

Information letter: Registration Process & Cost for REACH registration of Melamine

Summary

- Return signed SIEF agreement before June 1st to minimize costs of Letter of Access (LoA)
 - Order and pay in time the LoA necessary for timely registration
 - More details can be found at consortium website
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General Background about REACH

REACH stands for the Regulation for Registration, Evaluation, Authorisation and Restriction of Chemicals. The REACH Regulation entered into force on 1st June 2007 to streamline and improve the former legislative framework for chemicals of the European Union (EU). REACH also created the European Chemicals Agency (ECHA) which has a central co-ordination and implementation role in the overall process. ECHA is located in Helsinki, Finland and manages the registration, evaluation, authorisation and restriction processes for chemical substances to ensure consistency across the countries in which REACH applies.

Under REACH, all chemical substances manufactured and imported into the EU will need to be registered through the submission of a dossier to a new chemicals Agency, ECHA¹.

General brochure: http://echa.europa.eu/doc/reachit/reach_leaflet_20091028.pdf

Frequently Asked Questions: http://echa.europa.eu/reach/reach_faq_en.asp

Publications from ECHA: http://echa.europa.eu/publications_en.asp

Some key characteristics of the REACH legislation:

- REACH involves the registration of substances by legal entities individually per substance
- Registration has to be done through submission of a technical dossier (IUCLID5) and preparation of a Chemical Safety Report (CSR) detailing risks and risk management measures (RMMs) to ensure safe uses in the entire supply chain.
- Failure to comply with this legislation means removal from the market. I.e. no longer allowed to import or manufacture a substance in the EU.
- For existing chemicals, like melamine, a phase-in period is defined ending at different dates depending on the product volume involved. For melamine with a production or import volume above 1 kton/annum this phase-in period ends Nov 30, 2010.
- To comply with the REACH legislation it is possible to use a joint submission, whereby the joint part contains the substance specific data (containing the chapters 4 till 13 of the IUCLID file). Next to this each legal entity has to provide an entity specific part of the IUCLID dossier (Chapter 1 till 3 containing general information), whereby for the substance specific data a link is made to the joint submission dossier that covers the other required chapters.

Some key characteristics from a Melamine perspective:

- For the registration of melamine a consortium is formed including DSM Melamine. The purpose of this consortium is the joint development of the technical parts of the IUCLID dossier. The members of this consortium are: BASF SE, Borealis Agrolinz Melamine GmbH, Cytec Surface Specialties SA, DSM Melamine BV, Helm AG, Zaklady Azotowe "Pulawy" (<http://www.reachcentrum.eu/EN/consortium-management/consortia-under-reach/melamine-reach-consortium.aspx>)
- DSM Melamine has taken the responsibility to be the lead company for the preparation of the technical part of the IUCLID dossier for melamine.

¹ ECHA = European Chemicals Agency (www.echa.europa.eu)

Melamine REACH Consortium

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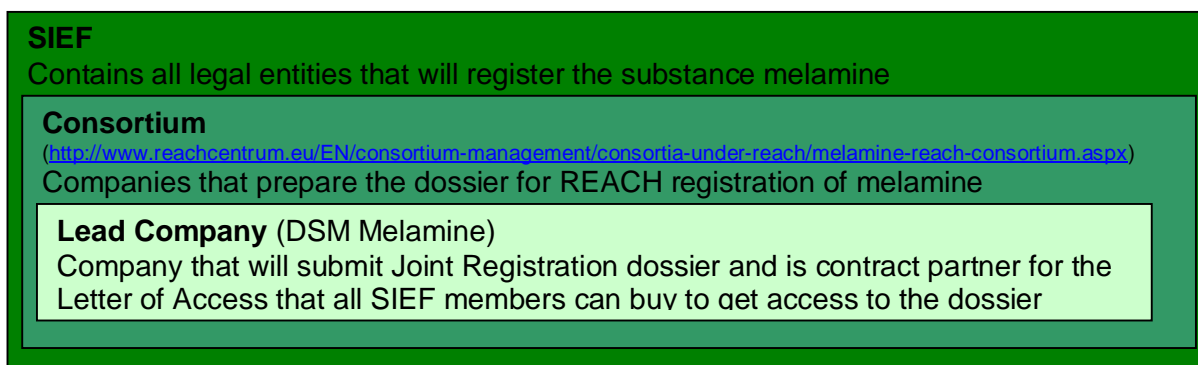


Registration Process & Cost for REACH² registration of Melamine

Hereunder follows a general overview for the REACH registration process of melamine, wherefore DSM Melamine is selected by the SIEF³ members as the Lead Company. A SIEF contains all legal entities that will register the same substance.

