ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000004104-86-02/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, C8-18 and C18-unsatd., esters with trimethylolpropane, CAS No 85186-89-6 (EC No 286-075-2), 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, C8-18 and C18-unsatd., esters with trimethylolpropane, CAS No 85186-89-6 (EC No 286-075-2) 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 of the receipt of the draft decision. That draft decision was based on submission number [redacted].

On 12 September 2012 the Registrant provided comments on the draft decision to ECHA.

On 21 December 2012 the Registrant updated his registration dossier (submission number [redacted]). On 22 March 2013 the Registrant updated his registration dossier again (submission number [redacted]).

ECHA considered the Registrant's comment and the updated dossier. Based on the comments and the updated dossiers, 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 from initiating 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:

- Name or other identifier of the substance (Annex VI, 2.1.), as specified under section III. below.

Taking into consideration the data currently available in the dossier, ECHA considers the following. Section III below specifies in detail all the information that ECHA considers appropriate in order to identify any substance of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB). UVCB substances cannot be sufficiently identified by their chemical composition, because the number of constituents is relatively large; and/or the composition is, to a significant part, unknown; and/or the variability of composition is relatively large or poorly predictable. As a consequence, UVCB substances require other types of information for their identification, in addition to what is known about their chemical composition.

As a result, ECHA cannot be in a position, before receiving suitable information, to determine precisely the other types of information that is actually required to identify a specific UVCB substance. Only the Registrant of that UVCB substance knows the details of its identity. Based on this knowledge, he may consider that some of the information requested by ECHA is not suitable and necessary in order to identify the substance. Nevertheless, it is the Registrant's exclusive responsibility 1) to ensure that ECHA is in a position to identify precisely the substance and 2) to justify the reasons for which some information requested may have been omitted.

Therefore, if the Registrant eventually decides to submit only part of the detailed information specified in Section III and if the submitted information does not enable ECHA to establish and verify the identity of the substance actually covered by the dossier, the registration will not be considered valid.

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 Articles 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.

ECHA wishes to stress that the information currently contained in the dossier which the present decision does not require to remove or modify is considered as necessary for the determination of the identity of the substance. Such information shall therefore not be removed or modified by the Registrant. In the absence of valid justification, any change made by the Registrant to such information will not be taken into consideration by ECHA and will be considered as a deliberate obstruction to the determination of the identity of the substance.

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, including requirements relating to the 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: (1) the chemical name and (2) 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 points (i) and (ii) thereinafter).

(i) A chemical name representative of the registered substance

The chemical name originally specified in the registration dossier ("C8-18 (even numbered) and C18-unsatd., esters with trimethylolpropane") did not take into account the level of esterification of the pentaerythritol in the substance. ECHA thus requested in the draft decision the Registrant to revise the name so as to take this element into account. ECHA also requested the Registrant to ensure that the fatty acids starting material designated in the chemical name of the registered is constructed around specific principles specified in the draft decision and outlined below.

ECHA notes that the Registrant revised, in a registration update submitted on 21 December 2012 following the notification of the draft decision, the chemical name assigned to the registered substance to "Fatty acids, C8-10(even), C14-18(even) and C16-18(even)-unsatd., triesters with trimethylolpropane". With this updated name, the Registrant not only qualified the level of esterification but also defined more narrowly the fatty acids starting material from which the substance is manufactured. However, in a subsequent registration update submitted on 22 March 2013 (thereinafter the "March 2013 update dossier"), the Registrant changed once again the chemical name to "Fatty acids, C8-18 and C18-unsatd., esters with trimethylolpropane". At the same time, ECHA notes that the Registrant designates, in the description field of the reference substance in IUCLID section 1.1 and in the Name field of the substance composition in IUCLID section 1.2 of the March 2013 update dossier, the registered substance as "Fatty acids, C8-10(even), C14-18(even) and C16-18(even)-unsatd., triesters with trimethylolpropane". ECHA also notes that the Registrant indicates, in the March 2013 update dossier, that the EC entry currently assigned to the registered substance, for which the EC name is "Fatty

acids, C8-18 and C18-unsatd., esters with trimethylolpropane", does not specifically correspond to the registered substance.

