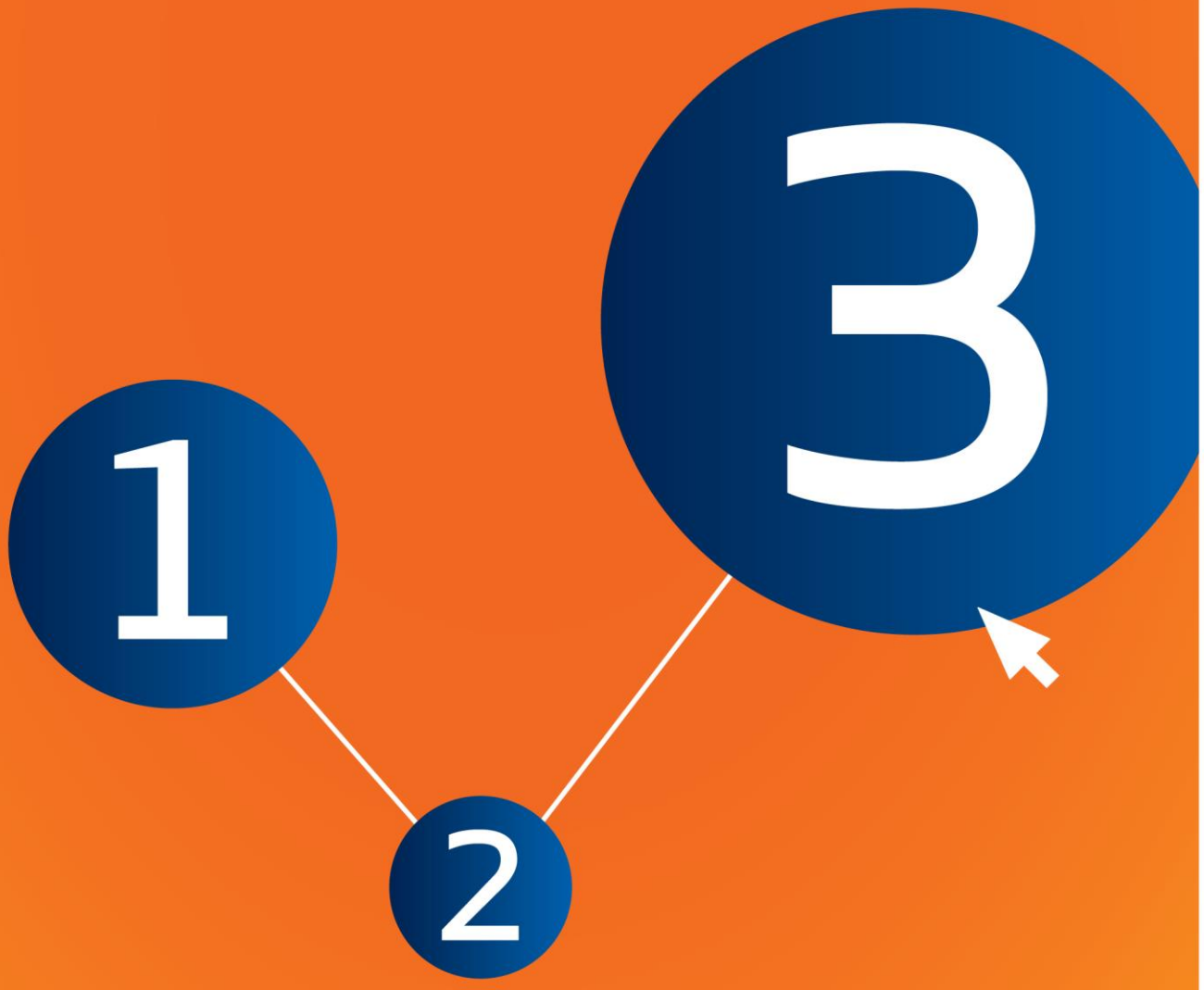
ECHA
EUROPEAN CHEMICALS AGENCY

MANUAL

Dissemination and Confidentiality under REACH Regulation



Changes to this document

Version	Changes
1.0	First version

Legal notice

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This is a working translation of a document originally produced in English. Please note that only the English version, also available on the ECHA website, is the original version.

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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 website, in the section "Information on Chemicals", under the title "Registered Substances".

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 will be assessed by ECHA in accordance with Article 119(2), and where the justification is accepted as valid by ECHA, the information concerned will not be published. Claiming information confidential may be subject to a fee.

It should be noted that in cases 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 in particular managers and technical experts in companies who are responsible for preparing registration dossiers to understand:

- what are the steps in the dissemination process;
- which information will be made publicly available on the ECHA website;
- how to make a confidentiality request, prepare a justification and the basic procedure ECHA will follow 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

Dissemination of information from Registration Dossiers and the assessment of the confidentiality of information will be 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 preparations 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, 2.15 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 preparations 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.

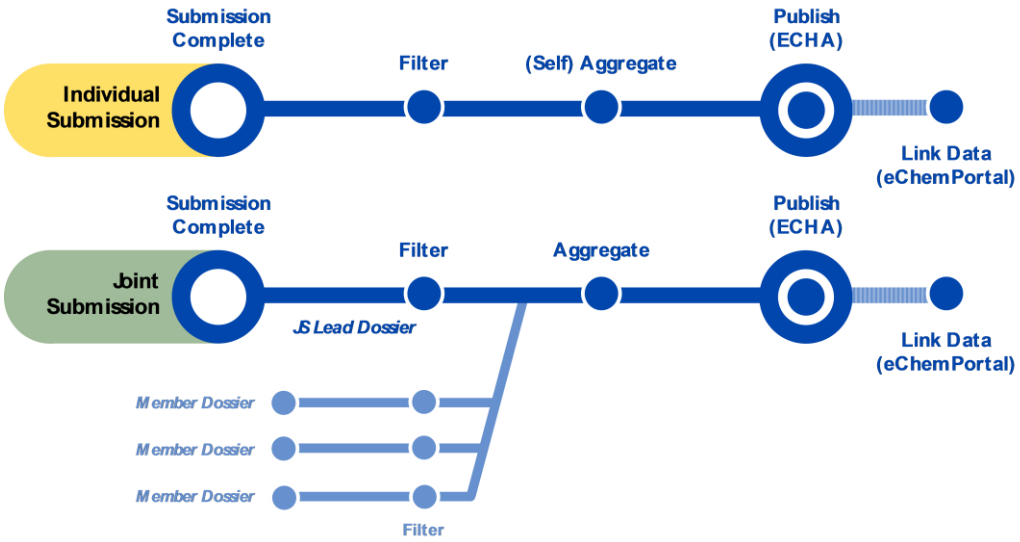
Note that all of the information listed under REACH Article 119(1) will always be disseminated, regardless of whether a registrant attempts to request this information confidential. Hence, any confidentiality requests on this information will be disregarded and no fee will be incurred by such requests. Additionally, the information listed under REACH Article 119(2) will also be disseminated unless a confidentiality request has been submitted and accepted as valid, and the relevant fee paid if applicable.

2. Dissemination

2.1. Dissemination Process

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

Figure 1: The dissemination process



2.1.1. Submission Complete

The process of disseminating 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 will have been informed of his 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. Once a submission is complete the associated dossier will be picked up for dissemination and enters the dissemination workflow.

All complete successful submissions are eligible for dissemination. Publication of the data from a submitted dossier normally takes place within 4 - 6 weeks after the date of submission. The only exception is those dossiers which contain a confidentiality flag set on the IUPAC name of the registered substances, and which do not contain a testing proposal. In these cases the dossier will normally not be published until after the IUPAC name confidentiality claim has been assessed.

2.1.2. Filtering

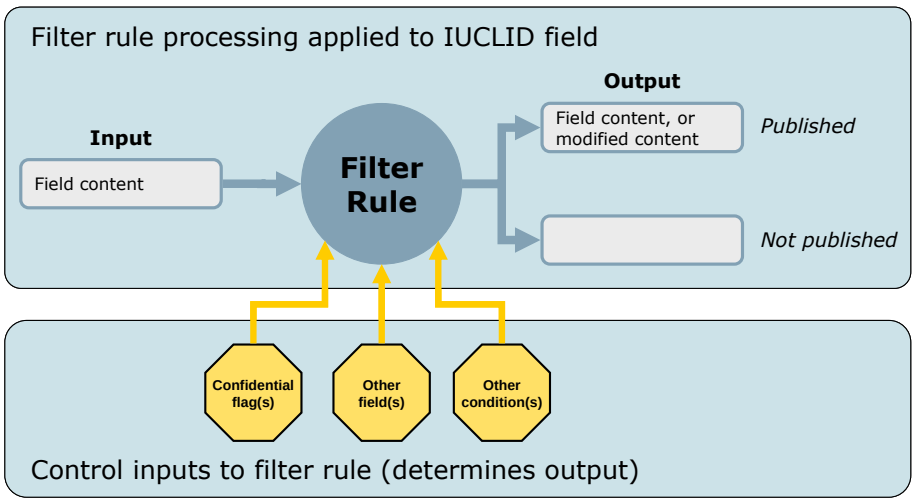
The most important step in the dissemination process is the filtering step in which information not meant to be published is removed from the dossier, along with information flagged or claimed to be confidential (Figure 2).

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. company 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**.

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

Figure 2: Filter Rules



2.1.3. Aggregation

After the filtering step all dossiers pass through another IT tool. This "aggregation" tool is designed mainly for joint submissions, to merge the information from all dossiers in the joint submission into a single aggregated dossier. Nevertheless, it should be pointed out that in case of individual submissions the dossier is treated as if it were a joint submission lead without any members.

Information is to be published by substance, therefore from joint submissions all of the different information from all dossiers in the joint submission is combined into a single dossier prior to publication. The aggregation tool applies three basic rules, based on a prioritisation of the dossiers which are the input to the aggregation process. In general the joint submission lead dossier is given the highest priority. Note however that in cases where for whatever reason no joint submission lead is available to the dissemination system, it has been programmed to select the earliest submitted dossier available to be treated as though it were the lead. The three aggregation rules are:

1. The "Lead dossier rule"

   Information in the aggregated dossier comes only from the joint submission lead dossier. This rule is applied to the most critical data in IUCLID sections 1 to 3, for example the substance identity of the section 1.1 reference substance.

2. The "Add rule"

   Information in the aggregated dossier comes first from the joint submission lead dossier followed by any additional information from joint submission members. Data is taken first from the lead and then from members in a prioritised order (full registrations from high to low tonnage, then On-Site Isolated Itermediate 'OSII' registrations from high to low tonnage, and finally Transported Isolated Intermediate 'TII' registrations from high to low

tonnage). Any duplicate data is removed. This rule is applied to any repeatable elements in IUCLID (repeatable blocks or table rows).

3. The "Merge rule"

   Information in the aggregated dossier comes first from the joint submission lead dossier; any gaps in this information will be filled in if possible from joint submission members in a prioritised order as described above. This rule is applied for example to the "Yes/No" fields in IUCLID.

After the aggregation step, the aggregated dossiers are processed to create a set of html web pages.

2.1.4. Publication and Dissemination Portal

Detailed information on chemical substances for which ECHA has received a REACH registration dossier will be made available on the ECHA website. Information will be 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 will be 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 REACH regulation the information from these notifications will also be disseminated.

