EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114290223-55-01/F Helsinki, 28 November 2014

DECISION ON A COMPLIANCE CHECK OF A REGISTRATION PURSUANT TO ARTICLE 41(3) OF REGULATION (EC) NO 1907/2006

For Reaction product of Fatty acids, C16-18 and C18-unsaturated and reaction mass of 1,3-alkanediol, 2-(hydroxymethyl)-2-[(methoxymethoxy)methyl]- and 1,3-heteromonocycle-5,5-dimethanol ( ), CAS No 98859-60-0 (EC No 484-360-8), registration number:

Addressee:

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 for Reaction products of Fatty acids, C16-18 and C18-unsaturated and reaction mass of 1,3-alkanediol, 2-(hydroxymethyl)-2-[(methoxymethoxy)methyl]- and 1,3-heteromonocycle-5,5-dimethanol ( ), CAS No 98859-60-0 (EC No 484-360-8), submitted by (Registrant). The scope of this compliance check is limited to the standard information requirements of Annex VI, Section 2 of the REACH Regulation regarding the identification of the substance.

This decision is based on the registration dossier as submitted with submission number , for the tonnage band of 1000 tonnes or more per year. This decision does not take into account any updates submitted after 4 September 2014, 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.

This compliance check decision does not prevent ECHA from initiating further compliance checks on the present registration at a later stage.

The compliance check was initiated on 01 July 2013.

On 26 July 2013 ECHA sent the draft decision with communication number CCH-D-0000003930-76-01/D to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision.

After having received the Registrant's comments on the draft decision on 14 August 2013, ECHA found that the draft decision had included an error because no deadline for submitting the required information had been specified. Therefore, the draft decision was corrected in this respect; *i.e.* Section II was amended by including Section II.B entitled "*Deadline for submitting the required information*".

On 30 June 2014 ECHA sent the corrected draft decision to the Registrant and invited them to provide comments within 30 days of the receipt of the draft decision.

On 16 July 2014 ECHA received comments from the Registrant agreeing to ECHA's draft decision with respect to *"the ECHA observations in the latest draft decision"*.

On 04 September 2014 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 for amendment

As no proposal for amendment was submitted, ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

II. Information required

A. Information in the technical dossier related to the identity of the substance

Pursuant to Articles 41(1)(a), 41(3), 10(a)(ii) and Annex VI, Section 2 of the REACH Regulation the Registrant shall submit the following information for the registered substance subject to the present decision:

1. Name or other identifier of each substance (Annex VI, Section 2.1)
2. Composition of each substance (Annex VI, Section 2.3)

B. Deadline for submitting the required information

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 **9 March 2015.**

III. Statement of reasons

Pursuant to Article 41(3) of the REACH Regulation, ECHA may require the Registrant to submit any information needed to bring the registration into compliance with the relevant information requirements.

A. Information in the technical dossier related to the identity of the substance

Pursuant to Article 10(a)(ii) of the REACH Regulation, the technical dossier shall contain information on the identity of the substance as specified in Annex VI, Section 2 of the REACH Regulation. In accordance with Annex VI, Section 2 the information provided shall be sufficient to enable the identification of the registered substance.

1. Name or other identifier of each substance

"Name or other identifier of the substance" is an information requirement as laid down in Annex VI, Section 2.1 of the REACH Regulation. The name and other identifiers are used to identify the substance in an unambiguous manner and are therefore fundamental for substance identification. Adequate information needs to be present in the technical dossier for the registered substance to meet this information requirement.

ECHA notes that the Registrant identified the registered substance as of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB). As the chemical composition alone is not sufficient for substance identification of an UVCB like the registered substance, the substance shall in general be identified by its chemical name, its origin or source and the most relevant steps taken during processing.

Therefore, the information required to be provided on the naming of UVCB substances shall consist of two parts: (i) the chemical name and (ii) 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: 1.3, February 2014) - referred to as "the Guidance" hereinafter. The Registrant did not provide sufficient and appropriate information on the naming of the registered substance or on the manufacturing process, as explained under points (i) and (ii) hereinafter.

