Decision number: CCH-D-2114313139-56-01/F Helsinki, 09 December 2015

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

For Fatty acids, C14-18 and C16-18-unsatd., Me esters, EC No 267-007-0 (CAS No 67762-26-9), 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 for Fatty acids, C14-18 and C16-18-unsatd., Me esters, EC No 267-007-0 (CAS No 67762-26-9), 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 1000 tonnes or more 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 12 January 2015.

ECHA notified you of the draft decision on 11 September 2015 and invited you to provide comments.

You did not comment on the draft decision by 19 October 2015.

On 29 October 2015, ECHA notified the competent authorities of the Member States of its draft decision and invited them to propose amendments to the draft decision under Article 51 of the REACH Regulation.

As no amendments were proposed, 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), 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, Section 2.1.)
2. Composition of the substance (Annex VI, Section 2.3.)
3. Spectral data (Annex VI, Section 2.3.5.)

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 **16 March 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.

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, Section 2.1.)

"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.

The Registrant identified the registered substance as of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB). The naming of UVCB substances, such as the registered substance, 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" thereinafter. ECHA observes that the Registrant did not provide sufficient information on the identity of the substance as explained below.

(i) Chemical name

ECHA observes that the Registrant identified the substance with the following identifiers: EC number 267-007-0 (Fatty acids, C14-18 and C16-18-unsatd., Me esters) and CAS number 67762-26-9. Also, the following description is linked to the numerical identifiers: "This substance is identified by SDA Substance Name: C14-C18 and C16-C18 unsaturated alkyl carboxylic acid methyl ester and SDA Reporting Number: 04-010-00." In addition, in the "IUPAC name field" in IUCLID, the Registrant provided the following statement: "*UVCB substance, no IUPAC name avalilable*".
The Registrant shall note that, as explained in chapter 4.3.2.1 (Substances with variation in the carbon-chain lengths) of the Guidance, the alkyl descriptor Cx-y presents in the name "Fatty acids, C14-18 and C16-18-unsatd., Me esters ", refers to saturated, linear alkyl-chains comprising all chain lengths from x to y, e.g. C14-18 corresponds to C14, C15, C16, C17 and C18. However, according to the information contained in the present dossier, the registered substance contains only even numbered carbon chains, and therefore the name "Fatty acids, C14-18 and C16-18-unsatd., Me esters" is not representative of the registered substance.

Consequently, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to provide in the IUPAC name field of the IUCLID dossier a chemical name representative of the registered substance. More information on how to name a UVCB substance with variation in the carbon-chain lengths can be found in the Guidance. The Registrant shall ensure that the information on the name is consistent throughout the dossier.

(ii) Description of the manufacturing process

The Registrant provided a limited description of the manufacturing process in IUCLID sections 1.1 and 1.3. More specifically, the following was reported in the description field of section 1.1: "[redacted]", and also "[redacted]." In section 3.1 the following was reported: "*1* [redacted].

Based on the information provided, it is not clear if the substance is produced according to different manufacturing processes (e.g. [redacted]). In addition, no further details on the identity (including composition) of the starting materials, their ratio, as well as on the process parameters and steps have been provided.
Moreover, ECHA notes that the Registrant reported in IUCLID section 1.2 a composition where the concentration ranges for some of the constituents are very broad (e.g. [redacted]%, for "[redacted]", [redacted]% for "[redacted]"). Such broad concentration ranges are not explained by the manufacturing process description due to its lack of details.

Therefore, ECHA considers that the Registrant did not provide sufficient information on the manufacturing process description to allow for an accurate and complete identification of the registered substance.

Elements of the manufacturing process description which are essential for the identification of the registered UVCB substance, and should therefore be provided, include:

- Information on the identity and composition of starting materials, and
- Ratio of reactants, 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.
- It should be clarified how the starting materials and /or process parameters affect the composition of the registered substance (and in particular the concentration ranges), in order to understand its variability.

ECHA points out that 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 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.

Regarding how to report the chemical name and the manufacturing process description of the UVCB substance, the chemical name shall be included in the "IUPAC name" field in section 1.1; the manufacturing process description shall be included in the "Description" field in IUCLID section 1.1.

Further technical details on how to report the chemical name of UVCB substances in IUCLID are available in 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.

Note for consideration by the Registrant

The Registrant shall note that the registration is currently linked to chemical identifiers (including the EC number 267-007-0) referring to fatty acids, C14-18 and C16-18-unsatd., Me esters. In addition, the Registrant included in the descpription field in section 1.1 reference to other EC numbers that could potentially refer to the same substance "This substance is identified by SDA Substance Name: C14-C18 and 16-C18 unsaturated alkyl carboxylic acid methyl ester and SDA Reporting Number: 04-010-00. The following other substances from the EC inventory will fall within the same description:
Fatty acids, rape-oil, me esters - EINECS 287-828-8 - CAS 85586-25-0
Fatty acids, tallow, Me esters - EINECS 262-989-7 - CAS 61788-61-2
Tallow, Me esters - EINECS 272-743-0 - CAS 68910-48-5"