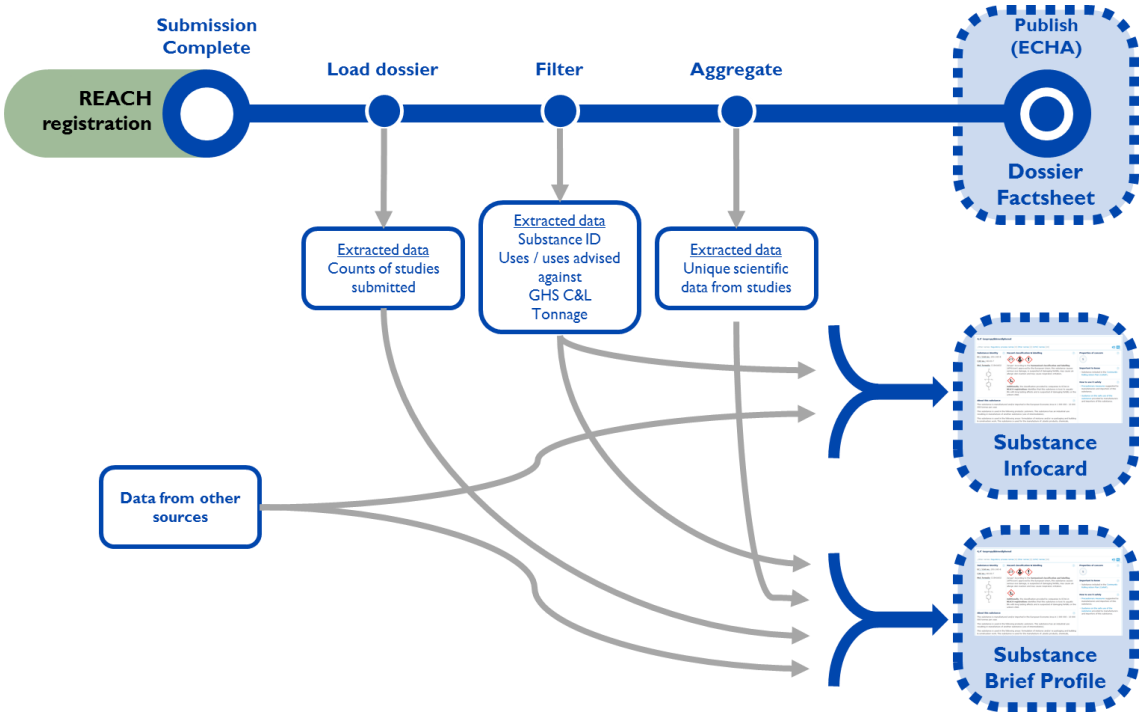
Note that the most recent version of the dossier submitted to ECHA will be published and consequently information from a dossier update will replace information from the previous one. Therefore, in case registrant requests some information confidential special care should be taken to ensure that precisely the same confidentiality requests are selected in the updated dossier as were selected in the original submission unless a 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 ECHA website; detailed information on chemical substances for which a dossier has been registered under REACH can be accessed via the ECHA Website > Information on Chemicals > Registered Substances: http://echa.europa.eu/information-on-chemicals/registered-substances

You can search for a substance by its substance identity (name, EC/List number or CAS number), administrative data (registration type, registrant name, publication date, country, etc), substance data (total tonnage band, PBT assessment outcome and CSA performed) and Uses and Exposure.

ECHA has also developed InfoCards and Brief Profiles for substances, which are significantly based on the data submitted in REACH registrations. Details on the substance classification, uses and exposure and scientific properties are summarised and aggregated in the InfoCards and Brief Profiles. These will be automatically updated whenever the registrations dossiers update with different data. Note that the Infocards and Brief Profiles are also based on data from other sources, including the C&L Inventory, other REACH regulatory processes, and data from the PIC and Biocides regulations.

Figure 3: Substance Infocard and Brief Profile



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 and 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. Aggregated dossier files are processed and key data is extracted to allow searches by chemical name and number or chemical properties such as physicochemical, environmental, ecotoxicological and / or toxicological properties.

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. Aggregated dossier files are processed and key data is extracted to allow QSAR modelling of chemical properties, using from the aggregated dossier files the chemical name and number and 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. Dissemination preview

ECHA has developed a IUCLID plugin 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 Dissemination preview allows registrants to use it while they are preparing their registration dossiers in IUCLID. 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 will be published by ECHA. The tool also produces a report, listing for all information whether it was removed or left in the filtered dossier.

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

2.5. Dissemination 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 disseminated. Confidentiality requests accepted under Directive 67/548/EEC will remain valid under REACH, and no fee will be incurred by such requests. In such circumstances, ECHA will normally not follow the regular assessment procedure, however, plausibility checks (such as if the information can be found in public domain) will be 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 publically 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.

For further information about submitting or updating NONS and how to submit confidentiality requests for NONS, please consult the document "Questions and Answers for the registrants of previously Notified Substances" available at:http://echa.europa.eu/web/guest/support/faqs.

Since NONS notifications were originally submitted in a format different from that of the current IUCLID the full information set was and will continue to be released gradually.

NONS notifications which were 1) Claimed properly in REACH-IT, and 2) Ceased manufacture before 31 May 2012, are considered ineligible for dissemination as these substances were no longer on the European Economic Area (EEA) market.

The publication of NONS registration follows three main steps:

2.5.1. Step One

The first set of data has been disseminated since May 2012. The published information has been reduced compared to what is normally made available from REACH registration dossiers. In ECHA's dissemination website NONS dossiers can be recognised by their purple background

while other registration dossiers have a blue background. The set of disseminated data consists of information which cannot be requested confidential:

- the EC number of the substance (in section 1.1 of the IUCLID dossier);
- the classification and labelling of the substance (sections 2.1 and 2.2);
- physicochemical data concerning the substance and on pathways and environmental fate [excluding information entered in free text fields in the IUCLID dossier] (in sections 4 and 5);
- the result of each toxicological and ecotoxicological study [excluding information entered in free text fields in the IUCLID dossier] (in sections 6 and 7);
- the derived no-effect level (DNEL) and predicted no-effect concentration (PNEC) (in sections 6 and 7);
- the guidance on safe use (section 11).

2.5.2. Step Two

Since November 2012, information which could not be requested confidential under Directive 67/548/EEC was disseminated, if registrants had not updated to indicate their wish for confidentiality.

In particular, whereas under article 19 of Directive 67/548/EEC it was foreseen that secrecy shall not apply to this information, confidentiality could be requested on the following information under REACH:

- the name of the notifier (which under REACH is considered to be part of the information contained in the safety data sheet);
- the information contained in the safety data sheet (including registration number, uses and uses advised against);
- the trade name of the substance;
- 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.

Therefore, requests on this information cannot be justified using the statement "Request previously made under Directive 67/548/EEC", but a full justification needs to be provided and the request will be subject to the corresponding fee under REACH.

2.5.3. Step Three

At some point in the future, the full set of information contained in the NONS dossiers may be disseminated. Before this step, any updates or confidentiality requests should be finalised by registrants.

You are advised to review each of your company's NONS dossiers and ensure that you find it suitable for dissemination. In particular, you should review the free text describing physicochemical data, environmental fate data, and results of toxicological and ecotoxicological studies and ensure that no information you consider as confidential is available in these parts of the dossier, since this information cannot be requested confidential. You should also review the (robust) study summaries and ensure that either no information you consider as confidential is available in these parts of the dossier, or that you have included the necessary confidentiality requests.

To help you review your company's dossier, you can use the Dissemination Preview described in Section 2.4 of this manual. Additionaly, for further information about submitting or updating NONS and how to submit confidentiality requests for NONS, please consult the document "Questions and Answers" at: http://echa.europa.eu/web/guest/support/faqs.

2.5.4. Exceptions

2.5.4.1. Cases with an earlier dissemination timeline

When the quantity of the notified substance reaches the next tonnage threshold, and you submit a **tonnage band update** in accordance with article 24(2), the registration dossier will be disseminated in full as soon as possible after its submission.

An update of a NONS notification containing a testing proposal requiring a public consultation will need to be disseminated in full as soon as possible after its submission, in view of maximising the available information for the public consultation.

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

2.5.4.2. Cases with later dissemination timelines

For **NONS notifications below 1 tonne per year** a reduced set of data has been published as described in Steps one and two above. However, the rest of the information included in such dossiers will be disseminated with later timelines, once a practical solution for submitting this dossier type and/or communicating any confidentiality need has been put in place. All notifiers in such situation will be informed individually by ECHA on how to proceed.

NONS notifications for which the registration number assigned by ECHA has not been requested by the notifier have been disseminated as described in Step one above. The remainder of the data will be published, but with later timelines. Should your company own NONS notifications for which you have not received this message, please request your registration numbers in REACH-IT for these NONS. This will enable us to communicate with you via REACH-IT on these NONS.

2.6. Information disseminated 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 will summarise which fields from a IUCLID dossier will be disseminated.

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 dissemination 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 SIEF or Joint Submission members align where necessary your confidentaility claims 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 will be 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 claim the data confidential.

2.6.2. Assessment entities (IUCLID section 0.4)

From the Assessment entities main record, the public description of the approach to fate/hazard assessment, and the Assessment entities list is published; the relation is displayed but the name of the documents are anonymised.

From the Assessment entity documents, the relation to registered substance, 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 the compositions they relate to have been indicated as confidential. Information on specific Assessment entity composition is also not published if the reference substance describing the material itself has a confidentiality claim.

2.6.3. General Information (IUCLID section 1)

2.6.3.1. Identification (section 1.1)

2.6.3.1.1. EINECS name

The EINECS name of the substance – if one exists – will always be 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=publicfor 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.

2.6.3.1.2. IUPAC Name

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

The IUPAC name of the substance will be 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 section 1.2, to cover the case of multi-constituent substances or reaction masses.

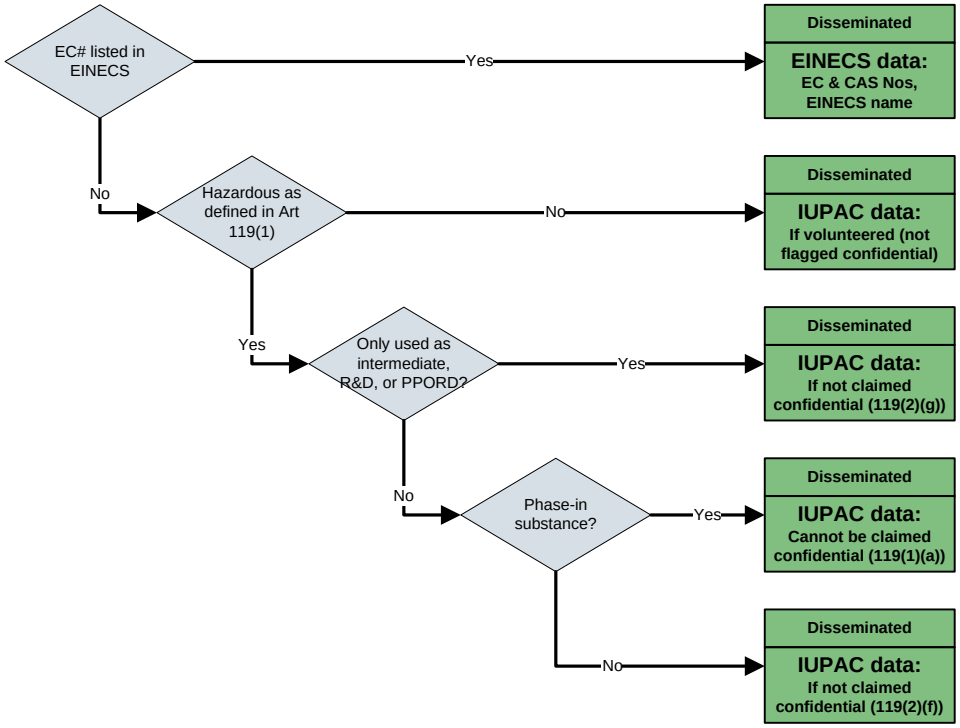
A number of fields related to the IUPAC name, or which can easily be deduced from it, such as the EC information for non-EINECS substances, CAS number, synonyms, molecular formula, molecular weight range, SMILES notation, InChl code and structural formula are considered linked to the IUPAC name. These 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 Section 1.1 or only in 1.2 on one or more constituents plays an important role in terms of dissemination of the information on substance constituents:

In both scenarios all IUPAC name information provided in section 1.1 will be disseminated. Information on constituents in section 1.2 will be maintained confidential ONLY if the constituents were flagged confidential. In such case registrants will be 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 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 he wants the IUPAC name of the substance published or not. For how to proceed with such claims, see chapter 3.6.6.

