

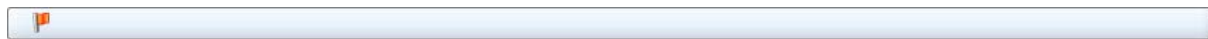
REACH-IT Data Submission Manual

Annex I - Instructions for the Confidentiality Claims Justification Template

Instructions

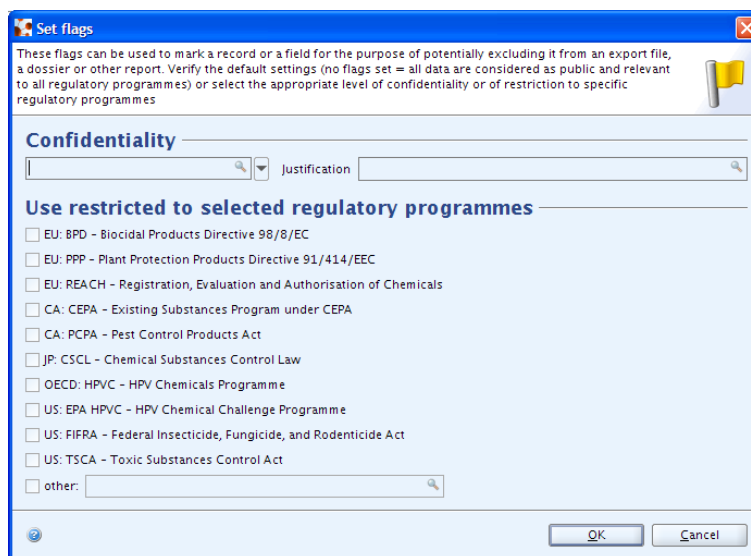
- In IUCLID, for each piece of information you wish to claim confidential you must set at least one relevant confidentiality claim flag: (See Data Submission Manual Part 16 – Confidentiality Claims, Section 3.3 for a table listing the relevant flags which can be set for information covered by REACH Article 119(2))

Figure 1: Example of an Unset Confidentiality Claim Flag



- Click on the flag to open the ‘Set Flags’ window:

Figure 2: Confidentiality Justification Text Box



Set flags

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

Confidentiality

Justification

Use restricted to selected regulatory programmes

- EU: BPD - Biocidal Products Directive 98/8/EC
- EU: PPP - Plant Protection Products Directive 91/414/EEC
- EU: REACH - Registration, Evaluation and Authorisation of Chemicals
- CA: CEPA - Existing Substances Program under CEPA
- CA: PCPA - Pest Control Products Act
- JP: CSCL - Chemical Substances Control Law
- OECD: HPV - HPV Chemicals Programme
- US: EPA HPV - HPV Chemical Challenge Programme
- US: FIFRA - Federal Insecticide, Fungicide, and Rodenticide Act
- US: TSCA - Toxic Substances Control Act
- other:

OK Cancel

- Click on the text box under ‘Confidentiality’, and use the drop down menu to select ‘CBI’ (Confidential Business Information), ‘IP’ (Intellectual Property), or ‘no PA’ (Not Publicly Available). You should also tick the box for ‘EU: REACH’.
- Enter some text in the justification text box, as illustrated. Note that for claims on information covered by REACH Article 119(2) some text is required, otherwise the dossier will fail its Technical Completeness Check.

Figure 3: Justification Text Box Entry in ‘Set Flags’ Window



Set flags

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

Confidentiality

CBI Justification: See Justification 1.1 Trade Name pdf (attached)

Use restricted to selected regulatory programmes

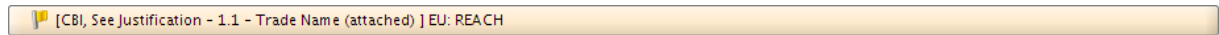
- EU: BPD - Biocidal Products Directive 98/8/EC
- EU: PPP - Plant Protection Products Directive 91/414/EEC
- EU: REACH - Registration, Evaluation and Authorisation of Chemicals
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- OECD: HPV - HPV Chemicals Programme
- US: EPA HPV - HPV Chemical Challenge Programme
- US: FIFRA - Federal Insecticide, Fungicide, and Rodenticide Act
- US: TSCA - Toxic Substances Control Act
- other:

OK Cancel

- For claims on information covered by Article 119(2) the justification text should refer to the pdf justification document you will create using the justification template: **“See Justification – [IUCLID Section where the confidentiality claim flag you set is located] – [Topic of Confidentiality Claim].pdf (attached)”**. For example: **“See Justification – 1.1 – Trade Name.pdf (attached)”**, as illustrated below.

