Decision number: CCH-D-2114313123-69-01/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 Castor oil, hydrogenated, EC No 232-292-2 (CAS No 8001-78-3), 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 Castor oil, hydrogenated, EC No 232-292-2 (CAS No 8001-78-3), 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 12 February 2015.

On 4 August 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.

By 10 September 2015 the Registrant did not provide any comments on the draft decision to ECHA.

On 29 October 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

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 (ultra-violet, infra-red, nuclear magnetic resonance or mass spectrum) (Annex VI, Section 2.3.5.)
4. High-pressure liquid chromatogram, gas chromatogram (Annex VI, Section 2.3.6.)
5. Description of the analytical methods (Annex VI, Section 2.3.7.)

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.)

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 identified the registered substance as of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB). Information required to be provided according to Annex VI, Section 2.1. of the REACH Regulation on the naming of UVCB substances such as the registered substance shall consist of two parts: (1) the chemical name and (2) 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: 1.2, March 2012) – referred to as "the Guidance" thereinafter.

ECHA observes that the Registrant did not provide sufficient information on the manufacturing process of the substance.

More specifically ECHA notes that the chemical name and the EC and CAS information assigned by the Registrant in the registration dossier would indicate that the registered substance is the result from a hydrogenation process of castor oil. However, the description of the manufacturing process is missing from the registration dossier. In particular, the following information has not been given:

- The identity and ratio of all the starting materials used;
- The description of the manufacturing steps in the order they occur
- The relevant process parameters applied to control the composition of the manufactured substance (including the parameters determining the level of hydrogenation of the substance);
- Information on processing steps applied to isolate the manufactured substance and any purification/fractionation steps used.

As these abovementioned elements of the manufacturing process are expected to determine the composition of the registered UVCB substance, and given also the limited information on the composition in the current dossier (see section III.A.2 of this decision), ECHA considers that they are necessary for the identification of the registered substance.

Therefore the Registrant shall 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 of the UVCB substance, the information shall be included in the "Description" field in IUCLID section 1.1.

The Registrant shall ensure that the chemical name, the identifiers and the manufacturing process description to be reported according to Annex VI, Section 2.1 of the REACH Regulation are consistent with each other and with the composition required to be provided according to Annex VI, Section 2.3 of the REACH Regulation.

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

Annex VI, section 2.3 of the REACH Regulation requires that each registration dossier contains sufficient information for establishing the composition of the registered substance and therefore its identity.

In that respect, according to chapter 4.3 of the Guidance, for UVCB substances such as the registered substance, the Registrant shall note that 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; and
- For each constituent and group of constituents, the typical, minimum and maximum concentration levels shall be specified.

The Registrant reported the presence of the following 3 constituents or groups of constituents together with their typical concentration levels:

[redacted]

ECHA however considers that the registration does not contain sufficient and appropriate information for establishing the composition of the registered substance and therefore its identity for the following reasons:

- The attached chromatographic "fingerprint" suggests that the composition of the substance is not limited to the three reported (groups of) constituents. The fingerprint instead shows the presence of a multitude of peaks suggesting the existence of constituents which have not been reported in the composition;
- There are no concentration ranges provided for the constituents and therefore the variability of the composition cannot be determined;
- [redacted] reported in the composition of the registered substance present a stereocenter. However, the Registrant did not report any information on the ratio of stereoisomers, as further required according to Annex VI Section 2.2.2. of the REACH Regulation;
- The typical concentration values reported by the registrant for the 3 reported constituents or groups of constituents add up to more than [redacted]% and can therefore not all be considered representative of the typical composition of the registered substance.

ECHA therefore concludes that the compositional information has not been provided to the required level of detail.

The registrant is accordingly requested to revise the composition of the registered substance by providing appropriate information on the identity and concentration levels of the constituents and groups of constituents. The Registrant shall note that, for substances such as the registered substance, reporting the unknown constituents according to the level of esterification of the glycerol is appropriate. For each group of unknown constituents presenting the same level of esterification, the ratio of fatty acid blocks shall be specified.

