EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-0000002624-76-05/F Helsinki, 30 July 2013

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

For barium chloride, CAS No 10361-37-2 (EC No 233-788-1), 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 jointly submitted registration dossier in accordance with Articles 10(a)(ix) and 12(1)(e) thereof for barium chloride, CAS No 10361-37-2 (EC No 233-788-1), by [redacted] (Registrant).

- Fish, early-life stage toxicity test (OECD 210; Annex IX, 9.1.6.2.);
- Developmental toxicity test (OECD 414; Annex X, 8.7.2.).
- Two-generation reproductive toxicity test (OECD 416; Annex X, 8.7.3.).

The present decision relates to the examination of the testing proposals for a fish, early-life stage toxicity study and for a developmental toxicity study for the purposes of fulfilling the information requirement for proposals for a fish, early-life stage toxicity study (Annex IX, 9.1.6.2) and for a developmental toxicity study (Annex X, 8.7.2). The testing proposal for fulfilling the information requirement for a reproductive toxicity study (Annex X, 8.7.3) is addressed in a separate decision although all these were initially addressed together in the same draft decision.

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 27 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 29 April 2011 until 14 June 2011. ECHA did not receive information from third parties.

On 25 September 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 18 October 2012 ECHA received comments from the Registrant.

The comments are reflected in the Statement of Reasons (Section III) whereas no amendments to the Testing Required (Section II) were made.

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, Competent Authorities of the Member States submitted proposals for amendment to the draft decision.

On 21 February 2013 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.

ECHA reviewed the proposals for amendment received and decided to amend the draft decision.

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

On 19 March 2013 the Registrant provided comments on the proposed amendments. The Member State Committee took the comments of the Registrant into account.

The draft decision was split into two draft decision documents: one relating to the testing proposal for a two-generation reproductive toxicity study and one relating to the testing proposals for a fish, early-life stage toxicity study and for a developmental toxicity study.

A unanimous agreement of the Member State Committee on the draft decision relating to the testing proposal for a fish, early-life stage toxicity study and for a developmental toxicity study was reached on 8 April 2013 in a written procedure launched on 27 March 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) of the REACH Regulation using the indicated test methods and the registered substance subject to the present decision:

1. Fish, early-life stage (FELS) toxicity test (Annex IX, 9.1.6.2.; test method: Fish, early-life stage toxicity test, OECD 210);
2. Pre-natal developmental toxicity study in rats or rabbits, oral route (Annex X, 8.7.2.; test method: EU B.31/OECD 414);

The Registrant shall determine the appropriate order of the studies, taking into account the possible outcome and considering the possibilities for adaptations of the standard information requirements according to column 1 or 2 provisions of the relevant Annexes of the REACH Regulation.

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **30 July 2014** 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 fulfill 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 submitted by the Registrant for the registered substance.

1. Fish, early-life stage (FELS) toxicity test

a) Examination of the testing proposal

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

According to column 1 of Section 9.1.6 of Annex IX of the REACH Regulation, long-term toxicity testing on fish is required to fulfil the standard information requirements. 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.

In the Chemical Safety Report, the Registrant has provided a justification for conducting the long-term toxicity testing on fish which states that *'No reliable chronic data point for barium as test substance has been identified for fish. A testing proposal has been put forward, and the chronic NOEC/EC10 that will be generated in this study will cover the data requirement for this specific end point.'*
And
'It is recommended to refine this PNEC value in the near future by generating more reliable chronic ecotoxicity data: - conducting a chronic fish test (e.g., ELS test) would reduce the AF on the lowest NOEC to 10'

In investigating aquatic toxicity for the substance, the Registrant has submitted in the registration dossier a number of acute studies on fish and Daphnia, which were performed primarily using barium chloride as the test substance and which, according to the Registrant, vary in their reliability. ECHA notes that the reported values for the key studies, based on total barium concentrations, are: Daphnia magna 48h EC50 14.5 mg L, fish (Danio rerio) 96h LC50 >97.5 mg L and algae (Pseudokirchnerella subcapitata) 72h EC50 >34.3 mg/L. From the available data set it is difficult to establish with certainty which is the most sensitive species, and none of the species can be regarded as substantially more sensitive than the other.

According to ECHA *Guidance on information requirements and chemical safety assessment* (version 1.1., August 2008), Chapter R7b, Figure R.7.8-4 page 53, if based on acute aquatic toxicity data neither fish nor invertebrates are shown to be substantially more sensitive, long-term studies may be required on both. According to the integrated testing strategy, the Daphnia study is to be conducted first. If based on the results of the long-term Daphnia

study and an applied assessment factor of 50 no risks for aquatic organisms are indicated, no long-term fish testing may need to be conducted. However, if a risk for aquatic organisms is indicated when applying an assessment factor of 50, long-term fish testing may need to be conducted.

In the technical dossier, the Registrant has already provided a long term toxicity study in Daphnia (3 week EC16 5.8 mg/l, NOEC 2.9 mg/l based on total barium concentrations). The Registrant has applied an assessment factor of 50, providing a PNECaquatic value of 0.058 mg Ba/L. ECHA notes that a long-term toxicity study with fish is also available in the registration dossier. However, the Registrant deems the study to be reliability 3 (not reliable) with the justification that *'This study contains no relevant endpoint for evaluation of chronic effect levels. There was little information on test methodology. Test concentrations (measured/nominal) are not reported. Also there was no pshysico-chemical data recorderd during the test.'* Consequently, there is an information gap for this endpoint.

ECHA finds the Registrant's justification for the test proposed, in the light of the data in the dossier, as acceptable.

In their comments, the Registrant agreed with ECHA's draft decision requesting an OECD 210 study.

b) Outcome

Therefore, pursuant to Article 40(3)(a)of the REACH Regulation, the Registrant is required to carry out the proposed study: Fish, early-life stage (FELS) toxicity test (Annex IX, 9.1.6.1.; test method: Fish, early-life stage toxicity test, OECD 210); using the registered substance.

2. Pre-natal developmental toxicity study

a) Examination of the testing proposal

Pre-natal developmental toxicity studies are part of the standard information requirements as laid down in Annexes IX and X, section 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 provide information for this endpoint.

The Registrant did not specify the species and route to be used for testing. According to the test method EU B.31/OECD 414, the rat is the preferred rodent species, the rabbit the preferred non-rodent species and the test substance is usually administered orally. ECHA considers these default parameters appropriate and testing should be performed by the oral route with the rat or the rabbit as a first species to be used.

In their comments, the Registrant agreed with ECHA's draft decision requesting a B.31/OECD 414 study.

b) Outcome

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 or rabbits, 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.

3. Deadline for submitting information

In the draft decision communicated to the Registrant, the time indicated to provide the requested information was 30 months from the date of adoption of the decision. This period of time took into account the fact that the draft decision also requested a two-generation reproductive toxicity study, according to the standard information requirement of Annex IX, 8.7.3 of the REACH Regulation. As the testing proposal for this studys is not addressed in the present draft decision, 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, 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 joint registrants of the same substance to agree to the tests proposed (as applicable to their tonnage level) 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 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 by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new studies must be suitable to assess these grades.

Finally there must be adequate information on substance identity for the sample tested and the grades 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).

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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Geert Dancet
Executive Director