EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000002053-87-04/F Helsinki, 11 April 2012

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

For Naphtenic acids, CAS No 1338-24-5 (EC No 215-662-8), 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 Naphtenic acids, CAS No. 1338-24-5 (EC No. 215-662-8), submitted by [redacted] (Registrant), latest submission number [redacted], for 100 - 1000 tonnes per year.

The compliance check was initiated on 28 October 2011.

On 4 November 2011 ECHA sent a draft decision to the Registrant for comments.

The Registrant did not provide any comments on the draft decision.

On 20 January 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. 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. The name or other identifier of each substance (Annex VI, 2.1).
   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;

c. The spectral data (Annex VI, 2.3.5.): ultraviolet (UV), and nuclear magnetic resonance, such as a ^{1}H-NMR. As an alternative to the NMR spectrum, a mass spectroscopic analysis of the registered substance can be provided; and
d. The description of the analytical methods (Annex VI, 2.3.7.): description of the 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.

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 **11 June 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 100 to 1000 tonnes per year in accordance with Article 6 of the REACH Regulation 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.

1) 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 each substance (Annex VI, 2.1)

ECHA notes that the Registrant provided a chemical name indicating that the registered substance corresponds to Naphthenic acids. However, further information is required to appropriately identify the registered substance, in line with Annex VI, section 2.1 of the REACH Regulation. More specifically, the naming of a UVCB substance such as the registered substance consists of two parts: the chemical name and the more detailed description of the manufacturing process. ECHA observes that details of the process circumstances under which Naphthenic acids are produced have not been sufficiently described. In particular, more information shall be provided clarifying which refining steps are performed to recover and/or purify the substance and which distillation fraction is intended to be registered.

Accordingly, the Registrant is requested to provide details of the process used for the manufacturing of the registered substance.

Regarding how to report the description of the UVCB substance, the information shall be included in the Description field in section 1.1 of the IUCLID dossier.

(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 IUCLID dossier does not provide sufficient information on the identity and concentration of the different constituents or groups of constituents such as highly branched alkyl-substituted acyclic and cycloaliphatic carboxylic acids which the substance consists of. For each group of constituents, information on the carbon number range is also needed in order to set the limits of the constituents covered.

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, 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 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.

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) The spectral data (Annex VI, 2.3.5.):

ECHA points out that the registration dossier contains neither a UV spectrum nor nuclear magnetic resonance (NMR) spectral data, which are required according to Annex VI, Section 2.3.5 of the REACH Regulation to support the indicated substance identity. Therefore, the Registrant is requested to submit a UV spectrum and an NMR. If it is not technically possible or if it does not appear scientifically necessary to give information on one or more of these items, a scientifically based justification should be given in Section 1.4 of the substance dataset in the analytical methods and spectral data field.

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

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

The analytical results provided are not sufficient to establish and verify the composition of the substance (e.g. no information is provided on the analytical method used to confirm the presence of branched alkyl carbon chains). The Registrant provides the results of a GC-FID and a GC-MS analyses; however a description of the experimental protocol is missing for both. Therefore the information provided is not sufficient to have the necessary overview of the composition of the registered UVCB substance for its identification.

Accordingly, in line with Annex VI, 2.3.7, the Registrant is requested to submit descriptions of the analytical methods, which are sufficient to confirm the composition of the registered substance. The description should be given in such detail that the methods can be reproduced. Such information should include a detailed experimental protocol.

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.

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