Decision number: CCH-D-2114306668-44-01/F Helsinki, 28 August 2015

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

For addition products of conjugated sunflower-oil fatty acids with tall-oil fatty acids and maleic anhydride, CAS No 85711-46-2 (EC No 288-306-2), 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 addition products of conjugated sunflower-oil fatty acids with tall-oil fatty acids and maleic anhydride, CAS No 85711-46-2 (EC No 288-306-2), 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 [redacted] tonnes per year. This decision does not take into account any updates after the deadline for updating (27 April 2015) communicated to the Registrant by ECHA on 26 March 2015.

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 30 September 2014.

On 14 November 2014 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 1 December 2014 ECHA received comments from the Registrant agreeing to ECHA's 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.

On 11 June 2015 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 of the draft decision within 30 days of the receipt of the notification.

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

II. Information required

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.) as specified under section III.1 below;
2. Description of the analytical methods (Annex VI, Section 2.3.7.) as specified under section III.2 below.

Pursuant to Articles 41(4) and 22(2) of the REACH Regulation the Registrant shall submit to ECHA by **7 December 2015** an update of the registration dossier containing the information required by this decision.

III. Statement of reasons

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.

ECHA notes that the Registrant has specified that the registered substance is of unknown or variable composition, complex reaction products or biological materials (UVCB). The naming of UVCB substances shall consist of two parts: the chemical name and the more detailed description of the manufacturing process. ECHA observes that the Registrant did not provide sufficient information on the name and the description of the substance for its proper identification, as required under Annex VI Section 2.1. of the REACH Regulation.

More specifically, the information currently provided by the Registrant on the composition of the registered substance indicates that this substance consists of a complex set of constituents that result from the reaction of maleic anhydride with the C=C double bonds of fatty acids. The exact position of the C=C double bonds is variable and the reaction products can contain one or two cyclic substructures. However, the generic description of the manufacturing process reported in IUCLID section 3.1 is not sufficiently detailed to unambiguously identify the registered substance.

In particular, information on the composition of the fatty acids used as the starting materials is missing as well as details of the chemical reaction(s) like ratio of reactants and

the process parameters used to control the composition of the substance.

In addition, the type of reactions that take place in the manufacturing process is also not clear. The Registrant states that it is a Diels-Alder reaction but some of the constituents identified by the Registrant (e.g. "[redacted]") seem to be formed via another mechanism that is not explained.

If the substance covered by the registration is manufactured according to different manufacturing processes, including the use of different sources, then the detailed description of the manufacturing process required hereinabove shall be reported separately for each manufacturing process. A manufacturing process may be considered different when the relevant 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.

Moreover, the composition of the starting materials is particularly relevant for verifying the identity of the registered substance and verifying if the provided EC entry describes it adequately. In section 1.1 of the IUCLID dossier the Registrant states that "*fatty acids with carbon chain lengths of less than 18 or more than 18 are only present in small amounts. Fatty acids with 18 carbon atoms constitute the vast majority of "conjugated sunflower-oil fatty acids", of which the biggest part is made up of conjugated C18:2 fatty acids. Only a minor fraction is made up of fatty acids which are not conjugated C18:2. Moreover, C18:1 fatty acids are also present in significant amounts*". The Registrant shall note that the EC entry used in the registration dosser (EC number 288-306-2) covers substance that contains C14-C18 and C16-18 unsaturated fatty acids used as starting materials. However, the Registrant states that the registered substance is mainly composed by C18 unsaturated maleated fatty acids, which is not in line with the identity described by the numerical identifiers used. This information must be consistent throughout the registration dossier.

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.

Regarding how to report the description of the manufacturing process of the UVCB substance, the information shall be included in the Description field in IUCLID section 1.1.

If the current numerical identifiers (EC number 288-306-2 and CAS number 85711-46-2) do not correctly identify the registered substance, they will need to be revised. For technical reasons the Registrant is requested at this stage, 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 shall instead 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 CAS entry 85711-46-2 would need to be removed from the "CAS information" field and included in the "Related CAS information" field. The appropriate CAS entry that describes the substance identity, if available, shall be included in the "CAS information" 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 "he will prepare a more detailed description of the production process including information regarding the composition of the fatty acids used as raw materials and process parameters used to control the chemical composition of the registered substance, e.g. the ratio of reactants".

