ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000004093-81-02/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, C16-18 (even numbered) and C18-unsatd., branched and linear, di and triesters with trimethylolpropane, (List No 931-531-4) 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, C16-18 (even numbered) and C18-unsatd., branched and linear, di and triesters with trimethylolpropane, (List No 931-531-4) 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 21 December 2013, the Registrant updated his registration dossier (submission number [redacted]).

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

ECHA considered the Registrant's comments and the updated dossier. 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:

a. Name or other identifier of the substance (Annex VI, 2.1.), as specified under section III.(a) below;
b. Composition (Annex VI section 2.3.), as specified under section III.(b) below;
c. Description of the analytical methods or the appropriate bibliographical references for the identification of the substance (Annex VI, 2.3.7.), as specified under section III.(c) 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. ECHA observes that the Registrant did not provide sufficient information on the manufacturing process description of the registered substance as explained thereinafter.

The identity of 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 thus requested in the draft decision the Registrant to provide detailed compositional information of the fatty acid starting material. ECHA underlined 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 linear carboxylic acids as well as of each group of saturated branched carboxylic acids presenting the same carbon number, of unsaturated linear carboxylic acids presenting the same carbon number and of unsaturated branched carboxylic acids presenting the same carbon number) is a necessary element for its identification and therefore for the identification of the registered substance itself.

ECHA notes that the Registrant included, in a registration update following the notification of the draft decision (thereinafter the "update dossier"), further information on the composition of that fatty acids starting material. Whilst this composition indicates the predominance of both linear and branched fatty acids and of both C16 and C18 carbon numbers, no information is provided on the presence and concentration level of unsaturated fatty acids, including in particular the unsaturated C18 fatty acids.

However, ECHA notes that the chemical name assigned to the registered substance in the update dossier refers to the esters of "Fatty acids, C16-18 (even numbered) and C18-unsatd., branched and linear" with trimethylolpropane. Such fatty acids should therefore allegedly include unsaturated C18 fatty acids.

ECHA therefore concludes that the manufacturing process description has 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 manufacturing process description. This information shall include compositional information of the starting material in terms of identity and upper and lower concentration levels of the individual saturated linear carboxylic acids, as well as of each group of saturated branched carboxylic acids presenting the same carbon number, of unsaturated linear carboxylic acids presenting the same carbon number and of unsaturated branched carboxylic acids presenting the same carbon number.

In its draft decision, ECHA also required the Registrant to ensure that the chemical name assigned to the registered substance is consistent with the information given on the manufacturing process. In particular, regarding the designation of the fatty acid starting material in the chemical name of the registered substance, specified in the IUPAC name field of IUCLID, ECHA points out that constructing the chemical name of that starting material 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 fatty acids presenting the same carbon number, the same backbone type 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. linear saturated, linear unsaturated, branched saturated) 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. ECHA would like to stress that the Registrant shall ensure that the above principle, as set out in the draft decision, is complied with.

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 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 over 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 registration.

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

(b) Composition (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 cornerstone 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 notes that the Registrant specified in the original dossier the overall concentration levels of four groups of constituents, such as the unreacted fatty acids and mono-esters, di-esters and tri-esters with trimethylolpropane, in the composition. However, the reported composition did not include any further qualitative and quantitative information on the constituents which each group consists of. ECHA acknowledges that, unless indicated otherwise by the manufacturing process description and the analytical information required to be included in the dossier, the number of constituents covered by each group can be so large that they cannot be reported individually. However, information on the relative content of the different fatty acid blocks which the mono-, di- and tri-ester groups of constituents consist of can be provided and such data is necessary to derive qualitative and quantitative information on the constituents covered by these groups. ECHA thus requests the Registrant to specify the quantitative contribution of the different acid blocks in the different groups of esters reported in the composition.

ECHA notes that the Registrant specified in the update dossier, in the description field of the reference substance for the mono-, di- and tri-ester groups of constituents, information on the typical alkyl chain distribution of fatty acids. Whilst this information would indicate the predominance of both linear and branched fatty acid blocks as well as predominance of both C16 and C18 carbon number for each group, no information is provided on the presence and concentration level of unsaturated fatty acid blocks, in spite of the explicit request. In particular, there is no indication on the presence and concentration level of blocks such as the unsaturated C18 fatty acid block although this block is quoted in the name describing the chemical nature of the constituents covered by each group.

