

Decision number: CCH-D-0000004814-71-02/F

Helsinki, 30 June 2014

DECISION ON A COMPLIANCE CHECK OF A REGISTRATION PURSUANT TO ARTICLE 41(3) OF REGULATION (EC) NO 1907/2006**For tert-butyl methacrylate, CAS No 585-07-9 (EC No 209-548-7), 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 tert-butyl methacrylate, CAS No 585-07-9 (EC No 209-548-7), submitted by [REDACTED] (Registrant). The scope of this compliance check is limited to the standard information requirement of Annex VIII, Section 9.2.2.1. 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 6 March 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 30 July 2013.

On 30 September 2013, ECHA sent a draft decision based on submission number [REDACTED] to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision.

On 29 October 2013, ECHA received comments from the Registrant and on 29 October 2013, ECHA received an update of the registration dossier (submission number [REDACTED]).

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

On 6 March 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 Annex VIII of the REACH Regulation the Registrant shall submit the following information using the indicated test method and the substance subject to the present decision:

Hydrolysis as a function of pH (Annex VIII, 9.2.2.1.; test method: Hydrolysis as a function of pH, EU C.7/OECD 111).

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 **7 January 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.

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 tonnes or more per year per manufacturer/importer shall contain information on hydrolysis as a function of pH. This is a standard information requirement as laid down in Annex VIII, Section 9.2.2.1. of the REACH Regulation.

The Registrant has not submitted information on hydrolysis as a function of pH in the technical dossier. Instead, the Registrant sought to adapt the information requirement of Annex VIII, Section 9.2.2.1. of the REACH Regulation according to column 2 "*The study does not need to be conducted if: — the substance is readily biodegradable.*" However, the information submitted in the dossier indicates that the substance is only "moderately" biodegradable. The adaptation according Annex VIII, Section 9.2.2.1. column 2 therefore fails.

Furthermore, the Registrant sought to adapt the standard testing scheme by means of providing results from a qualitative or quantitative structure–activity relationship model ((Q)SAR). In accordance with Annex XI, section 1.3. of the REACH Regulation, 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.

In the updated technical dossier (submission number [REDACTED]), evidence for the scientific validity of the QSAR model and the applicability of the model to the substance subject to this decision has been provided. However, the predicted values provided cover only the pH-range of 7-8 and do not indicate any hydrolysis products. The relevant test method EU C.7/OECD 111 requires the determination of hydrolysis rates at pH 4, 7 and 9 as well as the identification of relevant hydrolysis products. Without knowledge of the hydrolysis rate at environmentally relevant pH and the identity of the relevant hydrolysis products the chemical risk assessments cannot be completed. Accordingly, the submitted data do not fulfill the condition to be adequate for the purpose of risk assessment.

In his comments submitted to ECHA according Article 50(1), the Registrant has indicated the existence of supporting information on analogue substances. However, this information needs to be available in the dossier in order to contribute to fulfill the information requirement.

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 Hydrolysis as function of pH.

Therefore, the Registrant is requested to provide information on the hydrolysis as a function of pH 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 by the Registrant and 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. The Registrant is reminded of his responsibility and that of joint registrants to ensure that the joint registration covers one substance only and that the substance is correctly identified in accordance with Annex VI, Section 2 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 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.



Leena Ylä-Mononen
Director of Evaluation