ECHA
EUROPEAN CHEMICALS AGENCY

For final decision: CCH-D-0000002131-91-04/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 Nonene, CAS No 27215-95-8 (EC No. 248-339-5), 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 nonene, CAS No 27215-95-8 (EC No 248-339-5) 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.

By 2 February 2012, the Registrant had not provided comments.

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, 2.3.) as specified under section III. (a) below;
b. Spectral data (Annex VI, 2.3.5.): an infrared (IR) spectrum and a nuclear magnetic resonance (NMR) spectrum, such as a 1H NMR spectrum. As an alternative, a mass spectroscopic analysis of the registered substance can be provided, as specified under section III. (b) below;
c. The description of the analytical methods or the appropriate bibliographical references for the identification of the substance (Annex VI, 2.3.7.) 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) 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 substance nonene (EC number 248-339-5) of Unknown or Variable composition, complex reaction products and or biological materials (UVCB). Such UVCB substance shall predominantly consist of linear C9 mono-unsaturated alkenes where the unsaturation is present at any of the four possible positions on the C9 backbone. Whilst the Registrant indicated that the substance indeed includes 1-nonene, 2-nonene, 3-nonene and 4-nonene structural isomers, the Registrant did not specify any information on their individual concentrations. The Registrant reported instead the generic group of constituents "C9 Mono olefins" which covers, but is not limited to, any linear C9 mono-unsaturated alkenes. ECHA points out that a distinction between the constituents expected to be present in the composition of the registered substance (i.e. the different linear C9 mono-unsaturated alkene constituents), is technically

possible and is essential to verify the identity of the registered substance. ECHA therefore concludes that information on the composition of the registered UVCB substance is not sufficiently detailed.

According to ECHA Guidance chapter 4.3 on the identification and naming of substances under REACH[1], 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 C9 alkene structural isomer shall be known for the substance to be identified as nonene 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.

In line with the above, the Registrant is requested to report the missing compositional information of the registered UVCB substance nonene.

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.[2]

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

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

[1] http://echa.europa.eu/web/guest/guidance-documents/guidance-on-the-different-methods-under-reach
[2] http://echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it/registration

ECHA notes that the Registrant did not provide any of the required spectral data which is required according to Annex VI section 2.3.5. of the REACH Regulation.

More specifically, the Registrant included justifications for not providing the required spectra. According to the justifications, the Registrant considered the spectral data scientifically unnecessary to identify the substance. ECHA points out that spectral data is a standard information requirement of Annex VI section 2.3.5. Contrary to the Registrant, ECHA regards both IR and NMR spectral data as scientifically necessary for the identification of the registered substance for the following reasons:

- The IR spectrum displays characteristic vibration bands for the covalent bonds in alkenes. As a consequence an IR spectrum provides information on the identity of the substance;
- An NMR spectrum such as a ^{1}H-NMR spectrum provides structural information on the types of unsaturation present in alkenes and on the relative abundance of characteristic atoms or functional groups in the registered substance.

The Registrant is accordingly requested to submit an IR spectrum and a NMR spectrum, such as a ^{1}H-NMR. As an alternative to the NMR spectrum, a mass spectroscopic analysis of the registered substance can be provided.

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

(c) The description of the analytical methods (Annex VI, 2.3.7.)

ECHA observes that the Registrant did not provide a description of the analytical methods that are necessary for the identification and quantification of the constituents required to be reported in the composition of the registered UVCB substance nonene.

More specifically, the Registrant provided the results of the method ASTM D1319 for the quantification of saturates, aromatics, mono-olefins and di-olefins. However, the analysis of the olefin content in substances containing >55% (v/v) olefins, such as the registered substance, is outside the domain of applicability of this standard method. Furthermore, the experimental protocol described in this standard method does not make any distinction between mono-olefins and di-olefins. It is therefore unclear how the content of the substance in terms of mono- and di-olefins was determined.
In addition, the Registrant presented the results from the quantification of hydrocarbon classes having the same carbon number based on the method ASTM D4492. However, this method corresponds to an experimental protocol for the analysis of benzene by gas chromatography and therefore cannot be used to determine the carbon number distribution in the registered substance.
ECHA therefore concludes that appropriate description of the analytical methods for the identification of the registered substance is missing from the dossier.

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
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