EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000004521-82-03/F Helsinki, 16 September 2014

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

For bis(2,2,6,6-tetramethyl-4-piperidyl) sebacate, CAS No 52829-07-9 (EC No 258-207-9), 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 bis(2,2,6,6-tetramethyl-4-piperidyl) sebacate, CAS No 52829-07-9 (EC No 258-207-9), submitted by [redacted] (Registrant). The initial scope of this compliance check was limited to the standard information requirement of Annex VI, Sections 4.1 and 4.2 relating to classification and labelling for aquatic hazard. Due to the significance of the Registrants comments, the scope of this compliance check was redirected to the standard information requirement of Annex VII section 9.1.2. relating to Growth inhibition study aquatic plants. ECHA stresses that it has not checked the information provided by the Registrant and other joint registrants for compliance with the requirements regarding the identification of the substance (Section 2 of Annex VI).

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 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 29 October 2013.

On 22 November 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 20 December 2013 ECHA received comments from the Registrant on the draft decision.

The ECHA Secretariat considered the Registrant's comments. On basis of this information, Section II was amended and the scope of the decision was changed. 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

Pursuant to Articles 41(1), 41(3), 10(a)(vii), 12(1)(e), 13 and Annexes VII of the REACH Regulation the Registrant shall submit the following information using the indicated test method and the registered substance subject to the present decision:

- Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.; test method: Alga, growth inhibition test, EU C.3./OECD 201).

Note for consideration by the Registrant:

The Registrant may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI of the REACH Regulation. In order to ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring to and conforming with the appropriate rules in the respective Annex, and an adequate and reliable documentation.

Failure to comply with the request(s) in this decision, or to fulfil otherwise the information requirement(s) with a valid and documented adaptation, will result in a notification to the Enforcement Authorities of the Member States.

Pursuant to Articles 41(4) and 22(2) of the REACH Regulation the Registrant shall to ECHA by **23 March 2015** an update of the registration dossier containing the information required by this decision, including, where relevant, an update of the Chemical Safety Report.

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.

A. Information in the technical dossier derived from the application of Annexes VII to XI

Pursuant to Articles 10(a)(vii), 12(1)(e) of the REACH Regulation, a technical dossier for a substance manufactured or imported by the Registrant in quantities of 1000 tonnes or more per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation. The scope of this compliance check decision is limited to the standard information requirement of Annex VII, Section 9.1.2. of the REACH Regulation.

- Growth inhibition study aquatic plants

"Growth inhibition aquatic plants" is a standard information requirement as laid down in Annex VII, Section 9.1.2. 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.

In the technical dossier the Registrant has included an OECD 201 Alga growth inhibition test study by NITE Japan (1999) with a NOEC of 0.05 mg/L. The Registrant had assigned a Klimisch Score of 2 to the study. The aquatic chronic toxicity study indicates a NOEC or equivalent value equal to or lower than 0.01 mg/l, but the Registrant had not classified the substance as Aquatic Chronic Hazard Category 1 and used the resulting hazard statement "H410: Very toxic to aquatic life with long lasting effects". This deficiency was addressed in the initial draft decision sent to the Registrant for comments.

In his comments submitted on 20 December 2013 the Registrant agreed with ECHA to update the classification according to the current scheme. However, he also informed ECHA that he had reassessed the reliability of the NITE study. He now argued that the study is not valid due to high concentrations of solvents used in the study and high variation of growth rates in controls. The Registrant proposed to update the registration dossier with a new algae study and to include a classification for the environment according to the current CLP Regulation. The respective assessment would also take into account all data from acute and long-term aquatic studies available.

ECHA considers that based on the Registrant comments it is clear that the algae study currently in the dossier is indeed invalid. However, the robust study summary currently in the technical dossier is so poor that it is not possible to evaluate the validity of the study fully.

In conclusion, the comments revealed that there is an information gap for Annex VII, Section 9.1.2. of the REACH Regulation and it is necessary to provide information for this endpoint.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision: Growth inhibition study aquatic plants (test method: Alga, growth inhibition test, EU C.3./OECD 201).

Notes for consideration by the Registrant:

ECHA notes further that in the technical dossier the Registrant should also substantiate why the current NITE algae study is not considered valid for classification purposes. Furthermore, once the new data is available the Registrant in accordance with the REACH Regulation has to revise the hazard classification for aquatic toxicity of the registered substance as per the application of Title I and II of the CLP Regulation to be consistent with the data on aquatic toxicity available in the registration dossier. If a classification is needed, the Registrant shall also provide a resulting hazard statement in line with the criteria set out in Part 4 of Annex I of the CLP Regulation, as amended by Commission Regulation (EU) No 286/2011 of 10 March 2011 (Tables 4.1.0. (b) and 4.1.4). In the alternative, the Registrant is required to provide the scientifically justified reasons for why no such classification is given.

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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