

REACH-IT Data Submission Manual

Part 16 - Confidentiality Claims: How to make confidentiality claims, and how to write Art 119(2) confidentiality claim justifications



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http://echa.europa.eu/reach/helpdesk/echahelp_en.asp

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1 Introduction

The European Chemicals Agency (ECHA) is required to publish information it holds on registered substances free of charge on the internet, in accordance with Articles 119(1) and (2) of the REACH Regulation. However in certain cases information can be withheld, if the registrant submitting the information also 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accordance with Article 119(2), and where the justification is accepted as valid by ECHA the information concerned will not be published.

This manual provides information on the content and assessments of such confidentiality claims. It is aimed at industry, and in particular, at managers and technical experts in companies who are responsible for preparing registration dossiers. This document should help readers understand:

- How to make a confidentiality claim;
- The basic procedure ECHA will follow to assess confidentiality claims;
- What information ECHA will look for in confidentiality claim justifications; and
- How it is suggested to write such confidentiality claim justifications.

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 REACH.

ECHA has recently released a Dissemination Plug-in for IUCLID 5.2, which is designed to give registrants an opportunity to check which information from their REACH Registration dossiers will be disseminated by ECHA. It is strongly recommended that companies use the plug-in before submitting their Registration dossier(s), to see which information from these dossier(s) will be disseminated by ECHA. The plug-in can be downloaded from the IUCLID website, at:

<http://iuclid.echa.europa.eu/>

Note that as the plug-in cannot assess confidentiality claims it will automatically remove any information claimed confidential, as though the confidentiality claim were accepted. This does not mean that ECHA will do the same – each piece of information falling under REACH Article 119(2) which is claimed confidential will be assessed based on the justification provided, and only those pieces of information whose justifications for confidentiality are **accepted as valid** by ECHA will not be disseminated.



Very Important: The Dissemination Plug-in creates a 'Filtered Dossier' from an input Registration Dossier by removing all non-disseminated information and information claimed confidential, using the same filtering rules as will be used by ECHA. This 'Filtered Dossier' is for registrant's information only, to allow them to see which information from their Registration Dossier will be published by ECHA. **Do not submit a 'Filtered Dossier' to ECHA as your Registration Dossier.** Since all non-disseminated information is removed from a 'Filtered Dossier' such dossiers will **FAIL** REACH-IT Business Rules and Completeness Checks.

2 The Dissemination Process

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:

“REACH Article 119 – Electronic Public Access:

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) name in the IUPAC Nomenclature, for dangerous substances within the meaning of Directive 67/548/EEC, without prejudice to paragraph 2(f) and (g);
- 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 dangerous substance when discharged into the environment as well as to determine the direct exposure of humans.

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 dangerous;
- 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) the name in the IUPAC Nomenclature for non-phase-in substances which are dangerous within the meaning of Directive 67/548/EEC for a period of six years;

- g) the name in the IUPAC Nomenclature for dangerous substances within the meaning of Directive 67/548/EEC that are only used as one or more of the following:
- as an intermediate;
 - in scientific research and development;
 - in product and process orientated research and development.”

From Article 119 of the REACH Regulation, quoted above, it can be seen that all of the information listed under Article 119(1) will always be disseminated on the Dissemination Portal, regardless of whether a registrant attempts to claim this information confidential. Additionally, the information listed under REACH Article 119(2) will also be disseminated by ECHA, unless a confidentiality claim has been submitted and accepted as valid, and the relevant fee paid if applicable.

-  Note – information listed in REACH Article 119(1) cannot be claimed confidential and will always be disseminated. Confidentiality claims on this information will be disregarded, and no fee will be incurred by such claims.

2.1 The Dissemination Portal

The ECHA Dissemination Portal is where information on registered substances can be accessed via the ECHA website, by selecting “ECHA CHEM” in the left menu, and clicking “Registered Substances” or by entering the following address:

<http://apps.echa.europa.eu/registered/registered-sub.aspx>.


2.2 Special Case: Dissemination for NONS

Information contained in Notifications of New Substances under Directive 67/548/EEC (NONS), which are considered as registrations under REACH according to Article 24, will also be disseminated in accordance with Article 119. Confidentiality claims accepted under Directive 67/548/EEC will remain valid under REACH, and no fee will be incurred by such claims.

For further information about submitting or updating NONS and how to put in confidentiality claims for NONS, please consult the latest NONS Q&A at:

http://echa.europa.eu/doc/reachit/prev_not_sub_registrants_qa.pdf.

-  Note – information on substances contained in NONS will be considered as REACH registrations according to REACH Article 24(1), and so this information will be disseminated in accordance with REACH Article 119 unless claimed confidential.

	<p>From original NONS, dissemination is in accordance with REACH Article 119(1). However from NONS update submissions, dissemination is in accordance with REACH Articles 119(1) and (2). Thus if information in an updated NONS is desired to be kept confidential, a confidentiality claim may need to be included in the IUCLID submission dossier:</p> <ul style="list-style-type: none">If the information was claimed confidential under NONS and the claim accepted, no fee will be incurred to maintain the claim under REACH. Simply ensure the confidentiality flag relating to the information is set, and the justification text box reads “Claim previously made under Directive 67/548/EEC”. See also Section 3.5
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	<p>of this document, Confidentiality Claim Justification.</p> <ul style="list-style-type: none">For additional confidentiality claims on information not claimed under Directive 67/548/EEC a justification in accordance with this manual should be included, and a fee will be incurred.
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3 Confidentiality Claims

3.1 Introduction

The IUCLID template allows registrants to set confidentiality claim flags on many pieces of information. For every piece of information that a registrant wishes to keep confidential, a confidentiality claim must be submitted to ECHA according to REACH Article 10(a)(xi). For information desired to be kept confidential such claims are submitted by setting the confidentiality flag(s) next to the information in the IUCLID registration dossier to 'CBI', 'IP', or 'No PA'.

