

Claiming Confidentiality under REACH

Lead Registrant Workshop

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Agenda

- The process of claiming information confidential
 - What can I claim confidential?
 - How can a confidentiality claim be introduced?
 - Cost of a confidentiality claim
- Justification for claiming information confidential
 - Elements of a justification
 - How to include it in the dossier
- Feedback from ECHA
- Key messages

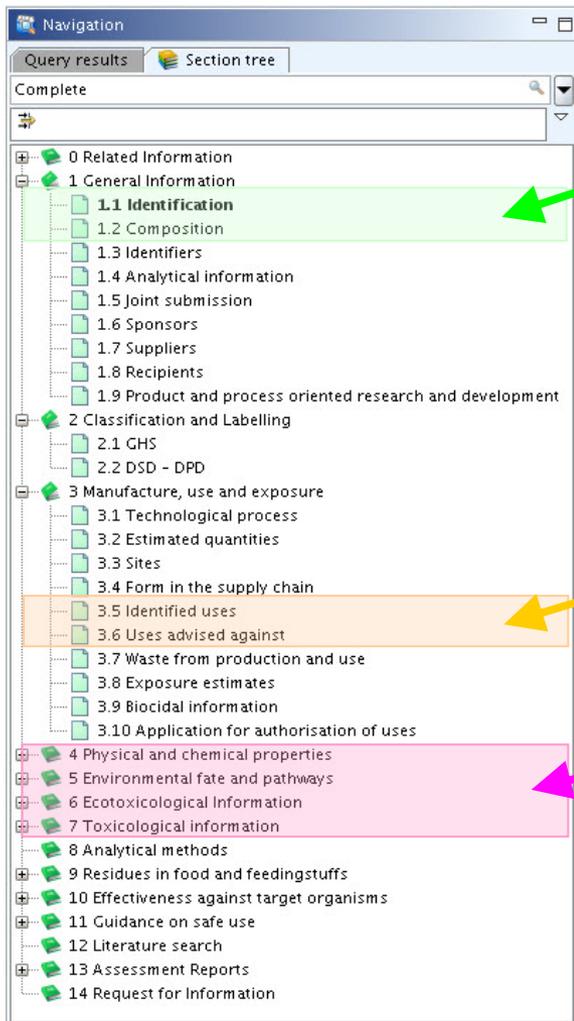
The Process of Claiming Information Confidential



Confidentiality Under REACH

- REACH identifies certain information as CBI, these are never published
- Other parts of the IUCLID dossier are always published (Art. 119(1) of REACH lists the criteria)
- Some information can be claimed confidential if fee paid and adequate justification is provided (listed in Art. 119(2))

What Can I Claim Confidential?



- IUPAC name
- Degree of Purity / Identity of Impurities and/or Additives
- Trade Name

• Certain information in the Safety Data Sheet

• Study Summary or Robust Study Summary

• Tonnage Band

How Can A Confidentiality Claim Be Introduced?

- Flag in the relevant IUCLID section(s)
- Reference in the free text field to the justification
- Justification as an attachment (for most cases)

The screenshot displays the 'Constituents' section of the IUCLID interface. At the top, a status bar indicates '>= 90 % (w/w) 6,9-bis(hexadecyloxymethyl)-4,7-dioxanonane-1,2,9-triol / 6,9-bis(hexadecylox...'. Below this, a yellow banner contains the text: '[CBI, Please see the attached justification 'IUPAC_conf_claim.pdf'.]'. The 'Reference substance' section shows the chemical name: '6,9-bis(hexadecyloxymethyl)-4,7-dioxanonane-1,2,9-triol / 6,9-bis(hexa...'. Below the name, there are fields for 'EC number' (411-450-6), 'EC name' (6,9-bis(hexadecyloxymethyl)-4,7-dioxanonane-1,2,9-triol), 'CAS number' (143747-72-2), and 'CAS name'. The 'IUPAC name' field contains '6,9-bis(hexadecyloxymethyl)-4,7-dioxanonane-1,2,9-triol'. The 'Typical concentration' is set to '>= 90 % (w/w)'. The 'Concentration range' is currently empty. The 'Remarks' field is also empty. At the bottom, the 'Information' tab is active, showing a list of attachments. The attachment 'IUPAC_conf_claim.pdf / 123.93 KB' is highlighted with a red box and a red arrow pointing to it.

