ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000004086-76-02/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 Decanoic acid, ester with 2-ethyl-2-(hydroxymethyl)-1,3-propanediol octanoate, CAS No 11138-60-6 (EC No 234-392-1), 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 Decanoic acid, ester with 2-ethyl-2-(hydroxymethyl)-1,3-propanediol octanoate, CAS No 11138-60-6 (EC No 234-392-1) 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 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 21 December 2012 the Registrant updated his registration dossier (submission number [redacted]).

On 20 March 2013 the Registrant updated his registration dossier (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.

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:

a. Name or other identifier of the substance (Annex VI, 2.1.), as specified under section III.(a) below;
b. Composition of the substance (Annex VI, 2.3.), as specified 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 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.

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.)

The Registrant identified the registered substance in the dossier initially submitted as of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB). However, the substance identity information provided by the Registrant in the initial submission included indications that the composition of the registered substance was known and predictable. ECHA therefore requested the Registrant to identify the registered substance as a well-defined substance.

ECHA notes that the Registrant clarified, in section 3.1 of a registration update following the notification of the draft decision (thereinafter the "update dossier"), that the registered substance can be regarded as a substance of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB) on the basis of the inherent variability of the composition in the fatty acids starting material source used. 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 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

ECHA notes that the Registrant specified, in the update dossier, a chemical name reflecting the level of esterification indicating that the substance is designated as the di- and triesters of fatty acids with propylidynetrimethanol. However, ECHA considers that such name does not reflect the predominance of the triesters reported in the composition. ECHA notes in particular that, according to the manufacturing process description specified in IUCLID sections 1.1 and 3.1 of the dossier, the diesters never constitute more that [redacted] (w/w) of the composition, while the triesters represents up to [redacted] (w/w) of that composition. ECHA considers that qualifying the degree of esterification of the registered substance in the chemical as "triesters" is necessary for the proper identification of this substance.

ECHA therefore concludes that the chemical name assigned to the registered substance is not appropriate for its unambiguous identification.

The Registrant is accordingly 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 manufacturing process

ECHA observes that the description of the manufacturing process is not sufficiently detailed for the identification of the registered UVCB substance. In particular, ECHA notes that the Registrant specified, in IUCLID section 3.1 of the update dossier, that "[redacted]". ECHA also notes that the Registrant reported, in the Description field in IUCLID section 1.1 that the registered substance may include unreacted carboxylic acids as well as unreacted or partially reacted propylidynetrimethanol. The Registrant furthermore specified "*generic*" concentration limits for these constituents. However, ECHA cannot relate this information to the actual level of completion of the esterification and to the concentration level effectively observed for constituents such as the residual starting material.

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

The Registrant is accordingly required to provide the missing information on the manufacturing process, 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 requested to revise the chemical name assigned to the registered substance. The Registrant shall ensure that the chemical name is representative of the specific substance which is the subject of this registration.

In particular, reference to the main group(s) of ester constituents presenting the same degree of esterification (i.e. monoesters, diesters and/or triesters with propylidynetrimethanol) 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.

- Further detail on the manufacturing process must be provided

Based on the observation set out in sub-section (ii) above, the Registrant shall provide the specifications of the process parameters determining the degree of completion of the esterification, such as the acid and saponification values.

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.

(b) Composition of the substance (Annex VI, 2.3.)

The substance composition corresponds to the chemical representation of what the substance consists of and is therefore an essential part of substance identification and the corner stone of all the REACH obligations.

ECHA notes that the registration does not contain sufficient information for establishing the composition of the registered substance and therefore its identity, as required under Annex VI, section 2.3. of the REACH Regulation.

More specifically, ECHA noted that the compositional information specified in the dossier initially submitted was overly broad. In particular, exceptionally wide concentration ranges were specified for the mono-, di- and tri-esters ([redacted](w/w), [redacted](w/w) and [redacted](w/w), respectively) in the composition reported in IUCLID section 1.2. ECHA also noted that the composition of the sample from which the analytical data included in IUCLID section 1.4 of the initial dossier was generated was known and predictable. ECHA therefore requested the Registrant in its draft decision to revise the concentration values of the constituents reported in the composition and to report the identity and concentrations of the constituents according to the requirements for well-defined substance, as specified in the Guidance.

ECHA takes note that the Registrant has clarified, in the update dossier, that the registered substance may be regarded as a UVCB substance, as indicated in section III.(a) of this decision. ECHA also takes notes that the Registrant has provided more specific compositional information in section 1.2 of the update dossier.

However, ECHA also notes that the Registrant has reported, besides the constituents specified in the composition in IUCLID section 1.2 of the dossier, the possible presence of five other constituents in IUCLID section 1.1, including mono-esters of propylidynetrimethanol, unreacted fatty acids and unreacted propylidynetrimethanol. The Registrant specified, for each of these five constituents, a "*generic*" concentration limit of [redacted]. However, it is unclear how this "*generic*" limit represents the variability observed in the concentration of these constituents. ECHA therefore cannot conclude that the [redacted] value specified by the Registrant corresponds to the upper concentration level observed in the registered substance.

ECHA therefore concludes that the composition of the registered UVCB substance has not been reported in the dossier with sufficient level of details.

The Registrant is reminded that, in accordance with chapter 4.3 of the Guidance, the following applies to UVCB substances such as the registered substance:

- All constituents present in the substance with a concentration of ≥ 10 % shall be identified and reported individually;
- All known constituents and constituents relevant for the classification and/or PBT assessment of the registered substance shall be identified and reported individually; and
- Other constituents shall be identified as far as possible by a generic description of their chemical nature.

For each constituent or group of constituent, the typical, minimum and maximum concentration levels shall be specified.

The Registrant is accordingly requested to report individually each of the five known listed constituents currently specified in the description field in IUCLID section 1.1 in the composition of the registered substance in IUCLID section 1.2 together with their corresponding typical, upper and lower concentration levels.

As for the reporting of the information in IUCLID, further technical details on how to specify the composition of UVCB substances in IUCLID are available in paragraphs 2.1 and 2.2.2 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.

[redacted]

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