EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000005277-70-02/F Helsinki, 28 August 2014

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

For C16-18-(even numbered, saturated and unsaturated)-alkylamines, CAS No 1213789-63-9 (EC No 627-034-4), 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 C16-18-(even numbered, saturated and unsaturated)-alkylamines, CAS No 1213789-63-9 (EC No 627-034-4), submitted by [redacted] (Registrant). The scope of this compliance check is limited to the requirements regarding the identification of the substance (Section 2 of Annex VI). ECHA stresses that it has not checked the information provided by the other joint Registrants for compliance with requirements regarding the identification of the substance (Section 2 of Annex VI).

This decision is based on the registration as submitted with submission number [redacted] for the tonnage band of 1000 tonnes or more per year. This decision does not take into account any updates submitted after 12 June 2014, the date upon which ECHA notified its draft decision to the Competent Authorities of the Member States pursuant to Article 51(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 1 July 2013.

On 20 September 2013 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision. That draft decision was based on submission number [redacted]

On 10 October 2013 ECHA received comments from the Registrant on the draft decision. On 7 November 2013 the Registrant updated his registration dossier [redacted]

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

On 12 June 2014 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

Pursuant to Articles 41(1)(a), 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. Description of the analytical methods (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 registration to ECHA by **5 December 2014.**

III. Statement of reasons

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.)

The name and other identifiers are used to identify the substance in an unambiguous manner and are therefore essential parts of substance identification.

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. ECHA observes that the Registrant did not provide sufficient information on the manufacturing process of the substance.

ECHA notes also that the Registrant identified the source used for the manufacturing of the registered substance as "natural fatty acids". However, the identity of the source(s) has not been provided to a sufficient level of detail as the description does not include any information on the exact identity and concentrations of the individual constituents/groups of constituents of the source given as "natural fatty acids". In particular, as the description of the composition in section 1.2 of the dossier is not fully described by reference to functionality descriptors, i.e. subdivision of saturated and unsaturated constituents, identification based on the name and compositional information of that source (in terms of identity and concentration of predominant constituents or groups of constituents) is necessary for the identification of the registered substance. ECHA notes that if the information on composition of the registered substance is provided as described in Sections III.2 and III.3, then the detailed information on composition of the source material would not be necessary.

Moreover, in absence of the subdivision of saturated and unsaturated constituents in section 1.2 of the dossier, as described in Section III 2 and 3, the information provided on the manufacturing process steps is not detailed enough to allow ECHA to confirm the identity of the registered substance. In particular, specifications of manufacturing process parameters (e.g. temperature, pressure, solvent used, if any, reaction time) and detailed information on the purification step have not been given.

The Registrant is accordingly required to provide the exact identity of the source used for the manufacture of the registered substance. Information on the identity and concentration of constituents or groups of constituents present in the composition of the source (including unsaturation level, e.g. iodine value) shall also be provided. In addition the Registrant is required to provide details of the manufacturing processing steps that are applied to the source. This must include the following:

- Specifications of manufacturing process parameters (e.g. Temperature, pressure, solvent used, if any, reaction time);
- Description of the ammoniation–dehydration and hydrogenation steps. The information shall be supplemented with details of the reaction mechanisms involved. For instance, where the hydrogenation process involves catalytic reactions the information shall include, for each catalytic reaction, details of the type of catalyst(s) used in terms of reaction(s) that they catalyse (including detailed information on the selectivity of the catalyst towards the reaction products, reaction mechanisms etc.). The information on how the use of the specific catalyst affects the composition of the registered substance must also be included;
- If a purification step is applied (e.g. distillation), then the relevant process parameters needs to be provided (pressure and temperature ranges must be specified in case distillation is applied);
- Furthermore, the Registrant shall provide information on any other relevant process steps and parameters that are required for identifying the substance.

If the substance covered by the registration is manufactured according to different manufacturing processes, including the use of different sources, then the detailed description of the manufacturing process required hereinabove shall be reported separately for each manufacturing process. Any significant change of source or process might lead to a different substance for which a separate registration needs to be submitted.

The Registrant shall note that substances manufactured according to different manufacturing processes may indicate multiple substances and consequently the requirement for multiple registrations.

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, respectively.

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, the substance is identified as C16-18-(even numbered, saturated and unsaturated)-alkylamines in section 1.1 of the IUCLID file. The information given in section 1.2 of the IUCLID file on the composition includes the two reference substances "C16-(saturated and unsaturated)-alkylamine" and "C18-(saturated and unsaturated)-alkylamine". Furthermore the Registrant provided the result of a gas chromatographic analysis. The chromatogram reported shows a series of peaks that have been identified as two groups of constituents corresponding to C18-(saturated and unsaturated)-alkylamine and C16-(saturated and unsaturated)-alkylamine. However, no further qualitative nor quantitative information is given on the specific saturated alkylamines or unsaturated alkylamines present in the substance. ECHA therefore concludes that the current composition has not been provided to a sufficient level of detail.
The Registrant is accordingly requested to revise the compositional information reported in the dossier such that saturated and unsaturated constituents are reported separately. The concentration range values need to be specified for each reported constituents and these values must be representative for the registered substance as manufactured.

According to the Guidance, chapter 4.3, the Registrant should note that, for UVCB substances 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 known constituents and constituents relevant for the classification and/or PBT assessment of the registered substance shall be identified and reported individually;
- Unknown constituents shall be identified as far as possible by a generic description of their chemical nature. The identification of these unknown constituents must be provided for ECHA to establish the composition of the substance as manufactured and to use the compositional information as one identifier for the registered substance. For substances such as the registered substance, a distinction of the unknown constituents according to the carbon number and level of unsaturation (saturated, mono-unsaturated, di-unsaturated...) is necessary for this purpose as a baseline.

For each constituent or group of constituents, the typical, minimum and maximum concentration levels shall be specified.

The Registrant is accordingly requested to complete the above information on the composition of the registered substance provided in the registration dossier, for ECHA to have a precise chemical representation of what the substance consists of.

Regarding how to report the composition of the registered substance 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.

Where the Registrant covers different grades of the same substance in a registration, the Registrant shall report separately the compositional information of each grade.
This means that if the substance covered by the registration has two (or more) different compositions, then these must be presented separately. Information on how to report several compositions in IUCLID is specified in paragraph 2.3, Q&A8 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), available on the ECHA website.

The Registrant should also note that multiple compositions may indicate multiple substances and consequently the requirement for multiple registrations.

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).

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

ECHA observes that the Registrant did not provide sufficient description of the analytical methods used for the identification and quantification of the different constituents present in the composition of the registered substance, which is requested according to Annex VI section 2.3.7.

More specifically ECHA notes that the composition of the substance was analysed by a gas chromatographic method. The presented results consider only two groups of constituents, C16-(saturated and unsaturated)-alkylamines and C18-(saturated and unsaturated)-alkylamines. Such information is not sufficient to enable a distinction between the groups of constituents with different level of unsaturation.

The Registrant is accordingly requested to provide a description of the analytical methods used for the identification and quantification of the 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 followed, any calculation made and the results obtained. The description shall provide a distinction between the groups of constituents with different level of unsaturation and include peak assignment to appropriately subdivided constituents, as specified in Section III 2 of this decision. The peaks referring to C16 saturated, C16 unsaturated, C18 saturated and C18 unsaturated shall be integrated individually and peak areas with corresponding area % shall be reported.

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

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.

[redacted]
Leena Ylä-Mononen
Director of Evaluation