Cost Of A Confidentiality Claim

- Fee is for the processing of the claim, not for the confidentiality
- Fee depends on the claim type, company size and joint submission status
 - From 113€ to 4500€ (discounts for SMEs)
- IUCLID fee calculation plug-in



Justification For Claiming Information Confidential



Elements Of A Justification

- Declaration
- Commercial interest
- Potential harm
- Validity of claim duration*
- Contact person*
- Justification for multi-level masking public name**



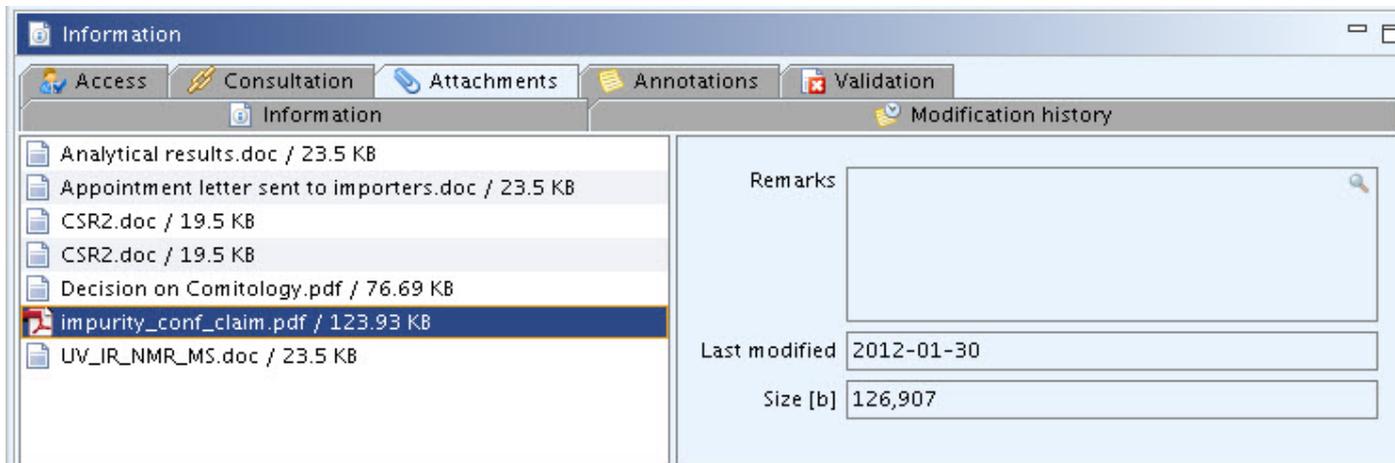
*Optional

**Only for IUPAC claims with multiple level of masking

How To Include The Justification In The IUCLID Dossier



- Free text field right next to the flag – usually insufficient
- Attachment in pdf format (templates as example are in DSM 16) – preferred option for the time being
- Enhancements with the upcoming IUCLID 5.4 release in the free text field



Feedback From ECHA



Feedback From ECHA

- Be flag aware – regulatory process, chargeable service
- Claims conflicting with the legislation
- Justifications based on NDA – provide evidence
- Information in public domain
- Confidential information in disseminated fields
 - Check Technical Annexes of DSM 15

Feedback From ECHA – Cont'd

- Use the IUCLID dissemination plug-in
- Ensure that an appropriate public name is provided in the correct field for IUPAC name claims
 - Check DSM 17
- Requested updates
 - Dropped claims must be entered correctly
 - No justification attachment is provided

Key Messages





Key Messages

- Confidentiality assessment is a regulatory process under REACH
- Read the released publications (DSM 15-17 + Annexes)
- Verify the non-availability of information in public domain
- Prepare a thorough justification (causal link between commercial interest and potential harm)
- Use the available IT tools (dissemination and fee calculation plug-in for IUCLID)
- Requested update – ensure that the deficiencies are addressed
- There is a second chance for everyone

Thank You!

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