REACH Registration Process

The scheme below gives a schematic overview of: 1) relationship between all parties 2) overview of main steps in Registration Process to be taken by the different parties. More detailed information is in the Guidance Document of ECHA ([link: http://guidance.echa.europa.eu/docs/guidance_document/registration_en.pdf](http://guidance.echa.europa.eu/docs/guidance_document/registration_en.pdf)).



Lead Company	SIEF Member
Prepare Dossier (together with Consortium)	Sign SIEF agreement (= CEFIC Standard)
Creates Joint Submission Dossier in REACH-IT ⁴	Indicate in REACH IT that a joint submission dossier will be used
Register melamine at ECHA	Pay for Letter of Access to get access to joint submission dossier
Pay registration fee to ECHA, same as for SIEF members	Register, here for the SIEF member has to fill in for them selves chapter 1 & 3 of the (IUCLID ⁵ -) dossier
After payment of the LoA by the SIEF member the Lead company provide all data necessary for joint registration 1) name of Joint submission dossier 2) token	Pay registration fee to ECHA

Expected time line

- Finishing dossier Mar - Apr
- Inform SIEF members about joint registration process and send out of SIEF agreement Mar
- Determine cost for Letter of Access to dossier Apr - May
- Registration by Lead registrant Jun - Jul
- Provide required info for registration to SIEF member if he has fulfilled all obligations Jul - Nov

Expected cost range:

The total costs for registration is currently expected to be around 30 – 50 k€ , this is based on:

1. Registration fee to ECHA for a joint registration dossier is €23.250 per legal entity
2. Dossier cost, which contains access to the required data and the management costs for preparation of the dossier. The dossier cost depends on the final number of SIEF members that will register melamine. Currently the dossier cost is estimated to be between € 10.000 and €20.000.

² REACH = Registration, Evaluation, Authorisation and Restriction of Chemical substances

³ SIEF = Substance Information Exchange Forum

⁴ REACH IT = IT system used by ECHA for registration (http://echa.europa.eu/reachit_en.asp)

⁵ IUCLID = International Uniform Chemical Information Database

Background Information about cost determination and Letter of Access ordering process

The dossier cost consists of 1) the management cost of the dossier 2) the data cost. To compensate the members of the consortium for the cost made in a fair and transparent way the consortium will sell letters of access (LoA) to the SIEF members who like to join the joint registration dossier. In the schematic drawing below this is shown in the blue box, including the build-up of the main cost elements.



Cost for the dossier will be shared with all registrants via Letters of Access in a non discriminatory way



The cost of a Letter of Access to the joint submission dossier of melamine will be determined by the Total Cost divided by the number of registrant, which include all parties that have returned a signed SIEF agreement and the Consortium members at June 1st, 2010. Parties who will return the signed SIEF agreement at a later date, but will apply for the > 1kt/y tonnage band have to pay the price of the LoA as determined by the known number of registrants at June 1st, 2010.

This means to get the lowest cost possible for the LoA make sure your signed SIEF agreement is returned to the lead company before June 1st, 2010.

To redistribute the payments from the SIEF members towards the consortium members who have made the management costs or own the data rights, REACHCentrum is hired by the consortium. So for a SIEF member that will register a Letter of Access have to be purchased at REACHCentrum and a registration fee has to be paid to ECHA.

More specific information, including the SIEF Agreement and the process of purchasing a Letter of Access can be found on the consortium website.

Link to Consortium website:

<http://www.reachcentrum.eu/EN/consortium-management/consortia-under-reach/melamine-reach-consortium.aspx>