ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000001476-72-03/F Helsinki, 6 February 2012

DECISION ON A COMPLIANCE CHECK OF A REGISTRATION PURSUANT TO ARTICLE 41(3) OF REGULATION (EC) NO 1907/2006

For 1,1,1-trimethyl-N-(trimethylsilyl)- Silanamine, CAS No 999-97-3, EC No 213-668-5, registration number: [redacted]

Addressee: [redacted]

The European Chemicals Agency (ECHA) has taken the following decision in accordance with the procedure set out in Articles 50 and 51 of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation).

I. Procedure

Pursuant to Article 41(1) of the REACH Regulation ECHA has performed a compliance check of the registration dossier for 1,1,1-trimethyl-N-(trimethylsilyl)- Silanamine, CAS No 999-97-3, EC No 213-668-5 submitted by [redacted] (Registrant), latest submission number [redacted], for 1-10 tonnes per year.

The compliance check was initiated on 27 October 2010.

On 22 August 2011 ECHA notified the Registrant of its draft decision and invited him pursuant to Article 50(1) of the REACH Regulation to provide comments within 30 days of the receipt of the draft decision.

The Registrant did not provide any comments on the draft decision.

On 4 November 2011 ECHA notified the Competent Authorities of the Member States of its draft decision and invited them pursuant to Article 51(1) of the REACH Regulation to submit proposals to amend the draft decision within 30 days of the receipt of the notification.

Subsequently, Competent Authorities of the Member States did not propose amendments to the draft decision and ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

This compliance check decision does not prevent ECHA to initiate further compliance checks on the present dossier at a later stage.

II. Information required

Pursuant to Articles 41(1)(a), 41(3) and 10(a)(ii) as well as Annex VI , Section 2 of the REACH Regulation the Registrant shall submit for the registered substance:

- Spectral data (ultra-violet, infra-red, nuclear magnetic resonance or mass spectrum) (REACH Annex VI(2)(2.3.5))
- High-pressure liquid chromatogram, gas chromatogram (REACH Annex VI(2)(2.3.6))
- Description of the analytical methods or the appropriate bibliographical references for the identification of the substance and, where appropriate, for the identification of impurities and additives. This information shall be sufficient to allow the methods to be reproduced.

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated IUCLID dossier to ECHA by 07 May 2012.

III. Statement of reasons

Based on the examination of the technical dossier, ECHA concludes that the information therein, submitted by the Registrant for registration of the above mentioned substance in accordance with Article 6 of the REACH Regulation, does not comply with the requirements of Article 10 and with Annex VI thereof. Consequently, the Registrant is requested to submit the information mentioned above that is needed to bring the registration into compliance with the relevant information requirements.

1) Missing information related to substance identity

Pursuant to Article 10(a)(ii) and Annex VI, Section 2 of the REACH Regulation, the technical dossier of the registration shall include information on the identity of the substance. Annex VI, Section 2 lists information requirements that shall be sufficient to identify the registered substance. Specifically, Annex VI(2) requires the Registrant to provide the following information that is missing from the technical dossier:

- Spectral data (ultra-violet, infra-red, nuclear magnetic resonance or mass spectrum) (REACH Annex VI(2)(2.3.5))
- High-pressure liquid chromatogram, gas chromatogram (REACH Annex VI(2)(2.3.6))
- Description of the analytical methods or the appropriate bibliographical references for the identification of the substance and, where appropriate, for the identification of impurities and additives. This information shall be sufficient to allow the methods to be reproduced.

In the IUCLID 5 section 1.4, the Registrant states that "*All the analytical methods and spectral data are available in the documents attached under "Results of analysis" field.*" However no such attachments are included in the dossier. Without this information the substance identity cannot be verified and consequently the dossier is non-compliant.
The Registrant is accordingly requested to submit the missing information on the substance identity of the registered substance.

IV. Information on right to appeal

An appeal may be brought against this decision to the Board of Appeal of ECHA under Article 51(8) of the REACH Regulation. Such an appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on ECHA's internet page at http://echa.europa.eu/appeals/app_procedure_en.asp. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

[redacted]

Jukka Malm
Director of Regulatory Affairs