ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000002596-67-03/F Helsinki, 20 December 2012

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

For Cyanuric acid, CAS No 108-80-5 (EC No 203-618-0), 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 Cyanuric acid, CAS No 108-80-5 (EC No 203-618-0) 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 6 September 2012, 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.

The scope of this compliance check is limited to the standard information requirements of Annex VI, Section 2 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.

Article 24(1) of the REACH Regulation provides that the notification is regarded as a registration and ECHA has assigned a registration number.

The compliance check was initiated on 20 April 2012.

On 20 June 2012 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision.

By 20 July 2012 the Registrant did not provide any comments on the draft decision to ECHA.

On 6 September 2012 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. The spectral data (Annex VI, Section 2.3.5.);

   b. Chromatogram (Annex VI, Section 2.3.6.);

   c. The description of the analytical methods or the appropriate bibliographical references for the identification of the substance (Annex VI, Section 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 **20 June 2013**.

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 Articles 10 and 12 and 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.

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) The spectral data (Annex VI, Section 2.3.5. of the REACH Regulation).

ECHA observes that the registration does not contain the UV and IR spectra required for the identification of the registered substance by Annex VI, Section 2.3.5 of the REACH Regulation.

ECHA points out that IR and UV spectra are standard information requirements under Annex VI, Section 2.3.5. ECHA regards this information scientifically necessary for the identification of the registered substance for the following reasons:

- The IR spectrum displays characteristic vibration bands of the functionalities present in the structure of the constituents
- The UV spectrum provides an analytical representation of the chromophores contained in the registered substance.

ECHA observes that the Registrant specified the absorption maxima from the UV spectroscopic analysis of the substance at the pH values of 1, 5 and 11. However the Registrant did not include a copy of the actual spectra recorded as part of this analysis. Without the spectra, ECHA cannot verify the absorption maxima declared in the analytical report.

The Registrant is therefore requested to submit IR and UV spectra for the registered substance.

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

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

ECHA notes that the registration does not contain a high-pressure liquid chromatogram or gas chromatogram which is a standard information requirement of Annex VI, Section 2.3.6. of the REACH Regulation for the identification of the registered substance.

ECHA regards this information scientifically necessary as it characterises the composition of substances such as the registered substance.

Therefore, the Registrant is requested to provide a high-pressure liquid chromatogram or a gas chromatogram of the substance which is the subject of this registration. The information shall include the report from the chromatographic analysis, including a peak list with the corresponding retention time and peak area.

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

c) The description of the analytical methods (Annex VI, Section 2.3.7.)

ECHA observes that the registration does not contain sufficient information on the analytical methods used to identify the registered substance, qualitatively and quantitatively, as required by Annex VI, Section 2.3.7. of the REACH Regulation.

For the qualitative identification the Registrant is required to provide a description and the results of the analytical method used to identify unambiguously the structure of the main constituent. For the quantitative identification and to confirm the composition of the substance a description of the method(s) used to quantify the main constituent and the impurities required to be reported in the composition shall be provided. However, this information is absent from the registration dossier. Without this information the composition of the substance cannot be derived and therefore the identity of the substance cannot be confirmed. The information to be provided should be sufficient to allow the methods to be reproduced.

The Registrant is accordingly requested to provide a description of the analytical methods used for the identification and quantification of the constituents 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 above 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