ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114322107-62-01/F Helsinki, 22 March 2016

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

For 1,2,3-Propanetriol, glycidyl ethers, EC No 292-011-4 (CAS No 90529-77-4), 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 ECHA has performed a compliance check of the registration for 1,2,3-Propanetriol, glycidyl ethers, EC No 292-011-4 (CAS No 90529-77-4), submitted by [redacted] (Registrant).

The scope of this compliance check decision is limited to the standard information requirements 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 29 May 2015.

ECHA notified the Registrant of the draft decision on 25 August 2015.

The Registrant provided comments to the draft decision within the commenting period which are taken into account in Section III of this decision.

On 21 Juanuary 2016 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 for amendment of the draft decision within 30 days of the receipt of the notification.

As no proposal for amendment was submitted, ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

II. Information required

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

Pursuant to Articles 41(1), 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:

1. Name or other identifier of the substance (Annex VI, 2.1.);
2. Composition of the substance (Annex VI, 2.3.);
3. High-pressure liquid chromatogram, gas chromatogram (Annex VI, 2.3.6.).

B. Deadline for submitting the required information

Pursuant to Articles 41(4) and 22(2) of the REACH Regulation the Registrant shall submit to ECHA by **29 June 2016** an update of the registration dossier containing the information required by this decision.

III. Statement of reasons

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

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.

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.

1. Name or other identifier of the substance (Annex VI, 2.1.)

ECHA notes that the Registrant identified the registered substance as of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB). Information required to be provided according to Annex VI, Section 2.1. of the REACH Regulation on the naming of UVCB substances such as the registered substance shall consist of two parts: (1) the chemical name and (2) a more detailed description of the manufacturing process, as indicated in chapter 4.3 of the Guidance for identification and naming of substances under REACH and CLP (Version: 1.2, March 2012) – referred to as "the Guidance" thereinafter. Other identifiers, including any CAS number (if available) and EC number (if available and appropriate) corresponding to the substance, shall also be reported. ECHA observes that the Registrant did not provide sufficient and appropriate information on the naming and description of the manufacturing process of the substance as explained under points (a) and (b) hereinafter.

a. Information on the chemical name and numerical identifiers to be submitted by the Registrant

ECHA notes that the provided identifiers (Chemical name, EC name, EC number, CAS name, CAS number and IUPAC name) specified by the Registrant in the registration dossier would indicate that the registered substance is the result of the reaction between epichlorohydrine and glycerol. However, the ambiguities on the name provided under the CAS name and IUPAC name fields in the registration dossier prevent ECHA from concluding on the appropriate and representative chemical identifiers for the registered substance.

The provided CAS name "*1,2,3-Propanetriol, polymer with (chloromethyl)-oxirane*" linked to the CAS entry 90529-77-4 used by the Registrant is not identical with the one in the CAS Registry database. The correct CAS name is "*1,2,3-Propanetriol, glycidyl ethers*" which does not refer to a polymer substance. In addition, the selected EC name "*1,2,3-Propanetriol, glycidyl ethers*" and EC number "292-011-4" used by the Registrant also refer to an oligomeric substance.
Similarly, the current IUPAC name "*Glycerol, polymer with 1-chloro-2,3-epoxypropane*" given in the registration dossier shall, for similar reason, also be revised by the Registrant, so that it is in line with the other chemical identifiers of the registered substance.

Based on the limited compositional information provided in section 1.2 of the registration dossier, it cannot be verified whether the substance meets the polymer definition specified in Article 3(5) of the REACH Regulation. ECHA therefore considers that the CAS and IUPAC names included in the registration dossier may not fully correspond to the registered substance unless more detailed compositional information is provided which clearly demonstrate that the substance meets the polymer definition according to Article 3(5) of the REACH Regulation.

For these reasons the provided CAS and IUPAC names cannot be considered appropriate at this stage based on the information provided in the dossier.

The Registrant shall revise the CAS name and the chemical name currently specified under the "CAS information" and "IUPAC name" headers of the reference substance in IUCLID section 1.1 and report instead correct CAS and chemical names specifically corresponding to the registered substance.

The Registrant shall ensure that appropriate and consistent identifiers are used throughout the registration whenever reference to the specific substance is made which is the subject of this registration.

b. A detailed manufacturing process description to be submitted by the Registrant

Based on the information provided by the Registrant regarding the composition of the registered substance, ECHA concludes that the exact identity and concentration levels of the individual constituents reported in section 1.2 of the dossier are not sufficiently known for the UVCB substance to be identified by its composition alone. ECHA also underlines that the chemical name used by the Registrant to identify the registered substance, which is based on its starting materials, does not allow for an accurate and complete identification of the substance. A detailed description of the manufacturing process, including the chemical identity of the starting materials and information on the most relevant steps of the manufacturing process, is therefore required.

The information provided by the Registrant on the manufacturing process is not sufficiently detailed and appropriate for the identification of the registered substance because the description does not include the exact ratio of reactants used which normally influences the composition of the substance and therefore is necessary for the identification of the registered UVCB substance. More specifically, the relative ratio of starting materials ([redacted]) used in the manufacture of the substance has not been specified.

The Registrant is accordingly required to provide the relative ratio of starting materials "[redacted]".

Regarding how to report the description of the manufacturing process of the UVCB substance, the information shall be included in the "Description" field in IUCLID section 1.1.

The Registrant shall ensure that the chemical name, the identifiers and the manufacturing process description to be reported according to Annex VI, Section 2.1 are consistent with each other and with the composition required to be provided according to Annex VI, Section 2.3.

In the comments to the draft decision, the Registrant agreed with the information requirements in the draft decision. In addition, he indicated his intention to address the information requirement in an update of the registration dossier.

