

Decision number: CCH-D-2114306526-54-01/F

Helsinki, 30 July 2015

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

For itaconic acid, CAS No 97-65-4 (EC No 202-599-6), 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 itaconic acid, CAS No 97-65-4 (EC No 202-599-6) submitted [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 the deadline for updating (3 April 2015) communicated to the Registrant by ECHA on 25 February 2015.

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 28 May 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. That draft decision was based on submission number [REDACTED].

On 8 August 2014 ECHA received comments from the Registrant on the draft decision.

On 5 August 2014 the Registrant updated his registration dossier with the 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 11 June 2015 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

A. Information in the technical dossier derived from the application of Annexes VII to XI

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).

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.

B. Deadline for submitting the required information

Pursuant to Articles 41(4) and 22(2) of the REACH Regulation the Registrant shall submit to ECHA by **8 February 2016** an update of the registration dossier containing the information required by this decision, including, where relevant, an update of the Chemical Safety Report.

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 dissociation constant standard information requirement (Section 7.16. of Annex IX of the REACH Regulation). In accordance with Articles 10(a)(vi) and 12(1)(e) of the REACH Regulation, any registration for a substance manufactured or imported in quantities of 1000 tonnes or more per year per manufacturer shall contain this information.

The technical dossier does not contain relevant data to fulfil this information requirement. ECHA understands that the Registrant sought to adapt the information requirement pursuant to Annex IX, section 7.16., column 2, by stating that it is scientifically not possible

to perform the test. However, the Registrant did not provide a sufficient justification nor adequate documentation to explain why it would be scientifically not possible to perform the test.

ECHA considers that the component itaconic acid dissociates and that its dissociation constant value might be relevant for the chemical behaviour of the substance in environmentally relevant pH range. Therefore, the Registrant shall provide the dissociation constant values for this component.

As the waiver provided by the Registrant in the dossier with submission number [REDACTED] is not adequately justified, it cannot be regarded by ECHA as an appropriate adaptation of the standard information requirement.

ECHA notes that in their comments on the draft decision the Registrant informs to have updated Endpoint of section 7.8.1, and endpoint summary 7.8 in IUCLID dossier, and the relevant CSR part. However, although the Registration dossier has been updated, the dissociation constant related sections were not updated and the original information requirement is still not fulfilled.

The Registrant is reminded that this decision does not take into account any updates submitted after 3 April 2015. All the new information in the later update(s) of the registration dossier will however be assessed for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation.

Therefore, the Registrant is requested to carry out a study on the dissociation constant using the test method, OECD 112: Dissociation Constants in Water, on 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.

Authorised^[1] by Leena Ylä-Mononen, Director of Evaluation

^[1] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.