ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000002691-75-03/F Helsinki, 03.10.2012

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

For 1,2-DIHYDRO-2,2,4-TRIMETHYLQUINOLINE, OLIGOMERS CAS 26780-96-1 (EC NO 500-051-3), 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 the ECHA has performed a compliance check of the registration dossier for 1,2-Dihydro-2,2,4-trimethylquinoline, oligomers CAS No 26780-96-1 (EC No 500-051-3) submitted by [redacted] (the Registrant).

This decision is based on the registration dossier 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 after 14 June 2012, 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.

The compliance check was initiated on 23 August 2011.

On 19 September 2011 ECHA notified the Registrant of its draft decision and invited him pursuant to Article 50(1) of the REACH Regulation to provide comments within 30 days of the receipt of the draft decision.

On 17 October 2011 ECHA received comments from the Registrant on the draft decision. On 1 December 2011 the Registrant updated his registration dossier.

ECHA reviewed the further information received and amended the draft decision accordingly. The comments are reflected in the Statement of Reasons (Section III) whereas no amendments to the Information Required (Section II) were made.

On 14 June 2012 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 to amend the draft decision within 30 days of the receipt of the notification.

Subsequently, Competent Authorities of the Member States did not propose amendments to the draft decision and ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

This compliance check decision is targeted to chapter 1 of the registration dossier and is a pre-requisite for conclusion on the substance as a whole. This compliance check decision

does not prevent ECHA to initiate further compliance checks on the present dossier at a later stage.

II. Information required

1) Pursuant to Articles 41(1)(a), 41(3) and 10(a)(ii) as well as Annex VI, section 2 of the REACH Regulation the Registrant shall submit for the registered substance:

   a. Name or other identifier of the substance (Annex VI, 2.1);
   b. Composition of the substance (Annex VI, 2.3.);
   c. The description of the analytical methods or the appropriate bibliographical references for the identification of the substance (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 IUCLID dossier to ECHA by ***03 December 2012***.

III. Statement of reasons

Based on the targeted examination of section 1 of the technical dossier, ECHA concludes that the information therein, submitted by the Registrant for registration of the above mentioned substance for the purpose of registration within the applicable tonnage band of 1000 or more tonnes per year in accordance with Article 6 of the REACH Regulation, does not comply with the requirements of Article 10 and Annex VI thereof. Consequently, the Registrant is requested to submit the information mentioned above that is needed to bring the registration into compliance with the relevant information requirements.

Missing information related to substance identity

Pursuant to Article 10(a)(ii) and Annex VI, section 2 of the REACH Regulation, the technical dossier of the registration shall include information on the identity of the substance. Annex VI, section 2 lists information requirements that shall be sufficient to identify the registered substance.

(a) Name or other identifier of the substance

ECHA notes that the Registrant provided a chemical name for the registered substance and indicated that it corresponds to the polymerised form of 1,2-dihydro-2,2,4-trimethylquinoline. However, further information is required to appropriately identify the registered substance, in line with Annex VI, section 2.1 of the REACH Regulation. More specifically, the naming of a UVCB substance such as the registered substance consists of two parts: the chemical name and the more detailed description of the manufacturing process. ECHA observes that details of the process circumstances under which 1,2-dihydro-2,2,4-trimethylquinoline is formed and polymerises have not been described.

Accordingly, the Registrant is requested to provide details of the process used for the manufacturing of the registered substance. The description shall include the chemical identity of the starting materials used, the ratio of the starting materials, the chemical process(es) involved and the corresponding process parameters.

Regarding how to report the description of the UVCB substance, the information shall be included in the Description field in section 1.1 of the IUCLID dossier.

In response to ECHA's draft decision the Registrant has updated the dossier, providing information on the identity of the starting materials used, the reaction types involved

and the chemical environment under which the oligomerisation reaction takes place. However, the information on the exact ratio of reactants used for the manufacturing of the substance has not been provided. In addition, relevant details of the processing steps, including the relevant operating parameters, used to control the degree of oligomerisation and to isolate the registered substance have not been included in the dossier.

Accordingly, the Registrant is requested to provide the missing information on the manufacturing process description of the registered substance.

(b) Composition of the substance

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 corner stone of all the REACH obligations.