Figure 4: Flowchart to determine if the IUPAC data of a registered substance will be published



2.6.3.1.3. 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 registrant name will be 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 will be published unless requested confidential, or unless suppliers are listed in section 1.7 whose identity is not requested confidential.

Note that if the OR chooses to have the supplier's name published instead of their own, the OR has to obtain and attach in section 1.7 the agreement by the supplier for the dissemination of their company name.

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

The name of the Third Party Representative (TPR), if provided, will not be published.

Table 1: Legal Entity dissemination

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 disseminated
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	Non-confidential supplier(s) LE name(s) & full address(es) (taken from IUCLID section 1.7)
Only representative	Yes	NA	NA	[Confidential]

2.6.3.1.4. Other 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, will be 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).

2.6.3.1.5. Competent Person responsible for the Safety Data Sheet

Information on the competent person responsible for the safety data sheet will be published unless requested confidential. Note that the competent person published is the legal rather than the natural person. The fields published are the organisation name, the full address and the phone number.

2.6.3.2. Composition (section 1.2)

The field 'Type of composition' allows registrants to indicate more precisely the nature of the composition they have provided. The field will be 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'.

2.6.3.2.1. 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 will be published unless there is a confidentiality request on the IUPAC name of the registered substance.

Constituents

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

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

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

Name

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

2.6.3.2.3. 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 with a tick-box for each impurity or additive whether it is essential to the classification and labelling of the substance (i.e. dangerous).

The degree of purity of the substance will be disseminated if the tick-box is ticked for at least one of the impurities or additives, unless the registrant claimed the degree of purity confidential.

The identity of the impurity or additive will be disseminated if the impurity or additive is essential to the classification and labelling of the substance, unless the registrant claimed the impurity or additive confidential.

The precise details of a composition will never be published (typical concentration or concentration ranges of constituents).

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 will be published.

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

When the registered substance covers nanoforms, IUCLID offers the possibility to provide additional characteristics relevant for the nanomaterial at the bottom of the section 1.2. The fields for reporting characteristics of nanomaterials will not be published until further notice. Information on how this section will be disseminated in the future will be made available in due time.

2.6.3.3. Identifiers (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 will therefore be published in full unless requested confidential (Note that confidentiality on the registration number can be requested either in the dossier header or in section 1.3).

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

Table 2: Registration Number dissemination

Regulatory Programme Field	Registration Number Confidential	Legal Entity Confidential	What will be 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	-

2.6.3.4. Suppliers (section 1.7)

See Legal Entity Details and Table 1 above.

2.6.4. Classification & Labelling, & PBT Assessment (IUCLID section 2)

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

All the IUCLID fields in section 2.1 GHS will be published, as illustrated 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. Dangerous Substances Directive / Dangerous Products Directive (DSD – DPD) (section 2.2)

If provided in the dossier, all the IUCLID fields in section 2.2 DSD – DPD will be published, as illustrated 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.

2.6.4.3. PBT assessment (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 will therefore be 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: overall result, justification and routes of exposure will be published. From the endpoint study records most fields will be published unless requested confidential. The first exception is the reference substance attached to the endpoint study record, which will be published unless 1) the PBT endpoint is flagged cofidential or 2) a flag is set in the reference substance or 3) the IUPAC name of the registered substance is claimed confidential or 4) a constituent is flagged confidential in a linked composition. The other exception is the remark for the assessed substance, which will not be 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 will be published, except for the ones requested confidential.

When members of a joint submission include a PBT/vPvB assessment in their dossier, there will be multiple PBT assessments available in the published dossier. The PBT/vPvB assessments provided by members will be displayed as “Member PBT/vPvB assessment”.

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

Sections 3.2, 3.3, 3.4 and 3.7 will not be published. Note that section 3.7 used to form the sub-section 3.7.2 in IUCLID 5.

2.6.5.1. Life Cycle description (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 (section 3.7.1 in IUCLID 5). The information on generic exposure potential is also incorporated into the life cycle description (previously in IUCLID 5 section 3.7.3). Information on uses and certain elements related to exposure scenarios are considered information contained in the safety data sheet. This information will therefore be published, unless the registrant requested it confidential and ECHA accepted the request as detailed in the IUCLID Dissemination preview.

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. Until 2018, information on exposure scenarios will only be published from updated and new dossiers.

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 will therefore be published, unless the registrant requested it confidential and ECHA accepted the request as illustrated in the IUCLID Dissemination preview.

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

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

2.6.6.1. Endpoint Study Records

Fields referring to results will always be 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 will be 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 will be 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 will be 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 will only be published if the endpoint study record is not requested confidential.

A number of IUCLID fields for Bibliographic references are part of the result. The reference type (e.g. review article, company data,…) determines which fields of the Bibliographic 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 will always be 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 will be published if not claimed confidential. Until 2018, information on endpoint summaries will only be published from new and updated summaries.

Note that as of 2016, the substances Brief Profiles will 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 make an assessment of 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:

1. **Confidential details on test material:** this field should be used to provide information about the test material which you consider confidential. Further information can be found in the IUCLID help text. The analytical purity, composition and impurities of the test material, the purity test date, the lot or batch number, the expiration date of the lot/batch, and the isomers composition for example should be provided here, if you do not want this information published on the internet.
2. **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.
3. **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 will be 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 your company 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 an indication of this will be 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 will not be 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 will be extracted for the last year reported, unless the tonnage band has been requested confidential. Data will not be extracted from dossiers for intermediate registrations under REACH Articles 17 or 18.

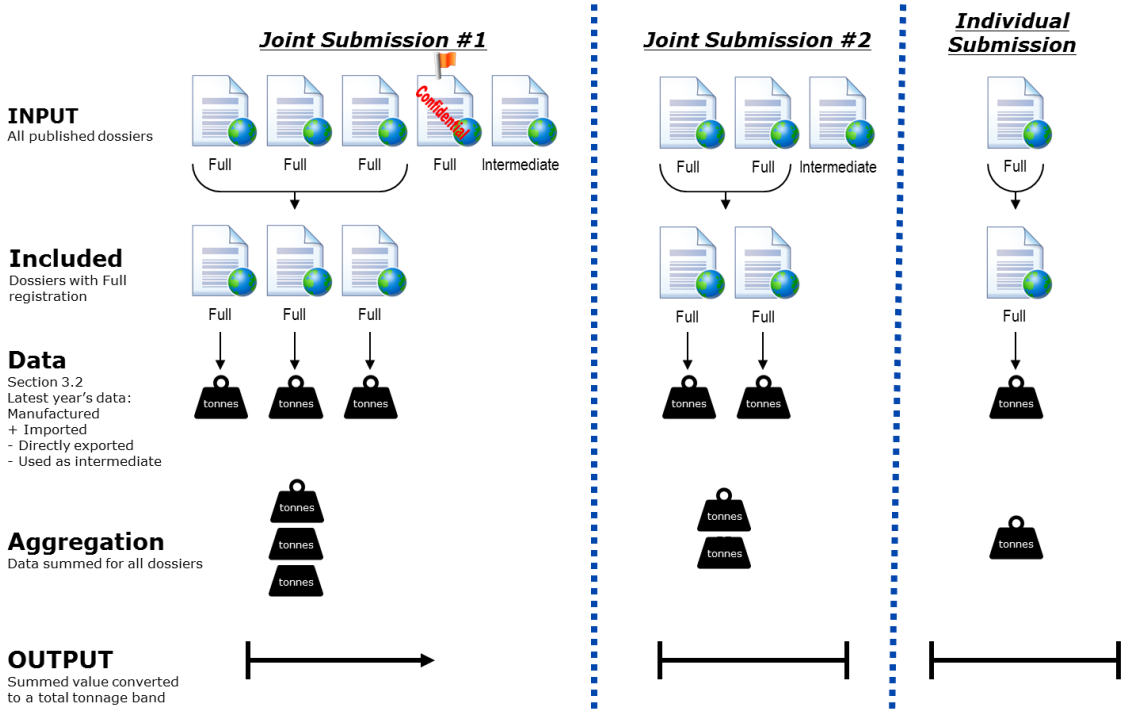
The tonnage data extracted per dossier from section 3.2 of IUCLID will be the manufactured + imported tonnage - tonnage directly exported – tonnage immediately used as intermediate.

For joint submissions a total tonnage is calculated by summing the data from all full registration dossiers in the joint submission, except those for which the tonnage band is requested confidential. For individual submissions a total tonnage is calculated if the submission is of a full registration dossier and the tonnage band is is not requested confidential. The exported tonnage is discounted from the manufactured and/or imported tonnage.

The total tonnage is then converted to a total tonnage band, and it is the total tonnage band that will be published on the ECHA website.

1) Total tonnage band calculation

Figure 5: Total tonnage band calculation



2) Tonnage bands explanation

Figure 6: Tonnage bands explanation

Open tonnage band
Where 1+ dossiers are claimed confidential. This indicates that there is additional tonnage data not accounted for in the calculation, which might bring the total tonnage up to the next band.

1+ tonnes
10+ tonnes
100+ tonnes
1 000+ tonnes
10 000+ tonnes
100 000+ tonnes
1 000 000+ tonnes etc

Closed tonnage band
Where tonnage data from all dossiers is accounted for in the calculation.

0 – 10 tonnes
10 – 100 tonnes
100 – 1 000 tonnes
1 000 – 10 000 tonnes
10 000 – 100 000 tonnes
100 000 – 1 000 000 tonnes
1 000 000 – 10 000 000 tonnes etc

Example 1:

A joint submission of 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 – 100 000 tonnes per annum

Example 2:

The same joint submission as above, but where one 50 000 tonnes are exported. The total net tonnage is 7 782 tonnes manufactured or imported. The published total tonnage band is then:

1000 – 10000 tonnes per annum

Example 3:

The same joint submission as the first, but this time some of the registrants with full registrations have requested their tonnage band confidential. The total tonnage calculated from only the non-confidential full registration dossiers is now 52 251 tonnes manufactured or imported. The published total tonnage band is then:

10 000+ tonnes per annum

Example 4:

An individual submission for a full registration, where the tonnage band is not requested confidential. The total tonnage calculated from the dossier is 180 000 tonnes manufactured or imported. The published total tonnage band is then:

100 000 – 1 000 000 tonnes per annum

Note that for published NONS notifications the tonnage band is automatically assumed to be confidential, except in cases where the NONS has been updated to increase the tonnage band registered. See chapter 2.5 for details.

2.6.12. Dissemination of the bibliographic references

Table 3 outlines the dissemination of information from the bibliograhic references in the endpoint records of sections 4 to 7 of IUCLID. Table 4 explains the publication criteria.

Table 3: Dissemination of the bibliographic references

Reference	Information published
Reference type	Always published
Title	Published unless protected (see Table 4)
Author	Published unless protected (see Table 4)
Year	Always published
Bibliographic source	Published unless protected (see Table 4)
Testing laboratory	Never published
Report no.	Never published
Owner company	Never published
Company study no.	Never published
Report date	Always published
Remarks	Never published

Table 4: Outcome for the publication of bibliographic references author, title and bibliographic source

Conditions				Outcome
Confidentiality request on the IUPAC name of the registered substance	**Confidentiality request on endpoint record**	**Reference type**	**Testing laboratory, Report no., Owner company, Company study no.**	**Dissemination of author / title / bibliographic 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 bibliographic 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 the study. This is to be noted if ECHA rejects a claim on the confidentiality 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.