It is important to note that in the case of confidentiality claims relating to information covered by REACH Article 119(2) a fee will be incurred and the claim must be accompanied by a full justification. In such cases the confidentiality claim will be upheld only where the appropriate fee is paid and the justification accepted as valid by ECHA. It is suggested that the template made available with this manual is used for justifications. At a minimum it is strongly recommended that all of the required elements as described in Section 4.1 of this manual are present in justifications.

	<p>Note – Even if information listed in REACH Article 119(1) is claimed confidential it will nevertheless still be disseminated. Every piece of information listed in REACH Article 119(1) will be disseminated. Confidentiality claims on this information will be disregarded, and no fees will be incurred.</p>
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3.2 Making a Confidentiality Claim

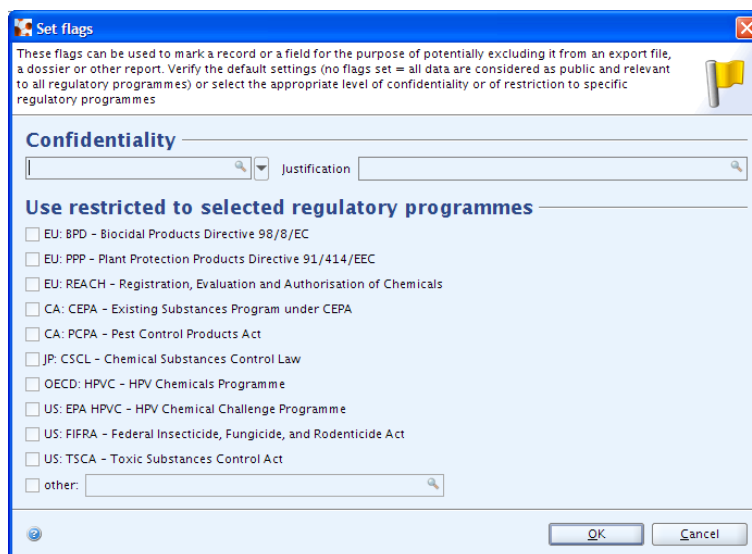
Next to each piece of information in a IUCLID 5 substance record is a confidentiality claim flag:

Figure 1: Example of an Unset Confidentiality Claim Flag in IUCLID



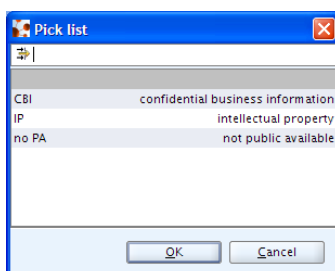
To claim the information confidential this confidentiality flag must be set to 'CBI' (Confidential Business Information), 'IP' (Intellectual Property), or 'no PA' (Not Publicly Available). Click on the flag to bring up the 'Set Flags' Window:

Figure 2: 'Set Flags' popup 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 claims even if the box is unticked.

Figure 3: Confidentiality Dropdown Pick List

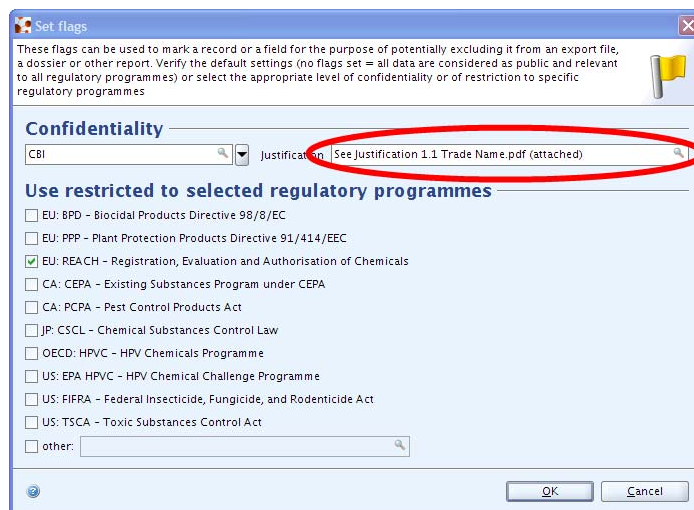



There is no difference in the treatment of confidentiality claims flagged 'CBI', 'IP' or 'no PA'. The selected type is simply for the information of the registrant – each type will be processed in an identical manner by ECHA.

Lastly, click on the justification text box to enter a justification for the confidentiality claim. 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. See Section 6 of this manual for full instructions.

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 4: Confidentiality Justification Text Box




 Some text **MUST** be entered in every confidentiality claim flag justification text box for claims in accordance with Article 119(2), otherwise the submitted dossier will not be accepted for processing by REACH-IT (i.e. a business rule failure). For Example: “See Justification – 1.1 – Trade Name.pdf (attached)”

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 5: Example of a Set Confidentiality Claim Flag



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

 Note – in some cases multiple flags in IUCLID are applicable to a single piece of information to be claimed confidential.

3.3 Article 119(2) Confidentiality Claim Flags & Fees


As stated above, in some cases multiple IUCLID flags are applicable to a single piece of information, for example the IUPAC Name of a substance can be flagged in Sections 1.1 and 1.2 of a Substance Dataset. If any of the flags relating to a piece of information are set, then the information will be regarded by ECHA as having been claimed confidential. In the case of flags referring 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 claim will be invoiced and processed accordingly. In the case of flags referring to information not covered by REACH Article 119(2) no fee will be incurred.

