ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000003450-84-02/F Helsinki, 16 August 2013

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

For 2-methylbutane, CAS No 78-78-4 (EC No 201-142-8), 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 2-methylbutane, CAS No 78-78-4 (EC No 201-142-8), 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. 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 dossier as submitted with submission number [redacted], for the tonnage band of 100-1000 tonnes per year. This decision does not take into account any updates after 20 June 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 11 September 2012.

On 19 December 2012 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 3 January 2013 ECHA received comments from the Registrant indicating that he has additional information for the requested endpoint.

On 22 January 2013 the Registrant updated his registration dossier.

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

On 20 June 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)(d), 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 (pages 54 to 61, Version of November 2012).

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 **17 February 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 proposed read-across substances for this standard information requirement. According to the information provided by the Registrant the data for these substances are handbook values. As no robust study summary was provided, even for the proposed read-across substances the data neither fulfils the standard information requirement nor the conditions for adapting it in accordance with Section 1.1.1. of Annex XI. As the data is insufficient even for the proposed read-across substances, ECHA does not need to assess whether the read-across adaptation has been justified by the Registrant. ECHA highlights that if the Registrant sought to build a weight of evidence adaptation for the standard information requirement, he would have had to provide a justification why the data from the studies constitute sufficient weight of evidence for concluding on the partition coefficient n-octanol water (Section 1.2. of Annex XI of the REACH Regulation). The Registrant is therefore requested to determine the partition coefficient n-octanol/water using an appropriate test method on the registered substance.

The Registrant updated the registration dossier on 22 January 2013. In the updated dossier the Registrant withdrew the read-across approach and provided a calculated value (QSAR) from an OECD SIDS report. ECHA points out, that if QSAR predictions are used to adapt the standard information requirements under the REACH Regulation, the REACH Annex XI, section 1.3. requirements have to be fulfilled. Specifically, the Registrant has not proved that the substance falls within the applicability domain of the (Q)SAR model, that the results are adequate for the purpose of classification and labelling and/or risk assessment, and he has not provided adequate and reliable documentation of the applied method.

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 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. General requirements for the generation of information

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.

VI. 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