ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114306527-52-01/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 Reaction mass of L-xylo-hex-2-ulosonic acid and ascorbic acid, EC No 932-019-3, 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 Reaction mass of L-xylo-hex-2-ulosonic acid and ascorbic acid, EC No 932-019-3, submitted by [redacted] (Registrant).

The scope of this compliance check decision 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 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 after the deadline for updating (28 May 2015) communicated to the Registrant by ECHA on 21 April 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 22 November 2013.

On 17 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.

On 22 August 2014 ECHA received comments from the Registrant on the draft decision.

The ECHA Secretariat considered the Registrant's comments. 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 **08 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 requirements. The scope of the present decision is the dissociation constant (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 100 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 both components [redacted] are readily biodegradable and do not dissociate. However, the Registrant did not provide a sufficient justification to explain why these components do not dissociate.

ECHA considers that both components dissociate and that their dissociation constant values might be relevant for the chemical behaviour of the substance in environmentally relevant pH range.

In addition, the Registrant did not provide a study proving the fact that the substance is

hydrolytically unstable. To use Annex IX column 2 adaptation possibility, the hydrolysis half-life of the substance should be less than 12 hours.

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

In their comments the Registrant concluded that ionisable constituents of the registered substance are [redacted] Of these constituents, there are well established pKa values in the literature for all except for [redacted]. Accordingly, the Registrant suggested that the initial draft decision be revised to require an OECD 112 test only for [redacted] as testing of the other constituents would not contribute to the state of knowledge of the registered substance.

ECHA considers the Registrant's view on the dissociation constant information requirement to be reasonable for a multi-constituent substance. Information on the dissociative properties of the main constituents need to be present in the technical dossier. In this case, there is no need to measure the complex mixture as a whole and the scope of the future testing might also be limited to individual main constituents for which the information is still missing.

The Registrant is reminded that this decision does not take into account any updates submitted after 28 May 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, or provide information on dissociative properties for the main components of the registered substance separately, and to submit the resulting information.

IV. Adequate identification of the composition of the tested material

ECHA stresses that the information submitted 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 to ensure that his registration covers one substance only and that the substance is correctly identified in accordance with Annex VI, Section 2 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.

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.