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

Table 1: Confidentiality Claim Flags & Fees for Information Covered by REACH Article 119(2)

Information Claimed Confidential	Legal Basis	Fee	Location(s) of Confidentiality Flag(s) in IUCLID	Comment
Degree of purity and/or identity of impurities or additives	REACH Article 119(2)(a)	€338 to €4500	<ul style="list-style-type: none"> Section 1.2: Degree of Purity Section 1.2: Impurities: Flag above Reference Substance Section 1.2: Impurities / Reference Substances: Flags in a linked Reference Substance (one or both flags: Reference Substance information; Molecular and Structural Information) Section 1.2: Additives: Flag above Reference Substance Section 1.2: Additives / 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 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)	€113 to €1500	<ul style="list-style-type: none"> Dossier Header: Request for the Tonnage Band (Checkboxes "Confidentiality Request" and "Specific Request on Tonnage Band" are selected and a justification is provided) 	
Study summary or robust study summary	REACH Article 119(2)(c)	€338 to €4500	<ul style="list-style-type: none"> Sections 4 – 7: Each study summary or robust study summary flagged confidential 	A fee will be calculated for each (robust) study summary claimed confidential.
Other information in the Safety Data Sheet	REACH Article 119(2)(d)	€225 to €3000 (for all use(s) / use(s) advised against)	<ul style="list-style-type: none"> Sections 3.5 and 3.6: Confidentiality requests in any Identified Use or Use advised against. Such requests should be flagged in the tables where the uses are reported ("Uses by workers in industrial settings (advised against)", "Uses by professional workers (advised against)", and "Uses by consumers (advised against)"). 	One single fee will be calculated no matter how many flags in relation to uses and / or uses advised against are selected.
Trade name(s) of the substance	REACH Article 119(2)(e)	€113 to €1500	<ul style="list-style-type: none"> Section 1.1: Flag next to the trade name(s) of the substance 	One single fee will be calculated for any trade name(s) claimed.
IUPAC Name of non-phase in substances which are dangerous	REACH Article 119(2)(f)	€113 to €1500	<ul style="list-style-type: none"> 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 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 has dangerous properties as reported in Section 2.2 of the dossier. This claim is only valid for a period of 6 years.

Information Claimed Confidential	Legal Basis	Fee	Location(s) of Confidentiality Flag(s) in IUCLID	Comment
IUPAC Name of dangerous substances used as intermediates, and / or in scientific research, and / or in product and process oriented research and development	REACH Article 119(2)(g)	€113 to €1500	<ul style="list-style-type: none"> 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 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 has dangerous properties as reported in Section 2.2 of the dossier 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.


	Substances used as intermediates or in product and process oriented research and development (PPORD) should only be submitted to ECHA in the appropriate Intermediate or PPORD Dossier templates, for which reduced fees are incurred.
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The precise fees which will be incurred for claiming 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):

http://www.echa.europa.eu/legislation/reach_legislation_en.asp#implementing_legislation

3.4 Confidentiality Claims in Joint Submissions

In an individual submission the registrant can make confidentiality claims 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 claimed confidential by all registrants.


	Note – For pieces of information in a joint submission that all registrants wish to claim confidential, all of the registrants involved should make a confidentiality claim on this information. If a lead registrant (or another registrant with additional information) wishes to claim some of this additional information confidential, then only the registrant with this additional information in their submission dossier needs to make a confidentiality claim.
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3.5 Confidentiality Claims in Dossier Updates

When a dossier is updated, whether spontaneously or following a request for more information, care should be taken to ensure that precisely the same confidentiality claims are selected in the updated dossier as were selected in the original submission. (Unless a registrant no longer wishes to claim a piece of information confidential in which case the relevant confidentiality flag should no longer be selected, or wishes to claim additional

information confidential in which case the relevant additional confidentiality flag should be selected).

Each confidentiality claim flag selected should be accompanied by an entry in the justification text box and an attachment to the dossier if required. These justifications should only be updated if relevant (for instance if the dossier update is to improve the reasoning of a confidentiality claim justification); otherwise the justifications should be the same as were submitted initially. No fee will be incurred for previously submitted claims – a fee will only be incurred if the registrant claims additional information falling under REACH Article 119(2) confidential.

	Note – the most recent version of the dossier is the version which will be disseminated by ECHA, and it is the confidentiality claims in this version which will be used to determine the information that will be published on the ECHA dissemination portal. If a registrant omits confidentiality claims from a dossier update this may result in information initially claimed confidential being made public.
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3.6 Confidentiality Claim Justification

For NONS, confidentiality claim justification should simply be “Claim previously made under Directive 67/548/EEC”;

For information not falling under REACH Article 119(1) or (2) the confidentiality claim justification could simply be a short sentence expanding on the selected confidentiality claim flag type, ‘CBI’, ‘IP’, or ‘No PA’;

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

And for information falling under REACH Article 119(2) confidentiality claim 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.**
- **claims 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 claim justification for ECHA to accept it as valid. Verification of whether all essential elements are present in a particular case and whether a claim can be accepted as valid will be performed by ECHA, as described in Section 4.2 below.

3.7 Recommended Elements for Justifications

As explained above, ECHA will seek certain elements in a confidentiality claim justification for confidentiality claims 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.

