ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000004082-84-02/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, C5-10, esters with pentaerythritol, CAS No 68424-31-7 (EC No 270-291-9), 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, C5-10, esters with pentaerythritol, CAS No 68424-31-7 (EC No 270-291-9) 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].

By 20 September 2012, the Registrant did not provide any comments on the draft decision to ECHA.

On 31 October 2012, the Registrant updated his registration dossier (submission number [redacted]). On 13 December 2012, 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 updated dossier. Based on 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:

a. Name or other identifier of the substance (Annex VI, 2.1.), as specified under section III.(a) 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, in that case 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 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.

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.

(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: (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 assigned inappropriate CAS number to the substance (as indicated in point (i) thereinafter). In addition the Registrant did not provide sufficient and appropriate information on the naming of the registered substance (as explained under point (ii) thereinafter).

(i) <u>The CAS information</u>

The chemical name associated with CAS number 68424-31-7 assigned to the registered substance in the dossier initially submitted indicated that the registered substance corresponds to the esters of C5-10 fatty acids with pentaerythritol. ECHA understands that such fatty acids refer to a starting material comprising, in line with the Guidance, the six linear carboxylic acids with chain lengths C5, C6, C7, C8, C9 and C10. However, ECHA noted that the Registrant indicated in the dossier header of the initial dossier that the fatty acids used for the manufacturing of the substance also include [redacted] acid. [redacted] acid is a [redacted] fatty acid presenting a very specific branching. The identification of the carboxylic acid starting material as "C5-10 fatty acids" was therefore not considered by ECHA as a representative descriptor of the carboxylic acids involved in the manufacturing of the registered substance under REACH. 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 68002-79-9.

ECHA observes that the Registrant reported, under the "Related CAS information" header in IUCLID section 1.1 of a registration update following the notification of the draft decision (thereinafter the "update dossier"), the CAS entry with CAS number 68424-31-7. 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 270-291-9 currently assigned to the substance (which is itself linked to the CAS number 68424-31-7) does not specifically correspond to the registered substance. The Registrant nevertheless maintained the CAS entry with CAS number 68424-31-7 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, i.e. it does not contradict 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 still required to revise the CAS information for the registered substance, as specified under the first bullet point of sub-section (iii) below.

(ii) The manufacturing process

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 linear carboxylic acids and of the specific branched carboxylic acid) is a necessary element for its identification and therefore for the identification of the registered substance itself. ECHA thus requested, in its draft decision, the Registrant to provide detailed overall compositional information of the fatty acids starting material.

ECHA notes that the Registrant specified, in the update dossier, the typical concentration ranges in the carboxylic acid "mixture" used for the manufacturing of the registered substance. ECHA however considers that the ranges reported in particular for both [redacted] acid and [redacted] acid are so broad (from [redacted] to [redacted]% for both acids) that they cannot be associated to variations inherent to the manufacturing process and may refer to the manufacturing of different grades corresponding to one or more substances under REACH. In addition, such broad ranges for these acids in the starting material are not consistent with the narrow concentration ranges (less than [redacted] (w/w)) reported for the ester constituents derived from [redacted] acid and [redacted] acid in IUCLID section 1.2.

ECHA therefore concludes that the Registrant did not provide, in the update dossier, appropriate information on the overall composition of the fatty acids starting material, which was requested in the draft decision.

The Registrant is accordingly requested to revise the compositional information reported for the fatty acids starting material, as specified in the second bullet point of sub-section (iii) below.

(iii) The information required from the Registrant

- The CAS information must be revised

  Based on the observation set out in sub-section (i) 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.

- Further detail on the manufacturing process must be provided

  Based on the observation set out in sub-section (ii) above, the Registrant is required to revise the overall compositional information of the fatty acids starting material, in terms of identity and upper and lower concentration levels of the individual carboxylic acids, provided in the update dossier. The Registrant shall justify the origin for any broad concentration range, such as the concentration ranges reported in the update dossier for [redacted] acid and [redacted] acid starting materials. Such justification will only be considered valid provided it demonstrates that any broad concentration range is not the result of deliberate adjustment of the overall composition of the fatty acids starting material for the manufacturing of different grades, but is inherent to the manufacturing process of the specific grade which the manufacturing process description refers to. ECHA would like to stress that, where the broad concentration ranges specified in the update dossier relates to the manufacturing of different grades of tetraesters with pentaerythritol, the manufacturing process description of each grade, and also the composition of each manufactured grade, shall be reported separately in the dossier, as already explained in the draft decision and further underlined thereinafter in the decision. Where a grade refers to another substance than the substance subject to this registration, a separate registration shall be submitted for the manufacturing and import of such other grade.

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 source, manufacturing 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 consequently the requirement for 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 the description should be specified in the "IUPAC name" and "Description" fields in IUCLID section 1.1, respectively. Any available CAS information should be reported under the CAS information header of the reference substance in IUCLID section 1.1.

The Registrant shall ensure that the chemical name assigned to the registered substance is consistent with the compositional information specified in the dossier. The Registrant shall also 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. In addition, taking into account that the composition of the carboxylic acid starting material reported by the Registrant may indicate the manufacturing of different grades, the Registrant shall also report separately the compositional information of each grade. ECHA underlines that the reporting of the composition of different grades under one generic composition may prevent ECHA from verifying that compositions referring to other substances are not covered by this registration. In addition, ECHA highlights that grades for which an individual composition would not be provided may eventually not be considered being covered by the registration. Information on how to report several compositions in IUCLID is specified in paragraph 2.3, Q&A8 of the Data Submission Manual – Part 18: How to report the substance identity in IUCLID 5 for registration under REACH (version: 2.0, July 2012) on the ECHA website.

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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