EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000004108-78-02/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]

On 19 September 2012 ECHA received comments from the Registrant to ECHA's draft decision.

On 19 December 2012 the Registrant updated his registration dossier (submission number [redacted]). On 20 March 2013 the Registrant updated again his registration dossier (submission number [redacted]).

ECHA considered the Registrant's comments and updates received. On basis of 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 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 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.)

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 numbers to the substance, as indicated thereinafter).

The Registrant identified the registered substance, in the dossier initially submitted, using the chemical name "Fatty acids, C5-10 (linear and branched and without 2-Ethylhexanoic acid), mixed esters with pentaerythritol". The Registrant also assigned, as CAS information for the registered substance, the CAS entry with CAS number 68424-31-7. However, the CAS name of that CAS entry is "Fatty acids, C5-10, esters with pentaerythritol" and does therefore not make reference to the presence of branched structures. ECHA therefore considered that the CAS entry did not specifically correspond to the registered substance. 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 68424-31-7.

ECHA notes that the Registrant revised, in a registration update following the notification of the draft decision (thereinafter the "update dossier"), the chemical name assigned to the registered substance to "Pentaerythritol tetraesters of n-decanoic, n-heptanoic, n-octanoic and n-valeric acids". This name therefore designates a substance corresponding to tetraesters of linear C5, C7, C8 and C10 carboxylic acids. ECHA also notes that the Registrant maintained, as CAS information for the registered substance, the CAS entry with CAS number 68424-31-7. According to the CAS name for this entry, this CAS entry does not reflect the absence of reference to the C6 and C9 carboxylic acid derivatives in the chemical name provided in the update dossier. ECHA therefore considers that the CAS entry assigned by the Registrant to the registered substance remains inappropriate for the identification of the registered substance. ECHA underlines that it is a prerequisite that the CAS number reported in the dossier matches the substance registered under REACH. This information shall not contradict with the substance identity provided for by the naming of the registered substance.

The Registrant is accordingly requested to 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.

As for the reporting of the information in IUCLID, any available CAS entry corresponding to the registered substance shall be specified under the "CAS information header" in IUCLID section 1.1.

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.

(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 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.

The composition reported in the dossier initially submitted did not make reference to constituents with branched structure and did not include meaningful information on the concentration levels of the constituents, the reported concentration ranges being 0-100%

for each of the nine constituents and groups of constituents initially reported. ECHA thus requested the Registrant to revise the composition so as to report all constituents and groups of constituents required to be identified and quantified and to provide meaningful concentration values for the specific substance covered by the registration.

The Registrant clarified, in the registration update, that the registered substance does not include esters of carboxylic acids with branched structures and specified the identity and concentration levels of eight different tetraesters of pentaerythritol. ECHA notes that, according to the analytical report attached in IUCLID section 1.4 of the dossier, esters derived from dipentaerythritol are also present in the composition. However, the contribution of these ester constituents in the composition of the registered substance has not been reported in the dossier.

ECHA therefore concludes that the Registrant did not provide the compositional information on the registered substance already specified in the draft decision. The compositional information has still not been provided to the required level of detail.

According to chapter 4.3 of the Guidance, the Registrant should note that, for UVCB substances presenting a large number of constituents such as the registered substance, the following applies:

- 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 ester functionalised constituents according to groups presenting the same polyol building block (i.e. pentaerythritol, dipentaerythritol) and the same level of esterification (i.e. mono-esters, di-esters and tri-esters...) is necessary for this aforementioned purpose. For each of these groups, information on the relative abundance of the different acid blocks (i.e. C5, C7, C8 and C10) shall also be specified.

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

The Registrant is accordingly requested to provide the missing compositional information of the registered substance with regard to the esters from the dipentaerythritol.

Regarding how to report the composition in IUCLID, the following applies: The Registrant should 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, should be

reported in the appropriate fields in IUCLID. The relative abundance of the different acid blocks within each group of ester constituents should be provided in the Remarks field of the repeatable block for that group of constituents.

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.

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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