ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-0000002398-67-02/F Helsinki, 13 June 2012

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

For Sodium hexahydroxoantimonate, CAS No 33908-66-6 (EC No 251-735-0), 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 Sodium hexahydroxoantimonate, CAS No 33908-66-6 (EC No 251-735-0), submitted by [redacted] (Registrant), latest submission number [redacted], for > 1000 tonnes 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, 8.6.2: Sub-chronic toxicity study (90-day) according to OECD test guideline 408 (Repeated Dose 90-day Oral Toxicity in Rodents)
> Annex IX, 8.7.2: Pre-natal developmental toxicity study according to OECD test guideline 414 (Prenatal Developmental Toxicity Study)

The examination of the testing proposals was initiated on 19/10/2010.

ECHA opened a third party consultation for the testing proposals including testing on vertebrate animals that was held from 15 July 2011 until 29 August 2011. ECHA received a comment from a third party concerning evaluation of read across options from other antimony compounds before conducting the studies proposed by the Registrant.

On 31 October 2011 ECHA notified the Registrant of its draft decision and invited him pursuant to Article 50(1) of the REACH Regulation to provide comments within 30 days of the receipt of the draft decision. The draft decision referred to submission number [redacted]

On 1 December 2011 the Registrant provided to ECHA comments indicating his agreement to the draft decision. On 14 December the Registrant updated the registration dossier (submission number [redacted]).

ECHA reviewed the further information received and did not amend the draft decision.

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, Competent Authorities of the Member States submitted proposals for amendment to the draft decision. ECHA reviewed the proposals for amendment received and decided not to modify the draft decision.

On 23 February 2012 ECHA notified the Registrant of proposals for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on those proposals for amendment within 30 days of the receipt of the notification.

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

On 19 March 2012 following an informal discussion the Member State Committee amended the draft decision.

On 26 March 2012 the Registrant provided comments on the proposals for amendment. The Member State Committee took the comments of the Registrant into account.

A unanimous agreement of the Member State Committee on the amended 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:

- Sub-chronic toxicity study (90-day), (Annex IX, 8.6.2, method B.26 of Regulation (EC) No 440/2008, OECD test guideline 408) in rat by the oral route
- Pre-natal developmental toxicity study (Annex IX, 8.7.2, method B.31 of Regulation (EC) No 440/2008, OECD test guideline 414) in rat by the oral route.

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA **by 13 December 2013** an update of the registration dossier containing the information required by this decision.

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 proposal of the Registrant for the registered substance and scientific information submitted by the third party.

a) Examination of the testing proposal

Pursuant to Article 40(3)(a) of the REACH Regulation ECHA may adopt a decision requiring the Registrant to carry out the proposed tests.

(i) Sub-chronic toxicity study

A sub-chronic toxicity study (90-day) is required under Annex IX, 8.6.2. The study is subject to all appropriate column 2 or Annex XI data adaptations. Since information on this endpoint is missing in the registration dossier, and since no acceptable adaptations to omit this information requirement have been received, ECHA accepts the proposed test. ECHA notes that the registered substance is a solid substance used in dust form with granulometric data indicating a fraction of the particles being able to enter not only the upper but also the lower respiratory airways. All the exposure scenarios developed by the Registrant refer to inhalation exposure by workers. ECHA further notes that a concern over chronic lung toxicity following inhalation exposure for another antimony compound (diantimony trioxide, EC No: 215-17-50) has been assessed both in the EU Risk Assessment Report and the opinion of the Scientific Committee on Health and Environmental Risks (SCHER). ECHA considered the Annex IX, 8.6.2 column 1 requirement for the most appropriate route of administration. ECHA notes that the further modelling of the pulmonary and tracheobronchial deposition of the registered substance under IUCLID section 4.5 indicates a low deposition in these areas. ECHA further observes that acute toxicity data do not indicate a particular concern for inhalation toxicity and that there is no repeated dose toxicity data for the registered substance. Therefore ECHA concludes that the oral route proposed by the Registrant and preferred by ECHA guidance (R.7.5.4.3) is the most appropriate route of administration in the sub-chronic toxicity study (90-day).

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study: Sub-chronic toxicity study (90-day) in rats, oral route (test method: EU B.26/OECD 408) using the registered substance.

(ii) Pre-natal developmental toxicity study

A pre-natal developmental toxicity study in one species is required under Annex IX, 8.7.2, and on a second species under Annexes IX and X, 8.7.2. The studies are subject to all appropriate column 2 or Annex XI data adaptations. Since information on these endpoints is missing in the registration dossier, and since no acceptable adaptations to omit these information requirements have been received, ECHA accepts the proposed test.

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 study in rats, oral route (test method: EU B.31/OECD 414) using the registered 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.

b) Consideration of third party information

ECHA received third party information concerning the testing proposal during the public consultation. For the reasons explained further below the information provided by the third party is not sufficient to fulfil these information requirements.

A third party submitted a suggestion of a strategy to evaluate all read-across options from other inorganic and organic antimony compounds and short descriptions of availability of data on a trivalent antimony compound diantimony trioxide on one hand and an in vivo toxicokinetic study comparing tri- and pentavalent antimony compounds on the other hand. However, third parties were invited, as specified by Article 40(2) of the REACH Regulation to submit "scientifically valid information and studies that address the relevant substance and hazard end-point, addressed by the testing proposal".

According to section 1.5 of Annex XI of the REACH Regulation, grouping of substances and read-across approach can be applied for substances whose physicochemical, toxicological and ecotoxicological properties are likely to be similar or follow a regular pattern as a result of structural similarity, and when the conditions in section 1.5 of Annex XI are met.

ECHA wants to underline that a consideration of read across approaches is particularly important in the case of metal compounds as the number of potentially relevant read across substances can be high. The consideration of the relevance of data from compounds of the same metal but having different oxidation states (valency) is important and metals vary in how their valency affects their chemical properties. Therefore this consideration has to be done case-by-case. ECHA is not in the position to evaluate the data available for all inorganic and organic antimony compounds, but notes that an information exchange forum has been formed in order to share such data between the registrants of the different antimony compounds. ECHA notes that the general strategy proposed by the third party and the short descriptions of data existing for other compounds do not allow the conclusion that the conditions laid down in section 1.5 of Annex XI of the REACH Regulation are fulfilled.

Therefore, the third party proposal does not provide a sufficient basis on which to reject the proposed tests.

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 your dossier was sufficient to confirm the identity of the substance for the purpose of assessing the testing proposal. You must note, 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.

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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