EUROPEAN CHEMICALS AGENCY

Helsinki, 15 September 2016

Addressee: [redacted]

Decision number: CCH-D-2114343416-52-01/F
Substance name: Amines, polyethylenepoly-
EC number: 268-626-9
CAS number: 68131-73-7
Registration number: [redacted]
Submission number: [redacted]
Submission date: 02.11.2015
Registered tonnage band: 1000+T

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 (Annex VI, Section 2.1.) of the registered substance**
   - **Description of the manufacturing process;**

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

You are required to submit the requested information in an updated registration dossier by **22 December 2016**. 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

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

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.

ECHA notes that you have 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: 1.3, February 2014) - referred to as "the Guidance" thereinafter.

ECHA observes that you have provided a chemical name (*Amines, polyethylenepoly-*) in IUCLID section 1.1 and a description of the manufacturing process in IUCLID section 3.1. According to the manufacturing description different products and side products of the reaction are separated in different sections of the plant. Based on the manufacturing process two fractions "[redacted]" are obtained.

However, the description is not sufficiently detailed to understand how the registered substance is manufactured and how the composition covered by this registration is obtained. Namely, it is not clear if the reported manufacturing process is representing both "[redacted]" and "[redacted]" fractions that are obtained during the process or only one of these fractions. This is as well relevant for the question if the substance registered represents either fractions or only one of them.
The information given in IUCLID section 1.2 that describes the most abundant constituent as "[redacted]" and the analytical information given in IUCLID section 1.4 that refers to "[redacted]", do not clarify this either.

ECHA therefore concludes that the manufacturing process has not been provided to a sufficient level of detail for the identification of the registered substance.

Consequently, you are requested to submit more detailed information on the description of the process used for the manufacturing of the registered substance. The description shall indicate the method(s) used and respective parameters applied (e.g. distillation temperature, etc.) to separate the fractions containing the constituents of the substance as reported in sections 1.2 and 1.4 of the registration dossier. You shall also clearly indicate which fractions lead to the registered substance and whether the constituents reported in section 1.2 and the analytical data given in section 1.4 are representative for both "[redacted]" and "[redacted]" fractions or only for one of them.

In the comments on the draft decision according to Article 50(1) you indicated your intention to clarify the acronyms used and update the description of the manufacturing process in Section 3.1. ECHA further notes that in your comment you further clarify the acronyms used and the manufacturing process. ECHA notes that while the information outlined would appear to meet the requirements of the draft decision, such information will be examined by ECHA only after the deadline set in the adopted decision has passed.

As for the reporting of the information in IUCLID, the manufacturing process description can be specified in the "Description" field in IUCLID section 1.1 or in IUCLID section 3.1. You may also include an attachment that illustrates the process steps and their sequence in the IUCLID dossier.

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

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.

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 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.

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.

In the registration dossier you have identified the registered substance as a UVCB substance and specified in IUCLID section 1.2 that the substance contains [redacted] % of "[redacted] that are "[redacted]".

Based on the analytical data attached in IUCLID section 1.4 the "[redacted] consists of "[redacted] %) and "[redacted] %).

However, the breakdown to "[redacted] and "[redacted] is not indicated in IUCLID section 1.2 and a breakdown of the individual constituents present (e.g. as linear, branched and cyclic) is also missing.

Furthermore it is unclear if the composition given in IUCLID section 1.2 refers to the two fractions "[redacted]" and "[redacted]". This is because you have described the constituent "[redacted]-" in IUCLID section 1.2 as "[redacted]" whereas the names you have used in the analytical reports attached in IUCLID section 1.4 refer simultaneously to "[redacted]" and/or "[redacted]" even though based on the manufacturing description [redacted] refers to the "[redacted]".

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

Consequently, you are requested to provide further information on the composition and to clarify the above mentioned inconsistencies.

If the registered substance covers both fractions you are expected to report the compositions of both "[redacted]" and "[redacted]" in section 1.2 separately and where possible report individually the linear, branched and cyclic isomers of "[redacted])" and "[redacted]

You shall 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.2.3.7. of the REACH Regulation.

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.

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.

In the comments on the draft decision according to Article 50(1) you indicated your intention to revise the Section 1.2 of IUCLID in accordance with existing analytical data provided in Section 1.4 of IUCLID. ECHA further notes that your comment further clarifies the composition of the registered substance. ECHA notes that while the information outlined would appear to meet the requirements of the draft decision such information will be examined by ECHA only after the deadline set in the adopted decision has passed.

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 8 Decemeber 2015

The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation:

ECHA notified you of the draft decision and invited you to provide comments. ECHA took into account your comments and did not amend the requests.

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.