Confidentiality requests relating to information covered by REACH Article 119(2) a fee will be incurred and the request must be accompanied by a full justification. In such cases the request will be upheld only where the appropriate fee is paid and the justification 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) will be disseminated and confidentiality requests on this information will be disregarded, and no fees will be incurred.

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

3.2. Information on Public Names

Following the entry into force on the 1st of 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

As long as 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.

There are several cases where the information might not be provided in member dossiers, but is only provided in the lead dossier on behalf of all the members of the joint submission (e.g. a study summary). In these cases only the lead registrant is required to put 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 claims, in particular the confidentiality claim 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 will be incurred for previously submitted requests – a fee will only be incurred if the registrant requests additional information falling under REACH Article 119(2) confidential.

Note that the most recent version of the dossier is the version which will be disseminated by ECHA, and it is the confidentiality requests in this version which will be used to determine the information that will be published 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.

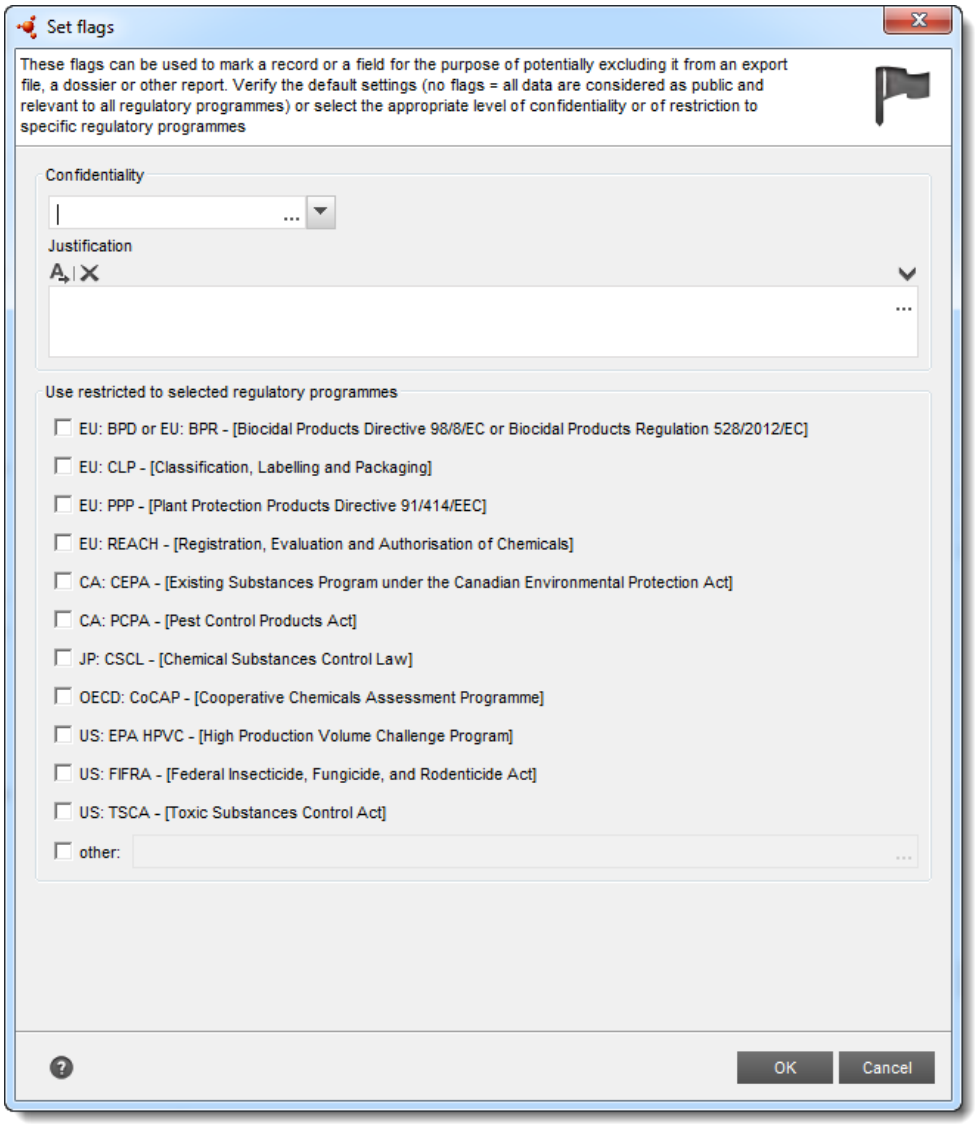
3.4. Making confidentiality requests

Next to each piece of information in IUCLID 6 substance dataset is a confidentiality request flag:

Figure 7: Example of an Unset Confidentiality Request Flag in IUCLID

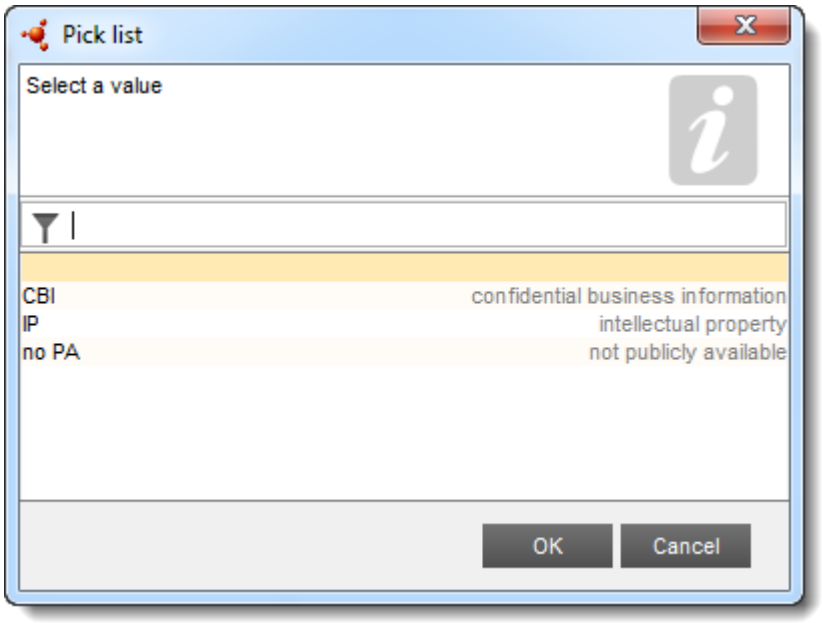
To request the information confidential this flag must be set to 'CBI' (Confidential Business Information), 'IP' (Intellectual Property), or 'no PA' (Not Publicly Available). Click on the flag to bring up the 'Set Flags' Window:

Figure 8: 'Set Flags' pop-up window in IUCLID



Click on the Confidentiality Dropdown arrow next to the 'Confidentiality' text box to select 'CBI', 'IP' or 'no PA'. The box for 'EU: REACH' may also be ticked, though ECHA will detect requests even if the box is unticked.

Figure 9: Confidentiality Dropdown Pick List



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

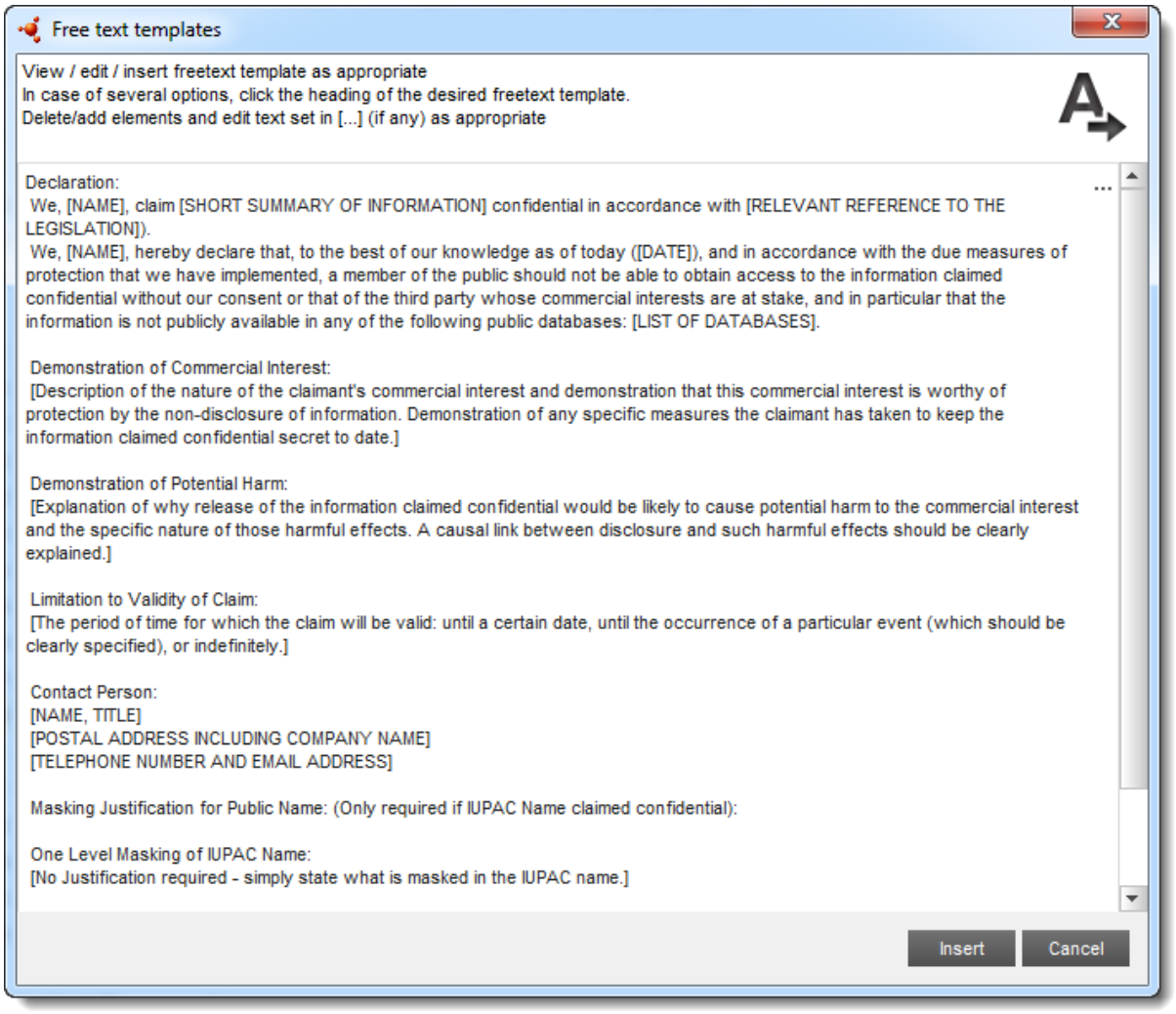
Next click on the justification text box to enter a justification for the confidentiality request. For information falling under REACH Article 119(2) it is strongly recommended to use the justification template described in this document. This will ensure that the justification contains all the necessary information to be assessed by ECHA.

Clicking the icon 'A' below the justification adds a sample justification to the free text field. Click on *insert* and adapt the justification accordingly. Make sure to delete irrelevant parts for the specific request type, e.g. delete the public name section for the case it is not applicaple for Non-IUPAC name requests.

A justification may also be provided as an attachment, but ensure that 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 expanding on the selected confidentiality flag type, 'CBI', 'IP' or 'no PA':

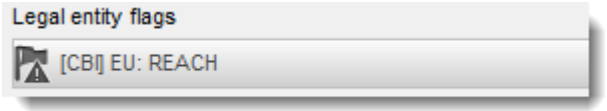
Figure 10: Confidentiality Justification Text Box



Some text must be entered in every confidentiality request flag justification text box for requests in accordance with Article 119(2), otherwise the submitted dossier will not be accepted for processing by REACH-IT (i.e. business rule failure).

When 'OK' is clicked to close the 'Set Flags' window, the flag should be shaded to indicate it is set, and the text entered in the justification text box should be visible:

Figure 11: Example of a Set Confidentiality Request Flag



Once the confidentiality flag next to a piece of information has been set, the information is regarded as having been requested confidential.

