl)alkane**

Table 21: Double masking of mono-constituent substances – Example 3

Double Masking	Acceptable Masked Name
Hexane parent (plus parent locants)	**Ethoxydodecafluoro(trifluoromethyl)alkane**

Example 4

Fully Defined Name

Ammonium bis(3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,14,14,15,15,16,16,16-nonacosafluorohexadecyl) phosphate

Figure 15: Structural formula – Example 4

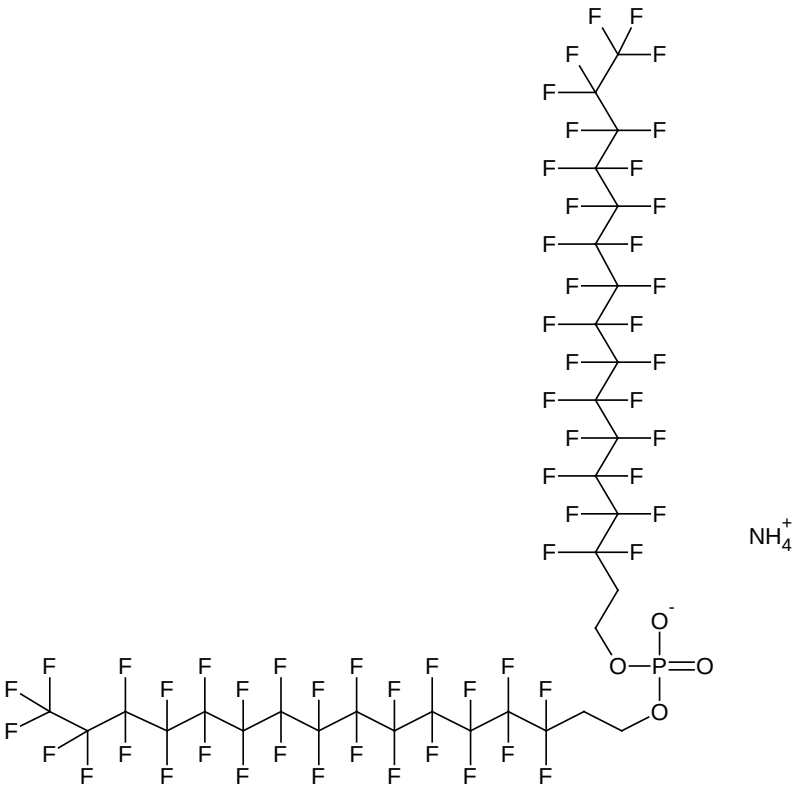


Table 22: Single masking of mono-constituent substances – Example 4

Single Masking	Acceptable Masked Name
Fluorine atoms	**Ammonium bis(3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10, 11,11,12,12,13,13,14,14,15,15,16,16,16-nonacosafluorohexadecyl) phosphate**
Number of fluorine atoms	**Ammonium bis(polyfluorohexadecyl) phosphate**
Ammonium cation	**bis(3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10, 11,11,12,12,13,13,14,14,15,15,16,16,16-nonacosafluorohexadecyl) phosphate salt**
Octane parent	**Ammonium bis(3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10, 11,11,12,12,13,13,14,14,15,15,16,16,16-nonacosafluoroalkyl) phosphate**

Table 23: Double masking of mono-constituent substances – Example 4

Double Masking	Acceptable Masked Name
Hexadecane parent (plus parent locants)	**Ammonium bis(nonacosafluoroalkyl) phosphate**

