ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114313085-61-01/F Helsinki, 11 January 2016

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

For Reaction products of tryglycerides, C8-C18 (even numbered) and C18-unsaturated, glycerine and ethylene oxide, EC No 939-459-5, 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 for Reaction products of tryglycerides, C8-C18 (even numbered) and C18-unsaturated, glycerine and ethylene oxide, EC No 939-459-5, submitted by [redacted] (Registrant).

The scope of this compliance check decision is limited to the standard information requirements of Annex VI, Section 2 of the REACH Regulation.

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band of 100 to 1000 tonnes per year.

This decision does not take into account any updates after the date when the draft decision was notified to the Registrant under Article 50(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 11 September 2014.

On 29 May 2015 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision.

On 3 July 2015 ECHA received comments from the Registrant on the draft decision.

The ECHA Secretariat considered the Registrant's comments. The information is reflected in the Statement of Reasons (Section III) whereas no amendments to the Information Required (Section II) were made.

ECHA notified the draft decision to the competent authorities of the Member States for proposal(s) for amendment(s).

As no amendments were proposed, ECHA took the decision according 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), 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 the substance (Annex VI, 2.1.), as further specified under section III.A.1;
2. Composition of the substance (Annex VI, 2.3.), as further specified under section III.A.2;
3. Description of the analytical methods (Annex VI, 2.3.7), as further specified under section III.A.3.

B. Deadline for submitting the required information

Pursuant to Articles 41(4) and 22(2) of the REACH Regulation the Registrant shall submit to ECHA by **18 April 2016** an update of the registration dossier containing the information required by this decision.

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 the substance (Annex VI, 2.1.)

ECHA notes that the Registrant has not provided sufficient information to identify the substance, as required by Annex VI, Section 2.1 of the REACH Regulation. Based on the information included in sections 1.1 and 3.1 of the IUCLID dossier, it is not possible to unambiguously establish the identity of the substance registered.

The Registrant identified the registered substance as of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB). The naming of UVCB substances in general shall consist of two parts: the chemical name and the 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. According to the Guidance, the description of the manufacturing process shall include information on the chemical identity of the starting materials and information on the most relevant steps of the process. ECHA notes that the Registrant did not provide sufficient information on the manufacturing process description to allow for an unambiguous identification of the registered substance, as explained hereinafter.

The substance has been identified as reaction products of triglycerides, C8-C18 (even numbered) and C18-unsaturated, glycerine and ethylene oxide. The description of the manufacturing process is however not detailed enough to verify the name and to conclude on the identity of this UVCB substance. In the description field in section 1.1 of the IUCLID dossier the Registrant provided only information about the carbon chain distribution. In section 3.1 the Registrant states that the substance is manufactured by "Transesterification of triglyceride-glycerol and subsequent ethoxylation". The exact identity of the starting materials, the level of ethoxylation and distribution of mono-, di- and tri- glycerides is however unknown, as indicated also in section III A 2. below.

Furthermore, the identity of the registered substance and starting materials cannot be deduced on the basis of the generic structural formula provided in section 1.1 of the IUCLID dossier, as it suggests that various ratios of ethylene oxide and triglyceride may be used in the manufacturing process and also that the free glycerin may be present in the registered substance.

Consequently, ECHA concludes that no clear information on the identity and ratio of the reactants, process parameters and relevant steps has been provided in the dossier. This information is necessary to unambigously identify the registered substance.

Therefore, the Registrant shall provide details of the manufacturing process of the registered substance, including the identity, composition and ratio of the starting materials, process parameters and steps.

This information shall include:

- Information on the identity and composition of the "Tryglycerides, C8-C18 (even numbered) and C18-unsaturated" starting materials, and
- Ratio of reactants, and
- Description of the transestrification and ethoxylation steps including information on the degree of ethoxylation and transestrification, and
- Specifications of all relevant process parameters, including temperatures and pressures, and any other process steps and their parameters including purification step(s) (if any) which are necessary to obtain the registered substance and which may affect the substance composition.

If the substance covered by the registration is manufactured according to different manufacturing processes, including the use of different sources or ratios of the reactants, then the detailed description of the manufacturing process required shall be reported separately for each manufacturing process. A manufacturing process may be considered different when the processing steps and/or processing parameters are different.

The Registrant shall note that substances manufactured according to different manufacturing processes may indicate multiple substances and consequently the requirement for multiple registrations.

As for the reporting of the requested information, the detailed description of the manufacturing process should be included in the description field in section 1.1 of the IUCLID dossier.

The Registrant outlined in the comments to the draft decision how he could address the information requirement by stating that "We will provide a better description of the technological process according to your request". The ECHA secretariat acknowledges the Registrant's comment and willingness to address the issue raised in the draft decision.

2. 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 cornerstone of all the REACH obligations.

According to ECHA Guidance chapter 4.3, 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; and,
- Unknown 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 each constituent or group of constituent, the typical, minimum and maximum concentration levels shall be specified.

