~~CONFIDENTIAL~~

European Chemicals Agency

Decision number: CCH-D-0000001668-65-04/F Helsinki, 10 November 2011

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

For [redacted], Alkenes, C7-9, hydroformylation products, distn. residues, heavy cracked fraction, CAS 98072-31-2 (EC No 308-482-7), 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 [redacted] **Alkenes, C7-9, hydroformylation products, distn. residues, heavy cracked fraction, CAS 98072-31-2 (EC No 308-482-7)** submitted by [redacted] (Registrant), latest submission number [redacted], for > 1000 tonnes per year.

The compliance check was initiated on 8 April 2011.

On 31 May 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 28 June 2011 the Registrant provided comments on the draft decision. ECHA has considered the comments, and amended point II.d. of the draft decision accordingly.

On 29 July 2011 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. 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 name or other identifiers for the substance (Annex VI, 2.1.). The Registrant shall provide sufficient information on the reference substance to enable the substance identity to be determined;
b. The composition of the substance (Annex VI, 2.3.). Any information which is suitable and necessary to allow ECHA to establish and verify the composition and name of the registered substance, as specified under point III: 1.b below;
c. The spectral data (Annex VI, 2.3.5.); ultra-violet (UV) and nuclear magnetic resonance (NMR) spectra. As an alternative to the NMR spectrum, a mass spectroscopic analysis of the registered substance can be provided;
d. Gas chromatogram (GC) (Annex VI, 2.3.6). As an alternative to a GC, a Gas chromagraphy-mass spectrometry (GC-MS) analysis can be provided. In any case, the chromatogram shall be sufficient to enable the constituents to be quantified;
e. The description of the analytical methods or the appropriate bibliographical references for the identification of the substance (Annex VI, 2.3.7.). The information shall be sufficient for each method to be reproduced, and shall therefore include details of the experimental protocol followed, the calculation used and the results obtained.

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 January 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 per year in accordance with Article 6 of the REACH Regulation, does not comply with the requirements of Article 10 and 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 identifiers (Annex VI, 2.1.):

The identity or composition of the substance cannot be ascertained based on the information included in the dossier. The included identifiers, EC and CAS names and numbers are not sufficient to enable the substance to be identified, because the names included are based only on the names of the reactants and the process used. In general, the naming of a UVCB substance has two parts: the chemical name which should be entered in the IUPAC name field and the more detailed description of the manufacturing process which should be included in the description field. The description should include the chemical identity of the starting materials used, the ratio of the starting materials, the chemical process and the process parameters. The Registrant is therefore requested to provide a name in the IUAPC field that enables the identity of the substance to be determined and a description of the manufacturing process that shall be sufficient to enable the substance to be identified. This shall include the chemical identity of the starting materials used, the ratio of the starting materials, the chemical process and the process parameters.

(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, section 1.2 of the technical dossier describes the composition of the substance as [redacted] of the reference substance "Alkenes, C7-9, hydroformylation products, distn. residues, heavy cracked fraction", with no additional information on the composition of the substance.

Following section 4.3 of the Guidance for identification and naming of substances under REACH
http://guidance.echa.europa.eu/docs/guidance_document/substance_id_en.pdf,
the Registrant should note that for UVCB substances (substances of Unknown, or Variable Composition, or of Biological origin) 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 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.

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), the carbon number range, 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 at:
http://echa.europa.eu/doc/reachit/dsm18/substance_id_report_iuclid_en.pdf

(c) Spectral data: Annex VI (2.3.5.)

ECHA points out that the dossier contains the results of an infra-red (IR) spectrum, but the technical dossier contains no ultra-violet (UV) or nuclear magnetic resonance (NMR) spectra, and no justification for their omission. Therefore, the Registrant is requested to submit an UV spectrum and an 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 spectra should be attached in IUCLID section 1.4.

(d) Gas Chromatogram Annex VI (2.3.6):

The registration contains a GC of the registered substance. However, the chromatogram does not enable the composition of the substance to be quantified. The chromatogram contains no identification of the peaks or their relative concentrations. Therefore the Registrant is requested to provide a chromatogram that includes information on the identity and concentrations of the substance's constituents. As an alternative to the GC, a GC-MS analysis can be provided. In any case, the chromatogram shall be consistent with the information on the composition of the substance, as described in section 1.2 of the technical dossier.

(e) The description of the analytical methods or the appropriate bibliographical references for the identification of the substance (Annex VI, 2.3.7.)

ECHA observes that the registration does not contain sufficient details of the analytical methods to identify the registered substance, including its composition, as required by Annex VI, Section 2.3.7 of the REACH Regulation. The description of the gas chromatographic method included in the dossier does not include any information on

how the substance composition may be quantified using this method. Therefore, ECHA concludes the provided information is not sufficient to identify the substance, including its composition.

Accordingly, in line with Annex VI, 2.3.7, the Registrant is requested to submit the description of the missing analytical methods, or the appropriate bibliographical references, to identify the registered substance, including its composition. The information shall be sufficient for each method to be reproduced and shall therefore include details of the experimental protocol followed, the calculation used and the result obtained.

As for the reporting of the above 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.

Done at Helsinki,

Jukka Malm
Director of Regulatory Affairs