Example 5

Fully Defined Name

6,9-bis(hexadecyloxymethyl)-4,7-dioxanonane-1,2,9-triol

Figure 16: Structural formula – Example 5

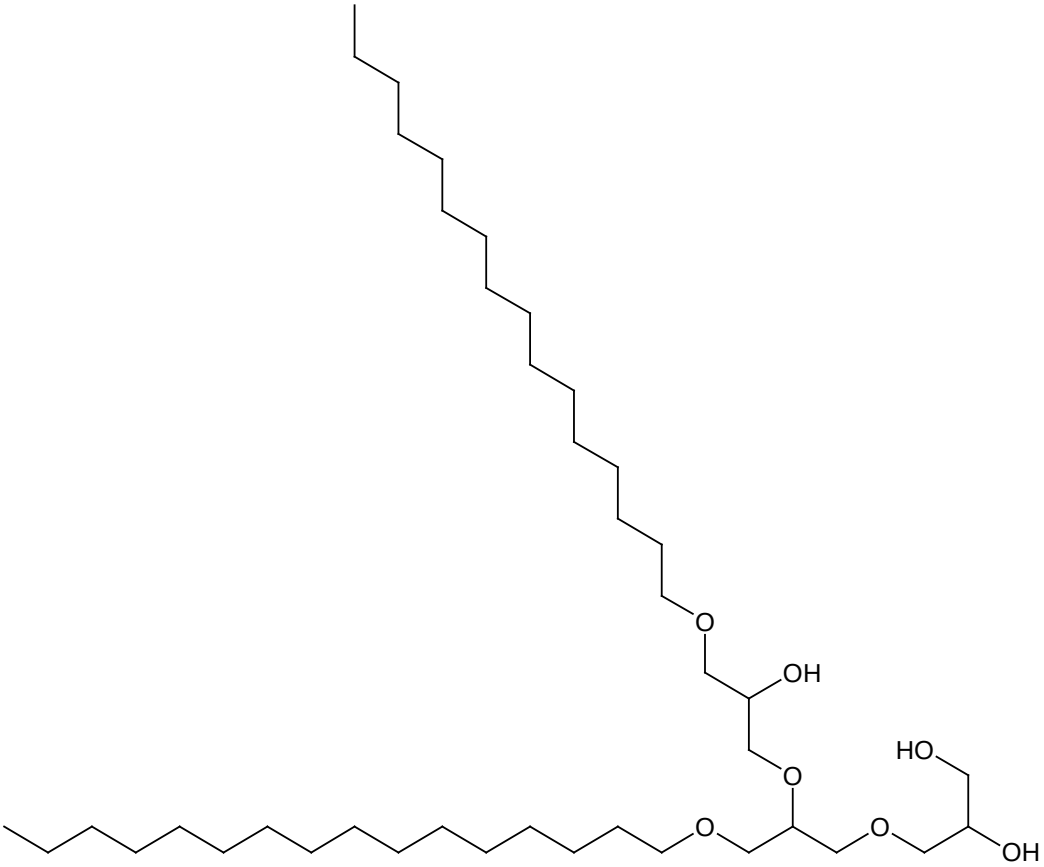


Table 24: Single masking of mono-constituent substances – Example 5

Single Masking	Acceptable Masked Name
Hydroxyl group positions	**6,9-bis(hexadecyloxymethyl)-4,7-dioxanonanetriol**
Hydroxyl groups	**6,9-bis(hexadecyloxymethyl)-4,7-dioxanonane-1,2,9-tri*substituted***
Hexadecyl groups	**6,9-bis(alkoxymethyl)-4,7-dioxanonane-1,2,9-triol**
Nonane parent	**6,9-bis(hexadecyloxymethyl)-4,7-dioxaalkane-1,2,9-triol**

Table 25: Double masking of mono-constituent substances – Example 5

Double Masking	Acceptable Masked Name
Nonane parent (plus parent locants)	**bis(hexadecyloxymethyl)dioxaalkanetriol**

Example 6

Fully Defined Name

Tetrazinc diacetate bis-hexakis(cyano-κC)cobaltate(3-)

Zn(II)4([Co(III)(CN)6]3-)2(CH3COO-)2

Figure 17: Structural formula – Example 6

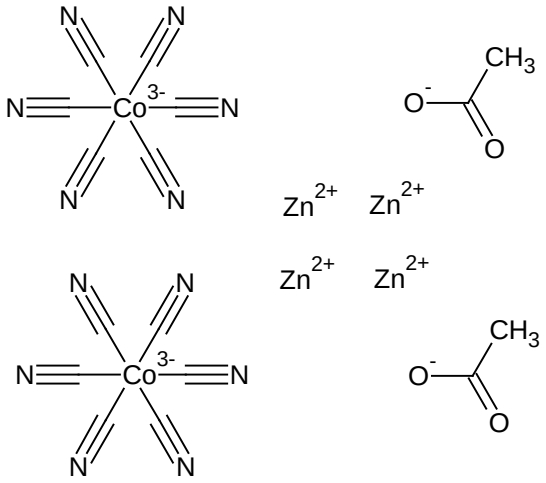


Table 26: Single masking of mono-constituent substances – Example 6

Single Masking	Acceptable Masked Name
Cyano groups	**Tetrazinc diacetate bis-hexakis(*substituted*-κ)cobaltate(3-)**
Acetate groups	**Tetrazinc dialkanoate bis-hexakis(cyano-κC)cobaltate(3-)**

