

Final decision: CCH-D-0000002653-75-03/F

Helsinki, 29 January 2013

DECISION ON A COMPLIANCE CHECK OF A REGISTRATION PURSUANT TO ARTICLE 41(3) OF REGULATION (EC) NO 1907/2006**For 2-acrylamido-2-methylpropanesulphonic acid, CAS No 15214-89-8 (EC No 239-268-0), 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-acrylamido-2-methylpropanesulphonic acid, CAS No 15214-89-8 (EC No 239-268-0) submitted by [REDACTED] (Registrant). The scope of the present decision is limited to obligation to submit a CSR pursuant to Article 14 and Annex I of the REACH Regulation.

This decision is based on the registration dossier 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 after 2 November 2012, 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 to initiate further compliance checks on the present dossier at a later stage.

The compliance check was initiated on 2 May 2012.

On 31 July 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.

By 30 August 2012 the Registrant did not provide any comments on the draft decision to ECHA.

On 2 November 2012 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) (c), 41(3), 10(b), 14 and Annex I of the REACH Regulation the Registrant shall submit the following information:

- a chemical safety report ("CSR") for the registered substance.

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the required CSR in the form of an updated IUCLID dossier to ECHA by **29 April 2013**.

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.

Pursuant to Article 10(b) of the REACH Regulation, the registration shall include a CSR when required under Article 14, in the format specified in Annex I to the REACH Regulation. Furthermore, pursuant to Article 14 of the REACH Regulation, a chemical safety assessment shall be performed and a chemical safety report completed for all substances subject to registration in accordance with Title II, Chapter 1 of the REACH Regulation in quantities of 10 tonnes or more per year per registrant.

The registration dossier does not contain the CSR and does not provide a valid justification why the CSR is missing pursuant to Article 14 (2) of the REACH Regulation. The justification of the Registrant for omitting the CSR is "Substance is not classified. A CSR is not required."

In accordance with Article 14 (4) of the REACH Regulation a chemical safety report has to be submitted regardless whether the registered substance meets the criteria for any of the hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008. Article 14 (4) also further lays down the conditions for additional steps of exposure assessment and risk characterisation.

The Registrant is therefore requested to submit the appropriate chemical safety report for the registered substance.

When documenting the outcome of the chemical safety assessment, the Registrant may use the recent version of the Chemical Safety Assessment and Reporting tool (Chesar, version 1.2), designed to help registrants to carry out their chemical safety assessments and preparing their CSR, available at <http://chesar.echa.europa.eu/>.

Regarding how to write a CSR or submit a CSR further information is provided in Guidance on information requirements and chemical safety assessment Part F. Chemical Safety Report, version 2, July 2008.

IV. 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.



Jukka Malm
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