Note that in some cases multiple flags in IUCLID are applicable to a single piece of information to be requested confidential, 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 will be incurred in accordance with Annex IV of the Fee Regulation, and the dossier containing the request will be invoiced and processed accordingly. If a flag refers to information not covered by REACH Article 119(2) no fee will be 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 3: 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	Section 1.2: Degree of Purity & ☑ "this impurity is considered relevant for the classification and labelling of the substance" & the type of composition is 'legal entity composition' AND / OR Section 1.2: Impurities: Flag above Reference Substance & ☑ "this impurity is considered …" & the type of composition is 'legal entity composition' AND / OR Section 1.2: Impurities / Reference Substances: Flags in a linked Reference Substance (one or both flags: Reference Substance information; Molecular and Structural Information) & ☑ "this impurity is considered …" & the type of composition is 'legal entity composition' AND / OR Section 1.2: Additives: Flag above Reference Substance & ☑ "this additive is considered …" & the type of composition is 'legal entity composition' AND / OR Section 1.2: Additives / Reference Substances: Flags in a linked Reference Substance (one or both flags: Reference Substance information; Molecular and Structural Information) & ☑ "this additive is considered …" & the type of composition is 'legal entity composition'	One single fee will be calculated regardless of how many or which of the above flags in relation to a particular piece of information are selected.
Tonnage Band	REACH Article 119(2)(b)	€61 to €1631	Dossier Header: Checkbox "Confidentiality request 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 fee will be calculated for each (robust) study summary requested confidential.
Other information in the Safety Data Sheet – Life cycle description and Uses advised	REACH Article 119(2)(d)	€122 to €3261 *	Sections 3.5.1 - 3.5.5: Confidentiality requests in any Identified Use. Such a request should be flagged on the first tab of any of the records where the use is reported. Sections 3.6.1 - 3.6.4: Confidentiality requests in any	* One single fee will be calculated no matter how many flags in relation to request types falling under Art. 119(2)(d) are selected. The fee will be invoiced for

against			Use Advised against. Such a request should be flagged on the first tab of any of the records where the use/use advised against is reported. Several records can be created on uses and uses advised against and each of them can be claimed confidential separately.	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 *	Dossier header: Checkbox "Confidentiality request on registration number" or within the corresponding table in Section 1.3 "Regulatory programme identifiers" when "REACH registration number" is selected as programme identifier.	* One single fee will be calculated regardless how many flags in relation to request types falling under Art. 119(2)(d) are selected. The fee will be 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 above Legal entity	* One single fee will be calculated no matter how many flags in relation to request types falling under Art. 119(2)(d) are selected. The fee will be 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 above the endpoint summary or Section 2.3: flag above each endpoint study record	* One single fee will be calculated no matter how many flags in relation to request types falling under Art. 119(2)(d) are selected. The fee will be 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 any of the tabs listed below below listed tabs: 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 will be calculated no matter how many flags in relation to request types falling under Art. 119(2)(d) are selected. The fee will be 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: flag in section 13 and the "REACH Chemical safety report (CSR)" is selected as report type.	* One single fee will be calculated no matter how many flags in relation to request types falling under Art. 119(2)(d) are selected. The fee will be 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. Such a request should be flagged on the first tab of any of the records where the article service life and article service life advised against is reported.	* One single fee will be calculated no matter how many flags in relation to request types falling under Art. 119(2)(d) are selected. The fee will be invoiced for dossiers that require a Safety Data Sheet according to REACH Art. 31(1) and that require a chemical safety report (CSR).
Trade name(s) of the substance	REACH Article 119(2)(e)	€61 to €1631	Section 1.1: Flag in table "Other names" if there is a confidentiality flag in a row with Name Type 'Trade name'.	One single fee will be 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	Regardless the location of the flag, a claim on the IUPAC name is valid only if in section 1.2 the type of composition is 'legal entity composition'. Section 1.1: Flag above the Reference Substance (preferred way of indicating a confidentiality request on the IUPAC name) Section 1.1: Flags in a linked Reference Substance (one or both flags: Reference Substance information; Molecular and Structural Information) Section 1.2: Constituents: Flag above 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 in particular useful when confidentiality requests on the IUPAC name of the registered substance are inadmissible. Section 1.2: Constituents / Reference Substances: Flags in a linked Reference Substance (one or both flags: Reference Substance information; Molecular and Structural Information)	One single fee will be calculated no matter how many flags from the list are selected. In addition, a fee is applicable only if the substance is a non-phase in substance and fulfils the criteria for any of the hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008. 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	Regardless the location of the flag, a claim on the IUPAC name is valid only if in section 1.2 the type of composition is 'legal entity composition'. Section 1.1: Flag above the Reference Substance (preferred way of indicating a confidentiality request on the IUPAC name) Section 1.1: Flags in a linked Reference Substance (one or both flags: Reference Substance information; Molecular and Structural Information) Section 1.2: Constituents: Flag above 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 in particular useful when confidentiality requests on the IUPAC name of the registered substance are inadmissible. Section 1.2: Constituents / Reference Substances: Flags in a linked Reference Substance (one or both flags: Reference Substance information; Molecular and Structural Information)	One single fee will be calculated no matter how many flags from the list are selected. In addition, a fee is applicable only if the substance fulfils the criteria for any of the hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008 and 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.

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

The precise fees which will be incurred for requesting the above information confidential, along with all other REACH related fees, can be found 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 (in particular 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 4: 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 in cases 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 will normally mean that effects on competition are lower.

For dissemination 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 that the tonnage band in which the

substance is manufactured / imported will not be disclosed, 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 5: 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).	

Note on the assessments of the confidentiality requests: 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 will assess whether the registrant requesting his tonnage information confidential can demonstrate that disclosure of his tonnage information could cause potential harm to his or a third party's commercial interest.

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

3.6.3. Requests 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 6: 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 dissemination 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 and indication on whether a chemical safety assessment was performed 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 7: 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 ECHA's dissemination 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.	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 dissemination 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.

Table 8: 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.

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

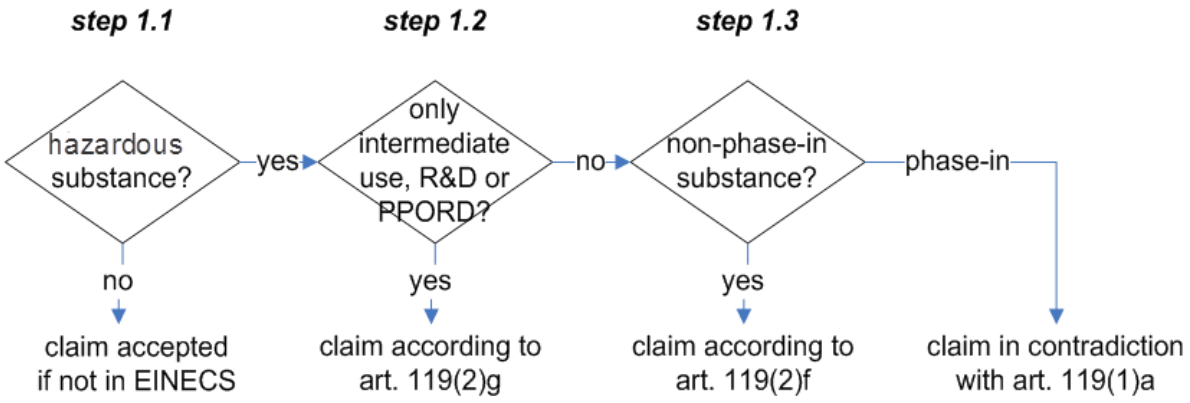
Rationale for requesting the information confidential:

The rationale for making confidentiality requests for the IUPAC name lies mainly with 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.

Note that where the IUPAC name is requested confidential a **public name must be provided** for dissemination. 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.

Regarding confidentiality flags on the IUPAC name ECHA distinguishes 4 cases:

Figure 12: Confidentiality of IUPAC name



a. Non-Hazardous substances (step 1.1.)

There are no provisions in REACH requiring dissemination 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 will be disseminated unless you flag it confidential in which case no fee will be incurred and no justification need to be provided.

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

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 into Art. 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 considered as an intermediate.

Note that registrants can submit a PPORD dossier, which is not subject to dissemination 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.

Note that 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 Art. 119(2)(f) (step 1.3)

If your substance is a hazardous non-phase-in substance, the request falls within the scope of REACH Art. 119(2)(f). This means that the IUPAC name can be kept confidential for a limited period of 6 years.

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

Confidentiality requests on the IUPAC name are considered as inadmissible if they neither fall in the scope of Art. 119(2)(f) nor in the scope of Art. 119(2)(g).

For example for a hazardous substance classified in one of the hazard classes listed in Article 119(1)(a), which has been registered as a phase-in substance, the conditions set out in Art. 119(2)(f) are not fulfilled. When additionally the use information provided in the registration dossier for such a substance indicates that the use(s) go(es) 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 Art. 119 (2)(g) are not fulfilled either.

However, such a substance falls into the scope of Article 119(1)(a), meaning that the IUPAC name will be published on the ECHA website.

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

Table 9: 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 in cases 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 (Note that PPORD dossiers are not disseminated 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 not falling under REACH Article 119(1) or (2) the confidentiality request justification could simply be a short sentence expanding on the selected confidentiality request flag type, 'CBI', 'IP', or 'No PA';. These confidentiality flags will not trigger an invoice nor any assessment.

For information falling under REACH Article 119(1) any confidentiality request justification will be disregarded, as such information will always be disseminated;

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:

- The information must be known only to a limited number of persons, 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 simple statements.
- The existence of a commercial interest must be demonstrated (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 particular case and whether a request can be accepted as valid will be performed by ECHA, as described in chapter 3.8.

As explained above, ECHA will seek certain elements in a confidentiality request justification for confidentiality requests on information falling under REACH Article 119(2). Note that 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.

3.7.1. Elements to be present in the justifications in general

ECHA will assess 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 of the required elements and are well reasoned.

Table 10: 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). In the particular case that any public authority has 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 the registrant or a third party	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 relationship between disclosure and such harmful effects should be explained. The description should be clear, transparent and persuasive.

Table 11: 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 in case further clarifications are needed.

Table 12: 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.

