Final decision: CCH-D-0000002158-75-03/F Helsinki, 29 March 2012

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

For Fatty acids C18 unsat, reaction products with polyethylene amines, CAS No. [redacted] (EC No. 629-742-9), 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 dossier Fatty acids C18 unsat, reaction products with polyethylene amines, CAS No. [redacted] (EC No. 629-742-9), submitted by [redacted] (Registrant), latest submission number [redacted], for 100 to 1000 tonnes per year.

The compliance check was initiated on 25 November 2011.

On 2 December 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 21 December 2011 the Registrant provided to ECHA comments on the draft decision. ECHA considered the information received and amended the draft decision accordingly.

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. Name(s) in the IUPAC nomenclature or other identifiers (Annex VI Section 2.1. of the REACH Regulation). Any information which is suitable and necessary to allow ECHA to identify the name of the registered substance as specified under section III a) below;
b. Composition of the registered substance (Annex VI Section 2.3. of the REACH Regulation). 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 b) below;
c. Chromatogram (Annex VI, 2.3.6), as specified under section III c) below; and
d. 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, as specified under section III d) 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 29 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 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, IX to 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.

a) Name(s) in the IUPAC nomenclature or other identifiers (Annex VI Section 2.1. of the REACH Regulation)

The name and other identifiers are used to identify the substance in an unambiguous manner and are therefore essential parts of substance identification and the corner stone of all the REACH obligations.

ECHA notes that the Registrant provided a chemical name for the registered substance that corresponds to Fatty acids C18 unsat, reaction products with polyethylene amines. 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. A generic description of the manufacturing process has been included in the registration dossier; however the identity of the specific starting material used for its manufacturing requires further clarification. The Registrant shall note that "polyethylene amines" does not refer to one specific substance but corresponds to a generic chemical name potentially covering several substances under REACH.

Accordingly, the Registrant is requested to provide details of the process used for the manufacturing of the registered substance. The description shall include the chemical identity of the starting materials used, the ratio of the starting materials, the chemical process(es) involved and the corresponding process parameters.

The Registrant can find further indication in 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

Regarding how to report the name and other identifiers of the registered substance in IUCLID, the following applies:
The Registrant should report the chemical (generic) name of the registered substance in the IUPAC name field of IUCLID section 1.1 and give detailed description of the starting material and of the manufacturing process in writing in the description field.

b) Composition of the registered substance (Annex VI Section 2.3. of the REACH Regulation)

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 dossier 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 manufacturing process indicates that the substance is obtained from polyethylene amines and fatty acids. 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 constituents deriving from different polyethylene amines has not been made in the composition.

The composition information in the registration dossier, in fact, indicates two groups of constituents both including products obtained from pentaethylenehexamine which is a polyethylene polyamine with specific number of ethylene and amine units, and products obtained from "higher polyethylene polyamines" for which the amount of ethylene and amine units is not known. Other groups of constituents include both products obtained from triethylenetetramine and from tetraethylenepentamine with no distinction on the respective concentrations.

Furthermore, in the remarks field of the reference substance of the different groups of constituents, the Registrant refers to the presence of amidoimidazoline, diamide and dimidazoline forms in the substance. However, no information has been provided on the respective concentration of these forms.

The Registrant shall revise the information provided on the identity and concentration of the constituents reported in IUCLID section 1.2 in order to ensure that a composition that is representative of the registered substance is provided. Therefore the following information shall be included in the IUCLID dossier: the identity and relative concentration of the different reacted polyethylene amines and the respective concentration of the amidoimidazolinic, diamidic and dimidazolinic forms present in the 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. The Registrant shall report different group of constituents distinguishing between constituents deriving from different polyethylene amines and shall specify the relative amidoimidazolinic, diamidic and dimidazolinic forms. For each group of constituents, 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.

The Registrant shall ensure that the information provided on the composition of the substance is confirmed by the analytical data included in section 1.4 of the IUCLID dossier.

c) Chromatogram (Annex VI, 2.3.6 of the REACH Regulation)

ECHA recognized that a chromatogram for identifying the composition of the substance is not provided in the registration dossier.
ECHA points out that chromatographic data are a standard requirement of Annex VI, Section 2.3.6.

Accordingly, in line with Annex VI, 2.3.6, the Registrant is requested to submit a chromatogram. The chromatogram is requested to be recorded in such way that the individual constituents are separated, identified and quantified. Similar constituents might be grouped if it is not possible to identify individual constituents.

As for the reporting of the chromatogram in the registration dossier, the chromatogram should be attached in IUCLID section 1.4. Furthermore, as specified in point b), the results should be used to report the composition of the registered substance in IUCLID section 1.2.

d) Description of the analytical methods (Annex VI Section 2.3.7. of the REACH Regulation)

ECHA notes that the registration dossier does not include enough information on the description of the analytical methods used for the identification and quantification of the constituents and groups of constituents present in the substance, as required according to Annex VI Section 2.3.7 of the REACH Regulation.

The Registrant provided the result of the analysis of the ratio between the amidic and the imidazolinic forms present in the substance. The information given, however is not sufficient to confirm the identity and composition of the substance. The analytical methods used for the quantification of the groups of constituents present in the substance and specified in the composition information have not been provided.

The Registrant shall provide the complete description of the analytical methods and results thereof used to identify and quantify the constituents and groups of constituents required to be reported in the composition. The information shall be sufficient for the methods to be reproduced and shall therefore include complete details of the experimental protocol followed, the calculation used and the results obtained.

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

IV. General requirements for the generation of information and Good Laboratory Practice

ECHA always reminds registrants of the requirements of Article 13(4) of the REACH Regulation that ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice (GLP). National authorities monitoring GLP maintain lists of test facilities indicating the relevant areas of expertise of each facility.

According to Article 13(3) of the REACH Regulation, tests that are required to generate information on intrinsic properties of substances shall be conducted in accordance with the test methods laid down in a Commission Regulation or in accordance with other international test methods recognised by the Commission or the European Chemicals Agency as being appropriate. Thus, the Registrant shall refer to Commission Regulation (EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 as adapted to technical progress or to other international test methods recognised as being appropriate and use the applicable test methods to generate the information on the endpoints indicated above.

V. 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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Director of Regulatory Affairs