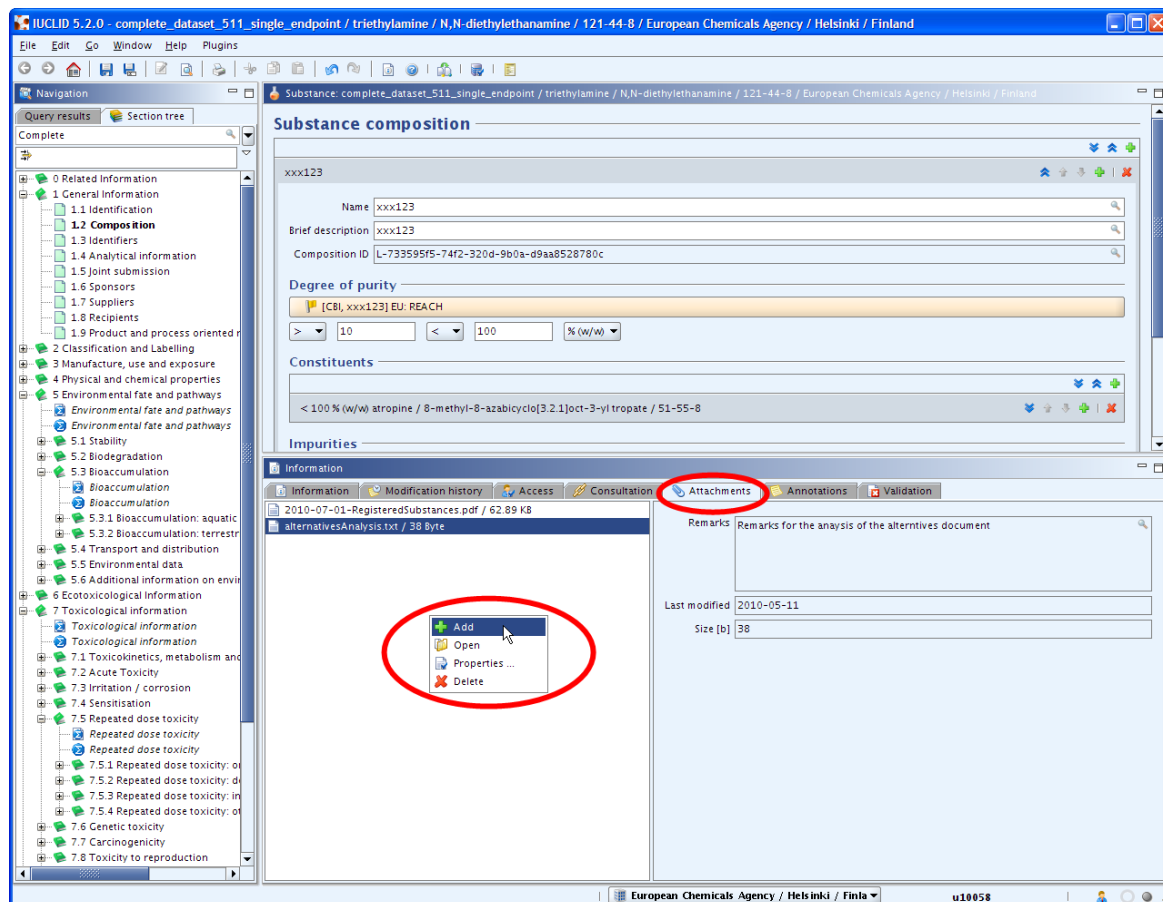
- Click 'OK' to close the 'Set Flags' dialog. If the flag has been correctly set then it should be shaded, and the details entered in the 'Set Flags' dialog should be visible, as illustrated:

Figure 4: Set Confidentiality Claim Flag



- Now prepare for each confidentiality claim justification for information covered by REACH Article 119(2) a new MS Word document using your standard company template, ensuring your company details (and logo if available) are contained in the document header and / or footer.
- Copy the five Template Sections from the Justification Template (Declaration, Demonstration of Commercial Interest, Demonstration of Potential Harm, Limitation to Validity of Claim, and Contact Person), and paste them into the new document.
- Fill in each section as required, using details appropriate to the substance and the information you wish to claim confidential, as in the example included in this document.
- Create a pdf of your completed confidentiality claim justification, naming the pdf: **“Justification – [IUCLID Section where the confidentiality claim flag you set is located] – [Topic of Confidentiality Claim].pdf”**. For example: “Justification – 1.1 – Trade Name.pdf”.
- Attach the pdf to the 'Attachments' tab of the Information pane of your substance dataset in your IUCLID 5 database. With the 'Attachments' tab visible, right click as illustrated to bring up the 'Add' dialog box:

Figure 5: Attachments Tab of IUCLID Information Pane



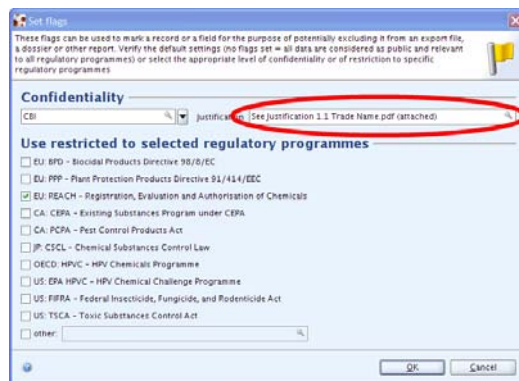
- Select the pdf of your justification in the dialog box that opens, and click 'OK' to attach the pdf.
- Repeat this as necessary to attach as many pdf justifications as required for the substance dataset in question. One such justification will be required for each of the REACH Articles 119(2)(a), (b), (c), (d), (e), (f), or (g) under which information is claimed confidential.
- Carefully check that at least one of the relevant confidentiality flags relating to any information you wish to claim confidential is set. Note that when a flag is set it should be shaded, and the justification text box entry visible on the flag:

Figure 6: Set Confidentiality Claim Flag



- Check to ensure that for each relevant confidentiality flag which is set (relating to information falling under REACH Article 119(2)) there is an entry in the justification text box that refers to the confidentiality claim justification pdf document by the same name you gave the document:

Figure 7: Justification Text Box Entry in 'Set Flags' Window



- When you have completed a final check that your substance dataset is ready, that any information you wish to claim confidential has at least one confidentiality flag set and an entry in the justification text box referring to the relevant completed pdf justification template, and that any pdf justification templates have been attached, create your REACH registration dossier for submission to ECHA.

Example Corporation

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Tel +44 1 123 4567 Fax +44 1 123 4568
www.examplecorporation.com



Example

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 and 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

