EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114292072-54-01/F Helsinki, 25 February 2015

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

For 2-Propenoic acid, 2-methyl-, C12-15-branched and linear alkyl esters, CAS No 90552-02-6 (EC No 292-122-8), 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 2-Propenoic acid, 2-methyl-, C12-15-branched and linear alkyl esters, CAS No 90552-02-6 (EC No 292-122-8), submitted by [redacted] (Registrant) The scope of this compliance check 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 submitted after 30 October 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 6 November 2013.

On 17 December 2013 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 28 January 2014 ECHA received comments from the Registrant agreeing to ECHA's draft decision.

On 30 October 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 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

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): A more detailed description of the manufacturing process, as specified under section III.1 below;
2. Composition of the substance (Annex VI, Section 2.3): More detailed information on composition, as specified under section III.2 below;
3. Spectral data (ultra-violet, infra-red, nuclear magnetic resonance or mass spectrum) (Annex VI, Section 2.3.5). A ultra-violet spectrum, as specified under section III.3 below.

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated registration to ECHA by **1 June 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.

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)

The Registrant identified the registered substance as 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. The Registrant did not provide sufficient information on the description of the substance for its proper identification, as required under Annex VI Section 2.1 of the REACH Regulation.

More specifically, the description of the manufacturing process reported in section 3.1 of the IUCLID dossier is not sufficiently detailed to identify the substance. In particular, the relevant process parameters used for its manufacturing, including details of the identify of the starting materials and their ratio have not been specified.

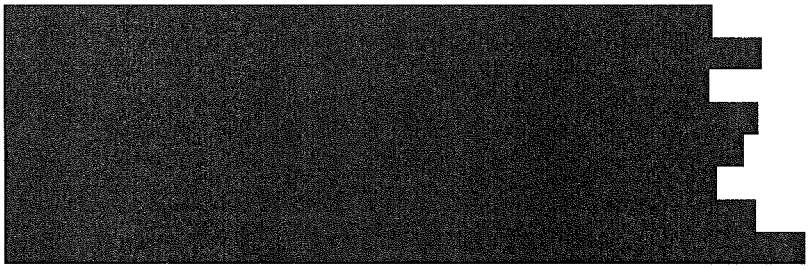
The Registrant is therefore requested to provide the missing information on the description of the process used for the manufacturing of the substance registered.

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

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

The Registrant did not provide separate entries in section 1.2 of the IUCLID dossier for branched and linear constituents. ECHA therefore concludes that the composition of the registered substance has not been provided to the required level of detail.

Regarding how to report the composition in the IUCLID dosier, the following applies: The Registrant shall report separately branched and linear constituents. Based on the current presentation in section 1.2 of the IUCLID dossier this means that the four listed constituents shall be further divided into eight constituents as follows:



In addition, any consituent that individually has a concentration greater than 10 % (w/w) shall be reported separately in section 1.2 of the IUCLID dossier

For each constituent required to be reported, at least one of the following identifiers shall be specified: chemical name, CAS number, EC number and/or molecular formula, as well as the minimum, maximum and typical concentration, in the appropriate fields in IUCLID section 1.2.

Furthermore, section 1.4 of the IUCLID dossier contains information that indicates that several specifications or grades of the registered substance are manufactured. The composition of different specifications or grades of the registered substance shall be separately reported in section 1.2 of the IUCLID dossier.

The Registrant shall ensure that any information provided on different specifications or grades is consistent with the chemical name and description of the substance specified in IUCLID section 1.1 and is confirmed by the required analytical data in IUCLID section 1.4.

Further technical details on how to report the composition of two or more specifications or grades in IUCLID are available under Q&A8 of the Data Submission Manual 18 on the ECHA website.

3. Spectral data (ultra-violet, infra-red, nuclear magnetic resonance or mass spectrum) (Annex VI, 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.
The registration does not contain a Ultra-Violet (UV) spectrum which is required by Annex VI 2.3.5 to support the identity of the registered substance.

Accordingly, the Registrant is requested to provide the missing UV spectrum.

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

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.

[redacted]
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Director of Evaluation