In addition, the spectral data attached to the dossier indicate the presence of aromatic functionalised constituents which had not been reported in the composition in the dossier initially submitted. The Registrant clarified in the update dossier that the aromatic protons originate from the fatty acid starting material used for the manufacturing of the registered substance. However, the identity and concentration level of the constituents of the registered substance presenting these aromatic constituents has not been represented in the composition.

ECHA therefore concludes that the Registrant did not provide the compositional information on the registered substance requested in the draft decision. The current compositional information is still not provided to the required level of detail.

The Registrant is therefore required to submit the following compositional information, in accordance to chapter 4.3 of the Guidance:

- All constituents present in the substance with a concentration of ≥ 10 % shall be identified and reported individually;
- All 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. The identification of these other constituents must be provided for ECHA to establish the composition of the substance as manufactured and to use the compositional information as one identifier for the registered substance. For the substance which is the subject of this registration, the reporting of the unreacted fatty acids under one group and the reporting of the ester functionalised constituents according to groups presenting the same level of esterification (i.e. mono-esters, di-esters and tri-esters) is necessary for this aforementioned purpose. For each group of constituents, information on the relative abundance of the different acid blocks shall also be specified, including C16 saturated linear, C16 saturated branched, C18 saturated linear, C18 saturated branched, C18 unsaturated linear, C18 unsaturated branched as well as any other acid block also present.

The constituents including a benzyl functional group shall be reported individually or under a generic group, as appropriate.

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

Where the Registrant covers different grades of the substance in a registration based on different constituents, the Registrant shall report separately the source, manufacturing process and 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.

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 over 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.

Regarding how to report the composition in IUCLID, the following applies: The Registrant shall indicate each composition of the registered substance in IUCLID Section 1.2. For each constituent required to be reported individually, the IUPAC name, CAS name and CAS number (if available), molecular and structural formula, as well as the minimum, maximum and typical concentration, should be reported in the appropriate fields in IUCLID. For the other constituents to be reported under a generic description, a generic chemical name describing the group of constituents, generic molecular and structural information (if applicable), as well as the minimum, maximum and typical concentration, shall be reported in the appropriate fields in IUCLID. The relative abundance of the different acid blocks within each group of constituents should be provided in the "Remarks" field of the repeatable block for that group.

Further technical details on how to report 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. Information on how to report several compositions in IUCLID is specified in paragraph 2.3, Q&A8 of that manual.

(c) Description of the analytical methods (Annex VI, 2.3.7.)

ECHA observes that the Registrant did not provide sufficient description of the analytical methods used for the identification and quantification of the constituents and groups of constituents required to be reported in the composition of the registered substance, as requested according to Annex VI section 2.3.7.

The dossier initially submitted did not include sufficient analytical information for the quantification of the constituents and groups of constituents required to be reported in the composition. ECHA thus requested the Registrant to provide the missing description of the analytical methods, one of them being the description of the analytical methods used to quantify the contribution of the different fatty acid blocks in the composition of the registered substance (such as C16 saturated linear, C16 saturated branched, C18 saturated linear, C18 saturated branched, C18 unsaturated linear, C18 unsaturated branched).

ECHA observes that the Registrant included, in the updated dossier, an analytical report based on gas chromatography for the characterisation of the fatty acids used as starting material in the manufacturing of the registered substance. ECHA understands that the analysis of the starting material may be used to derive quantitative information on the different acid blocks which the constituents of the registered substance consist of. This report however does not describe how quantitative information on the different unsaturated acid blocks expected to be present in the registered substance could be derived. In particular, the method used to differentiate between C18 saturated linear and C18 saturated branched on the one hand and C18 unsaturated linear and C18 unsaturated branched on the other hand is not described.

ECHA therefore concludes that the Registrant did not provide in the updated dossier the full description of the analytical methods requested in the draft decision.

The Registrant is accordingly required to provide a description of the analytical methods used for the identification and quantification of the constituents and groups of constituents required to be reported in the composition of the registered substance. The description shall be sufficient for the methods to be reproduced and shall therefore include details of the experimental protocol followed, any calculation made and the results obtained.

As for the reporting of the data in the registration dossier, the information should be attached in IUCLID section 1.4.

The Registrant shall ensure that the composition reported in the dossier is consistent with the analytical results obtained.

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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