Decision number: CCH-D-2114289263-44-01/F Helsinki, 25 November 2014

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

**For Ethanol, 2,2'-iminobis-, N-(C13-15-branched and linear alkyl) derivs., CAS No 97925-95-6 (EC No 308-208-6), 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 for Ethanol, 2,2'-iminobis-, N-(C13-15-branched and linear alkyl) derivs., CAS No 97925-95-6 (EC No 308-208-6), submitted by [redacted] (Registrant). The scope of this compliance check decision is limited to the standard information requirements of Annex VII, Section 7.8. of the REACH Regulation. ECHA stresses that it has not checked the information provided by the Registrant for compliance with requirements regarding the identification of the substance (Section 2 of Annex VI).

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band of 1000 tonnes or more per year. This decision does not take into account any updates submitted after 4 September 2014, the date upon which ECHA notified its draft decision to the Competent Authorities of the Member States pursuant to Article 51(1) of the REACH Regulation.

This compliance check decision does not prevent ECHA from initiating further compliance checks on the present registration at a later stage.

The compliance check was initiated on 27 March 2014.

On 20 June 2014 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision.

On 15 July 2014 ECHA received comments from the Registrant agreeing to ECHA's draft decision.

The ECHA Secretariat considered the Registrant's comments. The information is reflected in the Statement of Reasons (Section III) whereas no amendments to the Information Required (Section II) were made.

On 4 September 2014 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 for amendment of the draft decision within 30 days of the receipt of the notification.

As no proposal for amendment was submitted, ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

II. Information required

Pursuant to Articles 41(1), 41(3), 10(a)(vi) and/or (vii), 12(1)(e), 13 and Annex VII of the REACH Regulation the Registrant shall submit the following information for the registered substance subject to the present decision:

- a calculated value for log P as well as details of the calculation method (Column 2 of Annex VII, 7.8.)

Pursuant to Articles 41(4) and 22(2) of the REACH Regulation the Registrant shall submit the information required by this decision in the form of an updated registration to ECHA by **4 March 2015**.

III. Statement of reasons

Pursuant to Article 41(3) of the REACH Regulation, ECHA may require the Registrant to submit any information needed to bring the registration into compliance with the relevant information requirements.

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(e) of the REACH Regulation, a technical dossier for a substance manufactured or imported by the Registrant in quantities of 1000 tonnes or more per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation.

"Partition coefficient n-octanol/water" is a standard information requirement as laid down in Annex VII, Section 7.8. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

The Registrant has sought to adapt the information requirement of Annex VII, Section 7.8. of the REACH Regulation by means of providing results from a (Q)SAR. In accordance with Section 1.3. of Annex XI the conditions for this adaptation are the following:

1. results are derived from a (Q)SAR model whose scientific validity has been established,
2. the substance falls within the applicability domain of the (Q)SAR model,
3. results are adequate for the purpose of classification and labelling and/or risk assessment, and
4. adequate and reliable documentation of the applied method is provided.

ECHA points out that the Registrant has failed to explain if the substance falls within the applicability domain of the (Q)SAR model, if the results are adequate for the purpose of classification and labelling and/or risk assessment and the Registrant has not provided adequate and reliable documentation of the applied method. Therefore the adaptation based on Annex XI, Section 1.3 of the REACH Regulation cannot be accepted. Guidance on how to report (Q)SAR studies is available in ECHA's Guidance on information requirements and chemical safety assessment, Chapter R.6, section R.6.1. (pages 9-66, Version of May 2008) and in ECHA's Practical Guide 5: How to report (Q)SARs.

The Registrant has justified in his registration dossier that the test required by column 1 of Annex VII, Section 7.8. cannot be performed on the registered substance. In accordance with Column 2 of Section 7.8. of the REACH Regulation, in such cases a calculated value for Log Kow as well as details of the calculation method shall be provided.

In his comments, following the procedure set out in Article 50(1) of the REACH Regulation, the Registrant indicated his agreement to perform the test requested and his intention to submit an updated dossier containing this information by 30 September 2014.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit a calculated value for partition coefficient n-octanol/water derived with the registered substance subject to the present decision. Results derived from a (Q)SAR constitute a calculated value, if the requirements under Annex XI, Section 1.3 are fulfilled.

IV. Adequate identification of the composition of the tested material

ECHA stresses that the information submitted for identifying the substance has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation. The Registrant is reminded of his responsibility to ensure that his registration covers one substance only and that the substance is correctly identified in accordance with Annex VI, Section 2 of the REACH Regulation.

In carrying out the study required by the present decision it is important to ensure that the substance modelled is appropriate to assess the properties of the registered substance, taking into account any variation in the composition of the technical grade of the substance as actually manufactured. If the registration of the substance covers different grades, the substance used for the new study must be suitable to assess these.

Furthermore, there must be adequate information on substance identity for the substance modelled and the grade(s) registered to enable the relevance of the study to be assessed.

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://www.echa.europa.eu/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

[redacted]

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