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

More specifically, the Registrant reported two groups of constituents in section 1.2 of the dossier: "Glycerides mono-, di- and tri-, C8-C18 (even numbered) and C18-unsaturated, ethoxylated" [redacted] and "Reaction products of glycerin and ethylene oxide"[redacted]

However the identity of these groups of constituents is not clear. For the first group of constituents the carbon number distribution has been determined by GC (after hydrolysis) recorded on a spot sample, however this information has not been reported in section 1.2 of the dossier. Furthermore, the attached GC analysis does not provide information on the distribution of mono-, di- and tri- glycerides and the level of ethoxylation is unknown. The second group of constituents listed in section 1.2 ("Reaction products of glycerin and ethylene oxyde") refers to the constituents obtained from 1 - 6.5 moles of ethylene oxide units (based on the description for the assigned EC number 500-075-4), while in the analytical report (attached in section 1.4) only a glycerin derivative with average 2 ethylene oxide units was identified.

ECHA also notes that the EC number 500-075-4 specified for the second group of constituents is included in the No-Longer Polymer (NLP) list. In this list, the EC number 500-270-4 is linked to CAS number 31694-55-0. The Registrant shall note, however, that as explained in the NLP list (page 8 of the document) "NLP-Nos and name descriptions take precedence. The CAS-RN given are to be treated as indicative and for a use as a searching tool". ECHA considers that the CAS information included in the registration dossier is generic and does not fully correspond to the group of constituents listed in section 1.2. Therefore the identity and composition of this group of constituent is also uclear.

In line with the above, the Registrant shall revise the composition of the registered substance.

The generic constituents shall be subdivided into more specific ones, e.g. the first group of constituents may be subdivided depending on the level of ethoxylation, esterification and/or carbon chain length. The second group of constituents may be subdivided based on the level of ethoxylation. This information shall be supported by the analytical data.

Where the Registrant covers different grades of the substance in the registration, the Registrant shall report separately the compositional information of each grade. This means that if the substance covered by the registration has two (or more) different compositions, then these must be presented separately. ECHA highlights that failure to report separately the compositional information of each grade of a substance may result in one or more grades not being covered by this registration.

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

Information on how to report several compositions in IUCLID is specified in paragraph 2.3, Q&A 8 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), available on the ECHA website.

The ECHA secretariat acknowledges the Registrant's comment. The registrant has indicated he does not have a method capable to sub-divide the constituents based on level of ethoxylation, esterification and/or carbon chain length. The registrant has offered to submit an explanation regarding the carbon chain distribution and a further GC chromtogram that confirms the level of ethoxylation in the second constituent. However, this information would not help sub-divide the constituents which is important to get an accurate picture of the composition. Consequently the draft decision is not amended on this point.

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

ECHA notes 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 required according to Annex VI section 2.3.7 of the REACH Regulation.

More specifically, the Registrant used the high-performance liquid chromatography (HPLC) method for the quantification of ethoxylated glycerine and gas chromatography (GC) for the alkyl chain determination. However the description of these methods is not sufficient to verify the composition and therefore the identity of the registered substance.

The HPLC chromatogram shows several peaks and groups of peaks. The Registrant combined all peaks into two groups that have been integrated. The identification of the chromatographic peaks / groups of peaks has not been provided. Without information on the identity of constituents /groups of constituents, the reason for the peak grouping is unclear. The quantification revealed [redacted]% of "free glycerin plus glycerin with average 2 EO" and [redacted]% of "ethoxylated glycerides" (by difference). These values cannot be correlated with the relative peak areas (ca. [redacted] and [redacted] % respectively, based on the peak areas given on the chromatogram) and the calibration curve. Additionally, the quantification of "ethoxylated glycerides" constituents by difference seems not appropriate.

Therefore, ECHA concludes that the analytical information provided by the Registrant cannot, in absence of further justification, be considered appropriate to verify the identity and composition of the registered substance.

The Registrant is therefore requested to provide detailed description of the methods used to quantify the registered substance and its constituents /groups of constituents. These methods shall allow sufficient subdivision and quantification of the constituents /groups of constituents as explained in section A III 2 hereinabove. The description shall be sufficient to reproduce these methods and shall include peak tables with peak identities and corresponding areas.

The results of the analyses, generated on the substance as manufactured/imported by the Registrant, shall also be reported.

For chromatographic methods, the method description information shall include a legible chromatogram as well as the report from the chromatographic analysis including the table of peak assignments that report the peak areas and corresponding amounts of each relevant constituent/group of constituents.

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

The ECHA secretariat acknowledges the Registrant's comment. The registrant has indicated he does not have a method capable to sub-divide the constituents based on level of ethoxylation, esterification and/or carbon chain length. The registrant has offered to submit additional analytical parameters for the GC and HPLC methods and chromatograms of standard materials. However, this information would not help sub-divide the constituents which is important to get an accurate picture of the composition. Consequently the draft decision is not amended on this point.

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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/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

Authorised[1] by Leena Ylä-Mononen, Director of Evaluation

[1] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.