EUROPEAN CHEMICALS AGENCY

For final decision: CCH-D-0000002284-78-03/F Helsinki, 10 May 2012

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

For octadecene, CAS No 27070-58-2 (EC No 248-205-6), 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 octadecene, CAS No 27070-58-2 (EC No 248-205-6) submitted by [redacted] (Registrant), latest submission number [redacted], for the tonnage band of 1000 tonnes or more per year.

The compliance check was initiated on 20 December 2011.

On 3 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.

On 2 February 2012 the Registrant provided to ECHA supportive comments on the draft decision, agreeing to provide the information requested.

ECHA reviewed the further information received and did not amend the draft decision.

On 2 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. Composition of the substance (Annex VI Section 2.3.) as specified under section III. (a) below;
b. Spectral data (Annex VI, 2.3.5.): a ^{1}H-Nuclear Magnetic Resonance (NMR) spectrum including integral values of the signals observed, as specified under section III. (b) below;
c. High-pressure liquid chromatogram or a gas chromatogram (Annex VI, 2.3.6.), as specified under section III. (c) below;
d. The description of the analytical methods (Annex VI section 2.3.7.), as specified under section III. (d) 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 **10 July 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 or more per year in accordance with Article 6 of the REACH Regulation, does not comply with the requirements of Articles 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.

(a) 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 and 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 Registrant identified the registered substance as the octadecene (EC number 248-205-6) of Unknown or Variable composition, Complex reaction products and or Biological materials (UVCB). This UVCB substance shall predominantly consist of [redacted] ECHA notes that the results from the chromatographic analysis of the test sample indicate a predominance of [redacted]. In addition, the signals observed in the region [redacted] of the 1H-NMR spectrum support the presence of unsaturations. However, ECHA observes that the absence of integral values in the NMR spectrum and ambiguities on the [redacted] quoted in the chromatographic report does not enable to conclude on the identity and concentration of the different alkenes

which the substance consists of.[1] Furthermore, ECHA points out that the Registrant did not specify any compositional information including details on the typical concentration and concentration ranges of the constituents. It follows that the composition of the registered substance can not be established and is therefore considered missing from the dossier.

According to ECHA Guidance chapter 4.3 on the identification and naming of substances under REACH[2], the Registrant should note that, for UVCB substances 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 known constituents and constituents relevant for the classification and/or PBT assessment of the registered substance shall be identified and reported individually. The Registrant shall note in particular that each linear mono-unsaturated C18 alkene structural isomer is expected to be known for the substance to be identified as octadecene and shall therefore be reported individually; and
- Unknown constituents shall be identified as far as possible by a generic description of their chemical nature. The identification of these unknown constituents must be provided for ECHA to establish the composition of the substance as manufactured and to use the compositional information as one identifier for the registered substance. For substances such as the registered substance, a distinction of the unknown constituents according to the carbon number, backbone type (linear, branched, cyclic) and unsaturation type (such as saturated, vinyl-, cis/trans disubstituted, vinylidenes, trisubstituted, etc.) is necessary for this purpose as a baseline.

For each constituent or group of constituents, the typical, minimum and maximum concentration levels shall be specified.

The Registrant is accordingly requested to complete the above information on the composition of the registered substance provided in the registration dossier, for ECHA to have a precise chemical representation of what the substance consists of.

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.
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 18 on the ECHA website.[3]

The Registrant shall ensure that the information provided on the composition is consistent with the identity of the Registered UVCB substance octadecene and is confirmed by the analytical data included in section 1.4 of the IUCLID dossier.

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[1] These observations on the analytical information are further detailed in section III (b) and (d) of this communication.
[2] http://echa.europa.eu/web/guest/guidance-documents/guidance-on-the-different-methods-under-reach
[3] http://echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it/registration

(b) Spectral data (Annex VI, 2.3.5):

The dossier submitted by the Registrant contains a ^{1}H-NMR spectrum, as required under Annex VI section 2.3.5. However, ECHA observes that the spectrum does not specify any integral values of the signals observed. ECHA points out that the integration of the signals is essential to establish and verify the relative abundance of characteristic atoms or functional groups in the registered substance. More specifically, this information is necessary to verify the relative molar content of the different alkene classes present in the registered substance.

Accordingly, the Registrant is requested to provide the missing integral values of the NMR spectral data.

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

(c) The chromatogram (Annex VI, 2.3.6.)

The dossier submitted by the Registrant contains a gas chromatogram, as required by Annex VI Section 2.3.6. However, ECHA notes that the copy of the chromatogram as such is not legible, in so far as a clear distinction between the different peaks detected can not be visually made.

Accordingly, the Registrant is requested to provide a high-pressure liquid chromatogram or a gas chromatogram of the UVCB substance octadecene which is the subject of this registration. The information shall include a legible print-out of the chromatogram as well as the report from the chromatographic analysis, including a peak list with the corresponding retention time and peak area.

As for the reporting of the chromatographic data in the dossier, the information should be attached in IUCLID section 1.4.

The registrant shall ensure that the description of the analytical method used for the chromatographic analysis, including the experimental set-up (i.e. the column type, length and diameter; injection volume; mobile phase/carrier gas; GC temperature programme; flow rate; concentrations of HPLC standard solutions; detection technique; and run time) and preparation of solutions and identity of standards, is specified, in line with the requirements of Annex VI section 2.3.7.

(d) The description of the analytical methods (Annex VI section 2.3.7.)

ECHA observes that the Registrant did not provide any appropriate description of the analytical methods used for the identification and quantification of the constituents required to be reported in the composition of the registered substance, as requested according to Annex VI section 2.3.7.

More specifically ECHA notes that the Registrant provided information on the relative integral area values of groups of constituents (including [redacted] as part of a chromatographic analysis. The results indicate the predominance of [redacted]. These results are not consistent with the profile of ^{1}H-NMR spectrum where the signals originating from [redacted] appear significantly smaller than the other [redacted]. In addition, ECHA observes that the analytical report does not include any information as to

how the results from the chromatographic analysis have been translated into concentrations of the saturated and unsaturated hydrocarbon classes listed in that report.
The Registrant also provided information on the relative integral area values of groups of constituents according to the carbon numbers as part of the same chromatographic analysis. However, the report does not include any description of the experimental procedure used to derive this information from the chromatogram.
ECHA therefore concludes that the provided chromatographic analysis can not be used as such to draw any conclusion on the composition of the registered substance.

The Registrant is accordingly requested to provide a description of the analytical methods used for the identification and quantification of the constituents required to be reported in the composition 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.

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://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