

March 2018

How to protect your confidential business information

What is this document about?

REACH foresees that you can claim certain information confidential¹ in your registration dossier and have it excluded from publication on ECHA's website².

If you claim confidentiality, you will be charged a fee, to cover our work assessing the claim. If the justification for the claim is not sufficient to be accepted, ECHA will ask you to improve your justification and resubmit it through an update of the registration dossier. If the justification is not sufficiently improved, ECHA will reject the confidentiality claim and publish the information. In the past years, about 25% of confidentiality claims were rejected.

This document describes our three main recommendations if you are considering claiming information in your registration as confidential, based on our experiences assessing confidentiality claims during the past seven years. We also briefly explain how to claim confidentiality and check which information will be published from your registration dossier.

1. Make sure that the information is not already public

When we assess a confidentiality claim, we check that the information is not already available in the public domain, meaning we will search the internet. If the information is publicly available, confidentiality will not be granted. So, search the internet yourself, in particular when you consider a confidentiality claim on the substance name³, a use or hazardous impurities⁴.

2. Make sure that the confidentiality claim covers the information you want to protect

Be aware of how ECHA publishes the item you want to claim confidential⁵, and ensure that claiming confidentiality is useful for you.

For claims on	be aware that
the tonnage band	ECHA publishes the aggregated tonnage band of all registrants together ⁶ , so if you are in a large joint submission, consider if it is worth it to claim your tonnage band confidential.

¹ If not by default excluded from publication, such as the full composition, the precise function, or the precise tonnage of a substance, or the link between a manufacturer/importer and his suppliers or downstream users.

² At https://echa.europa.eu/information-on-chemicals/registered-substances.

³ When searching if a substance name is in the public domain, we enter the EC number or CAS number of the substance in a search engine and in the 'search for chemicals' on the ECHA website.

⁴ When searching if uses or hazardous impurities are in the public domain, we check for example the safety data sheets available online for the registered substance.

⁵ A manual entitled 'Dissemination and confidentiality under the REACH Regulation' is available in all EU languages at https://echa.europa.eu/manuals?panel=dissemination#dissemination.

⁶ See our news alert at https://echa.europa.eu/-/echa-to-publish-total-tonnage-band-for-registered-substances-corrigenda-25-july-2012-.

substance name	The EINECS inventory and the list of pre-registered substances are public. Therefore, claims on the substance name are not useful for pre-registered substances. If you want to protect the fact that you use a particular substance for a particular application, you may achieve this by claiming the application (use) and/or your company name confidential.
company name	Your company name will be available to your (potential) co-registrants in REACH-IT unless you use a Third Party Representative (TPR). Confidentiality claims cover only publication on the ECHA website.
study summaries	The claim covers mainly experimental details and details on examinations. The results of the studies cannot be claimed confidential and will in any case be published.
if chemical safety assessment (CSA) was performed	A claim in the section where the chemical safety report (CSR) is attached does not cover the CSR document itself, but the indication that a CSA was performed (yes/no). Avoid making this claim unless you have good reasons why it should not be known if a CSA was performed for the substance. The CSRs are not published as such by ECHA.

3. Make sure that your justification is reasoned and valid

Your justification needs to address both (1) the commercial interest of the information and (2) the potential harm to your company should this information be published. A statement such as 'Intellectual property that we do not want our competitors to know' is not enough. Your justification needs to be reasoned – rather than stated – and clearly explained. The risk of the commercial interest being harmed must be foreseeable and not only hypothetical.

Also ensure that your justification is valid. For example, concerns like 'others will use the studies for registration elsewhere' are not valid, as it is not specific enough. The legislator has decided that the public's right to know exceeds these concerns.

Justifications need to be specific to the information claimed confidential, even within one claim type, such as safety data sheet information. For example, a justification that is valid for a use or for the company name will normally not be valid for the outcome of the PBT assessment of the substance⁸.

Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | Fax +358 9 68618210 | echa.europa.eu

⁷ Examples are available in the manual referred to in footnote 5. The reporting template for justifications is also available inside the IUCLID application and the IUCLID cloud services.

⁸ So far our acceptance rate for claims on the outcome of the PBT assessment is zero.

How to claim confidentiality and check what will be published

There are five steps to claim information in a registration dossier confidential:

- 1. Tick the confidentiality flag in your IUCLID dataset before you create your dossier. You can also make confidentiality claims if you create your member dossier online in REACH-IT:
- 2. Enter the justifications in the justification fields for each piece of information⁷;
- 3. Create your dossier. Use the 'Dissemination preview' in IUCLID to check what will be published from your registration. Use the 'Fee calculator' to check how much your confidentiality claims will cost;
- 4. Submit your dossier and pay the fees mentioned on your invoice;
- 5. Watch your REACH-IT message box for our decision on your confidentiality claim. You may be requested to resubmit your dossier with an improved justification before we can accept it.

Still have questions? Contact ECHA through the contact forms.