ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000002513-81-03/F Helsinki, 27/08/2012

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

For 2-aminoethanol, monoester with boric acid, CAS No 10377-81-8 (EC No 233-829-3), 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 concerning standard information requirements relating to substance identity (Annex VI, 2.1., 2.3., 2.3.5., 2.3.6. and 2.3.7. of the REACH Regulation) of the registration dossier for 2-aminoethanol, monoester with boric acid, CAS No 10377-81-8 (EC No 233-829-3) 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 14 June 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 compliance check was initiated on 29 March 2012.

On 8 May 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.

On 6 June 2012 ECHA received comments from the Registrant concerning the letter by which he was notified of the draft decision. The comments did not concern elements raised in the draft decision.

Therefore, ECHA did not amend the draft decision.

On 14 June 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.

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:

a. Name or other identifier of the substance (Annex VI, 2.1.);
b. Composition of the substance (Annex VI, 2.3.);
c. Spectral data (Annex VI, 2.3.5.);
d. High-pressure liquid chromatogram, gas chromatogram (Annex VI, 2.3.6.); and
e. The description of the analytical methods (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 29 October 2012**.

III. Statement of reasons

Pursuant to Article 41(3) of the REACH Regulation, ECHA may require the Registrant to submit any information needed to bring the registration into compliance with the relevant information requirement. The scope of the present decision covers information requirements relating to substance identity (Sections 2.1., 2.3., 2.3.5., 2.3.6. and 2.3.7. of Annex VI of the REACH Regulation). In accordance with Article 10(a)(ii) of the REACH Regulation, any registration made pursuant to Chapter 1 of Title II of the REACH Regulation shall contain this information.

Missing information related to substance identity

(a) Name or other identifier of the substance (Annex VI, 2.1.)

ECHA notes that the Registrant identified the registered substance as of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB). The naming of UVCB substances shall consist of two parts: the chemical name and the more detailed description of the manufacturing process. According to the ECHA "Guidance for the identification and naming of substances under REACH and CLP" (Version: 1.1, November 2011), UVCB substances cannot be sufficiently identified by their chemical composition and the main identifier for UVCB substances is the description of the manufacturing process, including final or most relevant steps of the processing. ECHA notes that the registration however does not contain sufficient details on the manufacturing process.

More specifically, in IUCLID section 3.1 the Registrant provides only information on the identity of the starting materials used (mono ethanolamine, boric acid and water); however no further details on their ratio and on the process were given. In addition, the provided identifiers (EC and CAS) would suggest that a well-defined monoester of 2-aminoethanol with boric acid is the main constituent of the registered substance, whereas information given in the remark included in section 1.1 of the IUCLID dossier would suggest that different reaction products of ethanolamine with boric acid might be obtained by using different reactants ratio and reaction conditions (e.g. solvents, pH). However, no conditions specific for the manufacturing process of the registered

substance were indicated in the dossier. Furthermore no details on the collection and purification steps were provided.

In line with the above, the Registrant is requested to provide information on the ratios of starting materials used, process steps and process parameters applied to obtain the substance.

Regarding how to report the description of the UVCB substance, the information shall be included in the Description field in IUCLID section 1.1.

The registrant shall note that any significant change in the manufacturing process or source would lead to different UVCB substances which shall be registered separately. The Registrant shall also ensure that the compositional information is representative of the substance as manufactured.

(b) Composition of the substance (Annex VI, 2.3.)

The substance composition corresponds to the chemical representation of what the substance consists of and is therefore an essential part of substance identification and the corner stone of all the REACH obligations.

ECHA notes that the registration does not contain sufficient information for establishing the composition of the registered substance and therefore its identity, as required under Annex VI, Section 2.3. of the REACH Regulation.