Table 27: Double masking of mono-constituent substances – Example 6

Double Masking	Acceptable Masked Name
Acetate and Cyano groups	**Tetrazinc dialkanoate bis-hexakis(*substituted*-κ)cobaltate(3-)**

Example 7

Fully Defined Name

Potassium bis[2,2'-(methylimino-κN)diacetato-κO(2-)]ferrate(1-) monohydrate

Figure 18: Structural formula – Example 7

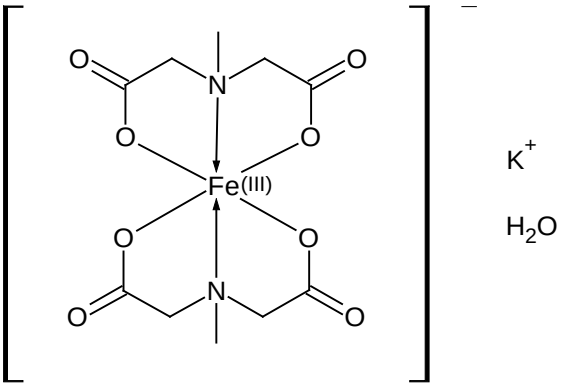


Table 28: Single masking of mono-constituent substances – Example 7

Single Masking	Acceptable Masked Name
Potassium cation	**Alkali metal bis[2,2'-(methylimino-κN)diacetato-κO(2-)]ferrate(1-) monohydrate**
Methyl groups	**Potassium bis[2,2'-(alkylimino-κN) diacetato-κO(2-)]ferrate(1-) monohydrate**
Amine groups	**Potassium bis[2,2'-(methyl*substituted*-κ)diacetato-κO(2-) derivative]ferrate(1-) monohydrate**

Table 29: Double masking of mono-constituent substances – Example 7

Double Masking	Acceptable Masked Name
Amine groups (plus locants)	**Potassium bis[(methyl*substituted*)diacetato-κO(2-) derivative]ferrate(1-) monohydrate**

Example 8

Fully Defined Name

C7-C9 (linear and branched) alkyl 3-[3-(2H-benzotriazol-2-yl)-5-(1,1-dimethylethyl)-4-hydroxyphenyl]propionate

