EUROPEAN CHEMICALS AGENCY

Helsinki, 7 November 2016

Addressee: [redacted]

Decision number: CCH-D-2114347528-41-01/F
Substance name: Poly(oxy-1,2-ethanediyl),α-hydro-ω-hydroxy- Ethane-1,2-diol, ethoxylated
EC number: 500-038-2
CAS number: 25322-68-3
Registration number: [redacted]
Submission number: [redacted]
Submission date: 09.10.2013
Registered tonnage band: 100-1000T

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (the 'REACH Regulation'), ECHA requests you to submit information on

1. **Name or other identifier of the substance (Annex VI, Section 2.1.) of the registered substance**
   - **Manufacturing process**

2. **Composition (Annex VI, Section 2.3.) of the registered substance**

3. **Description of the analytical methods (Annex VI, Section 2.3.7) of the registered substance**

You are required to submit the requested information in an updated registration dossier by **14 February 2017**. You shall also update the chemical safety report, where relevant.

The reasons of this decision are set out in Appendix 1. The procedural history is described in Appendix 2. Advice and further observations are provided in Appendix 3.

The scope of this compliance check decision is limited to the standard information requirement(s) of Annex VI, Section 2 of the REACH Regulation.

Appeal

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, shall be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under http://echa.europa.eu/regulations/appeals.

Authorised[1] by Ofelia Bercaru, Head of Unit, Evaluation E3

[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.

Appendix 1: Reasons

IDENTIFICATION OF THE SUBSTANCE

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, Section 2.1.)

The name and other identifiers are used to identify the substance in an unambiguous manner and are therefore essential parts of substance identification and a corner stone of all the REACH obligations.

ECHA notes that you 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 shall consist of two parts: (1) the chemical name and (2) a more detailed description of the manufacturing process, as indicated in section 4.3 of the Guidance for identification and naming of substances under REACH and CLP (Version: 1.4, Jun 2016) – referred to as "the Guidance" hereinafter.

According to the Guidance, the description of the manufacturing process shall include information on the chemical identity of the starting materials and information on the most relevant steps of the process.

ECHA notes that no information on the manufacturing process description was provided.

Therefore, you have not fulfilled the requirements of the REACH Regulation on the identification of the registered substance.

You are accordingly required to provide details of the chemical identity of the starting materials and the manufacturing processing steps that are applied to the starting materials. The information submitted must at least include the following:

- The identity of the starting materials and the molar ratio between the different starting materials used.
- A description of the manufacturing steps in the order they occur, including any preliminary step, the steps involving chemical transformation as well as the isolation and purification steps carried out for the synthesis.

For each step, all relevant process parameters (e.g. temperature and pressure) that may affect the composition and therefore the identity of the substance must be provided.

If the substance covered by the registration is manufactured according to different manufacturing processes, including the use of different sources, steps and/or processing parameters, then the detailed description of the manufacturing process required hereinabove shall be reported separately for each manufacturing process. A manufacturing process may be considered different when the relevant processing steps and/or processing parameters are different. You shall note that substances manufactured according to different manufacturing processes may indicate multiple substances and consequently the requirement for multiple registrations.

As for the reporting of the information in IUCLID, the manufacturing process description for the registered substance shall be reported in the "Description" field of the reference substance in IUCLID section 1.1.

You shall ensure that the chemical name and other identifiers reported in section 1.1 of the IUCLID dossier are representative of the UVCB substance as described by the manufacturing process.

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.

You shall note that the registration is currently linked to chemical identifiers (including the EC number 500-038-2) referring to Poly(oxy-1,2-ethanediyl),α-hydro-ω-hydroxy- Ethane-1,2-diol, ethoxylated. In case the current identifiers are not appropriate to describe the registered substance, you should not remove or modify at this stage this EC entry for technical reasons, the registration being linked to that EC entry in REACH-IT. To ensure unambiguous identification of the registered substance, you should however indicate, in the "Remarks" field of the reference substance in IUCLID section 1.1, the following: "The EC number 500-038-2 currently assigned does not specifically correspond to the registered substance. This identifier cannot be modified or deleted at this stage in the present registration update for technical reasons". You should also specify, in the same "Remarks" field, any available and appropriate EC number for the substance. Any available CAS entry for the registered substance should be reported under the "CAS information" header of the reference substance in IUCLID section 1.1.

You should note that ECHA has established a process, subject to certain conditions, enabling registrants to adapt the EC identifier of an existing registration, while maintaining the regulatory rights already conferred to the substance concerned.

Pending the resolution of the non-compliances addressed in the present decision, any possible adaptation of the identifier can only become effective once ECHA is in a position to establish unambiguously the identity of the substance intended to be covered by you with this registration.

Should the information submitted by you as a result of the present decision enable ECHA to identify the substance unambiguously and result in a need to modify the identifier of the substance, the process of adapting the identifier will be considered relevant. In that case, ECHA will inform you in due time as to when and how the identifier adaptation process shall be initiated.
In any case, you should note that the application of the process of adapting the identifier does not affect your obligation to fulfil the requirements specified in this decision.