Note that absence of any required elements for requesting confidentiality will lead to a 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 SDS – 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

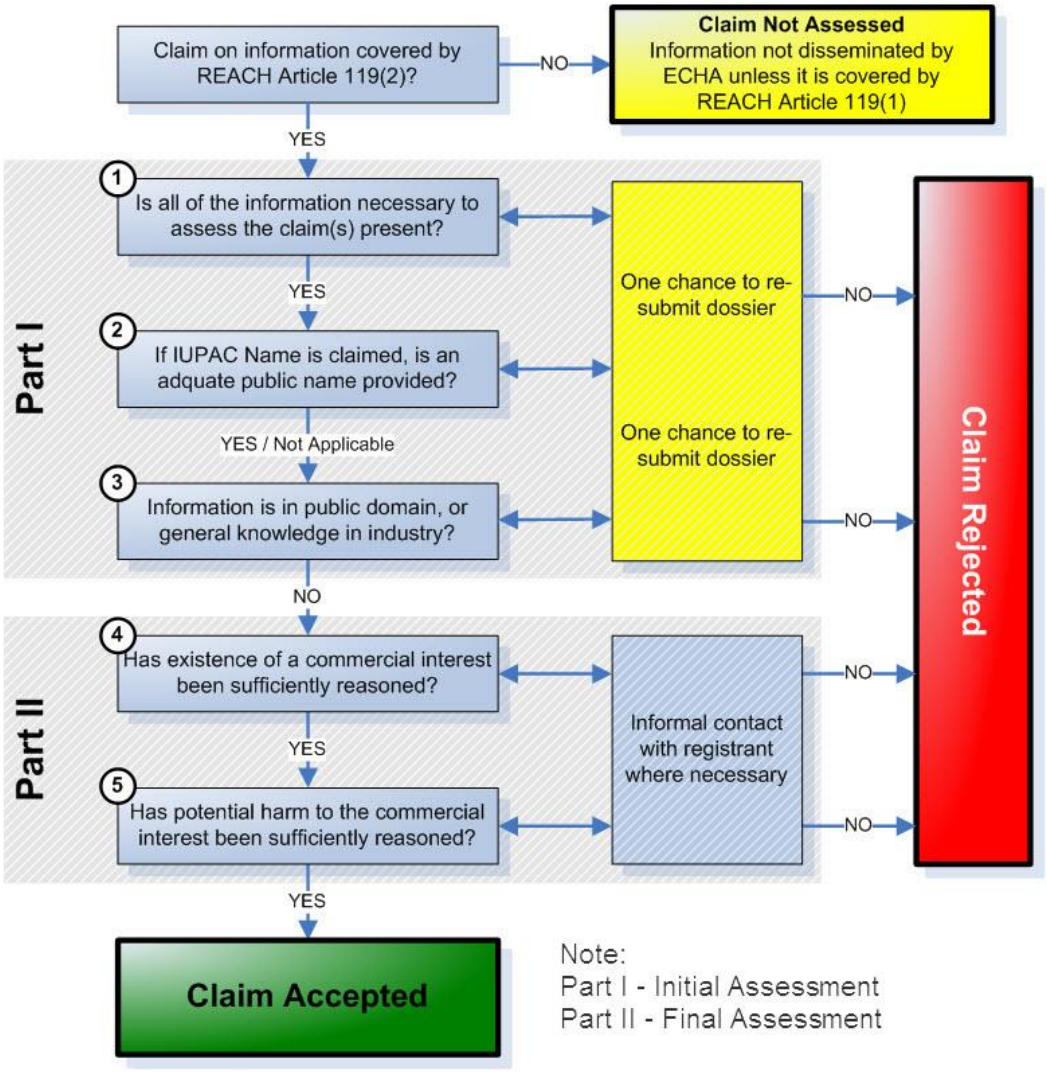
3.8.1. Assessment procedure

An important objective of REACH is to ensure that EU citizens have access to information about chemicals to which they may be exposed, 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 will only be 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 therefore the task of ECHA to assess registrants' 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 in all registration dossiers will be assessed.

The 5-step workflow ECHA will use to assess confidentiality request justifications is as follows:

Figure 13: Flowchart of standardised confidentiality request assessment process



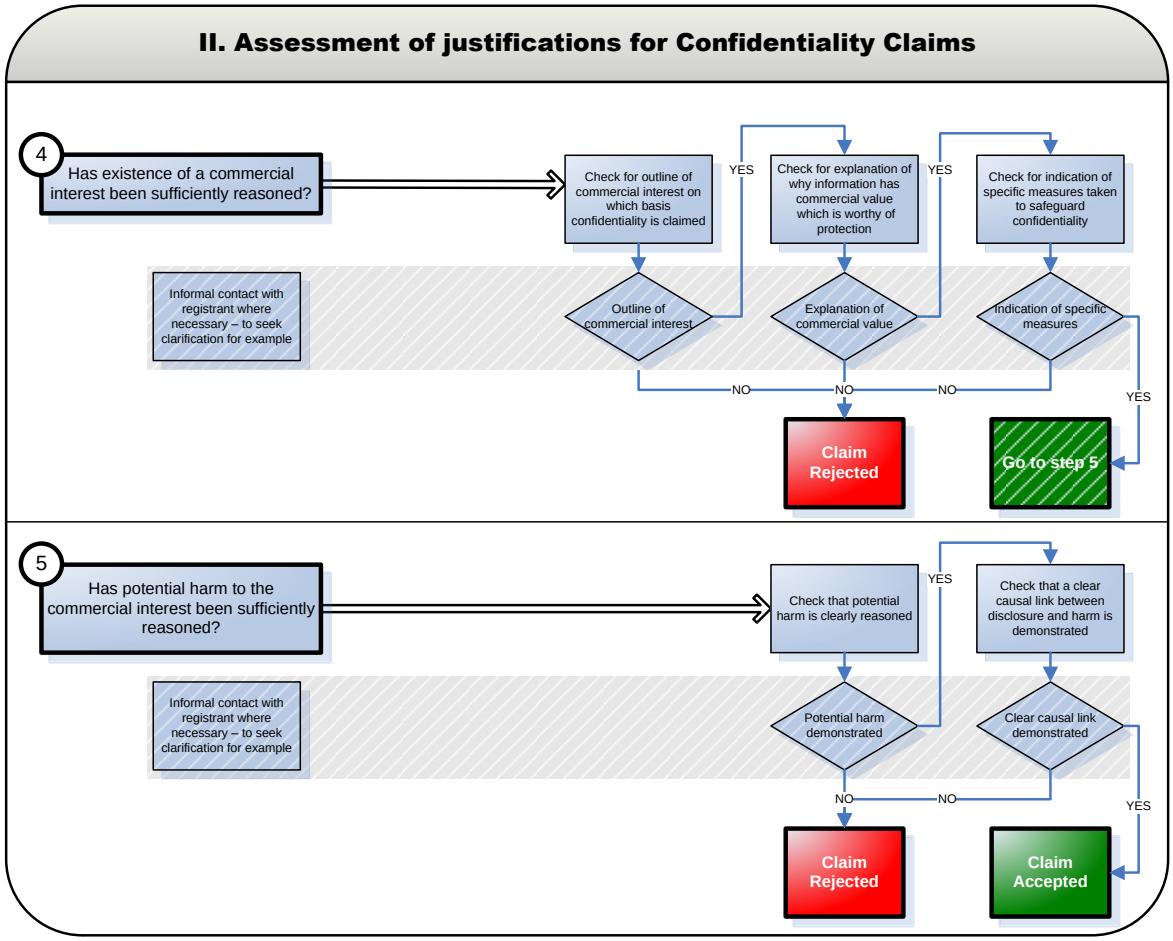
Before starting the assessment workflow, each confidentiality request will be examined to see if it relates to information covered by REACH Article 119(2). If not then the request is inadmissible and will not be assessed. In the cases of requests which are not assessed if the information requested confidential falls under REACH Article 119(1) then the request will be disregarded and the information will be published on ECHA's dissemination website; if the information requested confidential does not fall under REACH Articles 119(1) or (2) then the information concerned will not be published.

In the workflow itself, ECHA carries out an initial assessment of the request. In this step, it will be 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 will be checked that an adequate public name, and if two- or three-level masking are used that an appropriate justification is provided. Next, it will be checked that the information requested confidential is not in the public domain, using a list of databases as given below. During the initial assessment, ECHA will also highlight 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 will give registrants one chance to update the justification and provide missing/additional elements.

In a second step, and taking into account any potential updates and clarifications to the justification by the registrant following the initial assessment, ECHA will carry out a final assessment of the justification. During this assessment, ECHA will verify the following: firstly the existence of a commercial interest worthy of protection by the non-disclosure of information must be demonstrated in a well-reasoned manner and secondly the potential harm to this commercial interest if information is disclosed must be explained, and a clear causal link between disclosure and any harmful effects must be clearly demonstrated.

Requests made under the different subsections of Article 119(2) will vary in the assessment of pre-conditions in Part I above, but the assessment of the main elements of confidentiality request justifications will usually follow the same standard workflow, as follows:

Figure 14: Workflow for Assessment of Justifications for Confidentiality Requests



3.8.2. List of Databases

The databases which may be used by ECHA in the assessment of confidentiality request justifications for information requested confidential under REACH Article 119(2) include the following. These databases will be used during the assessment of whether the information requested confidential is in the public domain.

- 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 in the registrant's submitted dossier. If, after an initial assessment, the confidentiality request is found insufficiently complete to allow ECHA to accept it, the registrant will have one opportunity to re-submit their dossier and add additional elements to the justification. In this case, ECHA will contact the registrant outlining 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.

Note – to allow ECHA to engage in informal contact with a registrant during assessment of the main elements of a 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 their REACH-IT account regularly to be able to react to any communications from ECHA concerning their confidentiality requests promptly within the set deadlines.

3.8.4. Administrative review of confidentiality request decision

Based on Article 118(3) of the REACH Regulation, the Management Board of ECHA has adopted a review procedure, establishing a process whereby registrants can request a review following a partial or full rejection of a confidentiality request. The Decision establishing this process can be downloaded here:

http://echa.europa.eu/documents/10162/13608/final_mb_17_2008_decision_on_review_of_rejection_of_confidentiality_requests_en.pdf

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

Where ECHA has decided to wholly or partly reject a confidentiality request, this decision shall be notified to the registrant. 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 will not be disseminated 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 will substantiate those grounds. The request must be submitted to by filling

out the web-form to submit a request for review of a partial or full rejection of a confidentiality request 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 or fax:

By mail: European Chemicals Agency (ECHA)
Executive Director
P.O. Box 400
FI-00121 Helsinki

By fax: + 358 9 6861 8940

A decision on the review will be taken within two months from the date of receipt of the request, and will be notified to the registrant in writing via REACH-IT. Should the registrant disagree with the decision, he has 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. Note that the information requested confidential will not be disseminated 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 published dossiers. The information where the presence of a confidentiality request will be indicated is:

- 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
    - Registrant name
    - Registration number
    - PBT assessment outcome
    - Indication whether chemical safety assessment was performed
- 119(2)(e) Trade name(s)
- 119(2)(f) or (g) IUPAC name

Note that the presence of a confidentiality request will NOT be 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[1]
- 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[2] is claimed as confidential[3] 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 claimed 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 will often also be 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 claimed as confidential it will not be made publicly available nor will the structural information for that substance. If no other non-confidential substance identifier is available (e.g. an EINECS name), a public name will be disseminated.

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

[1] 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
[2] 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
[3] How to make a confidentiality claim for the IUPAC name in accordance with Article 119(2)(f) or (g) of the REACH Regulation is described in chapter 3 of this manual

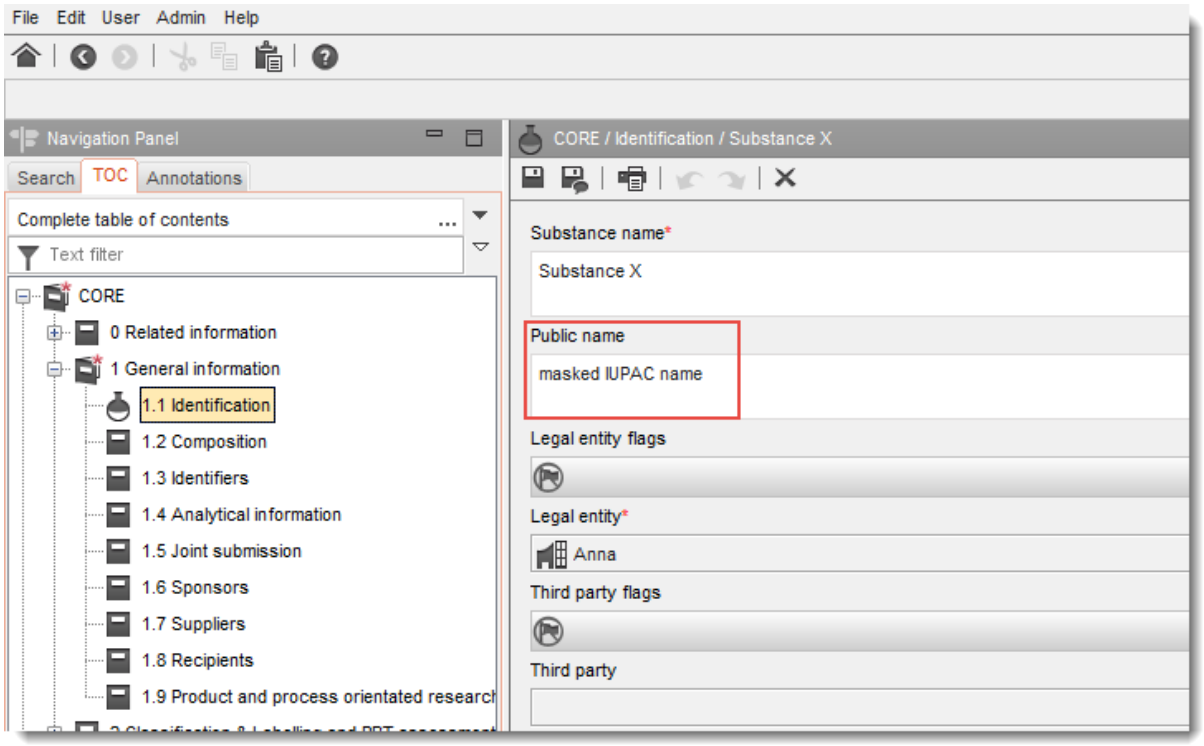
ECHA will need to use their professional judgement. The manual will be updated on the basis of experience in generating public names.