In the comments, the Registrant

- has addressed the change of the chemical name and numerical identifiers of the substance. While the name indicated by the Registrant corresponds to "[redacted]" ECHA notes that according to the Guidance, the generic format of the name of UVCB substances such as the registered substance is "Reaction products of [names of the starting materials]";

- has provided further clarifications on the manufacturing process description which have not been available earlier in section 1.1 of the IUCLID dossier.

The information in the comments appears to be in line with the expectations in the decision. However, the information to be provided by the Registrant upon receipt of the final ECHA decision will be assessed after the deadline provided in the decision, on the basis of the information then available in the updated dossier.

2. 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 cornerstone 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 and therefore its identity, as required under Annex VI, section 2.3. of the REACH Regulation.

More specifically, ECHA notes the following: the Registrant reported the presence of 100% of the registered substance "*1,2,3-Propanetriol, glycidyl ethers*". Further subdivision of the substance is needed which means qualitative and quantitative compositional information of the constituent(s) i.e. breakdown of the composition shall be included in the dossier.

In that respect, according to chapter 4.3 of the Guidance, for UVCB substances such as the registered substance, the Registrant shall note that 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; and
- For each constituent and group of constituents, the typical, minimum and maximum concentration levels shall be specified.

ECHA considers that the registration does not contain sufficient and appropriate information for establishing the composition of the registered substance and therefore its identity for the following reasons:

- The provided gas chromatogram (GC) analysis suggests, due to the number of peaks (ca. [redacted] present) in the chromatogram, that the substance consists of different constituents. The attached chromatographic "fingerprint" reveals that the composition of the substance is not limited only to the reported constituent "[redacted]". The fingerprint instead shows the presence of multiple peaks suggesting the existence of constituents which have not been reported in the composition in IUCLID section 1.2.
- It is further stated in the manufacturing process that "[redacted]". The statement also suggests the presence of multiple constituents in the substance. Therefore further identification is necessary on the "[redacted]" and other constituents/groups of constituents present in the substance and they shall be reported accordingly.

ECHA therefore concludes that the compositional information has not been provided to the required level of detail.

The Registrant is accordingly requested to revise the composition of the registered substance by providing appropriate information on the identity of the constituents and groups of constituents required to be reported.

Regarding how to report the composition 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 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 – Part 18: How to report the substance identity in IUCLID 5 for registration under REACH (version: 2.0, July 2012) which is available on the ECHA website. Information on how to report several compositions in IUCLID is specified in paragraph 2.3, Q&A8 of that manual.

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

In the comments to the draft decision concerning the composition of the substance (Annex VI, 2.3.), the Registrant indicated his intention to provide detailed information on the substance composition by further subdividing it.

Irrespective of whether the newly provided information may be sufficient to meet the information requirement addressed in the decision, ECHA can already point out the following: the information in the above-mentioned clarifications would seem to be in line with the expectations in the decision in relation to the composition of the substance. However, the information to be provided by the Registrant upon receipt of the final ECHA decision will be assessed after the deadline provided in the decision, on the basis of the information then available in the updated dossier.

3. High-pressure liquid chromatogram, gas chromatogram (Annex VI, 2.3.6.)

"High-pressure liquid chromatogram or gas chromatogram" is an information requirement as laid down in Annex VI, Section 2.3.6. of the REACH Regulation. Adequate information needs to be present in the technical dossier for the registered substance to meet this information requirement.

ECHA notes that a copy of a gas chromatogram has been attached to the dossier. However, the Registrant did not provide a comprehensive report for the chromatographic analysis. In particular a "fingerprint" GC chromatogram has been provided in the dossier however the peaks have not been identified in the peak table. As a result, there is no information as to how the detected and quantified peaks in the chromatogram correspond to the individual constituents and groups of constituents of the substance. Therefore it is not possible to conclude how the "fingerprint" relates to the substance composition expected to be reported in section 1.2 of the dossier.

Therefore, the Registrant is requested to submit an appropriate report for the chromatographic analysis in which the peaks of the chromatogram are identified and quantified in order to obtain a detailed compositional information of the registered substance.

The provided compositional information shall enable ECHA to verify whether the substance does meet the polymer definition according to Article 3(5) of the REACH Regulation or not.

As for the reporting in the registration dossier, the information should be included in IUCLID section 1.4.

In the comments to the draft decision the Registrant agreed with the information requirements in the draft decision. In addition, he indicated his intention to address the information requirement in an update of the registration.

The Registrant highlighted in his comments that the complexity of the composition of the registered substance hinders a clear determination of its constituents. Different analytical techniques such as GPC can be used to determine the approximate molecular weight distribution of the constituents of the substance as well as statistical analysis of the reaction kinetics are intended to be carried out in order to determine the composition of the substance as stated in the comments by the Registrant. ECHA points out that when the complexity of the composition of a substance is such that the concentration levels of its constituents cannot be derived using conventional analytical methods, alternative methods complemented with considerations on the manufacturing process of the substance can be applied for determining the composition. When this approach is followed, information on how the composition was derived including details of the analysis of the data obtained and including theoretical calculations carried out needs to be reported in the IUCLID dossier.

The information in the comments appears to be in line with the expectations in the decision. However, the information to be provided by the Registrant upon receipt of the final ECHA decision will be assessed after the deadline provided in the decision, on the basis of the information then available in the updated dossier.

The Registrant shall note that a comprehensive report for the chromatographic analysis shall be provided in the updated dossier. The report shall be in line with the substance composition expected to be reported in section 1.2 of the dossier.

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://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 Guilhem de Seze, Head of Unit, Evaluation E1

[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.