Figure 19: Structural formula – Example 8

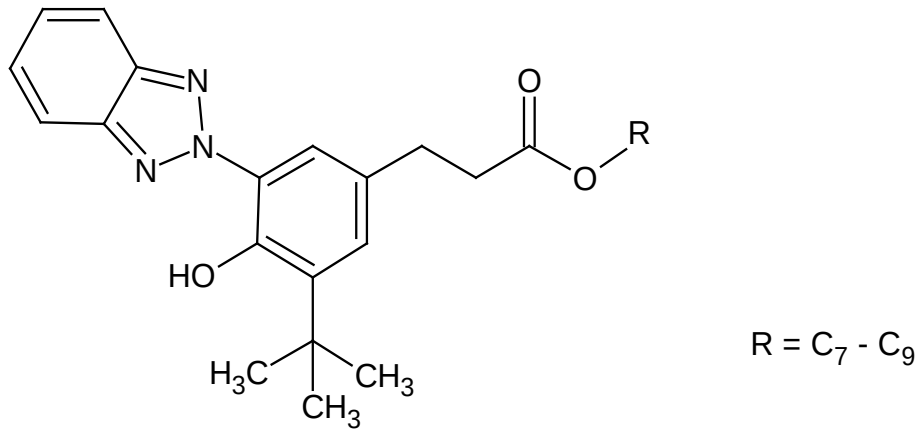


Table 30: Single masking of UVCB substances – Example 8

Single Masking	Acceptable Masked Name
Hydroxyl group	**C7-C9 (linear and branched) alkyl 3-[3-(2H-benzotriazol-2-yl)-5-(1,1-dimethylethyl)-4-*substituted* phenyl]propionate**
Methyl groups	**C7-C9 (linear and branched alkyl 3-[3-(2H-benzotriazol-2-yl)-5-(1,1-dialkylethyl)-4-hydroxyphenyl]propionate**
C7-C9 alkyl group	**(linear and branched) alkyl 3-[3-(2H-benzotriazol-2-yl)-5-(1,1-dimethylethyl)-4-hydroxyphenyl]propionate**
Benzotriazol parent	**C7-C9 (linear and branched) alkyl 3-[3-(2H-heteropolycycl-2-yl)-5-(1,1-dimethylethyl)-4-hydroxyphenyl]propionate**
Phenyl parent	**C7-C9 (linear and branched) alkyl 3-[3-(2H-benzotriazol-2-yl)-5-(1,1-dimethylethyl)-4-hydroxyaryl]propionate**
Propane parent	**C7-C9 (linear and branched) alkyl 3-[3-(2H-benzotriazol-2-yl)-5-(1,1-dimethylethyl)-4-hydroxyphenyl]alkanoate**

Table 31: Double masking of UVCB substances – Example 8

Double Masking	Acceptable Masked Name
Benzotriazol parent (plus parent locants)	**C7-C9 (linear and branched) alkyl 3-[3-(heteropolycyclyl)-5-(1,1-dimethylethyl)-4-hydroxyphenyl]propionate**
Phenyl parent (plus parent locants)	**C7-C9 (linear and branched) alkyl 3-[(2H-benzotriazol-2-yl)(1,1-dimethylethyl) hydroxyaryl]propionate**
Propane parent (plus parent locants)	**C7-C9 (linear and branched) alkyl [3-(2H-benzotriazol-2-yl)-5-(1,1-dimethylethyl)-4-hydroxyphenyl]alkanoate**

7.1.2. Multi-constituent substances

Example 9

Fully Defined Name

Reaction mass of (2S)-2-[(4R)-2-oxo-4-propylpyrrolidin-1-yl]butanamide and (2S)-2-[(4S)-2-oxo-4-propylpyrrolidin-1-yl]butanamide

Figure 20: Structural formula – Example 9

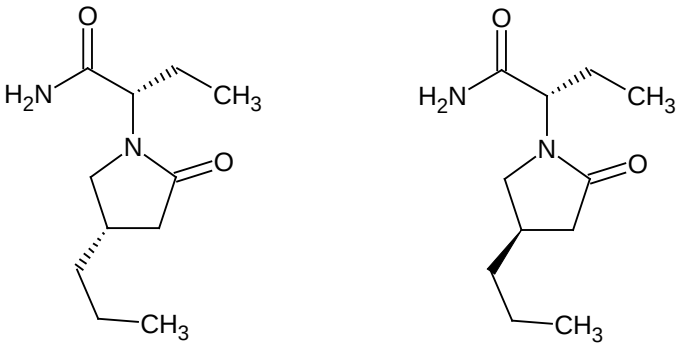


Table 32: Single masking of multi-constituent substances – Example 9

Single Masking	Acceptable Masked Name
Stereochemistry	**Stereoisomers of 2-[2-oxo-4-propylpyrrolidin-1-yl]butanamide**
Oxo group	**Reaction mass of (2S)-2-[(4R)-2-*substituted*-4-propylpyrrolidin-1-yl]butanamide and (2S)-2-[(4S)-2-*substituted*-4-propylpyrrolidin-1-yl]butanamide**
Propyl group	**Reaction mass of (2S)-2-[(4R)-2-oxo-4-alkylpyrrolidin-1-yl]butanamide and (2S)-2-[(4S)-2-oxo-4-alkylpyrrolidin-1-yl]butanamide**
Butane parent	**Reaction mass of (2S)-2-[(4R)-2-oxo-4-propylpyrrolidin-1-yl]alkanamide and (2S)-2-[(4S)-2-oxo-4-propylpyrrolidin-1-yl]alkanamide**
Pyrrolidine parent	**Reaction mass of (2S)-2-[(4R)-2-oxo-4-propylheteromonocycl-1-yl]butanamide and (2S)-2-[(4S)-2-oxo-4-propylheteromonocycl-1-yl]butanamide**

Table 33: Double masking of multi-constituent substances – Example 9

Double Masking	Acceptable Masked Name
Butane parent (plus parent locants)	**Reaction mass of (S)-[(4R)-2-oxo-4-propylpyrrolidin-1-yl]alkanamide and (S)-[(4S)-2-oxo-4-propylpyrrolidin-1-yl]alkanamide**
Pyrrolidine parent (plus parent locants)	**Reaction mass of (2S)-2-[(R)-oxopropylheteromonocyclyl]butanamide and (2S)-2-[(S)-oxopropylheteromonocyclyl]butanamide**