3. Where to include the public name?

If the registrant makes a confidentiality claim for the IUPAC name he is required to provide an appropriate public name (masked name) for ECHA to use for dissemination purposes. In the absence of an adequate public name, a confidentiality claim for 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 the user creates a substance following the steps as indicated by IUCLID he will arrive at the substance identification screen where he can include the masked name in the public name field as indicated in the next screen shot.

Figure 15: Location of the public name field in IUCLID



If the IUPAC name is claimed confidential, the justification for the confidentiality claim will also need to include a masking justification for the public name. In case of one level masking, this will 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 will lead to a rejection of the claim and publication of the IUPAC name.

If a claim on the IUPAC name has been accepted by ECHA, no structural information is disseminated. 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 dissemination 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 claim 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[4]. 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.[5]

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;

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

- 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;
- 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.

As a consequence 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 disseminated unless already published on EINECS[6].

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 of the Guidance document for identification and naming of substances under REACH 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.

[6] European Inventory of Existing Chemical Substances

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 disseminated unless already published on EINECS[7].

4.2.2.3. Enzymes

Enzymes are named according to the IUBMB nomenclature conventions[8]. The IUBMB 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 8 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) has to 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 claim justifications is provided in chapter 6 of this Annex.

For confidentiality claims of 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 claim cannot be accepted by ECHA.

When making a confidentiality claim 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 claims 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 the claim as valid if an adequate public name, and if applicable, a valid

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

justification as to why two or three levels of masking are necessary, is provided.

Absence of any other mandatory elements for claiming confidentiality will also lead to a rejection of the confidentiality claim for 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 claim template.

6. Further information

IUPAC Nomenclature of Organic Chemistry

http://www.chem.qmul.ac.uk/iupac/

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

http://www.chem.qmul.ac.uk/iupac/jcbn/index.html#6

Guidance document for identification and naming of substances under REACH

http://guidance.echa.europa.eu/docs/guidance_document/substance_id_en.pdf

7. Examples of Substances

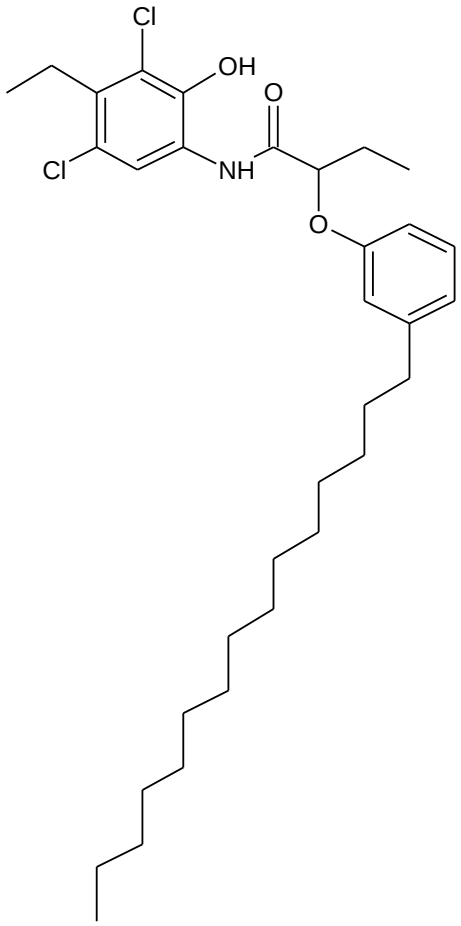
7.1. Well-Defined Substances

7.1.1. Mono-constituent substances

Example 1

Fully Defined Name

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



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**

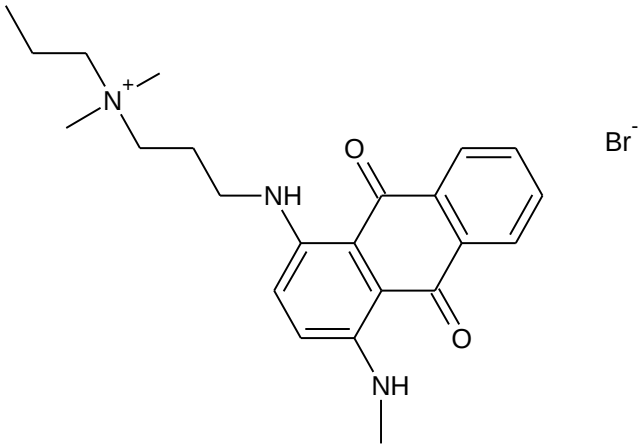
Ethyl group	**N-(3,5-dichloro-4-alkyl-2-hydroxyphenyl)-2-(3-pentadecylphenoxy)butanamide**
Pentadecyl group	**N-(3,5-dichloro-4-ethyl-2-hydroxyphenyl)-2-(3-alkylphenoxy)butanamide**
Butane parent	**N-(3,5-dichloro-4-ethyl-2-hydroxyphenyl)-2-(3-pentadecylphenoxy)alkanamide**

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



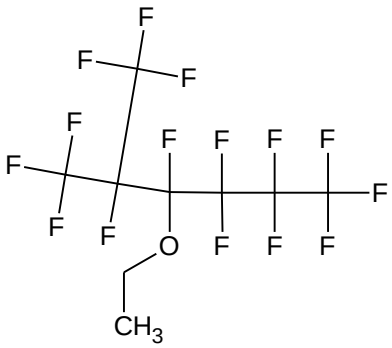
Single Masking	Acceptable Masked Name
Bromine anion	**N,N-Dimethyl-3-{[4-(methylamino)-9,10-dioxo-9,10-dihydroanthracen-1-yl]amino}-N-propylpropan-1-aminium salt**
Oxo groups	**N,N-Dimethyl-3-{[4-(methylamino)-9,10-di*substituted*-9,10-dihydroanthracen-1-yl]amino}-N-propylpropan-1-aminium bromide**
Methyl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

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



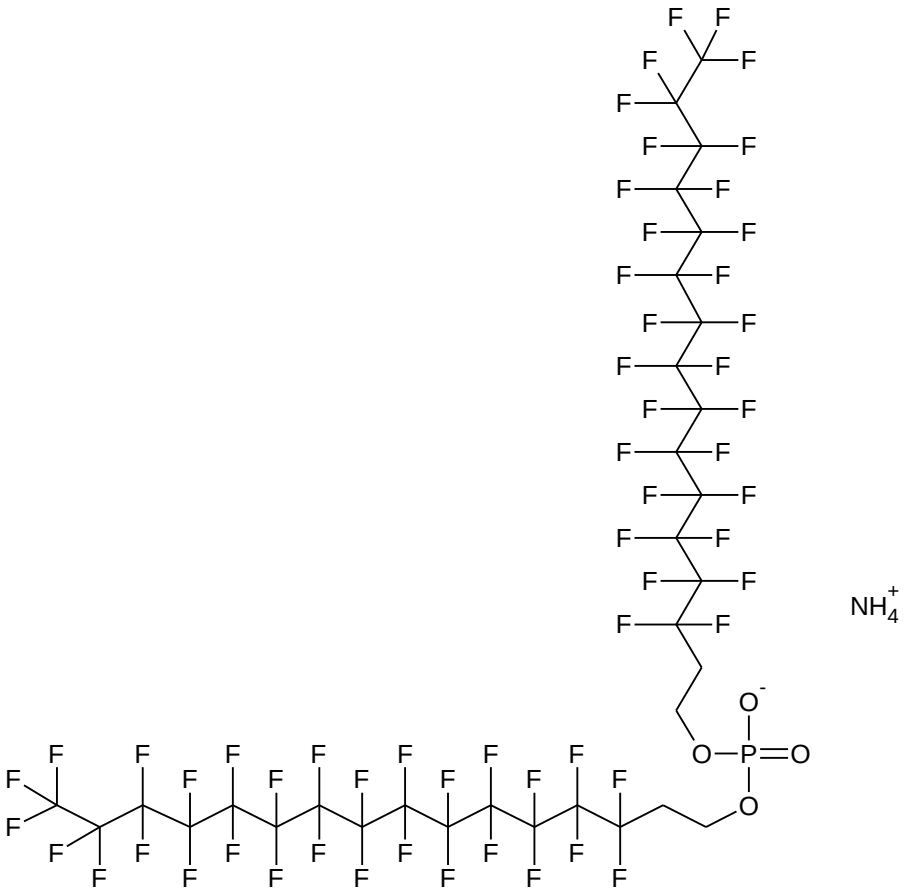
Single Masking	Acceptable Masked Name
Number of fluorine atoms	**3-ethoxy-polyfluoro-2-(polyfluoromethyl)hexane**
Fluorine atoms	**3-ethoxy-1,1,1,2,3,4,4,5,5,6,6,6-dodecahalo-2-(trihalomethyl)hexane**
Ethoxy group	**3-(alkoxy)-1,1,1,2,3,4,4,5,5,6,6,6-dodecafluoro-2-(trifluoromethyl)hexane**
Hexane parent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