Regarding how to report the composition 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. The relative abundance of the different fatty acid blocks (including where relevant information on the stereochemistry or the ratio of stereoisomers for the [redacted]) within each group of ester constituents should be provided in the Remarks field of the repeatable block for that group of constituents.

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 the information on the composition of the substance is verifiable and therefore supported by a description of the analytical methods used for its identification, as required under Annex VI section 2.3.7. of the REACH Regulation.

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 does not contain any spectral data, including infra-red (IR), ultraviolet (UV) spectra and nuclear magnetic resonance (NMR) spectrum or Mass spectrum (MS), which are required to support the identity of the registered substance. ECHA points out that the identity of the substance cannot be confirmed without providing appropriate spectral data in the dossier.

ECHA regards this required information scientifically necessary for the identification of the registered substance. If the substance includes chromophores, the UV spectrum displays characteristic absorptions by such functionalities. The IR spectrum displays characteristic vibration bands for the covalent bonds of organic compounds such as the registered substance. Moreover, NMR spectroscopic analyses such as a ^{1}H-NMR or a ^{13}C-NMR are powerful tools for structure characterisation and elucidation due to characteristic chemical shifts and spin-spin coupling which also reflect the relative abundance of individual atoms. Alternatively, a mass spectrum which is an appropriate analytical method to characterise the substance and determine its elemental composition, can be provided.

Accordingly, the Registrant is requested to provide the UV spectrum (or a scientific justification for not submitting the UV spectrum, should the Registrant consider it irrelevant for the identification of the substance), the IR spectrum as well as a NMR spectrum, such as ^{1}H-NMR and/or ^{13}C-NMR or, alternatively, a mass spectrum including the corresponding interpretation of the fragmentation scheme.

As for the reporting of the spectral data in the registration dossier, the information should be included in IUCLID section 1.4. The Registrant shall ensure that the description of the analytical methods used for the recording of the spectra is specified in the dossier, in line with the requirements under Annex VI section 2.3.7.

4. High-pressure liquid chromatogram, gas chromatogram (Annex VI, Section 2.3.6.)

"High-pressure liquid chromatogram or gas chromatogram" is an information requirement as laid down in Annex VI, Section 2.3.6. 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 copy of a gas chromatogram has been attached to the dossier. However, the Registrant did not provide any comprehensive report for the chromatographic analysis. In particular a "fingerprint" GC chromatogram is provided in the dossier however the peaks are not identified and integrated and there is no information as to how the listed constituents correspond to the detected peaks. Therefore it is not possible to conclude how the "fingerprint" relates to the substance composition expected to be reported in section 1.2 of the dossier.

Therefore, the Registrant is requested to submit an appropriate chromatographic report including the chromatogram and a peak table containing the retention times, peak areas and peak area % of the constituents.

Accordingly, the Registrant is requested to provide the report from the gas chromatographic analysis of the registered substance.

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

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

The description of analytical methods or appropriate bibliographical reference for the identification of the substance is a formal information requirement of Annex VI Section 2.3.7.

The Registrant provided a description of an analytical method based on gas chromatography (GC) and involving the derivatisation of the registered substance. The description includes the experimental protocol followed to record the chromatogram and a copy of the chromatogram itself.

However, it is not possible to establish from the described analysis the identity and concentration levels of the constituents and groups of constituents required to be reported in the dossier. More specifically, the Registrant has not provided information on the relative integral area values of the chromatographic peaks and how those peaks have been assigned to specific constituents of the registered substance.

ECHA therefore concludes that the Registrant did not provide sufficient description of the analytical methods for the identification and quantification of the constituents and groups of constituents required to be reported in the composition of the registered substance.

The Registrant is accordingly required to provide a proper description of the analytical methods used for the identification and quantification of all individual constituents and groups of constituents of the registered substance. The description shall be sufficient for the methods to be reproduced and shall therefore include details of the experimental protocol followed, any calculation made and the results obtained.

As for the reporting of the data in the registration dossier, the information should be attached in IUCLID section 1.4. The Registrant shall ensure that the composition reported in the dossier is consistent with the analytical results obtained.

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 E2

[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.