~~CONFIDENTIAL~~

European Chemicals Agency

Decision number: CCH-D-0000001714-76-03/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 Ethanol, 2-amino-, reaction products with ammonia, by-products from, CAS 68910-05-4 (EC No 272-729-4), 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 **Ethanol, 2-amino-, reaction products with ammonia, by-products from, CAS 68910-05-4 (EC No 272-729-4)** submitted by [redacted] (Registrant), latest submission number [redacted], for a transported isolated intermediate for > 1000 tonnes per year.

The compliance check was initiated on 29 April 2011.

On 8 June 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 5 July the Registrant provided to ECHA comments on the draft decision. ECHA considered the Registrant's comments and did not amend the draft decision.

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

1) Pursuant to Articles 41(1)(a), 41(3), and 18(2)(b) 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;

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 for a transported isolated intermediate in accordance with **Articles 6 and 18** of the REACH Regulation, does not comply with the requirements of Article **18 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.

1) Missing information related to substance identity

Pursuant to Article 18(2)(b) 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 point 2.1. of the REACH Regulation):

The Registrant has not specified IUPAC name or a description specific to his manufacturing process. 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 determined and a description of the manufacturing process that shall be sufficient to enable the substance to be

identified. This shall include chemical identity of the starting materials used, the ratio of the starting materials, the chemical process and the process parameters.

(b) Composition of the substance (Annex VI point 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 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 has included in section 1.2 of the registration dossier a constituent named "non-specified impurities". However as this constituent can be in a concentration of up to [redacted] a better identification is required. Based on the gas chromatogram included in section 1.4 of the registration dossier it can be seen that there are a multitude of peaks that are not identified which are assumed to be covered by this generic constituent. Some of these peaks appear quite large and well resolved indicating they may represent a single well-defined constituent. As a consequence this generic constituent "non-specified impurities" needs to be better defined. In particular, the peaks in the gas chromatogram to which it is linked to should be identified and included in the remarks field of reference substance specifying also their individual percentage area. Furthermore a more specific identity should be provided for this "non-specified impurities" as the gas chromatogram indicates they are polymeric in nature, as such a generic structure should be provided. In case where any peak in the GC represents a percentage area greater than 10 then the peak should be specifically identified and a separate reference should be created for this constituent and included in section 1.2

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.

## 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 reads:

> "Ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice provided for in Directive 2004/10/EC or other international standards recognised as being equivalent by the Commission or the Agency and with the provisions of Directive 86/609/EEC, if applicable."

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 and use the applicable test methods to generate the information on the endpoints indicated above.

National authorities monitoring good laboratory practice (GLP) maintain lists of test facilities indicating the relevant areas of expertise of each facility.

## 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.

Done at Helsinki,

[redacted]

Jukka Malm
Director of Regulatory Affairs