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



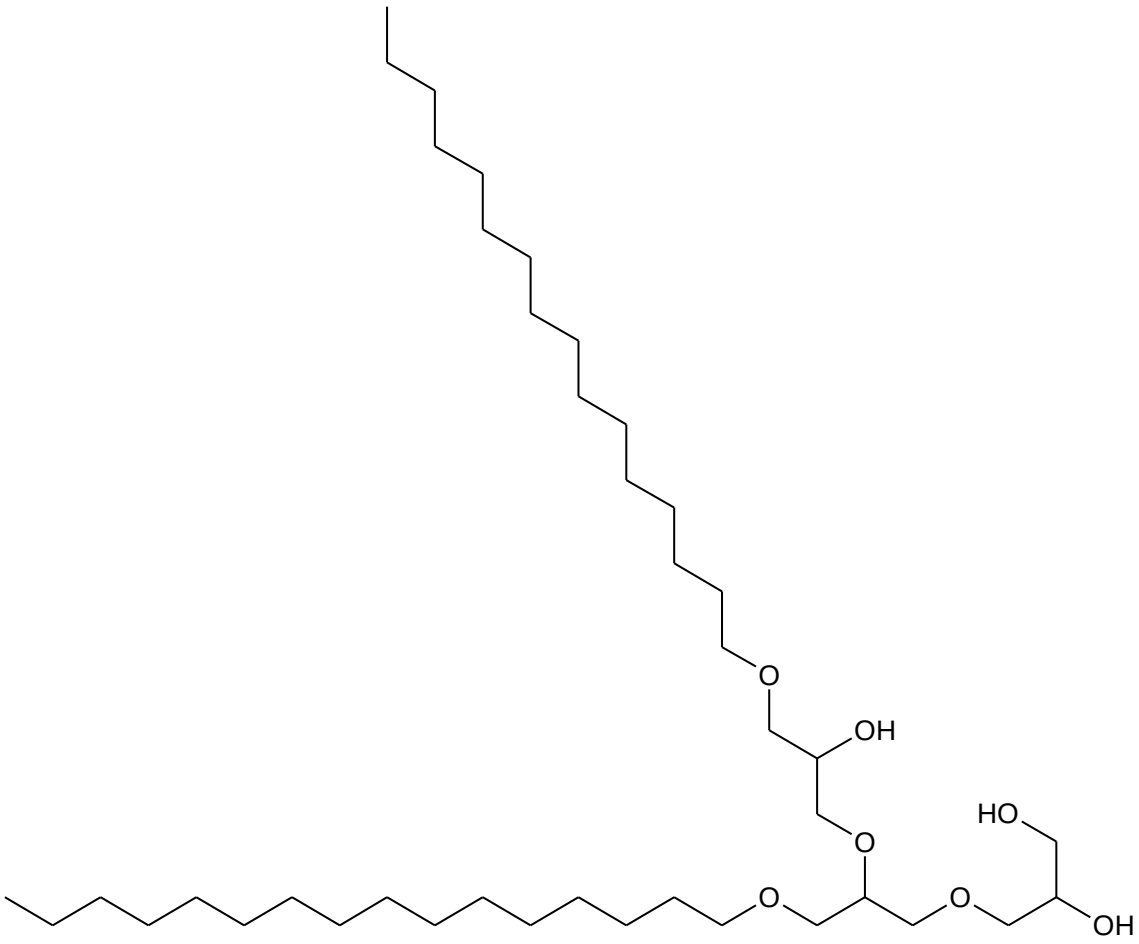
Single Masking	Acceptable Masked Name
Fluorine atoms	**Ammonium bis(3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10, 11,11,12,12,13,13,14,14,15,15,16,16,16-nonacosafluorohexadecyl) phosphate**
Number of fluorine atoms	**Ammonium bis(polyfluorohexadecyl) phosphate**
Ammonium cation	**bis(3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,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

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



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**

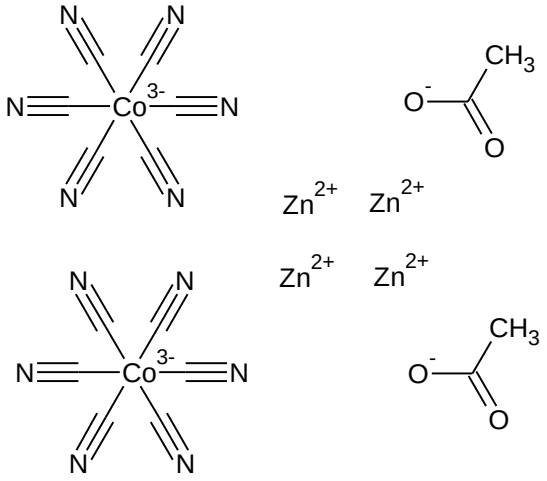
Double Masking	Acceptable Masked Name
Nonane parent (plus parent locants)	**bis(hexadecyloxymethyl)dioxaalkanetriol**

Example 6

Fully Defined Name

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

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



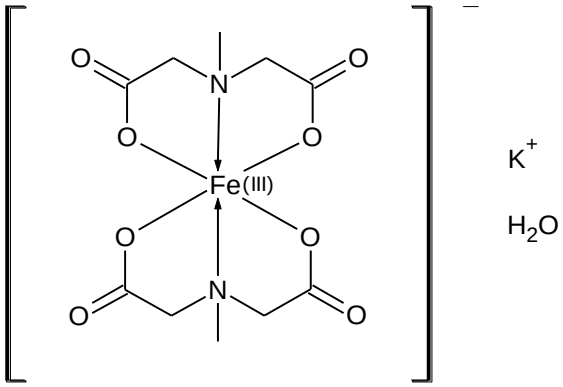
Single Masking	Acceptable Masked Name
Cyano groups	**Tetrazinc diacetate bis-hexakis(*substituted*-κ)cobaltate(3-)**
Acetate groups	**Tetrazinc dialkanoate bis-hexakis(cyano-κC)cobaltate(3-)**

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



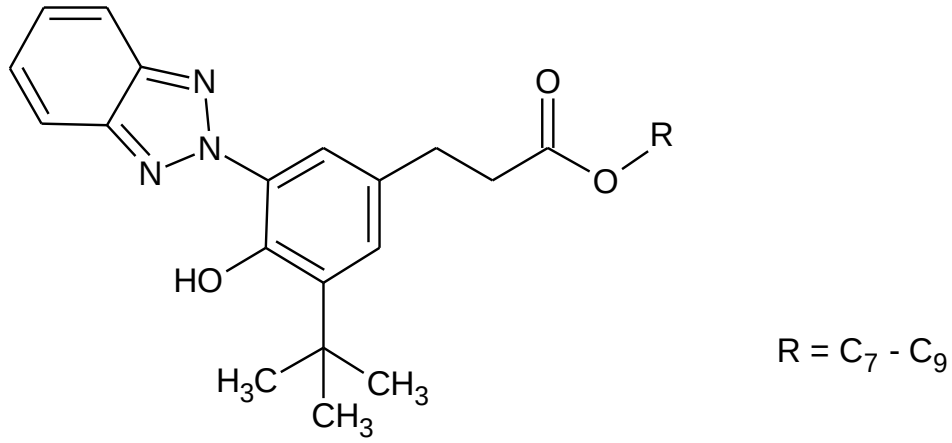
Single Masking	Acceptable Masked Name
Potassium cation	**Alkali metal bis[2,2'-(methylimino-κN)diacetato-κO(2-)]ferrate(1-) monohydrate**
Methyl groups	**Potassium bis[2,2'-(alkylimino-κN) diacetato-κO(2-)]ferrate(1-) monohydrate**
Amine groups	**Potassium bis[2,2'-(methyl*substituted*-κ)diacetato-κO(2-)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

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



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**

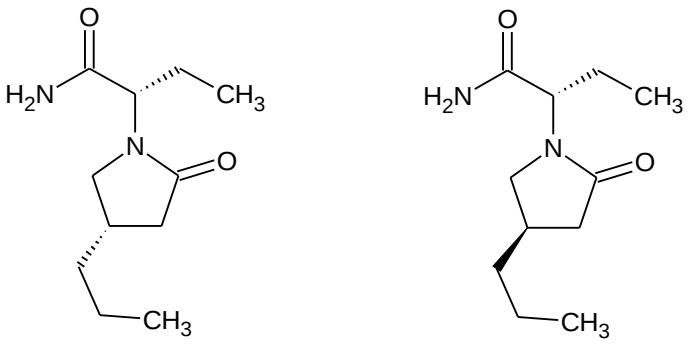
Double Masking	Acceptable Masked Name
Benzotriazol parent (plus parent locants)	**C7-C9 (linear and branched) alkyl 3-[3-(heteropolycyclyl)-5-(1,1-dimethylethyl)-4-hydroxyphenyl]propionate**
Phenyl parent (plus parent locants)	**C7-C9 (linear and branched) alkyl 3-[(2H-benzotriazol-2-yl)(1,1-dimethylethyl)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



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**

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

Example 10

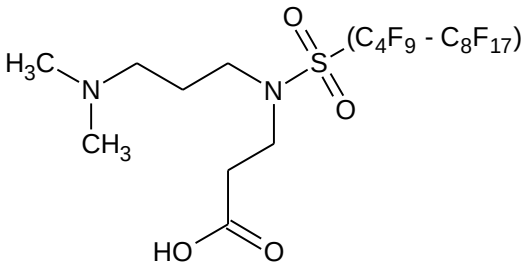
Fully Defined Name

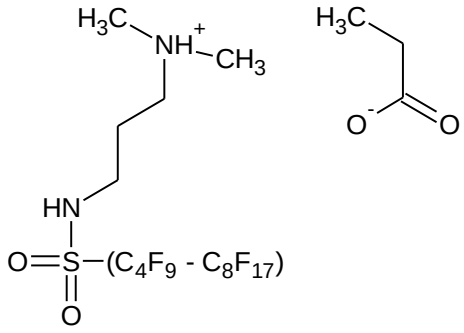
Reaction mass of

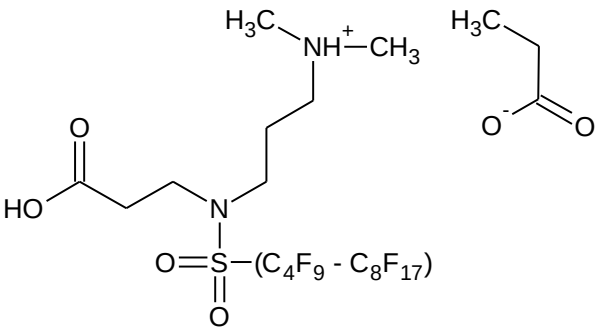
N-[3-(dimethylamino)propyl]-N-[(perfluoro-(C4-8)-alkyl)sulfonyl]-□-alanine and

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







Single Masking	Acceptable Masked Name
Methyl groups	**Reaction mass of** **N-[3-(dialkylamino)propyl]-N-[(perfluoro-(C4-8)-alkyl)sulfonyl]-□-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	**Reaction mass of** **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	**Reaction mass of** **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**

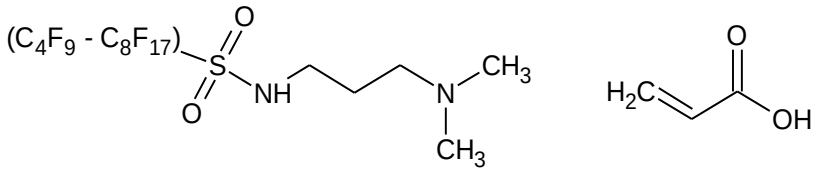
Double Masking	Acceptable Masked Name
Propane parent (plus parent locants)	**Reaction mass of** **N-[(dimethylamino)alkyl]-N-[(perfluoro-(C4-8)-alkyl)sulfonyl]-β-alanine** **and** **N,N-dimethyl{[(perfluoro-(C4-8)-alkyl)sulfonyl]amino}alkanaminium propanoate** **and** **{(2-carboxyethyl)[(perfluoro-(C4-8)-alkyl)sulfonyl]amino}-N,N-dimethylalkanaminium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

7.2. UVCB substances

Example 11

Fully Defined Name

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



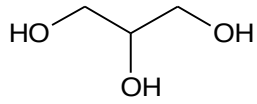
Single Masking	Acceptable Masked Name
Methyl groups	**Reaction products of N-[3-(dialkylamino)propyl]perfluoro-(C4-8)-alkylsulfonamide and acrylic acid**
Propyl group	**Reaction products of N-[3-(dimethylamino)alkyl]perfluoro-(C4-8)-alkylsulfonamide and acrylic acid**
Number of fluorine atoms	**Reaction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

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

ZnO 

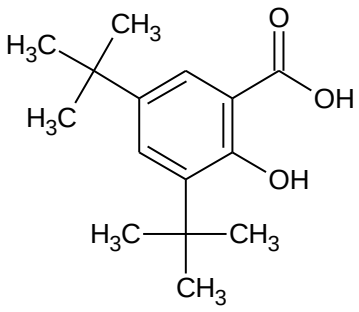
Single Masking	Acceptable Masked Name
Hydroxyl groups (glycerol)	**Reaction products of Zinc Oxide and 1,2,3-tri*substituted* propane**
Propyl parent (glycerol)	**Reaction products of Zinc Oxide and alkane-1,2,3-triol**

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



$Al_2(SO_4)_3$

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**

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

EC 4.1.2 Aldehyde-Lyases, EC 4.1.2

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

Example Corporation
1234 South Lime Street, London AZ5 12T, UK
Tel +44 1 123 4567 Fax +44 1 123 4568
www.examplecorporation.com

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 (10th July 2010), 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 claim 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 claim 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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