ECHA therefore concludes that the Registrant did not address the request in the draft decision on the chemical name. The chemical name currently specified for the registered substance in the March 2013 update dossier is not appropriate.

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

(ii) The manufacturing process

- Identity of the fatty acids starting material

The fatty acids starting material used to manufacture the registered substance had not been identified to a sufficient level of detail in the dossier initially submitted. ECHA pointed out in its draft decision that UVCB substances such as this starting material cannot be sufficiently identified by a chemical name only. As the composition of such starting material is to a significant extent known and is one of the factors determining the composition of the registered substance, compositional information of that starting material (in terms of identity and upper and lower concentration levels of the individual saturated carboxylic acids and of each group of linear unsaturated carboxylic acids presenting the same carbon number) is a necessary element of its identification and therefore for the identification of the registered substance itself.

ECHA notes that the Registrant specified, in the description field of IUCLID section 1.1 of the March 2013 update dossier, compositional information on the fatty acids starting material. However, this information alone is insufficient and inappropriate for the following reasons:

- No concentration value has been specified for the unsaturated C16 fatty acids;
- The concentration ranges for the C8, C10, C14, C16 and C18:3 are missing;
- A concentration range of "[redacted]%" was specified but was not associated to any fatty acids.

ECHA also notes that the Registrant attached in IUCLID section 1.4 details of the composition from a sample of the fatty acids starting material. However, this report does not specify the variability in the composition of the fatty acids.

ECHA therefore concludes that the Registrant did not provide a description of the manufacturing process of the registered substance to a sufficient level of detail, as specified requested in the draft decision.

The Registrant is accordingly required to provide the missing information on the composition of the fatty acids starting material, as specified in 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.

  In particular, regarding the designation of the fatty acids starting material in the chemical name of the registered substance, ECHA points out that constructing the chemical name on the basis of:

  - the main fatty acids (i.e. those linear fatty acids which individually present an upper concentration level ≥10% (w/w) in the starting material); and
  - the groups of unsaturated fatty acids presenting the same carbon number and an upper concentration level ≥10% (w/w) in the starting material),

  is considered appropriate provided that they altogether compose at least 80 % (w/w) of the substance. If this condition is not met, all fatty acid constituents in the starting material, as identified by their carbon number and alkyl chain type (e.g. saturated, unsaturated) shall be taken into account for the naming of that starting material. Where the starting material is composed of one specific fatty acid at a concentration level of ≥80% (w/w), this starting material shall be designated, in the chemical name of the registered substance, by the chemical name of that fatty acid.

  Furthermore, regarding the information on the level of esterification in the chemical name, reference to the main group(s) of ester constituents presenting the same degree of esterification (i.e. monoesters, 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) that shall be referred to in the chemical name.

- Further detail on the manufacturing process must be provided

  Based on the observation set out in sub-section (ii) above, the Registrant is requested to submit overall compositional information of the fatty acids starting material, in terms of identity and upper and lower concentration levels of the individual saturated carboxylic acids and of each group of linear unsaturated carboxylic acids presenting the same carbon number.

ECHA recognises that the Registrant may cover different grades of the same substance in a registration base 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.

More generally, the Registrant should note that substances manufactured according to different manufacturing processes may indicate multiple substances and may, consequently, require multiple registrations. ECHA has established processes, subject to certain conditions, enabling registrants to adapt an existing registration, while maintaining the regulatory rights already conferred to the substance concerned. Should the Registrant consider that his dossier actually concerns several substances, he is thus encouraged to contact ECHA for a possible adaptation of the registration.

As for the reporting of the information in IUCLID, the chemical name and manufacturing process description should be specified in the "IUPAC name" and "Description" field in IUCLID section 1.1, respectively.

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.

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