EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-0000003032-90-05/F Helsinki, 29 July 2013

DECISION ON A TESTING PROPOSAL SET OUT IN A REGISTRATION PURSUANT TO ARTICLE 40(3) OF REGULATION (EC) NO 1907/2006

For 3-hydroxy-2-(hydroxymethyl)-2-methylpropionaldehyde, CAS No 18516-18-2 (EC No 242-393-3), 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 40(1) of the REACH Regulation, ECHA has examined the following testing proposals submitted as part of the registration dossier in accordance with Articles 10(a)(ix) and 12 (1)(e) thereof for 3-hydroxy-2-(hydroxymethyl)-2-methylpropionaldehyde, CAS No 18516-18-2 (EC No 242-393-3), by [redacted] (Registrant).

- Dissociation constant (OECD 112)
- Viscosity (OECD 114)
- Mammalian Erythrocyte Micronucleus Test (OECD 474)

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 18 January 2013, 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 decision does not imply that the information provided by the Registrant in his registration dossier is in compliance with the REACH requirements. The decision does not prevent ECHA from initiating a compliance check on the present dossier at a later stage.

On 21 October 2010, pursuant to Article 40(1) of the REACH Regulation, ECHA initiated the examination of the testing proposals set out by the Registrant in the registration dossier for the substance mentioned above.

ECHA held a third party consultation for the testing proposals from 16 June 2011 until 1 August 2011. ECHA did not receive information from third parties.

On 3 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.

On 2 August 2012 the Registrant updated his registration dossier and removed several of the original testing proposals. This decision addresses the testing proposals which are still present in the updated dossier. On basis of the updated dossier, the deadline in Section II was amended. The Statement of Reasons (Section III) was changed accordingly.

On 2 August 2012 ECHA received comments from the Registrant. ECHA considered only the Registrant's comments which related to testing proposals present in the updated dossier. In these comments, the Registrant agreed to ECHA's draft decision.

On 18 January 2013 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, one Competent Authority of a Member State submitted a proposal for amendment to the draft decision.

On 21 February 2013 ECHA notified the Registrant of the proposal for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on the proposal for amendment within 30 days of the receipt of the notification.

ECHA reviewed the proposal for amendment received and decided not to amend the draft decision.

On 4 March 2013 ECHA referred the draft decision to the Member State Committee.

The Registrant did not provide any comments on the proposed amendment.

After discussion in the Member State Committee on 24-25 April 2013, a unanimous agreement of the Member State Committee on the draft decision as modified at the meeting was reached on 24 April 2013. ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Testing required

The Registrant shall carry out the following proposed tests pursuant to Article 40(3)(a) and (c) of the REACH Regulation using the indicated test methods and the registered substance subject to the present decision:

1. Dissociation constant (Annex IX, 7.16.; test method: OECD 112);
2. Viscosity (Annex IX, 7.17.; test method: OECD 114), and
3. Mutagenicity (Annex IX, 8.4; test method: EU B.12/OECD 474).

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **29 July 2014** an update of the registration dossier containing the information required by this decision.

III. Statement of reasons

The decision of ECHA is based on the examination of the testing proposals submitted by the Registrant for the registered substance.

1. Dissociation constant

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test.

A dissociation constant study is a standard information requirement as laid down in Annex IX, section 7.16 of the REACH Regulation. The information on this endpoint is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study: Dissociation constant (Annex IX, 7.16.; test method: OECD 112) using the registered substance.

2. Viscosity

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test.

A viscosity study is a standard information requirement as laid down in Annex IX, section 7.16 of the REACH Regulation. The information on this endpoint is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study: Viscosity (Annex IX, 7.17.; test method: OECD 114) using the registered substance.

3. Mutagenicity

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test.

As laid down in Annex IX, section 8.4 of the REACH Regulation, an appropriate *in vivo* somatic cell genotoxicity study shall be proposed by the registrant if there is a positive result in any of the *in vitro* genotoxicity studies in Annex VII or VIII and there are no results available from an *in vivo* study already. The Registrant has reported positive results in a bacterial reverse mutation test (EU B.13/OECD 471) and in a mammalian chromosome aberration test (EU B.10/OECD 473). No results from an in vivo study have been presented. Consequently there is an information gap and it is necessary to provide information for this endpoint.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study: *In vivo* somatic cell genotoxicity study in rats, oral route (Annex IX, 8.4; test method: EU B.12/OECD 474) using the registered substance.

Based on the results of the required *in vivo* micronucleus study, the registrant shall consider whether a second *in vivo* somatic cell test addressing gene mutation may be necessary in accordance with column 2 of Annex X 8.4.

4. Deadline for submitting the information

In the draft decision communicated to the Registrant the time indicated to provide the requested information was 24 months from the date of adoption of the decision. This period of time took into account the requests for information made based on the testing proposals present in the previous registration dossier (submission number: [redacted]). After receiving the draft decision and the invitation to comment on it, the Registrant updated his registration dossier (submission number: [redacted]) and removed several of the original

testing proposals. This decision was amended to address only the testing proposals which were submitted as part of the updated dossier and ECHA considers that a reasonable time period for providing the required information in the form of an updated IUCLID5 dossier is 12 months from the date of the adoption of the decision. The decision was therefore modified accordingly.

IV. Adequate identification of the composition of the tested material

The process of evaluation of testing proposals set out in Article 40 of the REACH Regulation aims at ensuring that the new studies meet real information needs. Within this context, the Registrant's dossier was sufficient to confirm the identity of the substance to the extent necessary for evaluation of the testing proposal. The Registrant must note, however, that this information has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation.

In addition, it is important to ensure that the particular sample of substance tested in the new studies 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 studies must be suitable to assess these.

Finally there must be adequate information on substance identity for the sample tested and the grade registered to enable the relevance of the studies to be assessed.

V. General requirements for the generation of information and Good Laboratory Practice

ECHA reminds registrants of the requirements of Article 13(4) of the REACH Regulation that ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice (GLP). National authorities monitoring GLP maintain lists of test facilities indicating the relevant areas of expertise of each facility.

According to Article 13(3) of the REACH Regulation, tests that are required to generate information on intrinsic properties of substances shall be conducted in accordance with the test methods laid down in a Commission Regulation or in accordance with other international test methods recognised by the Commission or the European Chemicals Agency as being appropriate. Thus, the Registrant shall refer to Commission Regulation (EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 as adapted to technical progress or to other international test methods recognised as being appropriate and use the applicable test methods to generate the information on the endpoints indicated above.

VI. 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 appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on the 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.

[redacted]
Geert Dancet
Executive Director