In particular, ECHA would usually look for the following elements to be present in justifications:

- **Declaration that the information (in the form claimed confidential) is not in the public domain or general knowledge in the industry with the registrant's permission.**
- **Demonstration that the registrant has a commercial interest worthy of protection for non-disclosure of the information.**
- **Demonstration that disclosure of the information would cause potential harm to the commercial interest of the registrant or a third party.**
- **Limitation to validity of the claim, if applicable.**
- **Details of a contact person responsible.**

Further details, as well as detailed recommendations on how best to write Article 119(2) confidentiality claim justifications, can be found in Section 4 of this manual.

4 Writing Confidentiality Claim Justifications

ECHA will assess confidentiality claims made on information covered by REACH Article 119(2) solely on what is present in the confidentiality claim justifications. Thus it is important that justifications contain all of the required elements and are well-reasoned.

4.1 Elements Required in a Justification

When writing a confidentiality claim justification, the main thing to recall is that the justification should include all the elements to allow ECHA's assessment. A justification template is provided with this document, and its use is strongly recommended. At a minimum, the required elements in a confidentiality claim justification would be the following:

Table 2: Required elements in a confidentiality claim justification

Element	Description
Declaration that the information (in the form claimed 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 Section 5.2). 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 claimed 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.
Limitation to validity of the claim	The registrant should specify the period of time for which the claim 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.

4.2 Additional Elements to substantiate a claim

Depending on the nature of the information claimed confidential, registrants may wish to include additional elements in order to be able 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, these additional elements may include:

- For claims 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 claims 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 claims concerning information in the SDS – an outline of why the information can only be made available to the registrant's direct customers.

- For claims 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.

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.

4.3 Factors to take into Account

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

- Statement explaining that this information point is claimed 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 claimed confidential (to be used as the introduction to each claim)
- 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 below

4.3.1 Claims under Article 119(2)(a) – Degree of Purity or Identity of Impurities

Likely Rationale:

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 3: Claims under Article 119(2)(a) – Degree of Purity or Identity of Impurities

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 claimed by companies, <u>in particular SMEs</u> , 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.

4.3.2 Claims under Article 119(2)(b) – Total Tonnage Band

Likely Rationale:

The exact volume in which a substance is manufactured / imported by a particular registrant is always confidential. However, a registrant may also have an interest that the total 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 4: Claims under Article 119(2)(b) – Total Tonnage Band

Supporting Factors	Non-Supporting Factors
Small number of competitors (e.g. only two registrants only one of whom claims the tonnage confidential).	The absence of potential harm associated with the disclosure of the tonnage band is normally deemed to exist if the volume claimed confidential does not affect the total tonnage band of the volume not claimed confidential (e.g. if the total tonnage band resulting from the sum of volumes in all the registration dossiers is already at >1000 tonnes)
Tonnage band claimed confidential is relatively precise (i.e. higher interest for confidential treatment if 1-10 tonnes, than if 100-1000 tonnes).	

4.3.3 Claims under Article 119(2)(c) – Study or Robust Study Summaries

Likely Rationale:

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 5: Claims under Article 119(2)(c) – Study or Robust Study Summaries

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

4.3.4 Claims under Article 119(2)(d) – Other Information from Safety Data Sheet

Likely Rationale:

The Safety Data Sheet may contain information intended only for the direct customer, such as detailed indications regarding use.

Table 6: Claims under Article 119(2)(d) – Other Information from Safety Data Sheet

Supporting Factors	Non-Supporting Factors
All registrants are claiming 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 claim 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)

4.3.5 Claims under Article 119(2)(e) – Trade Name(s)

Likely Rationale:

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

Table 7: Claims under Article 119(2)(e) – Trade Name(s)

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.

4.3.6 Claims under Article 119(2)(f) or (g) – IUPAC Name

Likely Rationale:

The rationale for making confidentiality claims 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 product(s).


	Note – where the IUPAC name is claimed confidential a public name should be provided for dissemination. Methods for deriving public names are being assessed by ECHA and practical guidance will be issued in due course.
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Table 8: Claims under Article 119(2)(f) or (g) – IUPAC Name

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 claimed 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