The Registrant is reminded that this decision does not take into account any updates submitted after 27 April 2015. All the new information in the later update(s) of the registration dossier will however be assessed for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation.

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

"Description of the analytical methods" is an information requirement as laid down in Annex VI, Section 2.3.7. of the REACH Regulation. Adequate information needs to be present in the technical dossier for the registered substance to meet this information requirement.

The Registrant claims that the quantification of the constituents of the registered substance was performed by gel permeation chromatography (GPC). At least three distinct peaks are present in the chromatogram provided by the Registrant. Two of these peaks (retention time between 26 and 28 minutes in the chromatogram) are integrated together and the Registrant stated that they correspond to 'Addition products of fatty acids with one equivalent of maleic anhydride').
However, ECHA notes that it is not explained why and how this group of constituents is represented by these two peaks. Moreover only a part of the recorded chromatogram is displayed (15-30 min), while the other parts (0-15 min) and 30-45 min are no included.

The Registrant has also provided an HPLC analysis to determine the concentration of maleic anhydride (attachment [redacted] However, it is not evident, from the analytical data provided, how the maleic anhydride content in the substance was calculated to be typically [redacted] % (w/w), and the concentration range for this constituent to be from [redacted] to [redacted] % (w/w). The other peaks on this chromatogram are not integrated and it is only explained that "*all other peaks are not relevant and are therefore not considered in the interpretation and discussion of the chromatograms*". If, however, these peaks represent the other constituents of the registered substance, the HPLC analysis could possibly provide more detailed compositional information than GPC analysis. In addition, this analytical information (attachment [redacted] is a fingerprint of the information provided by the Registrant for another substance (registration number [redacted]).

Therefore ECHA concludes that the quantitative analytical data submitted is not sufficient to verify the composition reported in section 1.2 of the IUCLID dossier. The Registrant has not provided detailed description of any of the analytical methods used for the identification and quantification of the different groups of constituents and therefore, the composition provided in section 1.2 of the IUCLID dossier cannot be confirmed.

In addition, ECHA also notes that the Registrant uses GPC as the analytical method for the identification of the substance but it might not be the most adequate analytical method to identify the substance constituents. For instance, its applicability for identification of unreacted fatty acids may be limited and the presence of such fatty acids in the substance composition cannot be excluded, based on the information provided in section 1.1 of the IUCLID dossier and on the NMR data included in section 1.4.

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 description of the methods used to identify and quantify the registered substance as specifically explained above. The Registrant shall ensure that the information is consistent throughout the dossier.

Regarding how to report the description of the analytical methods, the information shall be attached in IUCLID section 1.4 and the Registrant shall provide the following information:

1. Clarification on why one group of constituents is represented by two peaksin the GPC chromatogram.
2. Full chromatogram plot (0-45 min).
3. Explanation on how maleic anhydride content is calculated.
4. Identification of the constituents that are represented by the other peaks in the HPLC chromatogram.
5. The Registrant must demonstrate that the analytical information (attachment [redacted] and results thereof used for quantification of maleic anhydride is specific to the registered substance subject to this decision.
6. Detailed description of the chromatographic methods so they are reproducible including (but not limited to):
    a. molecular weight for all peaks in GPC,
    b. individual peaks integrated individually,
    c. identification of all the peaks in the chromatograms.

The Registrant shall ensure that the analytical information submitted is consistent with the composition of the substance reported in section 1.2 of the IUCLID dossier.

The Registrant outlined in the comments to the draft decision how he could address the information requirement by stating that "With regard to the questions related to the chromatographic characterization of the registered substance and its maleic anhydride content, we will give detailed answers to all points raised".

The Registrant is reminded that this decision does not take into account any updates submitted after 27 April 2015. All the new information in the later update(s) of the registration dossier will however be assessed for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 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 Claudio Carlon, 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.