

For final decision: CCH-D-0000002265-78-02/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 Reaction mass of Alkenes C20-24 and Alkenes C24-28, List No 931-746-3, 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 the ECHA has performed a compliance check of the registration dossier for Alkenes C20-24 and Alkenes C24-28, List No 931-746-3, submitted by [REDACTED] (Registrant), latest submission number [REDACTED], for 1000 tonnes or more per year.

The compliance check was initiated on 13 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.

The Registrant did not provide any comments on 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

- 1) 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.), as specified under section III. (a) below;
 - b. Composition of the substance (Annex VI, 2.3.), as specified under section III. (b) below;

- c. Spectral data (Annex VI, 2.3.6.): an infra-red (IR) spectrum as specified under section III. (c) 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 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.

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

Registrant identified the registered substance as a multi-constituent substance and provided a chemical name constructed according to the "reaction mass of" naming convention used for this type of substance. However, ECHA notes that the naming convention for the identification of the registered substance is not appropriate and does not accurately describe the composition of the substance.

More specifically, ECHA observes that the analytical report included in the dossier indicates the presence of a large number of constituents (>170) including alpha-, internal- and vinylidene-olefins having a carbon number distributed over the C16-34 (even numbered) range. The composition can not be considered sufficiently well-defined for the registered substance to be identified as a multi-constituent substance. ECHA therefore concludes that the substance which is the subject of this registration shall be regarded as a UVCB substance (substance of Unknown or Variable composition, Complex reaction products or Biological material). It follows that the "reaction mass of" naming convention used well-defined multi-constituent substances is not appropriate to name the registered substance. Furthermore, ECHA points out that the groups of constituents quoted in the name, said "Alkenes C20-24" and "Alkenes C20-28", do not reflect the fact that only alpha-, internal- and vinylidene-olefins with even-carbon numbers are present in the composition. "Alkenes C20-24" and "Alkenes C20-28" are therefore inappropriate identifiers to describe the composition of the composition of the registered substance.

The Registrant is accordingly requested to identify the registered substance as a UVCB and specify a chemical name that follows the general naming conventions for this type of substances, as exemplified in the Guidance for identification and naming of substances under REACH.¹ The Registrant shall ensure that the name specifically describes the chemical

¹ <http://echa.europa.eu/web/guest/guidance-documents/guidance-on-the-different-methods-under-reach>

nature of the olefins present in the composition and reflects as far as possible the manufacturing process involved.

As for the reporting of the information in the dossier, further technical details is available in paragraphs 2.1 and 2.2.2 of the Data Submission Manual 18 on the ECHA website.²

(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 and the corner stone of all the REACH obligations.

ECHA notes that the registration does not contain sufficient and appropriate information for establishing the composition of the registered UVCB substance and therefore its identity, as required under Annex VI, section 2.3. of the REACH Regulation.

More specifically, the Registrant only reported the presence of alpha-alkenes from C20 to C28 in the composition. ECHA observes that the identity of the reported alkenes is not consistent with the alkenes identified in the analytical report attached to the dossier. The report indicates the presence of other olefins, including vinylidene- and internal-olefins in predominant concentrations. The report also highlights that only alkenes with even carbon numbers have been identified and that these alkenes range from at least C16 to C34. ECHA therefore concludes that the identity of the different olefins has not been correctly reported in the composition.

Furthermore, the Registrant reported the presence of up to 15% of C16-18 alcohols in the substance. However, ECHA observes that the ¹H-NMR spectrum indicates that such constituents are not present in the analysed sample. It follows that the existence of this group of constituents can not be verified.

According to ECHA Guidance chapter 4.3 on the identification and naming of substances under REACH², 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;
- 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 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.

² <http://echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it/registration>

The Registrant is accordingly requested to complete or correct 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 of the registered substance 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 registration includes the necessary analytical information required under Annex VI section 2.3.7 to verify the reported composition.

(c) Spectral data ((Annex VI, 2.3.6.)

ECHA notes that the Registrant did not provide the IR spectral data which is required according to Annex VI section 2.3.5. of the REACH Regulation. ECHA points out that IR spectral data is a standard information requirement of Annex VI section 2.3.5. ECHA regards this required information scientifically necessary for the identification of the registered substance as the IR spectrum displays characteristic vibration bands for the covalent bonds in alkenes.

The Registrant is accordingly requested to submit an IR spectrum.

As for the reporting of the spectral 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.



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