EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000002375-75-02/F Helsinki, 18 June 2012

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

For Alkanes, C16-20-iso-, CAS No 90622-59-6 (EC No 292-461-1), 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 Alkanes, C16-20-iso-, CAS No 90622-59-6 (EC No 292-461-1), submitted by [redacted] (Registrant), latest submission number [redacted], for 1000 tonnes or more per year.

The compliance check was initiated on 9 September 2011.

On 22 September 2011 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 20 October 2011 the Registrant provided to ECHA comments on the draft decision. On 15 December 2011 the Registrant updated the dossier, including only part of the requested information.

ECHA reviewed the further information received and amended the draft decision accordingly.

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. The CAS name and CAS number of the substance (Annex VI, 2.1.4.) , as specified under section III.1)(a) below;
b. The composition (Annex VI, 2.3): Any information which is suitable and necessary to allow ECHA to establish and verify the composition and the name of the registered substance, as specified under section III.1)(b) 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 **18 December 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 in accordance with Article 6 of the REACH Regulation, does not comply with the requirements of Articles 10, 12 and 13 and with Annexes VI to X and XI 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) The CAS name and CAS number of the substance (Annex VI, 2.1.4.):

ECHA notes that the CAS information assigned in the dossier and required to be provided according to Annex VI, section 2.3.4. does not specifically correspond to the registered substance.

More specifically, the Registrant identified the registered substance as of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB). In line with the chemical name assigned to the registered substance, the predominant constituents include C16, C20 and C24 branched alkanes. However, ECHA observes that the CAS number 90622-59-6 used by the registrant to identify the substance refers to "Isoalkanes, C16-20" and does therefore not reflect the identity of the predominant constituents present in the composition. In addition, ECHA notes that the Registrant specified "C16-(branched), C20-(branched) and C24-(branched)-alkanes" as the CAS name for the CAS number 90622-59-6. ECHA points out that the correct CAS name for this CAS entry is "Isoalkanes, C16-20".
ECHA therefore concludes that the CAS information assigned to the registered substance is not appropriate for its unambiguous identification.

The Registrant is accordingly requested to delete the CAS information assigned in the dossier and replace it by any CAS name and CAS number specifically corresponding to the registered substance, if available. The CAS name "Isoalkanes, C16-20" and CAS number 90622-59-6 can however be reported as related CAS information in the dossier. As for the reporting of the information in IUCLID, any CAS name and CAS number corresponding to the registered substance should be reported under the "CAS information" header of the reference substance in IUCLID section 1.1. The CAS name "Isoalkanes, C16-20" and CAS number 90622-59-6 can be reported under the "Related CAS information" header of the reference substance in IUCLID section 1.1.

(b) Composition of the registered 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 provided analytical data indicate that the analysed sample includes different groups of constituents referred to as "lower boiling compounds", "tetrabutane isomers", "pentabutane isomers", "hexabutane isomers" and "higher boiling compounds". However, ECHA observes that the relevant individual constituents or groups of constituents have not been duly identified and reported in the composition information. In particular a distinction between the groups of constituents mentioned hereinabove has not been made in the composition. It follows that ECHA does not have an overview of what the registered substance consists of and of the variations in its composition that are inherent to the manufacturing process.

Following section 4.3 of the Guidance for identification and naming of substances under REACH, the Registrant should note that for UVCB substances presenting a large number of constituents, 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 constituents relevant for the classification and/or PBT assessment of the registered substance shall be identified and reported individually; and
- Other constituents shall be identified as far as possible by a generic description of their chemical nature. The identification of these other constituents must be provided in order to allow ECHA to establish the composition of the substance as manufactured and to use the compositional information as one identifier for the registered substance. This information must also allow ECHA to verify that the composition is consistent with the chemical name reported for the registered substance. The registrant must provide any information which is suitable and necessary to meet these objectives.
  For UVCB substances such as the registered substance, the reporting of the branched alkanes according to the carbon number is necessary for this purpose. The Registrant shall therefore report separately the groups of constituents "C16-branched alkanes", "C20-branched alkanes", "C24-branched" alkanes" and, as far as possible, any other group of constituents in the composition of the registered substance.

For each constituent and group of constituents, the minimum, maximum and typical concentration shall be reported.
In line with the above, the Registrant is requested to provide any information which is suitable and necessary to allow ECHA to establish and verify the composition and the name of the registered substance.

Regarding how to report the composition of the registered substance in IUCLID, the following applies: The Registrant should report 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.[1]

The Registrant shall ensure that the information provided on the composition of the substance is verifiable and therefore confirmed by the qualitative and quantitative analytical data included in section 1.4 of the IUCLID dossier, as required under Annex VI section 2.3.7. The description of the analytical methods used for the identification and quantification of the constituents and groups of constituents required to be reported shall be sufficient for these methods to be reproduced. The description shall therefore include details of the experimental protocol followed, any calculation made and the 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://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

[1] http://echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it/registration