ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000005478-64-02/F Helsinki, 3 November 2014

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

For Quaternary ammonium compounds, di-C16-18-alkyldimethyl, chlorides, CAS No 92129-33-4 (EC No 295-835-2), 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, di-C16-18-alkyldimethyl, chlorides, CAS No 92129-33-4 (EC No 295-835-2, 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 1000 tonnes or more per year. This decision does not take into account any updates submitted after 24 July 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 3 July 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 21 October 2013 ECHA received comments from the Registrant.

On 16 May 2014 the Registrant updated his registration dossier (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 24 July 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.);
2. Description of the analytical methods (Annex VI, Section 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 **10 February 2015**.

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.)

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: 1.3, February 2014). ECHA observes that the Registrant did not provide sufficient information on the manufacturing process, as explained hereinafter.

In the initial dossier (submission number [redacted]), the Registrant had provided a manufacturing process description where the starting materials used were designated as *"dialkylamine derived from fatty acids or fatty alcohols"* and *"methylhalides"*. However, the Registrant had 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. Furthermore, the ratio of the reactants had not been provided.

In the updated dossier (submission number [redacted]), the Registrant has clarified the identity of the methylhalides used as starting material. The Registrant specified the halide

as "*methylchloride*". The Registrant has also specified the ratio between the dialkylmethylamines and methylchloride as 1:1 (mass ratio).

However, the Registrant has not further clarified the exact identity of the dialkylmethylamines starting material.

For this specific registered UVCB substance, a very detailed information on the starting materials would not necessarily be required if the composition of the substance as given in IUCLID section 1.2 was verifiable from the analytical data provided in IUCLID section 1.4. However, since the analytical data currently provided by the Registrant cannot be used to verify the composition of the substance (see section III.2 of this decision), the exact identity of the starting material "*dialkylamines*" is still required as a baseline to identify the substance.

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

The Registrant is accordingly requested to provide the following missing information regarding the description of the manufacturing process: the exact identity of the starting material "*dialkylamines*" in the form of concentration levels (typical, upper and lower) of its individual constituents (such as tetradecylamine, pentadecylamine, hexadecylamine, heptadecylamine octadecylamine and any other relevant constituent).

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.

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

"Description of the analytical methods or the appropriate bibliographical references for the identification of the substance" is a standard information requirement as laid down in Annex VI, Section 2.3.7. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

The initial dossier (submission number [redacted]) did not contain details of analytical methods applied to analyze the quantitative composition of the substance. In addition, the substance is identified as a chloride salt. However, the Registrant did not include in the dossier the quantification of chloride in the substance.

In the updated dossier (submission number [redacted]), the Registrant provided a description of analytical methods for the quantification method of the constituents listed in IUCLID section 1.2. The Registrant used the proton NMR spectrum (^{1}H-NMR) to identify and quantify the groups of constituents according to nitrogen-containing functionalities, namely dimethyldialkyl-, methyltrialkyl- and trimethylalkyl ammonium chlorides and the tertiary amides. In addition the Registrant has provided an HPLC-MS analysis to identify and quantify the single constituents present in the substance and listed in IUCLID section 1.2. Furthermore, the Registrant has described a method for the chloride titration.

While the ^{1}H-NMR method for the identification and quantification of the different alkyl ammonium compounds and the titration method for the determination of the chloride content can be regarded as sufficient for quantifying the different ammonium compounds and the tertiary amides, ECHA could not verify the single constituents of the substance listed in IUCLID section 1.2 for the following reason:

The HPLC chromatogram attached in IUCLID section 1.4 shows three main peaks at retention times (RT) 22.46, 24.37 and 26.84 minutes. The respective relative integral area % indicated in the peak table are: 14.6, 40.7, 18.6. However, ECHA observes that these integral values do not appear to be in line with the copy of the chromatogram. In particular, the peak at RT=26.84 minutes would appear to have a significantly higher integral value (by a factor of ~2) compared with the peak at RT=22.46 minutes. Therefore ECHA cannot verify the correctness of the given %area for those 3 main peaks. Furthermore, those three peaks seem to consist in fact of several overlapping peaks which may indicate the presence of additional constituent on top of the specified 3 well-defined structures $C_{16}/C_{16}N(Me)_2^+$, $C_{18}/C_{16}N(Me)_2^+$, $C_{18}/C_{18}N(Me)_2^+$. Therefore, ECHA concludes that the provided HPLC-MS method is not sufficient for the unambiguous verification of the reported composition.

The Registrant is requested to either clarify the above specified ambiguities on the identification and quantification of the three main peaks or provide a more appropriate method for the verification of the composition of the substance as listed in IUCLID section 1.2.

In case no appropriate method can be applied on the substance due to the complexity of the UVCB substance, the Registrant can alternatively provide a description of a method for predicting the composition of the registered substance based on the composition (including the typical, upper and lower concentration levels of the relevant constituents and groups of constituents) in the starting materials used and any relevant consideration on the manufacturing process.

Therefore, pursuant to Article 41(1)(a) and (3) of the REACH Regulation, the Registrant is requested to submit sufficient and appropriate description of the analytical methods or the appropriate bibliographical references to analyze the quantitative composition of the substance subject to the present decision.

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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