ECHA
EUROPEAN CHEMICALS AGENCY

Final decision: CCH-D-0000002270-87-03/F Helsinki, 24 April 2012

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

For Fatty acids, C16-18 and C18-unsatd., Et esters, CAS No 85049-36-1 (EC No 285-206-0), 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, C16-18 and C18-unsatd., Et esters, CAS No 85049-36-1 (EC No 285-206-0) submitted by [redacted] (Registrant), latest submission number [redacted], for the tonnage band of [redacted].

The compliance check was initiated on 18 November 2011.

On 10 January 2012 ECHA notified the Registrant of its draft decision and invited him pursuant to Article 50(1) of the REACH Regulation to provide comments within 30 days of the receipt of the draft decision.

The Registrant did not provide any comments on the draft decision.

On 02 March 2012 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.

This compliance check decision does not prevent ECHA to initiate further compliance checks on the present dossier at a later stage.

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.): Any information which is suitable and necessary to allow ECHA to identify the name of the registered substance, including the description of the manufacturing process, as specified under section III. (a) below; and
b. Composition of the substance (Annex VI, 2.3.): Any information which is suitable and necessary to allow ECHA to establish and verify the composition and name of the registered substance, including concentration ranges of the constituents, 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 **25 June 2012**.

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 per year or more in accordance with Article 6 of the REACH Regulation, does not comply with the requirements of Article 10 and with 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.

Missing information related to substance identity

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 subject to this decision.

(a) Name or other identifier of the substance (Annex VI, 2.1.):

The name and other identifiers are used to identify the substance in unambiguous manner and are therefore essential parts of substance identification being the corner stone of all the REACH obligations.

ECHA notes that the Registrant provided a chemical name and a description in section 1.1 of the technical registration dossier. However, further information is required to appropriately identify the registered substance, in line with Annex VI, section 2.1. of the REACH Regulation. More specifically, the naming of a substance of unknown or variable composition, complex reaction products or biological materials (UVCB substance) such as the registered substance consists two parts: the chemical name which should be entered in the IUPAC name field and a more detailed description of the manufacturing process which should be included in the description field. ECHA observes that the description provided in section 1.1 of the registration dossier is not sufficiently detailed to identify the substance as details of the process circumstances under which the substance is produced have not been fully described.

Furthermore the provided name indicates that the registered substance corresponds to fatty acids, C16-18 and C18-unstd., **ethyl esters** and all other identifiers included in section 1.1 and 1.2 refer to ethyl esters. The generic description of the manufacturing process provided on the one side in section 3.1 and the ^{1}H NMR spectrum attached in section 1.4 on the other side, would suggest that the substance consists of **methyl esters**.

Accordingly, the Registrant is requested to clarify whether the substance consists of ethyl or methyl esters of fatty acids, C16-18 and C18-unstd. The Registrant shall also provide details of the process used for the manufacturing of the registered substance. The description shall include the chemical identity of the starting materials used, the ratio of the starting materials, the chemical process and the process parameters.

The Registrant can find further indication in section 4.3 of the Guidance for identification and naming of substances under REACH (2011, version 1.1., http://guidance.echa.europa.eu/docs/guidance_document/substance_id_en.pdf)

Regarding how to report the description of the UVCB substance in IUCLID, the following applies:
The Registrant should report the chemical (generic) name of the registered substance in the IUPAC name field of IUCLID section 1.1 and give detailed description of the starting material and of the manufacturing process in writing in the description field.

(b) 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 being 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. More specifically, the provided chemical name for the registered substance is **Fatty acids, C16-18 and C18-unsatd., Et esters** which corresponds to a UVCB substance including several constituents obtained from the esterification reaction of different fatty acids. The composition reported in section 1.2 of the registration dossier specifies wide concentration ranges, in particular, the concentration range for constituent, [redacted], is specified as [redacted].

ECHA points out that according to ECHA guidance chapter 4.2.1 on the identification and naming of substances under REACH (2011, version 1.1., http://guidance.echa.europa.eu/docs/guidance_document/substance_id_en.pdf), a substance in which one main constituent is present to at least 80% (w/w) is defined as a mono-constituent substance and its name corresponds to the IUPAC name of the main constituent present in the substance. In the specific case therefore if constituent "[redacted]" is present in the substance in a concentration of ≥ 80 %, [redacted], the substance would be named as [redacted] and would be regarded as a different substance from **Fatty acids, C16-18 and C18-unsatd., Et esters.** Such substance would require a separate registration under the REACH Regulation.

In line with the above, the Registrant is required to review the concentration ranges of the constituents reported in section 1.2 in order to be consistent with the identity of the substance reported in section 1.1. The Registrant shall provide any information which is suitable and necessary to allow ECHA to establish and verify the composition of the registered substance.

Regarding how to report the composition of UVCB substances in IUCLID, further technical details are available in paragraphs 2.1 and 2.2.2 of the Data Submission Manual 18 (2010, version 1.0) on the ECHA website at:
http://echa.europa.eu/doc/reachit/dsm18/substance_id_report_iuclid_en.pdf

IV. General requirements for the generation of information and Good Laboratory Practice

ECHA always reminds registrants of the requirements of Article 13(4) of the REACH Regulation that ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice (GLP). National authorities monitoring GLP maintain lists of test facilities indicating the relevant areas of expertise of each facility.

According to Article 13(3) of the REACH Regulation, tests that are required to generate information on intrinsic properties of substances shall be conducted in accordance with the test methods laid down in a Commission Regulation or in accordance with other international test methods recognised by the Commission or the European Chemicals Agency as being appropriate. Thus, the Registrant shall refer to Commission Regulation (EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 as adapted to technical progress or to other international test methods recognised as being appropriate and use the applicable test methods to generate the information on the endpoints indicated above.

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

[redacted]

Jukka Malm
Director of Regulatory Affairs