EUROPEAN CHEMICALS AGENCY

For final decision: CCH-D-0000002426-76-03/F Helsinki, 2 August 2012

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

For 1,4-bis(2,3-epoxypropoxy)butane, CAS No 2425-79-8 (EC No 219-371-7), 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 1,4-bis(2,3-epoxypropoxy)butane, CAS No 2425-79-8 (EC No 219-371-7) submitted by [redacted] (Registrant), latest submission number [redacted], for 1000 tonnes or more per year.

The compliance check was initiated on 22 December 2011.

On 17 April 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 18 May 2012 ECHA received comments from the Registrant.

The Registrant did not update his registration dossier.

ECHA considered the Registrant's comments received and did amend the draft decision.

On June 14 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 and other identifiers for the substance (Annex VI, 2.1): sufficient information on the registered substance to enable the substance identity to be determined, as specified under section III. (a), below;

b. The composition of the substance (Annex VI, 2.3), as specified under section III. (b), below;
c. Ratio of (stereo) isomers (Annex VI, 2.2.2.), as specified under section III. (c), below.

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 **3 September 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 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 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.

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 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, as indicated in chapter 4.3 of the Guidance for identification and naming of substances under REACH (Version: 1.1, November 2011). ECHA observes that the Registrant provided neither an appropriate chemical name nor a description of the manufacturing process for the proper identification of the registered UVCB substance, as required according to Annex VI Section 2.1 of the REACH Regulation, as further described below.

More specifically, the chemical name given for the substance, including also the chemical name associated with the EC and CAS entries and with the molecular and structural information reported in the dossier, are specific for the well-defined substance "1,4-bis(2,3-epoxypropoxy)butane". ECHA also notes that these identifiers are not representative of the registered substance since "1,4-bis(2,3-epoxypropoxy)butane" represents typically [redacted]% of the reported composition.
In line with the above mentioned ECHA guidance, 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 2425-79-8, currently assigned to the registered substance, by an appropriate CAS name and CAS number, if 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 UVCB substance. In addition, the Registrant shall provide a description of the process used for the manufacturing of the UVCB substance. The description shall also include, as appropriate, the identity of the starting materials, ratio of reactants, details of the relevant steps taken during processing (including the steps where the reaction(s) take place and the steps involved for the refining and isolation of the substance) and the associated operating parameters (such as temperature and pressure).

Further technical details on how to report the identifiers of UVCB substances in IUCLID are available in paragraph 2.1 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.

The Registrant shall note that for UVCB substances 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.

In his comments submitted to ECHA the Registrant provided a justification for allocating the CAS entry 2425-79-8 to the registered substance based on the historical use of such entry and its worldwide use in several inventories. ECHA points out that under REACH, identifiers such as CAS entries shall be used for the unambiguous identification of substances. The Registrant shall note that CAS entry 2425-79-8 does not correspond specifically to the registered substance and should not be used for its identification. The Registrant may include information in relation to CAS entry 2425-79-8 in the "Related CAS information" field in section 1.1 of the IUCLID dossier.
In addition, the Registrant stated in his comments to the draft decision, that a description of the manufacturing process will be included in the IUCLID dossier. ECHA would like to point out that such description shall reflect the way the substance is actually manufactured.

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

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 and appropriate information for establishing the composition of the registered substance, as required under Annex VI, Section 2.3. of the REACH Regulation.

More specifically, the composition reported in section 1.2 specifies exceptionally wide concentration ranges which can not be justified by variations that are inherent to the manufacturing process. In particular, the concentration range of the first listed constituent ("1,4-bis(2,3-epoxypropoxy)butane") is [redacted]% and the other three constituents or groups of constituents are reported with concentration ranges starting from [redacted]. It follows that the reported compositional information is not limited to the

UVCB substance which is the subject of this registration but includes also at least the well-defined substance "1,4-bis(2,3-epoxypropoxy)butane". ECHA therefore concludes that the reported compositional information is not appropriate.

In addition, ECHA notes that the Registrant reported the reaction products resulting from the multi-addition of [redacted] to 1,4-bis(2,3-epoxypropoxy)butane under one generic entry in the composition. However, the analytical information provided in the dossier indicates that the identity of the constituents covered by this generic entry (referred to as impurities No 4, 5 and 6 in the "BDDGE – identification – GC" report attached to the dossier) is known. ECHA therefore concludes that the Registrant did not report information on the identity and concentration of the constituents present in the composition of the registered UVCB substance to a sufficient level of detail.

According to ECHA Guidance chapter 4.3 on the identification and naming of substances under REACH (Version: 1.1, November 2011), 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 or group of constituent, the typical, minimum and maximum concentration levels shall be specified.

In line with the above, the Registrant is requested to revise the compositional information of the registered substance, specifying concentration values that solely pertain for the specific UVCB substance which is the subject of this registration and reporting the constituents and groups of constituents required to be specified in the composition.

Regarding how to report the composition of the registered substance in IUCLID, the following applies: The Registrant shall indicate 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 unknown 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.

The Registrant shall ensure that the information provided on the composition of the substance is confirmed by the analytical data included in section 1.4 of the IUCLID dossier.

In his comments submitted to ECHA the Registrant indicated that the use of a very generic description of the constituents present in the substance is linked to the presence of several unknown constituents. ECHA notes that the analytical report provided in the registration dossier shows that on the basis of a GS-MS analysis certain groups of constituents can be differentiated. The Registrant shall note that constituents with similar structure should be grouped using a description that provides as much as possible information on their identity.

(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.

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.

In his comments submitted to ECHA the Registrant provided information on the stereoisomerism of the registered substance specifying that the raw materials used are [redacted] and that the reaction involved is [redacted]. This important information would be considered as sufficient once it is included in the description of the manufacturing process of the substance in the updated dossier, as it provides clarification on identity of the registered substance.

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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Director of Regulatory Affairs