5 Assessment of Confidentiality Claims by ECHA

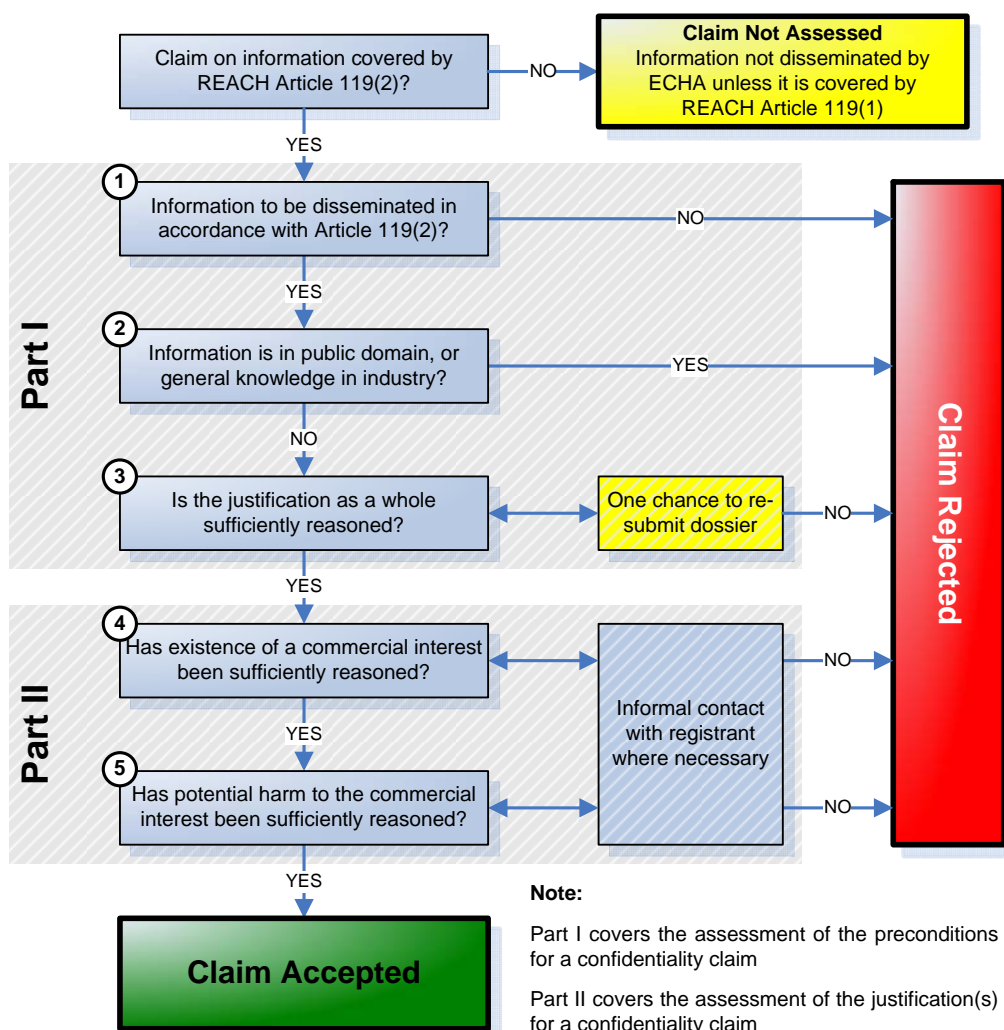
5.1 Introduction

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 claims 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 claim justifications in this light.

 The assessment of confidentiality claims is not part of the dossier evaluation or compliance check. **All** confidentiality claims 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 claim justifications is as follows:

Figure 6: Flowchart of standardised confidentiality claim assessment process



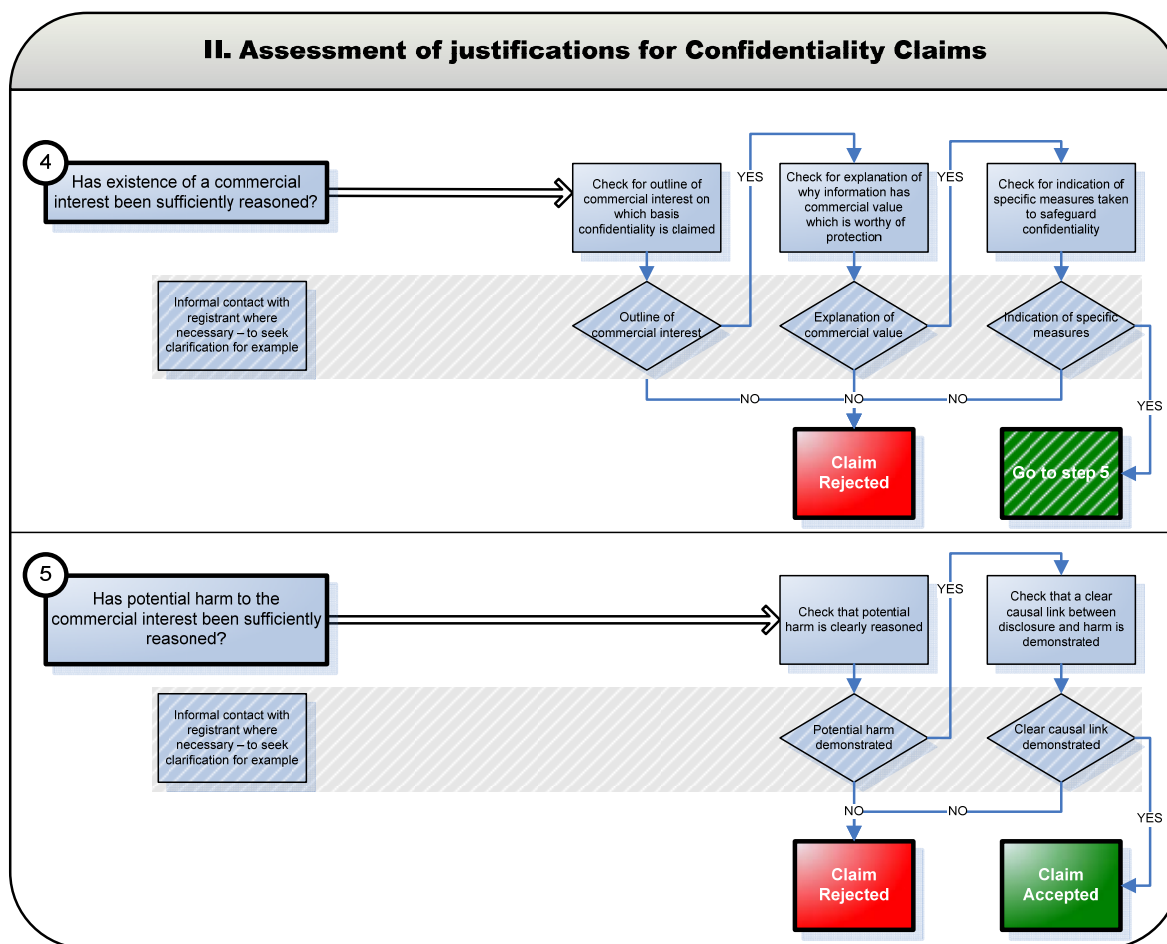
Before starting the assessment workflow each confidentiality claim will be examined to see if it relates to information covered by REACH Article 119(2). If not then the claim will not be assessed. In the cases of claims which are not assessed if the information claimed confidential falls under REACH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

In the workflow itself a claim will first be assessed to see whether it meets the precise criteria of the particular subsection of Article 119(2) under which confidentiality is claimed – 119(2)(a), (b), (c), (d), (e), (f), or (g). Next the claim will be assessed to see whether the information claimed confidential is in the public domain, by searching a pre-defined list of databases, as below.

