EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114292211-58-01/F Helsinki, 23 February 2015

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

For 2,4,6-tris(dimethylaminomethyl)phenol, CAS No 90-72-2 (EC No 202-013-9), 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 2,4,6-tris(dimethylaminomethyl)phenol, CAS No 90-72-2 (EC No 202-013-9), submitted by [redacted] (Registrant).

The scope of this compliance check is limited to the standard information requirement of Annex IX, Section 7.16. 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 30 October 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 23 April 2014.

On 28 July 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 3 September 2014 the Registrant did not provide any comments on the draft decision to ECHA.

On 30 October 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)(vi) and/or (vii), 12(1)(e), 13 and Annex IX of the REACH Regulation the Registrant shall submit the following information using the indicated test method and the registered substance subject to the present decision:

- Dissociation constant (Annex IX, section 7.16.; test method: OECD 112).

Pursuant to Articles 41(4) and 22(2) of the REACH Regulation the Registrant shall submit the information required by this decision in the form of an updated registration to ECHA by **31 August 2015**.

III. Statement of reasons

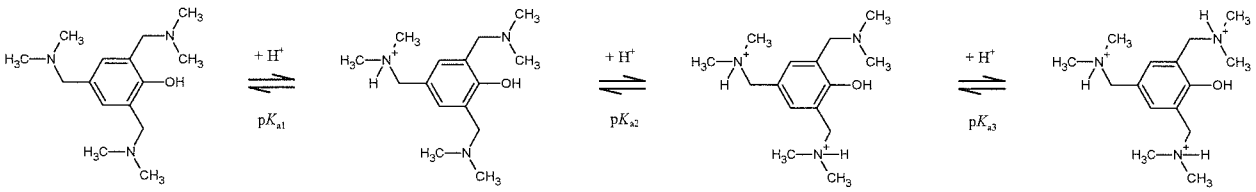
Pursuant to Article 41(3) of the REACH Regulation, ECHA may require the Registrant to submit any information needed to bring the registration into compliance with the relevant information requirements.

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(e) of the REACH Regulation, a technical dossier for a substance manufactured or imported by the Registrant in quantities of 1000 tonnes or more per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation.

"Dissociation constant" is a standard information requirement as laid down in Annex IX, Section 7.16. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

The technical dossier includes one study result for the endpoint dissociation constant (pK_a), with reliability 2 (reliable with restrictions). The estimated acid dissociation constants (pK_{a1} and pK_{a2}) for the first and second ionizable protons are 9.43 and 10.53, respectively.

However, there may be more than two dissociation events relevant for risk assessment for which dissociation constants need to be reported. Specifically, all events shown below may be relevant: the event between the neutral species and the singly-protonated (pK_{a1}); the event between the singly-protonated species and the doubly-protonated (pK_{a2}) and the event between the doubly-protonated species and the triply-protonated (pK_{a3}).



Therefore, in the technical dossier, not all dissociation events relevant for risk assessment have been accounted for. As the OECD Guideline 112 indicates in the 'Principle of the test method' section "Some compounds exhibit more than one dissociation constant". However, the Registrant has not provided any justification why all relevant dissociation events have not been reported.

As explained above, the information available on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint. Specifically: pK_a values for all dissociation events relevant for risk assessment need to be reported; or a reason, substantiated with evidence such as predicted pK_a values, needs to be provided on why the dissociation events not accounted for are not relevant for risk assessment. The reporting of raw data and calculated pK_a values is specified in the test guideline OECD 112 (dissociation constants in water).

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision: Dissociation constants in water (test method: OECD 112).

IV. Adequate identification of the composition of the tested material

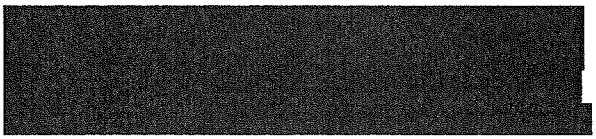
ECHA stresses that the information submitted by the Registrant and other joint registrants for identifying the substance has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation. The Registrant is reminded of his responsibility 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 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.



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