ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000004106-82-02/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 pentaerythritol, CAS No 85049-33-8 (EC No 285-202-9), 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 dossier for Fatty acids, C8-18 and C18-unsatd., esters with pentaerythritol, CAS No 85049-33-8 (EC No 285-202-9), 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.

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

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, ECHA received comments from the Registrant.

On 4 January 2013, the Registrant updated his registration dossier (submission number [redacted]). On 4 March 2013, the Registrant updated his registration dossier another time (submission number [redacted]). On 22 March 2013, the Registrant updated his registration dossier yet again (submission number [redacted]).

ECHA considered the Registrant's comments and updates. 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.

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.

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 including the name or other identifier of the substance (Annex VI, 2.1.).

In that respect, 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. Other identifiers, including any CAS number (if available) and EC number (if available and appropriate) corresponding to the substance, shall also be reported. ECHA observes that the Registrant did not provide sufficient and appropriate 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 chemical name originally specified in the registration dossier corresponds to esters of "Fatty acids, C8-18 and C18-unsatd.". ECHA understands that such fatty acids refer to a starting material comprising, in line with the Guidance, linear saturated carboxylic acids with chain lengths C8, C9, C10, C11, C13, C14, C15, C16, C17 and C18 as well as linear unsaturated fatty acids with chain length C18. However, the manufacturing process description specified in the original dossier indicated that the fatty acids used in the process corresponded to a specific blend of two different fatty acid starting materials, said "C8-C10 fatty acid" and "[redacted] fatty acids". Taking into account the chemical name "C8-C10 fatty acid" assigned to the first component of the blend and the typical composition of the fatty acids from [redacted] in the second component, the composition of the fatty acid constituents with carbon number higher than C10 in the specific blend used is expected to be determined by the "[redacted] fatty acids" starting material only. The [redacted] origin of the "[redacted] fatty acids" implied that the fatty acids with carbon number higher than C10 in the specific blend used for the manufacturing should be represented by chain lengths of even carbon numbers and therefore not by chain lengths including also odd numbers such as C11 or C13. In addition, the chemical name originally specified in the registration dossier did not make reference to the level of esterification of the pentaerythritol in the substance and was therefore also for this reason considered inappropriate for its unambiguous identification. ECHA thus requested in the draft decision the Registrant to revise the chemical name assigned to the registered substance.

ECHA notes that the Registrant did not revise the chemical name of the registered substance in the registration update he submitted following the notification of the draft decision (thereinafter the "update dossier") and therefore the Registrant did not address the request specified in the draft decision.

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

(ii) The CAS information

The CAS name corresponding to the CAS entry with CAS number 85049-33-8 assigned to the substance in the dossier initially submitted is "Fatty acids, C8-18 and C18-unsatd., esters with pentaerythritol". 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 thus requested in its draft decision the Registrant to delete from the "CAS information" header in section 1.1 of the IUCLID dossier the CAS entry with CAS number 85049-33-8. ECHA also indicated that the Registrant could nevertheless report this CAS entry under the "Related CAS information" header in IUCLID section 1.1.

ECHA observes that the Registrant reported, under the "Related CAS information" header in IUCLID section 1.1 of the update dossier, the CAS entry with CAS number 85049-33-8. ECHA also observes that the Registrant clarified, in the Remarks field of the reference substance in IUCLID section 1.1 of the update dossier, that the EC entry 285-202-9 currently assigned to the substance (which is itself linked to the CAS number 85049-33-8) does not specifically corresponds to the registered substance. The Registrant nevertheless maintained the CAS entry with CAS number

85049-33-8 under the "CAS information" header. 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. ECHA therefore concludes that the Registrant did not address the request specified in the draft decision.

The Registrant is required 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.

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 then 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, triesters and/or tetraesters with pentaerythritol) 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 process. In these cases, the Registrant shall provide the required information on the source, 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 shall be specified in the "IUPAC name" field and under the "CAS information" header in IUCLID section 1.1, respectively. The CAS entry with CAS number 85049-33-8 can be kept under the "Related CAS information" header in IUCLID section 1.1.

The Registrant shall ensure that the correct identifiers are used throughout the registration whenever reference to the specific substance which is the subject of this registration is made.

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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