EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000003523-79-03/F Helsinki, 29 October 2013

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

For dilactide, CAS No 95-96-5 (EC No 202-468-3), 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 dilactide, CAS No 95-96-5 (EC No 202-468-3), submitted by [redacted] (Registrant). The scope of this compliance check is limited to the standard information requirement of Annex VII, Section 7.8. of the REACH Regulation.

This decision is based on the registration dossier as submitted with submission number [redacted], for the tonnage band of 1 to 10 tonnes per year. This decision does not take into account any updates after 1 August 2013, 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 dossier at a later stage.

The compliance check was initiated on 6 March 2013.

On 13 May 2013 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision.

By 12 June 2013 the Registrant did not provide any comments on the draft decision to ECHA.

On 1 August 2013 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 of the receipt of the notification.

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.

II. Information required

Pursuant to Articles 41(1)(a), 41(3), 10(a)(vi), 12(1), 13 and Annex VII of the REACH Regulation the Registrant shall submit the following information for the registered substance subject to the present decision using an appropriate test method:

- partition coefficient n-octanol/water (Annex VII, 7.8.).

Guidance for determining appropriate test methods for the partition coefficient n-octanol/water is available in ECHA's Guidance on information requirements and chemical safety assessment, Chapter R.7(a), section R.7.1.8.3. (pages 101 to 103, Version of May 2008).

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 April 2014**.

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 requirement. The scope of the present decision is the partition coefficient n-octanol/water (Section 7.8. of Annex VII of the REACH Regulation). In accordance with Articles 10(a)(vi) and 12(1) of the REACH Regulation, any registration for a substance shall contain this information.

The technical dossier contains data for this standard information requirement, which according to the information provided by the Registrant meets Klimisch criterion 4 only and is therefore not assignable. The Klimisch criterion is a system to assess the reliability of data as laid out in the Guidance on information requirements and chemical safety assessment Chapter R.4: Evaluation of available information, Section R.4.2. (Version of December 2011).

The Registrant has further 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:

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

ECHA points out that the fulfilment of the above conditions has not been demonstrated. The Registrant did not provide the adequate and reliable documentation of the applied model referred to under the fourth bullet point above. Without such documentation ECHA is not in a position to assess whether the other conditions outlined in the first three bullet points are fulfilled. As the Registrant has not demonstrated that the conditions of the adaptation of Annex XI, Section 1.3. of the REACH Regulation are fulfilled, 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.

ECHA concludes that the Registrant has not provided any reliable information and has therefore not fulfilled the standard information requirement of Section 7.8. of Annex VII of the REACH Regulation. He has neither adequately justified an adaptation to the standard information requirement.

The Registrant is therefore requested to determine the partition coefficient n-octanol/water using an appropriate test method on the registered substance and to submit the resulting data.

IV. Adequate identification of the composition of the tested material

ECHA stresses that the information submitted by the Registrant and by other joint registrants 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.

In relation to the information required by the present decision, the sample of substance used for the new study must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is within the specifications of the substance composition that are given by the joint registrants. It is the responsibility of all joint registrants who manufacture or import the same substance to agree on the appropriate composition of the test material and to document the necessary information on their substance composition.

In addition, it is important to ensure that the particular sample of substance tested in the new study 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 by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new study must be suitable to assess these grades.

Finally there must be adequate information on substance identity for the sample tested and the grades 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://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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Jukka Malm
Director of Regulatory Affairs