

Decision number: CCH-D-0000002079-73-10/F

Helsinki, 16 September 2014

DECISION ON A COMPLIANCE CHECK OF A REGISTRATION PURSUANT TO ARTICLE 41(3) OF REGULATION (EC) NO 1907/2006**For 2-butyl-2-ethylpropanediol, CAS No 115-84-4 (EC No 204-111-7), 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 2-butyl-2-ethylpropanediol, CAS No 115-84-4 (EC No 204-111-7), submitted by [REDACTED] (Registrant). The scope of this compliance check is limited to the standard information requirement of Annex VII, Section 7.5 of the REACH Regulation. ECHA stresses that it has not checked the information provided by the Registrant and other joint registrants 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 12 June 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 29 October 2013.

On 31 March 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.

By 30 April 2014 the Registrant did not provide any comments on the draft decision to ECHA.

On 12 June 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)(vii), 12(1)(e), 13 and Annexes VII of the REACH Regulation the Registrant shall submit the following information using the indicated test methods and the registered substance subject to the present decision:

Vapour pressure (Annex VII, 7.5.; test method: EU A.4./OECD 104).

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated registration to ECHA by **23 March 2015**.

Note for consideration by the Registrant:

The Registrant may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI of the REACH Regulation. In order to ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring to and conforming with the appropriate rules in the respective Annex, and an adequate and reliable documentation.

Failure to comply with the request(s) in this decision, or to fulfil otherwise the information requirement(s) with a valid and documented adaptation, will result in a notification to the Enforcement Authorities of the Member States.

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.

In accordance with Articles 10(a)(vii) and 12(1) of the REACH Regulation, any registration for a substance manufactured or imported in quantities of 10 tonne or more per year per manufacturer/importer shall contain this information on the vapour pressure. This is a standard information requirement as laid down in Annex VII, Section 7.5. of the REACH Regulation.

The technical dossier does not contain relevant data to fulfil this information requirement. Instead, the Registrant sought to adapt the information requirement of Annex VII, Section 7.5. of the REACH Regulation by means of providing results from two quantitative structure-activity relationship models ((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 that the Registrant has failed to explain in the technical dossier 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 methods.

Therefore, the requirements for a general adaptation to the standard testing regime based on Annex XI, section 1.3. of the REACH Regulation were not met and the registration dossier is non compliant with the information requirement of vapour pressure. 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.

Therefore, the Registrant is requested to carry out a study on the vapour pressure using the appropriate test method and the registered substance and to submit the resulting information.

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 particular sample of substance tested 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 sample used for the new study must be suitable to assess these.

Furthermore, there must be adequate information on substance identity for the sample tested 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://echa.europa.eu/regulations/appeals>. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.



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