7.2. UVCB substances

Example 10

Fully Defined Name

N-[3-(dimethylamino)propyl]-N-[(perfluoro-(C4-8)-alkyl)sulfonyl]-□-alanine and

N,N-dimethyl-3-{[(perfluoro-(C4-8)-alkyl)sulfonyl]amino}propan-1-aminium propanoate and

3-{(2-carboxyethyl)[(perfluoro-(C4-8)-alkyl)sulfonyl]amino}-N,N-dimethylpropan-1-aminium propanoate

Figure 21: Structural formula – Example 10

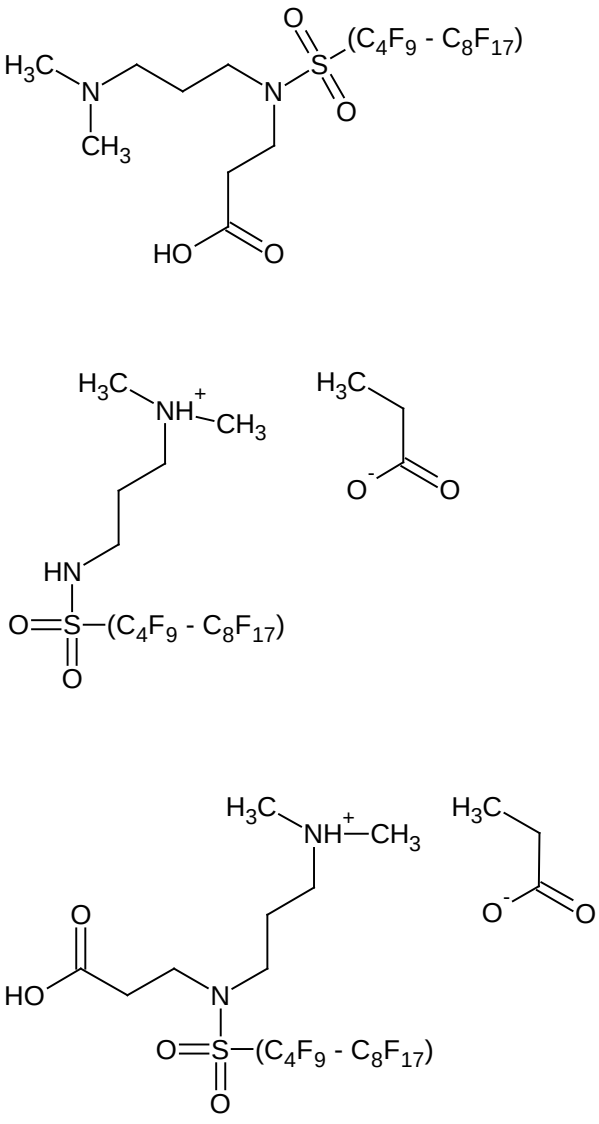


Table 34: Single masking of UVCB substances – Example 10

Single Masking	Acceptable Masked Name
Methyl groups	**N-[3-(dialkylamino)propyl]-N-[(perfluoro-(C4-8)-alkyl)sulfonyl]-β-alanine** **and** **N,N-dialkyl-3-{[(perfluoro-(C4-8)-alkyl)sulfonyl]amino}propan-1-aminium propanoate** **and** **3-{(2-carboxyethyl)[(perfluoro-(C4-8)-alkyl)sulfonyl]amino}-N,N-dialkylpropan-1-aminium propanoate**
Propanoate group	**N-[3-(dimethylamino)propyl]-N-[(perfluoro-(C4-8)-alkyl)sulfonyl]-β-alanine** **and** **N,N-dimethyl-3-{[(perfluoro-(C4-8)-alkyl)sulfonyl]amino}propan-1-aminium alkanoate** **and** **3-{(2-carboxyethyl)[(perfluoro-(C4-8)-alkyl)sulfonyl]amino}-N,N-dimethylpropan-1-aminium alkanoate**
Propane parent	**N-[3-(dimethylamino)alkyl]-N-[(perfluoro-(C4-8)-alkyl)sulfonyl]-β-alanine** **and** **N,N-dimethyl-3-{[(perfluoro-(C4-8)-alkyl)sulfonyl]amino}alkan-1-aminium propanoate** **and** **3-{(2-carboxyethyl)[(perfluoro-(C4-8)-alkyl)sulfonyl]amino}-N,N-dimethylalkan-1-aminium propanoate**

