ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000004107-80-02/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, C5-9, esters with pentaerythritol CAS No 68424-30-6 (EC No 270-290-3), 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, C5-9, esters with pentaerythritol CAS No 68424-30-6 (EC No 270-290-3) 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 12 September 2012 ECHA received comments from the Registrant to ECHA's draft decision.

On 20 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 comments and the 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;

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 this 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 with 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. 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 points (i) and (ii) thereinafter).

(i) A chemical name representative of the registered substance

The Registrant did not specify, in the dossier initially submitted, the chemical name of the registered UVCB substance which should be included in the "IUPAC name field", as indicated in chapter 8.2.4 of the Guidance. ECHA thus requested in the draft decision the Registrant to provide the missing chemical name.

ECHA notes that the Registrant included, in a registration update following the notification of the draft decision (thereinafter the "update dossier"), a chemical name indicating that the registered substance corresponds to the tetraesters of pentaerythritol with pentanoic, heptanoic and isononanoic acids. The carboxylic acids used in the process would therefore consist, according to this information, of linear carboxylic acids with carbon chain lengths of C5 and C7 and of carboxylic acids with a carbon number C9 presenting an undefined branching. However, ECHA notes that the Registrant specified, in the manufacturing process description in IUCLID section 3.1 of the update dossier, that the C9 carboxylic acid actually used for the manufacturing process is [redacted]. This carboxylic acid therefore presents a specific branching and would not be accurately designated as isononanoic acid.

ECHA therefore concludes that the chemical name currently assigned to the registered substance does not specifically correspond to the substance actually manufactured and imported.

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 different carboxylic acids) is a necessary element for its identification and therefore for the identification of the registered substance itself. ECHA thus requested in the draft decision the Registrant to provide this information which was missing in the original dossier.

ECHA notes that the Registrant specified, in the update dossier, the approximate molar ratio of the three different carboxylic acid starting materials used for the manufacturing of the registered substance. ECHA also observes that the Registrant referred, in the document entitled "[redacted]" attached in IUCLID section 1.4 of the update dossier, to different theoretical molar ratios of carboxylic acids to predict the composition of the registered substance. However, it is unclear how far these theoretical ratios represent the variability of the ratio actually used for the manufacturing of the registered substance, including any of its possible grades. ECHA points out that information on the overall composition of the fatty acids starting material (in terms of identity and upper and lower concentration levels of the individual carboxylic acids, such as [redacted] and [redacted]) is a necessary element of its identification and therefore for the identification of the registered substance itself.

ECHA therefore concludes that a description of the manufacturing process has still not been provided to a sufficient level of detail for the identification of the registered substance.

The Registrant is accordingly required to provide the missing information on the composition of the fatty acids starting material, 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 shall revise the chemical name currently assigned to the registered UVCB substance so that the C9 branched carboxylic acid starting material specifically used in the process is referred to as "[redacted]" instead of "[redacted]"

Regarding the designation of the fatty acid starting material in the chemical name of the registered substance, ECHA would like to stress that constructing the chemical name on the basis of:

- the main fatty acids (i.e. those individual fatty acids presenting an upper concentration level ≥10% (w/w) in the starting material); and
- the groups of fatty acids of the same carbon number with an undefined branched structure, which present an upper concentration level ≥10% (w/w) in the starting material, if any

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. linear, specific branching, undefined branching) 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.

- Further detail on the manufacturing process must be provided

Based on the observation set out in sub-section (ii) above, the Registrant shall specify the overall composition of the fatty acids starting material (in terms of identity and upper and lower concentration levels of the individual carboxylic acids (such as [redacted] and [redacted]) and the eventual groups of fatty acid of the same carbon number with an undefined branched structure).

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 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 multiple compositions 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 the description should be specified in the IUPAC name and description fields in IUCLID section 1.1, respectively.

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]

Leena Ylä-Mononen
Director of Evaluation