Decision number: CCH-D-0000002320-90-03/F Helsinki, 04/07/2012

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

For Formaldehyde, oligomeric reaction products with 1-chloro-2,3-epoxypropane and phenol, CAS No 903-36-5 (EC No 500-006-8), 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 Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation) the European Chemicals Agency (ECHA) has performed a compliance check of the registration dossier for Formaldehyde, oligomeric reaction products with 1-chloro-2,3-epoxypropane and phenol, CAS No 9003-36-5 (EC No 500-006-8) submitted by [redacted] (Registrant), latest submission number [redacted], for 1000 tonnes or more per year.

The compliance check was initiated on 31 January 2011.

On 23 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.

By 23 February 2012 the Registrant did not provide any comments on the draft decision to ECHA.

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. 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. Sufficient information on the identity and composition of the substance to allow the registered substance to be identified, as specified under section III a) below (Annex VI, 2.3.2 and 2.3.7);
b. A molecular and structural formula, as specified under section III b) below (Annex VI, 2.2.1.),
c. An ultra-violet spectrum (UV) and either a nuclear magnetic resonance (NMR) spectrum or a mass spectrum (MS) as specified under section III c) below (Annex VI, 2.3.5.);
d. The description of the analytical methods or the appropriate bibliographical references for the identification of the substance, as specified under section III d) below (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 **4 October 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 in accordance with Article 6 of the REACH Regulation, does not comply with the requirements of Articles 10 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) 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, including the composition of the registered 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.

The information provided by the Registrant does not allow a single substance to be identified. The identity of the registered substance cannot be established for the following reasons:

- The Registrant has identified the substance as a UVCB substance described using the manufacturing process. However, the identity of one of the reactants used for the manufacturing of the substance is unclear. Specifically, in accordance Section 3.1 of the IUCLID dossier, the substance is manufactured from the reaction of [redacted] with 1-chloro-2,3,-epoxypropane. [redacted] is known to refer to [redacted] obtained from the reaction of formaldehyde with phenol. In the Description field of the reference substance in Section 1.1 of the IUCLID dossier, the

Registrant confirms that [redacted] is a well- defined substance corresponding to the reaction mass of the three possible regioisomers of [redacted] (i.e. "[redacted] and [redacted] and [redacted]"). However, in the Remarks field of the reference substance in Section 1.1, the Registrant indicates that the registration also covers the reaction products of one specific isomer of [redacted], said [redacted], with 1-chloro-2,3-epoxypropane. "[redacted] and [redacted] and [redacted]" and "[redacted]" are different substances under REACH. While their reaction products with 1-chloro-2,3-epoxypropane can be covered by the generic EC entry for "Formaldehyde, oligomeric reaction products with 1-chloro-2,3-epoxypropane and phenol", these 2 reaction products are regarded as different substances, unless they are well-defined substances having the same main constituents.

- The extent of the reaction of [redacted] with 1-chloro-2,3-epoxypropane is unclear. The Registrant indicated in the Remarks field of the reference substance in Section 1.1 that the registration also covers the substance with CAS number [redacted] (the latest CAS index name of this entry is "[redacted]"). For this substance, the reaction of [redacted] with 1-chloro-2,3-epoxypropane referred to in the registration would be limited to the conversion of the [redacted] into their [redacted] equivalent. None of the other identifiers used in the dossier (EC number assigned to the substance, description of the substance and manufacturing process) specify the extent of this reaction.

Following section 4.3 of the Guidance for identification and naming of substances under REACH http://guidance.echa.europa.eu/docs/guidance_document/substance_id_en.pdf, the Registrant should note that for UVCB substances presenting a large number of constituents, 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 constituents relevant for the classification and/or PBT assessment of the registered substance shall be identified and reported individually; and
- Other constituents shall be identified by a generic description of their chemical nature. The identification of these other constituents must be provided in order to allow ECHA to establish the composition of the substance as manufactured and to use the compositional information as one identifier for the registered substance.

The Registrant is requested to provide information which is suitable and necessary to allow ECHA to verify the composition and the name of the registered substance.

Based on the registered substance composition and the relevant analytical data the Registrant is requested to reconsider the substance name and other identifiers and revise them, if necessary.

Regarding how to report the composition of the registered substance in IUCLID, 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 18 on the ECHA website at:
http://echa.europa.eu/doc/reachit/dsm18/substance_id_report_iuclid_en.pdf.

Moreover, the Registrant did not provide any information on the composition of the registered substance. The GC and HPLC chromatograms provided by the Registrant include 3 peaks > 10% accounting for [redacted]% of the composition. The chromatograms therefore indicate that the substance would be sufficiently defined by its chemical composition. However, the Registrant identified the substance as a UVCB and did not provide any information on the identity and concentration of the constituents in Section 1.2

The Registrant is requested to provide information on the identity and concentration ranges of the constituents giving rise to the 3 main peaks with a concentration of >10% observed on the GC and HPLC chromatograms. In addition, for a well-defined multi-constituent substance, the Registrant is requested to identify and quantify all impurities present at a concentration ≥ 1 %. The Registrant is also requested to identify and quantify all impurities and constituents contributing to the classification and labelling and/or PBT assessment of the substance irrespective of their concentration in the substance. For the identification of the constituents, the Registrant is requested to provide a name(s) in the IUPAC nomenclature (Annex VI point 2.1.1 of the REACH Regulation) and a molecular and structural formula (Annex VI point 2.2.1 of the REACH Regulation) as a minimum. The Registrant should report this information in Section 1.2 of the IUCLID dossier.

(b) The structural formula provided in Section 1.1 does not correspond to the registered substance itself but instead to the reactants used for the manufacturing of that substance. The Registrant is requested to provide a structural formula representative for the registered substance in Section 1.1 of the IUCLID dossier.

(c) The Registrant has provided only an infra-red spectrum for the registered substance, which alone is not sufficient to identify the substance. A UV spectrum is necessary in order to verify the appropriateness of the experimental conditions used for the GPC, GC and HPLC analyses provided by the Registrant, where a UV detector has been utilized. A proton NMR spectrum or a mass spectrum is necessary in order to verify the identity of the (main) constituents of the substance.

(d) The Registrant provided a detailed description of an HPLC method for the determination of the composition of a [redacted]. [redacted] correspond to (a group of) substances which the registered substance does not belong to as the constituents present in the registered substance are structurally different from [redacted]. As the method described in the registration solely enables the determination of the concentration of specific constituents of [redacted]

[redacted], it can not be directly applied to the registered substance.

Accordingly, in line with Annex VI, 2.3.7., the Registrant is requested to submit the description of the missing analytical methods, or the appropriate bibliographical references, to identify the registered substance, including its composition and results of the method used. The information shall be sufficient for each method to be reproduced and shall therefore include details of the experimental protocol followed, the calculation used and the result obtained.

Regarding how to report this information in the IUCLID, the following applies: The Registrant should attach information on the analytical methods or the appropriate bibliographical references used for the identification and quantification of the substance and its composition in IUCLID section 1.4.

IV. General requirements for the generation of information and Good Laboratory Practice

ECHA always reminds registrants of the requirements of Article 13(4) of the REACH Regulation that ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice (GLP).

According to Article 13(3) of the REACH Regulation, tests that are required to generate information on intrinsic properties of substances shall be conducted in accordance with the test methods laid down in a Commission Regulation or in accordance with other international test methods recognised by the Commission or the European Chemicals Agency as being appropriate. Thus, the Registrant shall refer to Commission Regulation (EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 as adapted to technical progress or to other international test methods recognised as being appropriate and use the applicable test methods to generate the information on the endpoints indicated above.

V. 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