Decision number: CCH-D-0000003092-84-03/F Helsinki, 11 November 2013

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

For trichlorosilane, CAS No 10025-78-2 (EC No 233-042-5), 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 trichlorosilane, CAS No 10025-78-2 (EC No 233-042-5), submitted by [redacted] (Registrant).

This decision is based on the registration dossier as submitted with submission number [redacted], for the tonnage band of 1000 tonnes or more per year. This decision does not take into account any updates after 20 June 2013, the date upon which ECHA notified its draft decision to the Competent Authorities of the Member States pursuant to Article 51(1) of the REACH Regulation.

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

The compliance check was initiated on 5 October 2012.

On 18 February 2013 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision. That draft decision was based on submission number [redacted].

By 20 March 2013 the Registrant did not provide any comments on the draft decision to ECHA.

On 20 June 2013 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.

II. Information required

1) 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:

   a. Spectral data (Annex VI, 2.3.5.);
   b. High-pressure liquid chromatogram, gas chromatogram (annex VI, 2.3.6.);
   c. Description of the analytical methods or the appropriate bibliographical references for the identification of the substance (Annex VI, 2.3.7.).

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 **11 February 2014**.

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 for the purpose of registration within the applicable tonnage band of 1000 tonnes or more per year 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.

(a) Spectral data (Annex VI, 2.3.5.)

ECHA notes that the registration does not contain infra-red (IR) and nuclear magnetic resonance (NMR) spectral data, as required under Annex VI section 2.3.5. of the REACH Regulation to support the indicated substance identity.

More specifically, the Registrant included a justification for not providing the required spectra. The Registrant stated in IUCLID Section 1.4 (analytical information) the following: "*[LC, IR, UV, NMR, MS] are not necessary in accordance with Note 1 in Annex VI of the REACH Regulation. Any additional information on molecular structure does not contribute to substance identification further to the information provided below* [i.e. gas chromatography]".

ECHA points out that spectral data are a standard information requirement of Annex VI section 2.3.5. Contrary to what the Registrant indicates, both IR and NMR spectral data are scientifically necessary for the identification of the registered substance for the following reasons:
- The IR spectrum displays characteristic vibration bands for the covalent bonds in the substance. As a consequence an IR spectrum provides information on the identity of the substance;

- An NMR spectrum such as a 1H-NMR spectrum provides information on the structure of the substance and on the relative abundance of characteristic atoms present in the registered substance.

The Registrant is accordingly requested to submit an IR spectrum and a NMR spectrum, such as a 1H-NMR. As an alternative to the NMR spectrum, a mass spectroscopic analysis of the registered substance can be provided.

As for the reporting of the spectral data in the registration dossier, the information should be attached in IUCLID section 1.4.

(b) High-pressure liquid chromatogram, gas chromatogram (Annex VI, 2.3.6.)

ECHA notes that the registration dossier does not contain any chromatographic data which is required according to Annex VI, Section 2.3.6. of the REACH Regulation to support the indicated substance composition. The Registrant has also not included scientific justifications for not providing all of the required information.

The Registrant is therefore requested to submit a high-pressure liquid chromatogram or gas chromatogram for the registered substance. The report from the chromatographic analysis, including a peak list with the corresponding retention time and peak area shall also be included.

As for the reporting of the information in the dossier, the results of the chromatographic analysis, or a scientific justification for not including this data should be attached in IUCLID section 1.4.

The Registrant shall ensure that the description of the analytical method used for the chromatographic analysis, including the experimental set-up (i.e. the column type, length and diameter; injection volume; mobile phase/carrier gas; GC temperature programme; flow rate; concentrations of HPLC standard solutions; detection technique; and run time) and preparation of solutions and identity of standards, is specified, in line with the requirements of Annex VI section 2.3.7.

(c) Description of the analytical methods or the appropriate bibliographical references for the identification of the substance (Annex VI, 2.3.7.).

ECHA observes that the Registrant did not provide any detailed description of the analytical method used for the identification and quantification of the different constituents present in the composition of the registered substance, which is required according to Annex VI section 2.3.7.

More specifically ECHA notes that the Registrant provided a certificate of analysis which is the result of a chromatographic analysis. However, as already underlined in the present decision, the actual chromatogram has not been attached in section 1.4 of the IUCLID dossier. In addition no spectral data have been included in the registration dossier. ECHA concludes that the Registrant did not provide a description of the analytical methods used to determine the identification and quantification of the registered substance.

The Registrant is accordingly requested to provide a description of the analytical methods used for the identification and quantification of the constituents (main constituent and the impurities) required to be reported in the composition of the registered substance. The description shall be sufficient for the methods to be reproduced and shall therefore include details of the experimental protocol followed, any calculation made and the results obtained.

As for the reporting of the data in the registration dossier, the information should be attached in IUCLID section 1.4.

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