(i) Chemical name

The name assigned to the registered substance, in the IUPAC field of section 1.1 of the registration dossier, indicates that the registered substance corresponds to "*Reaction products of Fatty acids, C16-18 and C18-unsatd. and a reaction mass of 1,3-Propanediol, 2-(hydroxymethyl)-2-[(methoxymethoxy)methyl]- and 1,3-dioxane-5,5-dimethanol*". The fatty acids part of the name refers to linear saturated carboxylic acids with chain lengths C16 and C17 and C18 as well as linear unsaturated carboxylic acids with chain length C18. This is confirmed by the provided chromatographic analysis ([redacted]). However, the compositional information reported by the Registrant in section 1.2 of the registration dossier indicates that the registered substance only consists of derivatives of fatty acids presenting only unsaturated C18 carbon numbers. Therefore the chemical name specified by the Registrant does not reflect the composition reported in section 1.2 of the registration dossier.

(ii) Manufacturing process

The description of the manufacturing process, in the description field of section 1.1 of the registration dossier, is not sufficiently detailed for the identification of the registered UVCB substance. More specifically, the description provided by the Registrant is limited to ambiguous information on the starting materials as well as on information on chemical functionalities formed during the process. Based on the submitted information, it is not clear whether the reaction mass of 1,3-Propanediol, 2-(hydroxymethyl)-2-[(methoxymethoxy)methyl]- and 1,3-dioxane-5,5-dimethanol is added already as a reaction mass or whether its formation is also part of the overall manufacturing process of the registered substance. Hence it is unclear whether the ratio (0.69:0.31) specified in the description refers to the ratio of fatty acids to the reaction mass, or to a ratio between the two main constituents of the reaction mass. If the reaction mass is added as such as one of the starting materials, then the ratio of its two constituents should also be specified, in addition to the ratio between the fatty acids and the reaction mass of the two alcohols. Please refer to the chapter 4.3 of the Guidance.

In conclusion, the Registrant shall ensure that the correct identifiers (name and numericals) are used in a consistent manner throughout the registration dossier, e.g. in sections 1.1 and 1.2, whenever reference to the specific substance which is the subject of this registration is made. 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 section 1.1. The Registrant is also requested to provide a clear reaction path including the ratio of each reactants as well as the ratio of each main constituent in the reaction mass.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the information derived from the registered substance subject to the present decision: correct name and other identifier of the registered substance as specifically explained above. The Registrant shall ensure that the information is consistent throughout the dossier.

Note for the attention of the Registrant

The Registrant specified, as CAS information for the registered substance, the CAS entry with CAS RN 98859-60-0 and corresponding CAS name "*fatty acids, C16-18 and C18-unsatd., esters with acetaldehyde-formaldehyde reaction byproducts*". This CAS information does not correspond to the IUPAC name and description of the manufacturing process in section 1.1 of the registration dossier. ECHA concludes that the CAS RN 98859-60-0, assigned by the Registrant does not correspond to the substance as described in the registration dossier. Consequently the Registrant should delete the CAS number and name from the CAS number and name fields in section 1.1 and should consider to replace this information with an appropriate CAS name and CAS number, if available.

2. Composition of each substance

"Composition of the substance" is an information requirement as laid down in Annex VI, Section 2.3. of the REACH Regulation. 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. Adequate information needs to be present in the technical dossier for the registered substance to meet this information requirement.

The registration dossier does not contain sufficient and appropriate 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, the Registrant reported in the dossier a specific monoester constituent "*9-Octadecenoic acid, monoester with pentaerythritol cyclic monoformal*" and a specific diester constituent "*9-Octadecenoic acid, diester with pentaerythritol cyclic monoformal*" whose contribution acounted for approximately [redacted]% of the substance. Other constituents which represent approximately [redacted]% of the substance have been reported in generic terms as "Other undefined constituents". It remains that approximately [redacted]% is not accounted for.

ECHA therefore concludes that the compositional information has 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 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 known constituents and constituents relevant for the classification and/or PBT assessment of the registered substance shall be identified and reported individually;
- Unknown constituents shall be identified as far as possible by a generic description of their chemical nature. For the substance which is the subject to this registration, 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) may be appropriate for this purpose.

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

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the information derived from the registered substance subject to the present decision: correct composition of the registered substance as specifically explained above, namely the missing compositional information of the registered substance. The Registrant shall ensure that the information is consistent throughout the dossier.

Regarding how to report the composition of the registered substance in IUCLID, the following applies: the Registrant shall report each composition of the registered substance in 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, shall 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.

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://echa.europa.eu/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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