Decision number: CCH-D-0000003582-75-04/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 lauric acid, CAS No 143-07-7 (EC No 205-582-1), 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 lauric acid, CAS No 143-07-7 (EC No 205-582-1), submitted by [redacted] (the Registrant). The scope of this compliance check is limited to the standard information requirement of Annex VI, Sections 4.1 and 4.2 relating to classification and labelling for aquatic hazard. ECHA stresses that it has not checked the information provided by the Registrant for compliance with the requirements regarding the identification of the substance (Section 2 of Annex VI) or those of Annexes VII to IX relating to aquatic toxicity.

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 20 September 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 19 December 2013 ECHA received comments from the Registrant on the draft decision.

The ECHA Secretariat considered the Registrant's comments. The information is reflected in the Statement of Reasons (Section III) whereas no amendments to the Information Required (Section II) were made.

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)(a), 41(3), 10(a)(iv) and Annex VI, sections 4.1. and 4.2. of the REACH Regulation in conjunction with Title I and II of Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP Regulation) the Registrant shall submit the following information for the registered substance subject to the present decision:

- the hazard classification of the registered substance for chronic aquatic toxicity Category 3 based on Title I and II of Regulation (EC) No 1272/2008 (CLP Regulation) and 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), as specified in section III below, or

- the scientifically justified reasons why no such classification is given.

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 **23 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 requirement. The scope of the present decision is limited to classification and labelling for aquatic toxicity (Annex VI, Section 4.1. and 4.2 of the REACH Regulation).

Lack of coherence between the data on aquatic toxicity and the hazard classification included in the dossier:

Pursuant to Article 10(a)(iv) and Annex VI, section 4 of the REACH Regulation, the technical dossier of the registration shall include information on the classification and labelling of the substance. Annex VI, section 4.1 clarifies that the hazard classification of the substance shall result from the application of Title I and II of the CLP Regulation. In the alternative, for each entry, the scientifically justified reasons for why no classification is given for a hazard class or differentiation of a hazard class should be provided. According to Article 5(1) of Title I and recitals 20 and 21 of the CLP Regulation, a substance shall be classified on the basis of available information.

Furthermore, the technical dossier must include the resulting hazard label for the substance in line with Title III of the CLP Regulation (Annex VI, section 4.2 of the REACH Regulation).

The technical dossier includes an aquatic chronic toxicity study indicating a NOEC or equivalent value equal to or lower than 1 mg/l which is considered reliable by the Registrant (Klimisch score 1 or 2) and the substance is considered as rapidly degradable by the Registrant. Therefore, he information currently provided for by the Registrant in the technical dossier fulfils the requirement of Aquatic Hazard Category 3, as laid down in Title I and II of Regulation of the CLP Regulation. However the Registrant has not classified the substance as Aquatic Chronic Hazard Category 3 nor used the resulting hazard statement "H412: Harmful to aquatic life with long lasting effects", which would in line with the criteria set out in Part 4 of Annex 1 of the CLP Regulation, as amended by Commission Regulation (EU) No 286/2011 of 10 March 2011 (see Tables 4.1.0. (b) and 4.1.4 of the CLP Regulation).

Furthermore, the technical dossier does not contain scientifically justified reasons relating to why the substance has not been classified in accordance with the available study.

In his comments submitted on the draft decision on 19 December 2013 the Registrant indicated that the current Daphnia study on which classification would be based on is not valid due to instable test substance concentration, no defined dose-response curve, unknown fate of the test substance. Consequently the Registrant considers that the study should be classified as a Klimisch score 3 rather than Klimisch 2 as indicated in the technical dossier.

ECHA evaluated the Daphnia study submitted in the technical dossier. In the study, six concentrations were used, in the lowest three there were problems keeping the substance in solution. However, the effects in the highest three concentrations show clear dose-response. The Registrant has chosen the lowest of the three as the NOEC when in fact considerable inhibition of reproduction was found also in the lower concentration. Hence ECHA concludes that the study itself can be considered valid, but the NOEC should be lower, <0.35 rather than 0.47 mg/L. ECHA notes that this would still lead to the same classification. Currently in the technical dossier the Daphnia study is assessed by the Registrant as being Klimisch 2 and as such the study is still appropriate for classification and labelling purposes. Also, the validity criteria set for OECD 211 have been met. ECHA hence considers this study as valid.

Furthermore, the Registrant has indicated that a new Daphnia reproduction test is already on-going. ECHA considers that acquiring new data does not affect the Registrant's ability to comply with the request in the draft decision as the Registrant, based on available information in the technical dossier, is able to either classify or to provide reasons why no such classification is given.

ECHA notes further that once the results of the new study are available the Registrant is to include the robust study summary of the study as an endpoint study record in the technical dossier as per article 22 of REACH regulation.

Therefore, the Registrant is requested to submit a hazard classification for aquatic toxicity of the registered substance which results from the application of Title I and II of the CLP Regulation as specified above and is consistent with the data on aquatic toxicity available in the registration dossier. 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.

ECHA notes that in reviewing whether the Registrant has complied with Sections 4.1. and 4.2. of Annex VI to the REACH Regulation with regard to classification and labelling for aquatic toxicity, it can only base its assessment on data on aquatic toxicity that is available in the registration dossier. Any other data on aquatic toxicity of the substance that the Registrant does not submit in his registration dossier but that he may need to consider in his classification, cannot be taken into consideration by ECHA. If there is any other data available on aquatic toxicity of the substance, the Registrant is required to include the data in the registration dossier in line with the second introductory paragraph of Annexes VI to X and step 1 of Annex VI to the REACH Regulation.

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://www.echa.europa.eu/web/guest/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

[redacted]

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