EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000004087-74-02/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. di and triesters with Propylidynetrimethanol, (List No 931-461-4), 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. di and triesters with Propylidynetrimethanol, (List No 931-461-4) 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. 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 (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 inititating 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:

- Name or other identifier of the substance (Annex VI, 2.1.), as specified under section III.(a) 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, 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. ECHA observes that the Registrant did not provide appropriate information on the chemical name of the registered substance, as explained thereinafter.

The chemical name originally specified in the registration dossier did not take into account the level of esterification of the propylidynetrimethanol in the substance. ECHA thus requested in the draft decision the Registrant to revise the name so as to take this element into account. For this purpose, ECHA requested the Registrant to ensure that the 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), which shall be referred to in the chemical name. ECHA also requested the Registrant to ensure that the chemical name assigned to the registered substance designates the fatty acids in accordance with specific principles specified in the draft decision

ECHA observes that the Registrant provided, in a registration update following the notification of the draft decision (thereinafter the "update dossier"), a chemical name reflecting the level of esterification. This chemical name designates the substance as the di- and triesters of fatty acids with propylidynetrimethanol. However, according to the compositional information in IUCLID section 1.2 of the update dossier, the diesters never constitute more that [redacted]% (w/w) of the composition, while the triesters typically represent at least [redacted]% (w/w) of that composition. In line with the abovementioned specifications already provided by ECHA in the draft decision on how to qualify the level of esterification in the name of the registered substance, designating the registered substance as triesters in the chemical name is appropriate.

ECHA also notes that the Registrant actually amended the initially submitted dossier so that the registered substance is designated, in the Description field of the reference substance in IUCLID section 1.1 and in the Name field of the substance composition in IUCLID section 1.2 of the update dossier, as the triesters of fatty acids with propylidynetrimethanol. Whilst this level of esterification is appropriate on the basis of the substance composition, it is a prerequisite that the chemical name in the IUPAC name field also designate the appropriate level of esterification.

ECHA also observes that the chemical name assigned by the Registrant to the registered substance indicates that it corresponds to esters of "C16-18 (even numbered) and C18-unsaturated fatty acids" with propylidynetrimethanol. ECHA understands that such fatty acids refer to a starting material comprising, in line with the Guidance, saturated carboxylic acids with chain lengths C16 and C18 as well as linear unsaturated carboxylic acids with chain lengths C18. ECHA notes that the Registrant specified, in the update dossier, the composition of the fatty acid starting material in terms of upper and lower concentration level of its constituents, as requested in the draft decision. However, according to this information, the linear unsaturated carboxylic acids with chain length C16 is present at concentration range of [redacted]% which is comparable to the concentration range of the linear saturated carboxylic acids with chain length C16 (present at [redacted]%) and higher than the linear saturated carboxylic acids with chain length C18 (present at [redacted]%). However, the fatty acids starting material is designated in the chemical name of the registered substance without reference to the unsaturated C16, while reference to the saturated C16 and the saturated C18 is made.

ECHA therefore considers that the chemical name assigned by the Registrant to the registered substances, in terms of level of esterification and designation of the fatty acid starting material, is not representative of the registered substance.

The Registrant is accordingly required 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, as already specified in the draft decision and underlined above, 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), which shall be referred to in the chemical name.

Regarding the compositional information of the fatty acid starting material and its designation in the chemical name of the registered substance specified 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 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 alkyl chain lengths shall be considered for the naming of the fatty acid. 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.

As for the reporting of the information in IUCLID, the chemical name should be specified in the "IUPAC name" field in IUCLID section 1.1.

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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