If all of these pre-conditions are met, then the elements of the justification itself will be assessed. 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.

Claims 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 claim justifications will usually follow the same standard workflow, as follows:

Figure 7: Workflow for Assessment of Justifications for Confidentiality Claims



5.2 List of Databases


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

- **eChemPortal:** <http://webnet3.oecd.org/echemportal/Home.aspx> (Participating databases: [CESAR](#), [CHRIP](#), [EnviChem](#), [ESIS](#), [GHS-J](#), [HPVIS](#), [HSDB](#), [HSNO CCID](#), [INCHEM](#), [JECDB](#), [NICNAS PEC](#), [OECD HPV](#), [SIDS UNEP](#), [UK CCRMP Outputs](#), [US EPA IRIS](#), [US EPA SRS](#))
- **Australian Chemical Assessment Reports:**
<http://www.nicnas.gov.au/Publications/CAR.asp>
- **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>
- **Substances in Products in the Nordic Countries (SPIN):**
<http://195.215.251.229/DotNetNuke/default.aspx>
- **Toxnet:** <http://toxnet.nlm.nih.gov/> (Participating databases: HSDB, TOXLINE, CCRIS, DART, GENETOX, IRIS, ITER, LactMed, Multi-Database, TRI, Haz-Map, Household Products, TOXMAP)

5.3 Contact with Registrant During Confidentiality Claim Assessment

ECHA may be in contact with the registrant during the assessment of confidentiality claim(s) in the registrant's submitted dossier. If, after assessment of the pre-conditions to claim information confidential, the confidentiality claim is rejected or is insufficiently complete to allow assessment of the main elements of the justification, the registrant will have one opportunity to re-submit their dossier. In this case, ECHA will notify the registrant.

Once a confidentiality claim has passed assessment of the pre-conditions and ECHA has begun assessing the main elements of the justification, ECHA may engage in informal contact with the registrant to seek clarification of certain elements of the confidentiality claim justification.

-  **Note** – to allow ECHA to engage in informal contact with a registrant during assessment of the main elements of a confidentiality claim justification, the contact details of a designated person (a name, email address and phone number at a minimum) must be included in the justification, as shown in the confidentiality claim justification template.

5.4 Administrative Review of Confidentiality Claim Decisions

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 claim. The Decision establishing this process can be downloaded here:

http://echa.europa.eu/doc/about/organisation/mb/FINAL_MB_17_2008_Ddecision_on_review_of_rejection_of_confidentiality_claims.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 claim, this decision shall be notified to the registrant. The registrant then has two months from receipt of the decision to request a review by the Agency; the information claimed 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 electronic mail: executive.director@echa.europa.eu
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. 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 claimed confidential will not be disseminated during the period of the review.

5.5 Interim Measures for Confidentiality Claim Assessment by ECHA

At the time of writing ECHA has received a number of confidentiality claims in REACH registration dossiers submitted prior to the publication of this manual. Few of these claims, however, include confidentiality claim justifications suitable to pass assessment as described in this manual.

Thus it has been decided that these pre-existing claims will be screened by ECHA staff; that registrants will be contacted and informed of the publication of this manual, and that registrants will be given the opportunity to update their registration dossier submissions in light of the recommendations and guidelines contained in this manual. Such dossier updates

will be considered spontaneous updates, and will not count towards the single update permitted during confidentiality claim assessment (See Section 5.1, Figure 6).

Claims submitted to ECHA before the 30th of September 2010 will be pre-screened as described above, to allow registrants to update their submissions if required. Given that this manual is released in July, this will allow registrants two months to familiarise themselves with the recommendations and justification templates provided, and to begin to produce confidentiality claim justifications containing all of the required elements as described in this manual. Claims submitted to ECHA after the 30th of September 2010 will no longer be pre-screened. Thus if claims submitted after the 30th of September 2010 need to be updated, the update will be considered to be the single update permitted during confidentiality claim assessment (See Section 5.1, Figure 6).

6 Confidentiality Claim Template

6.1 Template

<p>--- Company Letterhead --- (Template copied to company headed document)</p>

Declaration:

<p>We, [Registrants name], claim [Insert short summary of information] confidential in accordance with REACH Article 119(2)([Insert relevant sub section]).</p> <p>We, [Registrants name], hereby declare that, to the best of our knowledge as of today ([Date]), and in accordance with the due measures of protection that we have implemented, a member of the public should not be able to obtain access to the information claimed confidential without our consent or that of the third party whose commercial interests are at stake, and in particular that the information is not publicly available in any of the following public databases: [Insert databases].</p>
--

Demonstration of Commercial Interest:

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

Demonstration of Potential Harm:

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

Limitation to Validity of Claim:

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

Contact Person

<p><i>Name and contact details of a designated person to deal with any queries which may arise during the assessment by ECHA of the confidentiality claim justification.</i></p>
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6.2 Instructions on using the Template

