EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114308426-54-01/F Helsinki, 9 October 2015

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 (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 1000 tonnes or more per year. This decision does not take into account any updates after the deadline for updating (13 March 2015) communicated to the Registrant by ECHA on 04 February 2015.
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 26 September 2013.

On 22 September 2014 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 27 October 2014 ECHA received comments from the Registrant on the draft decision. On 16 February 2015 the Registrant updated his registration with the submission number [redacted].

The ECHA Secretariat considered the Registrant's comments and update. On basis of this information, Section II was amended. The Statement of Reasons (Section III) was changed accordingly.

On 23 July 2015 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

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

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:

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

Pursuant to Articles 41(4) and 22(2) of the REACH Regulation the Registrant shall submit to ECHA by **18 January 2016** an update of the registration dossier containing the information required by this decision.

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.

Information in the technical dossier related to the identity 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.

Description of the analytical methods (Annex 2.3.7.)

"Description of the analytical methods" for the identification of the substance is an information requirement as laid down in Annex VI, Section 2.3.7. of the REACH Regulation. Adequate information needs to be present in the technical dossier for the registered substance to meet this information requirement.

The Registrant provided analytical information as required by Annex VI, Section 2.3.7. However, the analytical information (attachments "[redacted]") included in the registration dossier is not sufficient for the verification of the composition of the registered substance, as the information is identical to the analytical information included in a registration dossier submitted by a different legal entity. In the report containing the analytical information it is indicated that the information relates to the manufacturing site of the other legal entity. The analytical information is a fingerprint of a substance manufactured or imported by a specific registrant. Therefore, ECHA cannot establish that the analytical information relates to the substance covered by the registration subject to the present decision.

Article 5 of the REACH Regulation requires legal entities to make sure that the substances they manufacture or place on the market are registered in accordance with Title II of the REACH Regulation. Based on Article 11(1) and 10(a)(ii) of the REACH Regulation, each Registrant is required to submit separately information on the identity of the substance he registers. Annex VI of the REACH Regulation provides that "the information given shall be sufficient to enable each substance to be identified". Analytical information generated on a substance that is not manufactured or imported by the Registrant cannot be used as evidence that would allow ECHA to verify the identity and composition of the registered substance.

Therefore, ECHA concludes that the analytical information provided by the Registrant cannot, in absence of further justification, be considered appropriate to verify the composition of the registered substance.

In accordance with the above and pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is required to provide a description of the methods used to analyse the registered substance. The descriptions shall be given in such detail that the methods can be reproduced. The results of the analyses, generated on the substance as manufactured/imported by the Registrant, shall also be reported. The Registrant shall ensure that the composition reported in the registration dossier is consistent with the analytical results obtained.

Any deviation from the standard requirement to provide analytical information derived from the substance as manufactured or imported by the legal entity actually holding the present registration will not be considered appropriate, unless it is supported by a robust scientific justification, including analytical evidence. Such documentary evidence shall enable ECHA to conclude with certainty that the analytical information is representative of the substance manufactured and/or imported by that specific legal entity.

The Registrant shall note that, in principle, such justification for relying on analytical information generated on a substance manufactured on a different site would only be considered valid provided that at least the following information is included in the registration:

- The chemical composition of the starting materials and any relevant processing aid (i.e. any substance other than the reactants used in the manufacturing process affecting the composition of the registered substance) used on the different sites. These compositions shall be described to the level required for the identification of substances under REACH, as also specified in the Guidance. For each difference in the chemical composition of a starting material and relevant processing aid used on different sites, the Registrant must scientifically demonstrate that the analytical information recorded on the substances manufactured on the different sites, including the chromatographic and spectroscopic fingerprints required to be provided under REACH, cannot differ;

- A detailed description of the manufacturing process setup of each manufacturing site, including information in terms of:
    - Equipment in which the synthesis takes place, e.g. reaction vessels, ancillary equipment, pipework for transferring to different reaction vessels used during the manufacturing of the substance;
    - Procedure followed during the manufacturing of the substance, including:
        - the ratio of the starting materials,
        - description of the manufacturing steps in the order they occur. Each process step, including preliminary steps, steps involving chemical transformation, isolation and purification steps shall be specified
        - For each step, all relevant process parameters (e.g. temperature, pressure) that affect the composition and therefore the identity of the substance must be provided
        - Description of the reactions occurring during each step, leading to the formation of unintended constituents shall be provided.

  For each single difference in the process setup (e.g. different scale of the process, different process design, different processing step, different process parameters),

the Registrant must scientifically demonstrate that the analytical information recorded on the substances manufactured on the different sites, including the chromatographic and spectroscopic fingerprints required to be provided under REACH, cannot differ;

- The description of all the analytical methods used to control the quality of each substance manufactured on each site. The description shall be given in such detail that the methods can be reproduced and shall therefore include a detailed experimental protocol. Typical results of the analysis, generated on the substance manufactured on each site shall also be reported. The Registrant must demonstrate that the analytical methods used for the monitoring, possibly correlated with the analytical methods required to be provided under REACH and described in the registration for one of the manufacturing sites, are sufficient to ascertain that (a) all constituents and groups of constituents required to be reported can be identified and quantified and (b) the chromatographic and spectroscopic fingerprints recorded on samples from each site necessarily are identical.

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

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.