EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000002244-82-03/F Helsinki, 05/06/2012

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

For 1,6-Bis(2,3-epoxypropoxy)hexane, CAS No 16096-31-4 (EC No 240-260-4), 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 the ECHA has performed a compliance check of the registration dossier for 1,6-Bis(2,3-epoxypropoxy)hexane, CAS No 16096-31-4 (EC No 240-260-4) submitted by [redacted] (Registrant), latest submission number [redacted], for 1000 tonnes or more per year.

The compliance check was initiated on 14 December 2011.

On 4 January 2012 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 2 March 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

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 name or other identifiers for the substance (Annex VI, 2.1.): sufficient information on the registered substance to enable the substance identity to be determined;

b. The composition of the substance (Annex VI, 2.3.): the concentration range of the constituents in the substance;
c. Ratio of (stereo) isomers (Annex VI Section 2.2.2. of the REACH Regulation)
d. The spectral data (Annex VI, 2.3.5.): a Nuclear Magnetic Resonance (NMR) spectrum (such as a ^{1}H-NMR or 13C-NMR). Alternatively a mass spectroscopic analysis of the registered substance can be provided.

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 **6 August 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 for the purpose of registration within the applicable tonnage band of 1000 or more tonnes per year in accordance with Article 6 of the REACH Regulation, does not comply with the requirements of Articles 10, 12 and with Annexe 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) The name or other identifiers for the substance (Annex VI Section 2.1. of the REACH Regulation).

ECHA notes that the Registrant has not provided appropriate identifiers for the registered substance, as required according to Annex VI Section 2.1. of the REACH Regulation. More specifically, the Registrant identified the registered substance as a substance of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB). However, the identifiers given for the substance (including not only the EC, CAS and IUPAC identifiers but also the molecular and structural information) are specific for the well-defined substance "1,6-bis(2,3-epoxypropoxy)hexane". ECHA also notes that these identifiers are not representative of the registered substance since "1,6-bis(2,3-epoxypropoxy)hexane" represents less than [redacted]% of the reported composition.

In line with the ECHA Guidance chapter 4.3 on the identification and naming of substances under REACH,[1] well-defined substances and UVCBs are different substances under REACH. In addition, for UVCB substances such as the registered substance, the main identifiers are related to the source of the substance and the specific manufacturing process used.

Accordingly, the Registrant is requested to specify a chemical name that is representative of the source and process used for the manufacturing of the registered UVCB substance. The Registrant is requested to replace the CAS entry with CAS number 16096-31-4 currently assigned to the registered substance by an appropriate CAS name and CAS number, if

[1] http://echa.europa.eu/web/guest/guidance-documents/guidance-on-the-different-methods-under-reach

available. The Registrant is also requested to revise the molecular and structural identifiers reported in IUCLID section 1.1 as these are not representative of the registered substance.

Regarding how to report the identifiers of the UVCB substance, the information shall be included in the reference substance assigned in IUCLID section 1.1. Given the fact that the naming of a UVCB substance such as the registered substance consists of both the chemical name and the detailed description of the manufacturing process, the Registrant shall also ensure that the specific manufacturing process reported in IUCLID section 3.1 is also reported as an identifier in the description field in IUCLID section 1.1. Further technical details on how to report the identifiers of UVCB substances in IUCLID are available in paragraphs 2.1 of the Data Submission Manual 18 on the ECHA website.[2]

The Registrant shall note that any significant change in the source or the manufacturing process or any further refinement step of the manufactured substance normally lead to a different substance that should be registered separately.

(b) The 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 information that is sufficient for establishing the composition of the registered substance, as required under Annex VI, Section 2.3. of the REACH Regulation. More specifically, ECHA notes that the Registrant has not specified any information on the minimum and maximum concentration values of the different constituents reported in IUCLID section 1.2. ECHA can therefore not conclude on the variations in the composition of the registered substance that are inherent to the specific process used for its manufacturing.

The Registrant is accordingly requested to complete the above information on the composition of the registered substance provided in the registration dossier for ECHA to have a precise chemical representation of what the substance consists of. The Registrant shall ensure that the information provided on the composition of the substance is consistent with the identity of the registered substance and solely relate to the specific manufacturing process involved.

Regarding how to report the composition of the registered substance in IUCLID, the following applies: the Registrant shall report the concentration ranges in Section 1.2 of the IUCLID dossier.

(c) Ratio of (stereo) isomers (Annex VI Section 2.2.2. of the REACH Regulation)

ECHA notes that the Registrant did not report any information on the ratio of stereoisomers, as required according to Annex VI Section 2.2.2. of the REACH Regulation. More specifically, ECHA observes that all the constituents reported in the composition of the registered substance present stereocenters. It follows that the information requirement on the ratio of (stereo) isomers applies and is appropriate for the substance. Nevertheless this information is missing from the registration.

[2] http://echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it/registration

The Registrant is therefore requested to report the ratio of the different isomers present in the composition of the registered substance.

Regarding how to report the composition of the registered substance in IUCLID, the Registrant shall specify the ratio of stereoisomers in the Remarks field of the repeatable block created for each group of constituents in IUCLID section 1.2. Alternatively, the Registrant can report separately each individual stereoisomer, including information on their typical, minimum and maximum concentration in IUCLID section 1.2.

The Registrant shall ensure that the information on the stereochemistry is verifiable and therefore supported by a description of the analytical methods used for the quantification, as required under Annex VI section 2.3.7. of the REACH Regulation.

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

ECHA observes that the registration does not contain any NMR spectral data which is required according to Annex VI Section 2.3.5. of the REACH Regulation to support the identity of the registered substance. ECHA points out that the identity of the substance cannot be confirmed based exclusively on the infrared data. NMR spectroscopic analyses such as a ^{1}H-NMR or a ^{13}C-NMR are powerful tools for structure characterisation and elucidation due to characteristic chemical shifts and spin-spin coupling which also reflect the relative abundance of individual atoms. As all reported constituents contain characteristic hydrogen and carbon atoms, NMR is an appropriate analytical method to characterise the substance.

The Registrant is therefore requested to submit a NMR spectrum such as a ^{1}H-NMR or a ^{13}C-NMR. Alternatively, a mass spectrum including the corresponding interpretation of the fragmentation scheme can be provided.

As for the reporting of the spectral data in the registration dossier, the information should be included 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]

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