EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000004088-72-02/F Helsinki, 13 December 2013

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

For Fatty acids, coco, triesters with trimethylolpropane, CAS No 85566-29-6 (EC No 287-640-6), 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 Fatty acids, coco, triesters with trimethylolpropane, CAS No 85566-29-6 (EC No 287-640-6) submitted by [redacted] (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 5 September 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. The scope of this compliance check is limited to the standard information requirements of Annex VI, Section 2 of the REACH Regulation.

The compliance check was initiated on 29 March 2012.

On 21 August 2012 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 19 September 2012 the Registrant provided comments on the draft decision to ECHA.

On 4 January 2013 the Registrant updated his registration dossier (submission number [redacted]).

On 4 March 2013 the Registrant updated his registration dossier (submission number [redacted]).

On 22 March 2013 the Registrant updated his registration dossier (submission number [redacted]).

ECHA considered the Registrant's comments and the updated dossier. Based on the comments and the updated dossier, Section II of the draft decision was amended and the Statement of Reasons (Section III) was modified accordingly.

On 5 September 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.

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

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.), as specified under section III.(a) below;
b. Description of the analytical methods or the appropriate bibliographical references for the identification of the substance (Annex VI, 2.3.7.), as described under section III.(b) below.

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 **13 March 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 tonnes or more 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.

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 (Annex VI, 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: the chemical name and 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: 1.2, March 2012) - referred to as "the Guidance" thereinafter. ECHA observes that the Registrant did not provide sufficient information on the naming of the registered substance (as explained under point (i)

thereinafter), including also the assigned CAS identifier (as indicated in point (ii) thereinafter).

(i) A chemical name representative of the registered substance

The Registrant did not report, in the dossier initially submitted, any of the constituents or groups of constituents required to be identified and quantified in the composition of the registered substance. ECHA thus requested, in its draft decision, the Registrant to provide detailed compositional information of the registered substance, including information on the groups of constituents presenting the same level of esterification.

ECHA notes that the Registrant specified, in a registration update following the notification of the draft decision (thereinafter the "update dossier"), a composition indicating that the registered substance typically consists not only of triesters ([redacted]% (w/w)), but also of a significant amount of diesters, typically [redacted]% (w/w). However, the presence of this significant amount of diesters is currently not reflected in the chemical name. The Registrant indeed assigned "Fatty acids, coco, triesters with trimethylolpropane" as chemical name for the registered substance.

ECHA therefore concludes that the current chemical name does not accurately reflect the composition of the registered substance and therefore does not properly identify the registered substance.

ECHA observes that this conclusion is consistent with the Registrant's conclusion to include on its own initiative a statement, in the Remarks field of the reference substance in IUCLID section 1.1 of the update dossier, that the EC entry 287-640-6 assigned in the original submission, for which the EC name is also "Fatty acids, coco, triesters with trimethylolpropane", does not specifically correspond to the registered substance.

The Registrant is therefore required to revise the chemical name assigned to the registered substance, as specified under the first bullet point of sub-section (iii) below.

(ii) The CAS information

The CAS name corresponding to the CAS entry with CAS number 85566-29-6 assigned to the substance in the dossier initially submitted is "Fatty acids, coco, triesters with trimethylolpropane". In line with the abovementioned observations on the chemical name assigned to the registered substance, such CAS entry does not specifically correspond to the registered substance. ECHA underlines that it is a prerequisite that the CAS number reported in the dossier matches the substance registered under REACH. This information shall not contradict with the substance identity provided for by the naming of the registered substance.

The Registrant is requested to revise the CAS information for the registered substance, as specified under the second bullet point of sub-section (iii) below.

(iii) The information required from the Registrant

- A chemical name representative of the registered substance must be provided

Based on the observation set out in sub-section (i) above, the Registrant is accordingly required to revise the chemical name assigned to the registered substance so as to reflect its degree of esterification. For this purpose, ECHA considers that reference to the main group(s) of ester constituents presenting the same degree of esterification (i.e. monoesters and/or diesters and/or triesters with trimethylolpropane) shall be made in the chemical name of the registered substance. Such main group is the group present at a concentration level of ≥80% (w/w) in the registered substance. If such group does not exist, all the groups present at a concentration of ≥10% (w/w) designate the main group(s) to be referred to in the chemical name.

- The CAS information must be revised

Based on the observation set out in sub-section (ii) above, the Registrant shall delete from the "CAS information" header in IUCLID section 1.1 of the update dossier the CAS information currently assigned to the substance. The Registrant shall provide instead any available CAS information specifically corresponding to the substance.

ECHA recognises that the Registrant may cover different grades of the same substance in a registration based on different sources and/or different manufacturing processes. In these cases, the Registrant shall provide the required information on the sources, manufacturing processes and constituents of each grade. ECHA underlines that the reporting of a generic process description covering the manufacturing of different grades may prevent ECHA from concluding that the manufacturing of other substances is not covered by that description. In addition, ECHA highlights that grades for which a description would not be provided may eventually not be considered as being covered by the registration.

As for the reporting of the information in IUCLID, the chemical name, and any available CAS entry for the substance should be specified in the "IUPAC name" field, "Description" field in IUCLID section 1.1 and under the "CAS information" header in IUCLID section 1.1, respectively. The CAS entry with CAS number 85566-29-6 can be kept under the "Related CAS information" header in IUCLID section 1.1.

(b) Description of the analytical methods (Annex VI, section 2.3.7.)

ECHA observes that the Registrant did not provide sufficient description of the analytical methods used for the identification and quantification of the constituents and groups of constituents required to be reported in the composition of the registered substance, as requested according to Annex VI section 2.3.7.

More specifically ECHA notes that the Registrant provided, in the dossier initially submitted, a report from the gas chromatographic analysis of a sample of the registered substance that has been derivatised by a silylation reagent. This report includes a peak table where peaks have been assigned to constituents and groups of constituents. The percentage of the reaction products from the derivatisation has also been reported in the table. However, the analytical report does not provide details of the method used for the identification of these groups of constituents. Furthermore, there is no information on the protocol followed to translate the results from the chromatographic analysis into concentration values of the

constituents and groups of constituents present in the derivatised sample and of the constituents present in the composition of the registered substance itself.

In addition, ECHA observes that the registration does not include any description of an analytical method used for quantifying the contribution of the saturated and unsaturated fatty acid blocks presenting the same carbon chain length within the ester constituents. ECHA therefore concludes that the registration does not include sufficient description of the analytical methods required for the identification of the registered substance.

Furthermore, ECHA would like to underline that, although an attachment entitled "[redacted]" is included in the registration dossier initially submitted, this attachment corresponds to a link and can therefore not be assessed by ECHA.

ECHA underlines that this incompliance was already specified in the draft decision but has not been addressed by the Registrant in his updated dossier.

The Registrant is therefore required to provide a description of the analytical methods used for the identification and quantification of the constituents and groups of constituents reported in the composition of the registered substance. The description shall be sufficient for the methods to be reproduced and shall therefore include details of the experimental protocol followed, any calculation made and the results obtained.

As for the reporting of the data in the registration dossier, the information shall be attached in IUCLID section 1.4.

The Registrant shall ensure that the composition reported in the dossier is consistent with the analytical results obtained.

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]
Leena Ylä-Mononen
Director of Evaluation