It is strongly recommended that a copy of this template should be completed for each individual confidentiality claim on information falling under REACH Article 119(2). The template structure should be copied to a company headed MS Word document, and each section completed with details appropriate to the confidentiality claim being made. The resulting file should be saved in .pdf format and named using the following structure, to clearly identify the confidentiality claim flag and piece of information to which the justification applies:

Justification – [IUCLID Section where confidentiality claim is located] – [Type of Confidentiality Claim].pdf

For example: Justification – Dossier Header – Tonnage Band.pdf

Justification – 1.1 – Trade Name.pdf

Justification – 1.1 – IUPAC Name.pdf

Justification – 3.5 – Information from SDS.pdf

Justification – 5.3.1 – Study Summary.pdf

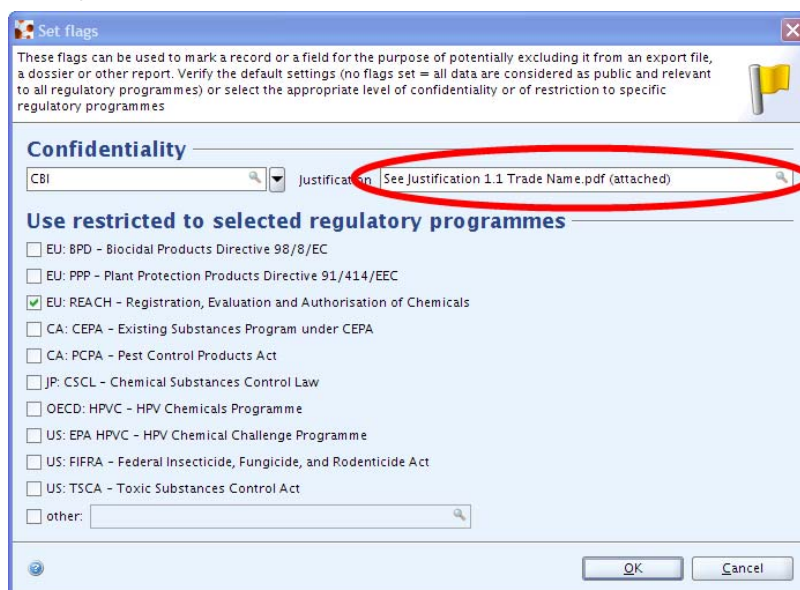
Justification – 7.5.2 – Robust Study Summary.pdf

For claims on information for which confidentiality flags are present in multiple IUCLID sections, such as claims on the IUPAC Name, simply enter the first IUCLID section where the confidentiality claim is located.

Next, ensure the Justification pdf is referenced in the justification text box of the relevant confidentiality claim flag in IUCLID. If multiple confidentiality flags in relation to a single piece of information are set, be sure in such cases to reference the Justification pdf in the justification text box of all of the flags set.

Reference the Justification pdf by entering “See Justification – [IUCLID Section] – [Type of Confidentiality Claim].pdf (attached)” in the justification text box of a confidentiality claim flag:

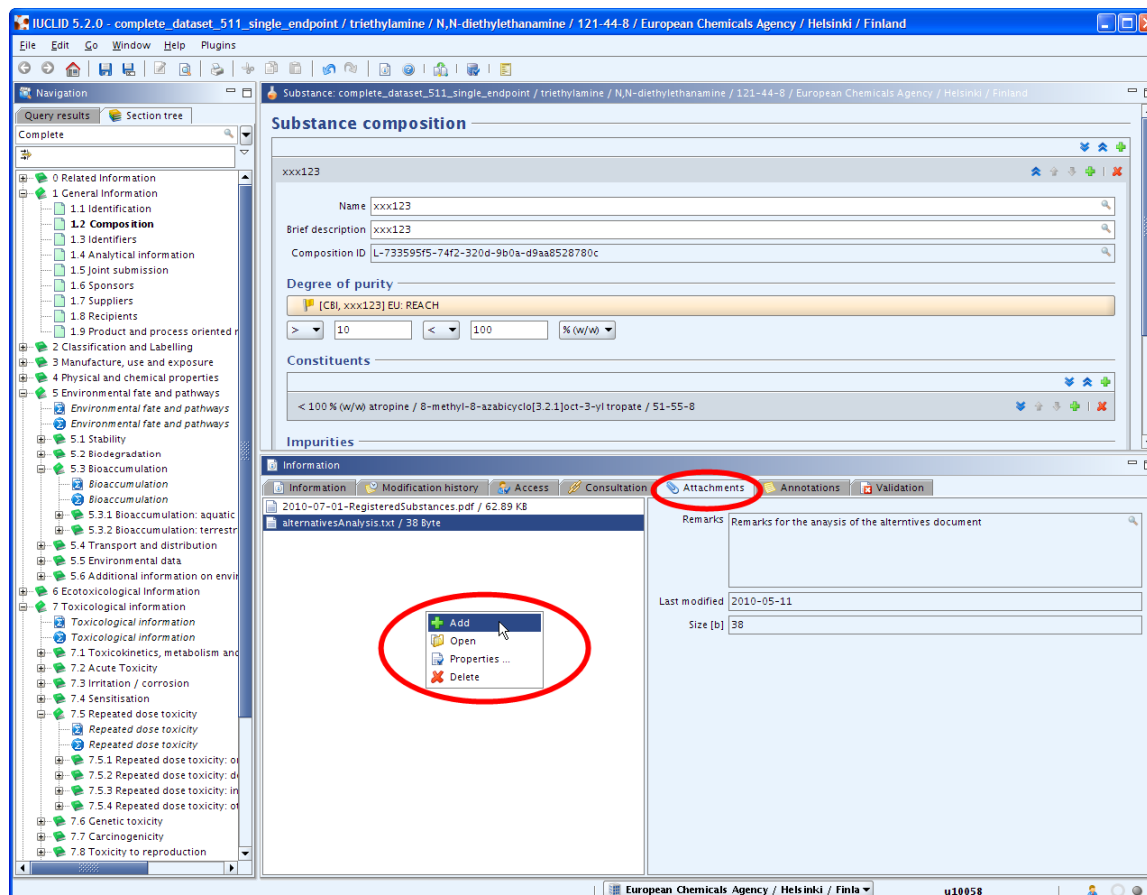
Figure 8: Confidentiality Justification Text Box



