ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-0000002057-79-05/F Helsinki, 18/07/2012

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

For 2-mercaptoethanol, CAS NO 60-24-2 (EC No 200-464-6), 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 40(1) of the REACH Regulation, ECHA has examined testing proposals set out in the registration dossier for 2-mercaptoethanol, CAS No 60-24-2 (EC No 200-464-6), submitted by [redacted] (Registrant), submission number [redacted], for 1000 tonnes or more per year.

In accordance with Articles 10(a)(ix) and 12(1)(e) of the REACH Regulation, the Registrant submitted the following testing proposals as part of the registration dossier to fulfil the information requirements set out in Annex IX:

- Annex IX, 9.1.5. Long-term toxicity testing on aquatic invertebrates according to OECD Guideline 211 (*Daphnia magna* Reproduction Test); and
- Annex IX, 8.7.2. Pre-natal developmental toxicity study according to OECD Guideline 414.

The examination of the testing proposal was initiated on 8 November 2010.

ECHA opened a third party consultation for testing proposal including testing on vertebrate animals that was held from 14 March to 30 May 2011. No comments were received.

On 1 December 2011 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 2 January 2012 the Registrant did not provide any comments on the draft decision to ECHA.

On 20 January 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, one Competent Authority of a Member State submitted a proposal for amendment to the draft decision.

On 23 February 2012 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 that proposal for amendment within 30 days of the receipt of the notification.

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

On 5 March 2012, the draft decision was referred to the Member State Committee.

The Registrant did not provide any comments on the proposal for amendment.

The Member State Committee modified the draft decision.

A unanimous agreement of the Member State Committee on the modified draft decision was reached on 12 April 2012 in a written procedure launched on 2 April 2012.

This decision does not imply that the information provided by the Registrant in his registration dossier is in compliance with the requirements of the REACH Regulation. The decision does not prevent ECHA to initiate a compliance check on the present dossier at a later stage.

II. Testing required

Pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant shall carry out the following tests using the indicated test method and the registered substance:

a) Long-term toxicity testing on aquatic invertebrates (Annex IX, 9.1.5., test method EU C.20/OECD Guideline 211, *Daphnia magna* Reproduction Test);
b) Pre-natal developmental toxicity study in rats: oral route (Annex IX, 8.7.2.; test method EU B.31/OECD Guideline 414),

Pursuant to Articles 40(4) and 22(2) of the REACH Regulation, the Registrant shall submit to ECHA an update of the dossier **by 20 January 2014**.

Data from a second pre-natal developmental toxicity study on another species is a standard information requirement according to Annex X, 8.7.2. of the REACH Regulation. The Registrant should firstly take into account the outcome of the pre-natal developmental toxicity on a first species and all other relevant available data to determine if the conditions are met for adaptations according to Annex X, 8.7. column 2, or according to Annex XI. If the Registrant considers that testing is necessary to fulfil this information requirement, he should include in the update of his dossier a testing proposal for a pre-natal developmental toxicity study on a second species.

At any time, the Registrant shall take into account that there may be an obligation to make every effort to agree on sharing of information and costs with other Registrants.

III. Statement of reasons

The decision of ECHA is based on the examination of the testing proposals of the Registrant for the registered substance. Pursuant to Article 40(3)(a) ECHA may require the Registrant to carry out the proposed test.

a) Annex IX, 9.1.5. OECD Guideline 211 (Long term toxicity testing on invertebrates);

The testing proposal for long term toxicity to aquatic invertebrates (test method: OECD 211) has been proposed by the Registrant in order to meet the information requirement of Section 9.1.5 of Annex IX 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. The chemical safety assessment indicates risk characterisation ratios for the aquatic compartment that are close to 1 for some exposure scenarios. The Registrant needs to refine his risk assessment for the aquatic compartment.

Therefore, and pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the following test: Long term toxicity testing on invertebrates (test method: EU C.20/OECD 211, *Daphnia magna* Reproduction Test).

b) Annex IX, 8.7.2. Pre-natal developmental toxicity study according to B.31/OECD 414

A pre-natal developmental toxicity study is a standard information requirement as laid down in Annex IX, 8.7.2 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 generate the data for this endpoint.

The Registrant did not specify the species to be tested or the route of administration. According to the test method B.31/OECD 414 the rat is the preferred species and oral route is the preferred route of administration. ECHA considers this species and route of administration as being appropriate.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study: pre-natal developmental toxicity in rats, oral route (test method: EU B.26/OECD 408) using the registered substance/substance.

When considering the need for a testing proposal for a prenatal developmental toxicity study in a second species, the Registrant should take into account the outcome of the pre-natal developmental toxicity study on the first species and all available data to determine if the conditions are met for adaptations according to Annex X, 8.7. column 2, or according to Annex XI; for example if the substance meets the criteria for classification as toxic for reproduction Category 1B: May damage the unborn child (H360D), and the available data are adequate to support a robust risk assessment, or alternatively, if Weight of Evidence assessment of all relevant available data provides scientific justification that the study in a second species is not needed.

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 generation of information is tailored to real information needs in order to prevent unnecessary testing. The information submitted in the registration dossier was sufficient to confirm the identity of the substance for the purpose of assessing the testing proposal. It is noted, however, that this information, or the information submitted by other registrants of the same substance, has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation.

In relation to the proposed tests, the sample of substance used for the new studies 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 the joint registrants of the same substance to agree with the tests proposed in the testing proposal (as applicable to their tonnage level) and to document the necessary information on its composition. The substance identity information of the registered substance and of the sample tested must enable ECHA to confirm the relevance of the testing for the substance actually registered by each joint registrant. Finally, the studies must be shared by the joint registrants concerned.

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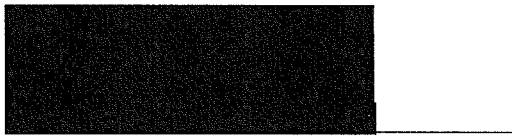
V. General requirements for the generation of information and Good Laboratory Practice

ECHA always 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.



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