

Decision number: CCH-D-0000003693-70-03/F

Helsinki, 20 August 2013

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

For 2-aminoethanol CAS No 141-43-5 (EC No 205-483-3), 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 of the registration for 2-aminoethanol, CAS No 141-43-5 (EC No 205-483-3) submitted by [REDACTED] (Registrant). The scope of this compliance check is limited to the standard information requirements of Annex VI, section 2.1. and 2.3. of the REACH Regulation.

This decision is based on the registration 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 submitted 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 registration at a later stage.

The compliance check was initiated on 2 May 2013.

On 12 May 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].

On 07 June 2013 ECHA received comments from the Registrant agreeing to ECHA's draft decision.

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

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

- Composition of the substance (Annex VI, 2.3. of the REACH Regulation) as further specified in Section III.

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated registration to ECHA by **20 November 2013**.

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 requirements.


Information in the technical dossier related to the identity of the substance

Pursuant to Article 10(a)(ii) of the REACH Regulation, the technical dossier shall contain information on the identity of the substance as specified in Annex VI, Section 2 of the REACH Regulation. In accordance with Annex VI, Section 2 the information provided shall be sufficient to enable the identification of the registered substance.

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 specific registered substance and therefore its identity, as required under Annex VI, Section 2.3. of the REACH Regulation.

More specifically, ECHA notes that the Registrant has included in Section 1.2 of the IUCLID dossier two composition blocks. The first block refers to the well-defined mono-constituent substance "2-aminoethanol", the subject of this registration, whereas the second composition "2-aminoethanol crude" 

According to the "Guidance for identification and naming of substances under REACH" (version 1.2, March 2012) chapter 4.2 on the identification and naming of substances under REACH, the Registrant should note that mono-constituent substances, such as the registered substance, are substances in which one constituent is present at a concentration of at least 80% (w/w) and which contains up to 20% (w/w) of impurities. The naming convention for this kind of well-defined substances is according to the one main constituent. However, the second composition indicated in the dossier as "2-aminoethanol crude", falls into the definition of multi-constituent substance, given that it consists of several constituents present at concentrations generally $\geq 10\%$ and $< 80\%$ (w/w), and therefore considered as main constituents. The naming convention in such case would be given as a reaction mass of two or more main constituents present.

In line with the above, the Registrant is requested to remove from Section 1.2 of the IUCLID dossier any information which is not considered to be part of the registered substance, i.e. the second composition block referring to "2-aminoethanol crude". The Registrant shall note that separate registration obligations pertain to this composition.

The Registrant shall also ensure that the information provided on the composition of the substance is confirmed by the required analytical data included in IUCLID Section 1.4. The Registrant shall ensure in particular to remove any analytical information which has not been generated on the substance which is the subject of this registration.

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.



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