Decision number: CCH-D-2114324104-66-01/F Helsinki, 13 April 2016

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

For Cyclohexanedimethanol diglycidylether, EC No 600-447-7 (CAS No 1035218-79-1), 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 1,4-Cyclohexanedimethanol, reaction products with epichlorohydrin, EC No 600-447-7 (CAS No 1035218-79-1), submitted by [redacted] (Registrant). The scope of this compliance check decision is limited to the standard information requirement of Annex VI, Section 2 of the REACH Regulation.

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band of 100 to 1000 tonnes per year.

This decision does not take into account any updates after the date when the draft decision was notified to the Registrant under Article 50(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 22 April 2015.

On 3 November 2015 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 7 December 2015 ECHA received comments from the Registrant on the draft decision.

The ECHA Secretariat considered the Registrant's comments. The information is reflected in the Statement of Reasons (Section III) whereas no amendments to the Information Required (Section II) were made.

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendments.

As no amendments were proposed, ECHA took the decision according to Article 51(3) of the REACH Regulation.

The second listed composition (Batch II) specifies a different combination of main constituents, i.e.:

[redacted]

ECHA therefore concludes that, based on the identification of Batch I and Batch II as multi-constituent substances by the Registrant, the two reported compositions refer to different substances under REACH. As far as Article 5 of the REACH Regulation requires that "*substances [...] shall not be manufactured in the Community or placed on the market unless they have been registered*" in accordance with the registration provisions under REACH, the present dossier can only cover one substance.

The Registrant is accordingly requested to clarify the composition of the specific multi-constituent substance covered by this registration. In that respect, ECHA foresees two possibilities:

i. If the Registrant considers that the substance subject to this registration is Batch I, the Registrant should update the dossier by removing the information about Batch II from section 1.2.

ii. If the Registrant considers that the substance subject to this registration is the well-defined substance identified as Batch II, the Registrant should update the dossier removing the information about Batch I from section 1.2.

In addition, ECHA notes that the chemical name reported by the Registrant in the "IUPAC name" field of the reference substance in IUCLID section 1.1 is constructed according to the naming conventions for UVCB substances (i.e. as a "reaction product of"). This may indicate that the Registrant has also considered the possibility to identify Batch I and Batch II as UVCB substances. ECHA recognises that Batch I and Batch II may possibly be claimed by the Registrant to present a level of complexity (due to the relatively large number of possible individual isomers present in the compositions) that would qualify Batch I or Batch II as two UVCB substances themselves. However, the systematic qualitative and quantitative differences in the isomers which can be present in the compositions of Batch I and Batch II, in particular the systematic absence of [redacted] (which is predominant in Batch I) in Batch II and the systematic absence of [redacted] (which is predominant in Batch II) in Batch I, indicates significant changes in the source or the in the relevant process circumstances. As explained in Chapter 4.3 of the Guidance, the description of the manufacturing process is a main identifier for UVCB substances and therefore a change in relevant process circumstances would be likely to lead to a different substance that should be registered separately. Thus even in case where the Registrant would consider the two compositions to refer to UVCB substances, these batches would refer to two different substances.

Further technical details on how to report the identity of the registered substance(s) in IUCLID - whether as well-defined substances or as UVCB substances - are available in the "Data Submission Manual – Part 18: How to report the substance identity in IUCLID 5 for registration under REACH" (version: 2.0, July 2012).

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://www.echa.europa.eu/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

Authorised[1] by Claudio Carlon, Head of Unit, Evaluation E2

[1] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.