EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000005218-74-02/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 Quaternary ammonium compounds, bis(hydrogenated tallow alkyl)dimethyl, chlorides, CAS No 61789-80-8 (EC No 263-090-2), 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 Quaternary ammonium compounds, bis(hydrogenated tallow alkyl)dimethyl, chlorides, CAS No 61789-80-8 (EC No 263-090-2), submitted by [redacted] (Registrant). The scope of this compliance check is limited to the information requirements of Annex VI, Section 2 of the REACH Regulation. 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 (Annex VI, Section 2).

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 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 14 May 2013.

On 26 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 11 October 2013 ECHA received comments from the Registrant.

On 14 November 2013 the Registrant updated his registration dossier (submission number Nr [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 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

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:

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

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.

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.

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

In the technical dossier (submission No.: [redacted] 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). ECHA observes that the Registrant did not provide sufficient information on the manufacturing process, as explained hereinafter.

The Registrant provided a manufacturing process description where the starting materials used are designated as "*Dialkylamines or dialkylmethylamines derived from fatty acids or fatty alcohols react with methylhalides*". However, the Registrant has not further specified the amine compounds effectively used in the process. Furthermore the identity of the halide used as starting material has not been further specified.

In addition, the EC name "Quaternary ammonium compounds, bis(hydrogenated tallow alkyl)dimethyl, chlorides" would indicate that the source from which the fatty acids are obtained is tallow. However no indication on the fatty acid source has been provided in the description of the manufacturing process.

Therefore ECHA is not able to verify the provided EC name.

Subsequently, the Registrant updated the technical dossier (submission No.: [redacted] In the updated dossier the Registrant provided "N,N-Dimethyl-N,N-di-n-alkyl(C16-18)-ammoniumchloride" as a chemical name in the "IUPAC name field" in section 1.1 of IUCLID. In addition, the manufacturing process was further specified with information on the exact identity of each starting material and the stoichiometric ratios of the reagents.

However, the information provided on the source from which the alkyl substituents are obtained is not sufficiently clear. The Registrant specifies that "*In general dialkylamines or dialkylmethylamines are derived from fatty acids from natural sources [...]*". From this information ECHA cannot verify whether the fatty acids are derived solely from tallow or also from other natural sources. In case the fatty acids are also obtained from other natural sources than tallow; the EC number and EC name under which the substance was registered would not be considered correct as this name suggests that the source of the fatty acids from which the substance is derived is exclusively tallow.

ECHA concludes that in the updated dossier some additional information on the manufacturing process has been provided, however, it is insufficient and an ambiguity remains which prevents ECHA from verifying the identity of the registered substance. Therefore, as there is still a need to provide missing information regarding the description of the manufacturing process, the he Registrant is accordingly requested to provide the following: The source from which the alkyl substituents are obtained.

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

If the source of the fatty acids in the substance is from tallow and other natural sources, then the Registrant shall specify, in the "Remarks" field of the reference substance in IUCLID Section 1.1, the following: "The EC entry 263-090-2 currently assigned does not specifically correspond to the registered substance. This identifier can technically not be modified or deleted at this stage in the present registration update". The Registrant shall also specify, in the same IUCLID field, any available and appropriate EC number for the substance.

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.

[redacted]

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