Should the substance intended to be covered by this registration refer to different identifiers, the Registrant should provide an appropriate CAS entry (if available) in the "CAS information" field and report the current CAS entry under the "Related CAS information" header in IUCLID Section 1.1. For technical reasons, at this stage the Registrant is requested not to remove or revise the EC entry in the updated dossier. As this registration is linked to this EC entry in REACH-IT, the IT system will not accept the updated dossier as an update when the EC entry has changed. The Registrant is requested to include the following in the "Remarks field" of the reference substance: "This EC entry is not appropriate to identify the registered substance. This identifier cannot be modified in the present registration at this stage for technical reasons". The Registrant shall note that ECHA has established a process, subject to certain conditions, enabling registrants to adapt an existing registration, while maintaining the regulatory rights already conferred to the substance concerned.

2. Composition of the substance (Annex VI, Section 2.3.)

"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.

In that respect, 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 by a generic description of their chemical nature.
- The composition shall represent the substance as it is manufactured.

The Registrant reported the constituents with their chemical name and numerical identifiers (when available), and with the typical concentration and concentration ranges. However, ECHA has observed the following deficiencies in the Registrant's description of the composition of the substance:

(i) The typical concentrations of the constituents

The typical concentrations of the constituents were reported based on the results obtained in the gas chromatogram attached in IUCLID section 1.4. The quantification of the different constituents was done on the base of the internal standard "[redacted]". However, ECHA notes that the reported typical concentrations do not reflect the actual values, because the results of the area% were not normalized (i.e. the contribution of the [redacted] was not deducted in the calculation of the composition for the different constituents). Therefore, the substance composition is accounted only up to [redacted]% (w/w).

The Registrant is accordingly requested, pursuant to Article 41(1) and (3) of the REACH Regulation, to revise the information on the composition of the registered substance in order to establish a precise chemical representation of what the substance consists of. In particular the Registrant shall revise the concentration of the constituents reported taking into account the contribution of the internal standard.

(ii) The concentration ranges

As indicated in section III.1.(ii), some of the constituents are reported with a very broad concentration range (e.g. [redacted]%, for "[redacted]", [redacted]% for "[redacted]"), which is not justified by the manufacturing process description due to its lack of details. Such broad concentration ranges may indicate that the registration dossier covers multiple substances (i.e. UVCB and well-defined mono-constituent substances – in compositions where one constituent, namely "[redacted]" is present at a concentration >[redacted]% (w/w)).

As a consequence, the Registrant shall provide an explanation for the expected high variability in the composition. A detailed description of the manufacturing process may

clarify the broad concentration ranges reported for the registered substance. The Registrant should also revise the concentration ranges, if those provided in the present dossier are not representative for the registered substance as manufactured. In addition, the Registrant shall also clarify how the minimum and maximum values for each constituent or group of constituents were obtained (i.e. information on the batch selection, sampling procedure, the measured values, calculations used etc.). Without this information ECHA is not able to conclude on the representativeness of these values.

In the event that the present registration dossier covers different compositions of the registered substance the Registrant shall report separately the compositional information.

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.

The Registrant shall ensure that there is sufficient analytical information included in Section 1.4 of the IUCLID dossier to identify and quantify the substance and to verify the information in Section 1.2.

3. Spectral data (ultra-violet, infra-red, nuclear magnetic resonance or mass spectrum) (Annex VI, Section 2.3.5.)

"Spectral data" is an information requirement as laid down in Annex VI, Section 2.3.5. of the REACH Regulation. Adequate information needs to be present in the technical dossier for the registered substance to meet this information requirement.

ECHA notes that the registration dossier does not contain the full set of analytical data for the registered substance. No ultra-violet (UV) and infra-red (IR) spectral data, as required under Annex VI Section 2.3.5 of the REACH Regulation have been submitted. Moreover, a scientifically based justification for not including this information has not been provided. ECHA regards particularly IR data as scientifically relevant for the identification of the registered substance, as the IR spectrum displays characteristic vibration bands of covalent bonds in molecules present in the substance, including characteristic vibration bands from the chemical functionalities expected to be present in the composition.

In addition, ECHA observes that the registration dossier contains a nuclear magnetic resonance (1H NMR) spectrum showing the chemical shift scale only up to 6 ppm. The Registrant stated that "*no aromatic signal was detected*". However, this statement cannot be verified because the aromatic region (7-8 ppm) of the 1H NMR spectrum is not shown. Therefore, ECHA consider that an NMR spectrum showing the region up to 15 ppm is necessary for the identification of the registered substance.

Accordingly, the Registrant is requested to provide the missing IR and UV spectral data as well as a full scale NMR spectrum, with legible integration values, or, alternatively, a mass spectrum including the corresponding interpretation of the fragmentation scheme.

Regarding how to report the spectral data, the information shall be attached in IUCLID section 1.4. The Registrant shall ensure that the description of the analytical methods used for recording the spectra is specified in the dossier in such detail to allow the methods to be reproduced, in line with the requirements under Annex VI Section 2.3.7 of the REACH Regulation.

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 Guilhem de Seze, Head of Unit, 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.