ECHA notes that the registration does not contain sufficient 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 provided chemical name indicates that the substance contains 1,2-Dihydro-2,2,4-trimethylquinoline oligomers. Furthermore, the Registrant indicated that the substance includes the monomer, dimers, trimers and tetramers of 1,2-dihydro-2,2,4-trimethylquinoline. However, ECHA observes that the relevant individual constituents or groups of constituents have not been identified and reported in section 1.2 of the substance dataset. A reference substance was not created for the constituents of the registered substance, so that a detailed identification is possible. In particular it is evident that all of the constituents identified in the report attached in section 1.4 of the IUCLID dossier have not been duly reported in the composition information.

In response to ECHA's draft decision the Registrant has updated the dossier, providing information on the identity and typical, lower and upper concentration values for a number of constituents and groups of constituents in IUCLID section 1.2 of the dossier. However, ECHA observes that, for the majority of the reported constituents, the Registrant also stated that "UVCB substance, exact concentration can not be defined". In addition, ECHA notes that especially broad concentration ranges have been reported for at least three major constituents ([redacted]) which cannot be justified by variations inherent to the manufacturing process. ECHA therefore concludes that the provided concentration values are not always appropriate. ECHA points out that information on the concentration of the constituents is an essential element of the compositional information and therefore needs to be accurate and representative of the substance as manufactured.

In addition ECHA notes that a significant fraction of the substance (at least [redacted] according to the provided typical concentration values) has not been accounted for. The high pressure liquid chromatographic analysis attached to the dossier indicates the presence of several constituents for which information on their identity and concentration levels has not been included. It follows that ECHA can not conclude with certainty that all constituents required to be identified and quantified have been reported and that the composition has been described as far as possible.

According to ECHA Guidance chapter 4.3 on the identification and naming of substances under REACH[1], the Registrant should note that for UVCB substances (substances of Unknown, or Variable Composition, or of Biological origin), 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; and

- Unknown constituents shall be identified as far as possible by a generic description of their chemical nature. The identification of these other constituents must be provided in order to allow ECHA to establish the composition of the substance as manufactured and to use the compositional information as one identifier for the registered substance. This information must also allow ECHA to verify that the composition is consistent with the chemical name reported for the registered substance. The Registrant must provide any information which is suitable and necessary to meet these objectives.

For each constituent, the minimum, maximum and typical concentration levels shall be specified.

In line with the above, the Registrant is requested to provide any information which is suitable and necessary to allow ECHA to establish and verify the composition and the name of the registered substance. The information shall be sufficient for ECHA to conclude that constituents required to be identified and quantified have been reported and that unknown constituents have been identified as far as possible.

Regarding how to report the composition of the registered substance in IUCLID, the following applies: The Registrant shall report 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.

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 18 on the ECHA website[2].

The Registrant shall ensure that the information provided on the composition of the substance is confirmed by the analytical data included in section 1.4 of the IUCLID dossier.

(c) Description of the analytical methods or appropriate bibliographical references for the identification of the substance

[1] http://echa.europa.eu/web/guest/guidance-documents/guidance-on-the-different-methods-under-reach
[2] http://echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it/registration

ECHA notes that the registration dossier does not include enough information on the description of the analytical methods used for the identification and quantification of the constituents and groups of constituents present in the substance, as required according to Annex VI, Section 2.3.7 of the REACH Regulation.

In particular, the identity of the standards used in the HPLC and the details of quantification calculations has not been specified. Furthermore a complete list of the peaks shown in the chromatogram, including retention time and peak area values, has not been provided.

In response to ECHA's draft decision the Registrant has updated the dossier, providing the description of the HPLC, IR, UV and NMR analytical methods. The description provided, however, does not contain any new information, but only the description already included in the initial dossier, in a different format.

Thus ECHA considers that the missing information required to be provided in the draft decision communicated to the Registrant has still not been included in the dossier: in particular the identity of the standards used in the HPLC, the details of quantification calculations and a complete list of the peaks shown in the chromatogram, including retention time and peak area values.

Furthermore, the method used for the identification and quantification of some of the constituents reported in the composition as part of the Registrant's update in response to ECHA's draft decision ("Components resulting of reaction of TMDQ with excess of acetone", "Components resulting of reaction of TMDQ with excess of aniline" and "Components resulting of reaction of TMDQ with excess of aniline and acetone") has not been described.

The Registrant shall provide the complete description of the analytical methods used to identify and quantify the constituents and groups of constituents required to be reported in the composition. The information shall be sufficient for the methods to be reproduced and shall therefore include complete details of the experimental protocol followed, the calculation used and the results obtained.

As for the reporting of the above data in the registration dossier, the information shall be attached 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://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.

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Jukka Malm
Director of Regulatory Affairs