2. Composition of the substance (Annex VI, Section 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 a corner stone of all the REACH obligations.

Annex VI, Section 2.3. of the REACH Regulation requires that each registration dossier contains sufficient information for establishing the composition of the registered substance and therefore its identity.

In that respect, according to chapter 4.3 of the Guidance, you shall note that for UVCB substances (substances of Unknown, or Variable Composition, or of Biological origin) 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
- Other constituents shall be identified as far as possible by a generic description of their chemical nature.

Furthermore 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, should 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, should be reported in the appropriate fields in IUCLID.

ECHA notes that one generic constituent (with IUPAC name [redacted] has been reported in the IUCLID section 1.2 with a typical concentration of 95% (concentration range of [redacted]%). For this constituent you reported the molecular formula '(C2-H4-O)mult-H2-O', a molecular weight range of (200-600) and a generic structural formula. ECHA observes that the registration does not contain sufficient information for establishing the composition of the registered substance and therefore its identity. More specifically, the constituents resulting from the chemical transformations are reported under one main generic group.

For this group of constituents, you provided a very generic molecular formula, a very broad molecular weight range and a very generic structural formula describing the different types of compounds that may be obtained as a result of the oligomerization reaction. These allow variations that could cover very different oligomers. ECHA therefore concludes that the compositional information has not been provided to the required level of specificity.

Pursuant to Article 41(1) and (3) of the REACH Regulation, you are accordingly requested to revise the information on the composition of the registered substance in order to establish a precise chemical representation of what the substance consists of.

For this type of substance consisting of different groups of constituents containing different numbers of monomeric unit of "ethylene oxide" (EO), we expect as compositional information the reporting of the different constituents separately (e.g. 3 EO, 4 EO, 5 EO, etc.) with a representative typical concentration and concentration range values.

Regarding how to report the composition in IUCLID, the following applies:

You shall indicate each 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) on the ECHA website. Information on how to report several compositions in IUCLID is specified in paragraph 2.3, Q&A8 of that manual.

You shall ensure that the reported composition is consistent with the description of the process used for the manufacturing of the registered substance, including the identity of the starting materials used. You shall also ensure that the composition is verifiable and therefore supported by a description of the analytical methods for the identification and quantification of the constituents required to be reported, as required under Annex VI, Section 2.3.7.

3. Description of the analytical methods (Annex VI, Section 2.3.7.)

The description of analytical methods or appropriate bibliographical reference for the identification of the substance is a formal information requirement of Annex VI Section 2.3.7. As explained in the above paragraph a description of the analytical methods is required and is important for the identification and quantification of the constituents allowing the verification of the composition and the identity of the substance.

You submitted a description of a Gel Permeation Chromatographic (GPC) analysis. One broad peak is visible in the chromatogram and you reported some specifications such as "Mw, Mn, Mz, polydispersity...". Furthermore there is no indication of calibration and calculation used to identify and quantify the different constituents.

This information does however not provide any indication of the identity of the actual constituents present in the analysed sample. It is not possible to establish the concentration values of the different constituents. In summary, the results from this analysis do not allow the identification and quantification of the different constituents of the substance. ECHA therefore concludes that you did not provide sufficient description of the analytical methods used for the identification and quantification of the constituents and groups of constituents required to be reported in the composition of the registered substance.

In line with Annex VI Section 2.3.7 you are accordingly requested to provide a description of the analytical methods enabling the identification and quantification of the constituents/groups of constituents required to be reported in the composition of the registered substance. The description shall be sufficient for the methods to be reproduced and shall therefore include details of the experimental protocol which should include any calculation made and the results obtained.

You should note that ECHA will consider any method that is suitable to verify the composition, including any indirect method involving chemical derivatisation of the substance or any analysis involving also considerations on the starting materials and the manufacturing process.

As for the reporting of the data in the registration dossier, the information shall be attached in IUCLID section 1.4. You shall ensure that the composition reported in the dossier according to Annex VI section 2.3. is consistent with the analytical results obtained.

In order to comply with the REACH requirements, you shall provide a detailed description of the analytical method used to identify the quantitative composition of the substance. The chromatographic method can be used to derive the quantitative composition but also alternative methods can be used. The results of the quantitative method together with the interpretation of the results, calculations (if relevant) shall also be provided.

Appendix 2: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of your registration after the date when the draft decision was notified to you under Article 50(1) of the REACH Regulation.

The compliance check was initiated on 19 February 2016.

The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation, as described below:

ECHA notified you of the draft decision and invited you to provide comments.

ECHA did not receive any comments by the end of the commenting period.

ECHA notified the draft decision to the competent authorities of the Member States for Proposal(s) for amendment.

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

Appendix 3: Further information, observations and technical guidance

1. This compliance check decision does not prevent ECHA from initiating further compliance checks on the present registration at a later stage.

2. Failure to comply with the request(s) in this decision, or to fulfil otherwise the information requirement(s) with a valid and documented adaptation, will result in a notification to the enforcement authorities of your Member State.