EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000003484-73-03/F Helsinki, 7 November 2013

**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 No 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 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] (Registrant). The scope of this compliance check is limited to the standard information requirements of 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 of 1000 tonnes or more per year. This decision does not take into account any updates submitted after 1 August 2013, 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 to initiate further compliance checks on the present dossier at a later stage.

The compliance check was initiated on 10 October 2012.

On 3 May 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.

On 31 May 2013 ECHA received comments from the Registrant. ECHA considered the comments received and did not amend the draft decision.

On 1 August 2013 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.

II. Information required

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. High-pressure-liquid chromatogram or gas chromatogram (Annex VI point 2.3.6.);
d. 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 **7 February 2014.**

III. Statement of reasons

Based on the examination 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 and 11(2)** of the REACH Regulation, does not comply with the requirements of Articles **10, and with 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 substances (substances of Unknown, or Variable Composition, or of Biological origin) such as the registered substance consists of two parts: the chemical name and the more detailed description of the manufacturing process. ECHA notes 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, the relevant details of the processing steps, including the relevant operating parameters, used to control the degree of oligomerisation of the registered substance.

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 their comment to the draft decision, the Registrant indicated their intention not to update the dossier with the requested information. The Registrant states that *'the CAS name (quinoline, 1,2-dihydro-2,2,4-trimethyl-, homopolymer) used is not contradicting Annex VI, 2.1. or other parts of the REACH regulation. Furthermore, this is a well established name, thus allowing downstream users to quickly identify the substance.'*. The Registrant further states their intention to *'update the reference substance contained in IUCLID section 1.1 in order to include a non-detailed description of the manufacturing process. The description however will not contain requested details like e.g. the ratio of starting materials. Such information is clearly regarded as confidential business information by the registrant.'*.

ECHA observes that the requested information is necessary in order to allow for the correct identification of the substance. For this reason, ECHA highlights that the chemical name provided by the Registrant is misleading to the true identity of the substance and, as such, shall be amended. Additionally, ECHA notes that detailed information on the manufacturing process, including the requested information on the ratio of starting material is also a key requirement for the identification of UVCB substances. The Registrant is reminded that should there be a concern about the confidentiality of their business information, the Registrant could opt to claim confidentiality for this information.

(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, three constituents have been reported in section 1.2 of the IUCLID dossier. According to the upper concentration levels specified by the Registrant, these constituents do however not cover more than [redacted]% of the composition of the substance. Therefore more than [redacted]% of the composition has not been accounted for. In addition, for the constituents reported in the dossier, no information was provided on their minimum and typical concentration values.

Furthermore, ECHA notes that the information in IUCLID section 1.1 indicates that the substance contains 1,2-Dihydro-2,2,4-trimethylquinoline oligomers predominantly consisting of the monomer, dimers, trimers and tetramers. However, ECHA observes that the registration does not include any information on the identity (in terms of structural information) and concentration levels of the different oligomers present in the substance. The high pressure liquid chromatographic (HPLC) analysis attached to the dossier also indicates the presence of several constituents for which information on identity and concentration levels has not been included.

ECHA therefore concludes that the Registrant did not report the composition of the registered substance to the required level of detail.

According to the Guidance for identification and naming of substances under REACH (Version: 1.2, March 2012), chapter 4.3, the Registrant should note that for UVCB substances, 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 – Part 18: How to report the substance identity in IUCLID 5 for registration under REACH (version: 1.0, June 2010) on the ECHA website.

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.

In their comment to the draft decision, the Registrant has agreed to provide the information required, which will be included in an updated dossier.

(c) High-pressure-liquid chromatogram or gas chromatogram (Annex VI point 2.3.6.)

ECHA notes that the copy of a chromatogram from an HPLC analysis has been attached to the dossier. However, ECHA observes that the registrant did not provide any complete report from the chromatographic analysis. In particular, a peak table listing all the peaks detected with the corresponding retention times and peak area has not been included. ECHA points out that this information is required since it constitutes a numerical representation of the chromatogram.

Accordingly, the Registrant is requested to provide the chromatogram including the report from the chromatographic analysis of the registered substance.

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

In their comment to the draft decision, the Registrant has agreed to provide the information required, which will be included in an updated dossier.

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

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.

More specifically, the Registrant attached an HPLC chromatogram including information on the integral value and estimated concentration level of the three constituents reported in the composition. However, details of the protocol followed to translate the integral values recorded by this method into concentration values have not been specified.

Furthermore a description of the analytical method used for the identification and quantification of the other constituents and groups of constituents required to be reported is missing from the dossier. ECHA notes that several constituents are detected by the HPLC analysis reported in IUCLID section 1.4. However, information on the identity and concentration of these constituents has not been reported.

Accordingly, 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.

In their comment to the draft decision, the Registrant has agreed to provide the information required, which will be included in an updated dossier.

(e) Timeline for providing the requested information

In their comments to the draft decision, the Registrant requested and extension of the deadline to provide the requested information. The Registrant justified this request '*in view of the time needed to updating IUCLID sections 1.1, 1.2 and 1.4 and the time required to generate relevant analytical data for a complex UVCB substance*'.

ECHA notes that Registrant's justification for this request to extend the deadline did not include arguments which are specific to the registered substance and the tests requested but provided only general arguments and/or statements. The deadline in the draft decision is in line with other similar ECHA decisions and is considered sufficient to provide the information. Therefore ECHA decided not to extend the deadline to provide the requested information.

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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