Table 35: Double masking of UVCB substances – Example 10

Double Masking	Acceptable Masked Name
Propane parent (plus parent locants)	**N-[(dimethylamino)alkyl]-N-[(perfluoro-(C4-8)-alkyl)sulfonyl]-β-alanine** **and** **N,N-dimethyl{[(perfluoro-(C4-8)-alkyl)sulfonyl]amino}alkanaminium propanoate** **and** **{(2-carboxyethyl)[(perfluoro-(C4-8)-alkyl)sulfonyl]amino}-N,N-dimethylalkanaminium propanoate**

Example 11

Fully Defined Name

Reaction products of N-[3-(dimethylamino)propyl]perfluoro-(C4-8)-alkylsulfonamide and acrylic acid

Figure 22: Structural formula – Example 11

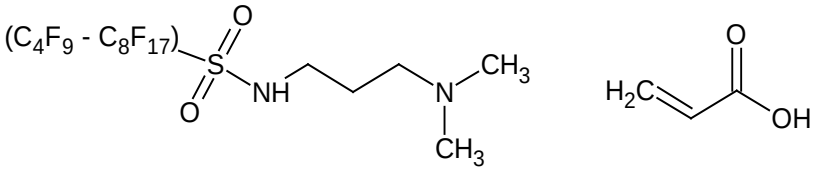


Table 36: Single masking of UVCB substances – Example 11

Single Masking	Acceptable Masked Name
Methyl groups	**Reaction products of N-[3-(dialkylamino)propyl]perfluoro-(C4-8)-alkylsulfonamide and acrylic acid**
Propyl group	**Reaction products of N-[3-(dimethylamino)alkyl]perfluoro-(C4-8)-alkylsulfonamide and acrylic acid**
Number of fluorine atoms	**Reaction products of N-[3-(dimethylamino)propyl]polyfluoro-(C4-8)-alkylsulfonamide and acrylic acid**
Fluoro groups	**Reaction products of N-[3-(dimethylamino)propyl]perhalo-(C4-8)-alkylsulfonamide and acrylic acid**
Propenyl group (propenoic acid/acrylic acid)	**Reaction products of N-[3-(dimethylamino)propyl]perfluoro-(C4-8)-alkylsulfonamide and alkenoic acid**

Table 37: Double masking of UVCB substances – Example 11

Double Masking	Acceptable Masked Name
Propyl group (plus locants)	**Reaction products of N-[(dimethylamino)alkyl]perfluoro-(C4-8)-alkylsulfonamide and acrylic acid**

Example 12

Fully Defined Name

Reaction products of Zinc Oxide and Glycerol

Figure 23: Structural formula – Example 12

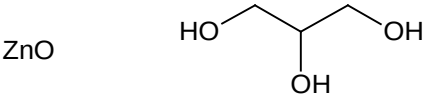


Table 38: Single masking of UVCB substances – Example 12

Single Masking	Acceptable Masked Name
Hydroxyl groups (glycerol)	**Reaction products of Zinc Oxide and 1,2,3-tri*substituted* propane**
Propyl parent (glycerol)	**Reaction products of Zinc Oxide and alkane-1,2,3-triol**

Table 39: Double masking of UVCB substances – Example 12

Double Masking	Acceptable Masked Name
Propyl parent (plus parent locants) (glycerol)	**Reaction products of Zinc Oxide and alkanetriol**