Once justification template(s) for each confidentiality claim on information falling under REACH Article 119(2) are completed, it must be ensured that the justification pdf are attached to the Substance dataset **before** a REACH submission dossier is created.


In the IUCLID information pane of your Substance dataset, click on the 'Attachments' tab, as illustrated below.

Figure 9: 'Attachments' Tab of Information Pane for Substance Dataset



Right click on the list of attachments in the 'Attachments' tab as illustrated, and select 'Add' to attach confidentiality claim justification(s).


Ensure justifications for all the confidentiality claim(s) on information covered by REACH Article 119(2) have been added.

 Note that confidentiality claims on information covered by REACH Article 119(2) can only be accepted if the appropriate fee is paid and the claim is accompanied by a justification which is accepted as valid by ECHA. If no justification is present the claim cannot be accepted.

Recall however that registrants have one chance to re-submit their REACH registration dossier for confidentiality claim assessment. In cases where confidentiality claim justifications are absent (but where confidentiality claim flags are set) then registrants will have the chance to re-submit their dossier to correct this oversight. ECHA will not disseminate information claimed confidential in such cases until after clarifying with the registrant as to whether the confidentiality claim flag was set in error, or whether the justification was accidentally omitted from the dossier.

7 Confidentiality Claim Examples

7.1 Example A – Claim on Degree of Purity / Identity of Impurities under Article 119(2)(a)

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

We, Example Corporation, claim the Degree of Purity and Identity of Impurities of ExampleSubstance confidential in accordance with REACH Article 119(2)(a).

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 or Toxnet.

Demonstration of Commercial Interest:

Example Corporation has sourced supplies of plant-based raw materials from an area of the Mato Grosso do Sul region of Brazil, building up relationships with suppliers over many years. In combination with purification technology developed in-house, this gives our ExampleSubstance product a much higher degree of purity compared to our competitors, which is the unique selling point for our product.

Demonstration of Potential Harm:

Our product has a purity higher than that possible with commonly known production technologies, and contains particular impurities arising from raw materials used. Thus dissemination of the degree of purity or identity of impurities will reveal to our competitors the technology lead possessed by Example Corporation, and / or the location from which our raw materials are sourced. This would allow our competitors to attempt to buy up our raw materials at source, or begin to attempt to copy our novel production technology, thereby harming the market position and commercial interest of Example Corporation.

Limitation to Validity of Claim:

The claim for confidentiality on the Degree of Purity and Identity of Impurities of ExampleSubstance should remain valid until 1 Jan 2020.

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

7.2 Example B – Claim on Tonnage Band under Article 119(2)(b)

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 total Tonnage Band of ExampleSubstance confidential in accordance with REACH Article 119(2)(b).

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, Australian Chemical Assessment Reports, Chemical Safety, GESTIS-Stoffdatenbank.

Demonstration of Commercial Interest:

For the European aerospace industry Example Corporation has created and developed a market for the substance covered by this dossier among a number of downstream users. Example Corporation is the sole manufacturer of this substance in Europe, and therefore the sole European company trading in the substance covered by this dossier.

Demonstration of Potential Harm:

Dissemination of the total tonnage band of the substance covered by this dossier, in combination with information from Eurostat or from various trade publications, would allow almost full commercial information about the market for the substance to be deduced. Competitors could derive trade statistics, market prices and clients quite easily since Example Corporation is the sole supplier. Such information could allow other EU and non-EU manufacturers to undercut Example Corporation on price, or to engage in other predatory practices to encroach on the market. Naturally this would severely harm the commercial interests of Example Corporation.


Limitation to Validity of Claim:

The claim for confidentiality on the tonnage band of ExampleSubstance will remain valid indefinitely.

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

7.3 Example C – Claim on Trade Name under Article 119(2)(e)

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

We, Example Corporation, claim the Trade Name of ExampleSubstance confidential in accordance with REACH Article 119(2)(e).

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, Australian Chemical Assessment Reports, Chemical Safety, GESTIS-Stoffdatenbank, Institut national de recherche et de sécurité (fiches toxicologiques), or Toxnet.

Demonstration of Commercial Interest:

For the fine chemicals market Example Corporation produces distinctly branded product families, of technical and analytical grade chemicals. The substance covered by this dossier is marketed separately under each of these product families using a different trade name. While the substance is identical, a premium price is charged for the analytical grade product, in line with other products in the same family.

Demonstration of Potential Harm:

If the trade names of this substance are disseminated, it will be apparent that the technical and analytical grade products are in fact the same. This will allow downstream users who previously used the analytical grade product to purchase the technical grade product and avoid paying the premium price. Naturally this will cause harm to the commercial interest of Example Corporation.

Limitation to Validity of Claim:

The claim for confidentiality on the trade name of ExampleSubstance will remain valid until 1 Jan 2018.

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

7.4 Example D – 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 our 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 directly replicate the functionalities of our SampleProduct 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 more quickly develop 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