More specifically, in the remarks field of section 1.1 of the IUCLID dossier, the Registrant provides information indicating that the significant fraction of the mono ethanolamine-borate systems consist of boric acid esters of the type $(HO)_2BOR$, $HOB(OR)_2$, and $B(OR)_3$, (where R represents an alcohol, alcoholamine etc.). Furthermore it was indicated that ammonium salts, polyborates and cyclization products might also be present in such a substance, and that all constituents are existing in rapid equilibrium. However, ECHA observes that the relevant individual constituents or groups of constituents have not been identified and reported in IUCLID section 1.2. The fact that constituents exist in fast equilibrium does not prevent the Registrant to provide representative information on the overall composition of the registered substance.

The Registrant should note that for UVCB substances such as the registered substance, the following applies:

- All constituents present in the substance with a concentration of ≥ 10 % shall be identified and reported individually;
- All known constituents and constituents relevant for the classification and/or PBT assessment of the registered substance shall be identified and reported individually; and
- Unknown constituents shall be identified as far as possible by a generic description of their chemical nature. The identification of these other constituents must be provided for ECHA to establish the composition of the substance as manufactured and to use the compositional information as one identifier for the registered substance.

For each constituent and group of constituents, the typical lower and upper concentration level shall be indicated. The concentration values shall be representative for the manufactured substance. It should be also noted that any quantity of solvent,

which can be removed without resulting in irreversible changes in the composition upon re-addition, shall not be included in the substance composition. This applies regardless of whether a shift in the equilibrium existing between the constituents takes place upon removal of that quantity of solvent.

In line with the above, the Registrant is requested to provide any information which is suitable and necessary to allow ECHA to establish and verify the composition and the name of the registered substance.

Regarding how to report the composition of the registered substance in IUCLID, the following applies: The Registrant shall report the composition of the registered substance in IUCLID Section 1.2. For each constituent required to be reported individually, the IUPAC name, CAS name and CAS number (if available), molecular and structural formula, as well as the minimum, maximum and typical concentration, shall be reported in the appropriate fields in IUCLID.
For the other constituents to be reported under a generic description, a generic chemical name describing the group of constituents, generic molecular and structural information (if applicable), as well as the minimum, maximum and typical concentration, shall be reported in the appropriate fields in IUCLID.

Further technical details on how to report the composition of UVCB substances in IUCLID are available in paragraphs 2.1 and 2.2.2 of the Data Submission Manual – Part 18: How to report the substance identity in IUCLID 5 for registration under REACH (version: 1.0, June 2010) on the ECHA website.

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

ECHA notes that the registration dossier does not contain all of the analytical data which is required according to Annex VI, Section 2.3.5. of the REACH Regulation to support the indicated substance identity. The Registrant has also not included scientific justifications for not providing all of the required information.

More specifically, the Registrant provided an infra-red spectrum and a nuclear magnetic resonance spectrum and the results of an elemental analysis. However, an ultraviolet (UV-Vis) spectrum that is as well required as spectral data was not provided in the dossier. Furthermore, one of the attachments contains information which does not refer to the registered substance ([redacted]).

The Registrant is therefore requested to submit an UV-Vis spectral data for the registered substance. If it is not technically possible or if it does not appear scientifically necessary to provide an UV-Vis spectrum, a scientifically based justification should be given. The Registrant shall also remove from the dossier the information which does not refer to the registered substance.

As for the reporting of the information in the dossier, the spectra or a scientific justification for not including these data should be attached in IUCLID section 1.4.

(d) 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. Instead only a statement "Purity cannot be determined by HPLC" was included in the remarks field of section 1.4.

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 be also included. If it is not technically possible or if it does not appear scientifically necessary to provide these chromatographic data, a scientifically based justification should be given.

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

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

ECHA notes that the Registrant has not provided any description of the analytical method used for the quantification of the registered substance including it's constituents as required by Annex VI, 2.3.7. of the REACH regulation.

As indicated in remarks in section 1.1 of the IUCLID dossier, the registered substance contains boric acid esters and potentially other constituents. However, no quantification of the substance including these constituents was provided in the dossier.

Accordingly, the Registrant is requested to submit the missing information on the description of the analytical method(s) used for the quantification of the registered substance, proving the identity of the substance including its composition. 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. The results of quantitative analysis shall be recorded on the manufactured substance.

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]

Geert Dancet
Executive Director