Example 13

Fully Defined Name

Reaction product of 3,5-di-tert-butylsalicylic acid and aluminium sulfate

Figure 24: Structural formula – Example 13

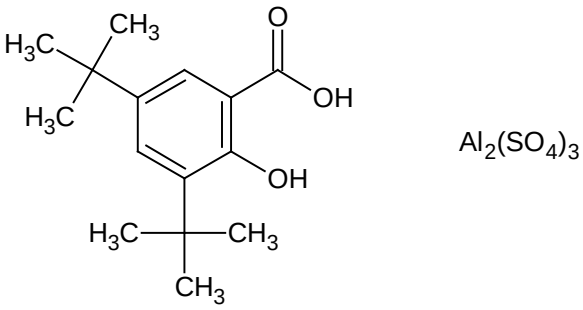


Table 40: Single masking of UVCB substances – Example 13

Single Masking	Acceptable Masked Name
Hydroxyl group (3,5-di-tert-butylsalicylic acid)	**Reaction product of 3,5-di-tert-butyl-2-*substituted*-benzoic acid and aluminium sulfate**
Tert-Butyl groups (3,5-di-tert-butylsalicylic acid)	**Reaction product of 3,5-di-tert-alkyl-salicylic acid and aluminium sulfate**
Benzene parent (3,5-di-tert-butylsalicylic acid)	**Reaction product of 3,5-di-tert-butyl-1-carboxyl-2-hydroxy-arene and aluminium sulfate**

Table 41: Double masking of UVCB substances – Example 13

Double Masking	Acceptable Masked Name
Benzene parent (plus locants) masked (3,5-bis-tert-butylsalicylic acid)	**Reaction product of di-tert-butyl-carboxyl-hydroxy-arene and aluminium sulfate**

7.2.1. Enzymes

Example 14

Fully Defined Name

(R,R)-butane-2,3-diol:NAD+ oxidoreductase, EC 1.1.1.4

Reaction: (R,R)-butane-2,3-diol + NAD+ = (R)-acetoin + NADH + H+

Public Name

Oxidoreductase with NAD+ or NADP+ as acceptor, EC 1.1.1

Example 15

Fully Defined Name

S-adenosyl-L-methionine hydrolase, EC 3.3.1.2

Reaction: S-adenosyl-L-methionine + H2O = L-homoserine + methylthioadenosine

Public Name

Thioether and trialkylsulfonium hydrolases, EC 3.3.1

Example 16

Fully Defined Name

(S)-4-hydroxymandelonitrile hydroxybenzaldehyde-lyase, EC 4.1.2.11

Reaction: (S)-4-hydroxymandelonitrile = cyanide + 4-hydroxybenzaldehyde

Public Name

Aldehyde-Lyases, EC 4.1.2

Annex 2. Example justification – Confidentiality request on IUPAC Name under Article 119(2)(f)

Declaration:

- We, Example Corporation, claim the IUPAC Name of ExampleSubstance confidential in accordance with REACH Article 119(2)(f).
- We, Example Corporation, hereby declare that, to the best of our knowledge as of today (dd mm yyyy), 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 is not publicly available in any of the following public databases: eChemPortal.

Demonstration of Commercial Interest:

- To produce thin film coatings Example Corporation has performed combinatorial experiments to add different organic groups a base plastic monomer, which has resulted in the discovery of the substance covered by this dossier. Such experimentation required substantial investments of time and resources to develop the particular functionalities unique to our SampleProduct range, which arise from the use of the substance covered by this dossier. These particular functionalities represent the major selling point for out SampleProduct range and represent our major competitive advantage in the coatings market.

Demonstration of Potential Harm:

- Disclosure of the IUPAC name of the substance covered by this dossier would allow our competitors to replicate directly the functionalities of our Sample Product range without the need to test a whole variety of organic groups. Disclosure would also allow our competitors to deduce certain of the alternatives explored by Example Corporation, as well as revealing the likely future direction of our product development research. Such immediate replication of the functionalities of our SampleProduct range would harm the market position of Example Corporation, and the ability to deduce the future direction of our product development would allow competitors the opportunity to develop more quickly their own competing products thereby reducing our period of maximum market share.

Limitation to Validity of Claim:

- The request for confidentiality on the IUPAC name of ExampleSubstance should remain valid for a period of six years, in accordance with REACH Article 119(2)(f).

Contact Person:

- Questions on this confidentiality request should be directed to John Q. Smith, REACH Implementation Manager
- Example Corporation, 1234 South Lime Street, London AZ5 12T, UK
- +44 1 123 4567; j.smith@examplecorporation.com

Masking Justification for Public Name - Only required if IUPAC Name claimed confidential

One Level Masking of IUPAC Name - Example 3 (see Annex 1)

- Number of fluorine atoms masked.

Two-Level Masking of IUPAC Name

- Hexane parent and number of fluorine atoms masked, and a valid well-reasoned justification why the second level masking is necessary by the registrant.

Three-Level Masking of IUPAC Name

- Ethoxy group, Hexane parent and number of fluorine atoms masked, and a valid well-reasoned justification why the third level masking is necessary by the registrant.

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