EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-0000002623-78-03/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 sulfate, CAS No 7727-43-7 (EC No 231-784-4), 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 sulfate, CAS No 7727-43-7 (EC No 231-784-4), by [redacted] (Registrant).

- Fish, early-life stage toxicity test (OECD 210; Annex IX, 9.1.6.2.), using the analogue substance barium chloride (CAS NO. 10361-37-2, EC NO. 233-788-1).

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 14 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 proposal 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.

By 25 October 2012 the Registrant did not provide any comments on the draft decision to ECHA.

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 did not propose amendments to the draft decision and ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

II. Testing required

The Registrant shall carry out the following proposed test pursuant to Article 40(3)(a) of the REACH Regulation using the indicated test methods and the analogue substance barium chloride instead of 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).

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.

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 on the analogue substance barium chloride (CAS NO. 10361-37-2, EC NO. 233-788-1) and submitted read-across justification.

Fish, early-life stage (FELS) toxicity test

a) Read-across approach

In relation to the testing proposal subject to the present decision, the Registrant has proposed using the read-across approach, in accordance with Annex XI, 1.5, and to perform the relevant test on another substance than the registered substance. ECHA has considered first the scientific validity of the proposed read-across approach, before assessing the testing proposed.

Article 13(1) of the REACH Regulation requires information on intrinsic properties of substances, in particular, on human toxicity, to be generated whenever possible by means other than vertebrate animal tests, including information from structurally related substances (grouping or read-across), "*provided that the conditions set out in Annex XI are met*".

The Registrant proposed to carry out the fish, early-life stage (FELS) toxicity study with barium chloride (CAS NO. 10361-37-2, EC NO. 233-788-1). The Registrant has justified the read-across approach based on the fact that barium ion concentrations are the most relevant parameter to evaluate barium toxicity and that barium chloride is more soluble than the registered substance. Water solubility in the technical dossier for barium chloride is ≥263 g/L (20-25°C; no pH given) (deemed to be Klimsch score 2 by the Registrant) while for barium sulfate it is 3.1 mg/L (25 °C; pH 9) (deemed to be Klimsch score 2 by the Registrant). ECHA notes, based on the available information in the technical dossier, that barium chloride is significantly more soluble than barium sulphate, the registered substance.

In the Chemical Safety Report, the Registrant states that *'[for the] current substance the chemical safety assessment is based on elemental metal concentration, i.e., the assessment of barium is conducted regardless of the (pH-dependent) speciation in the environment' and 'In that respect, the Ba-concentrations are more relevant for the evaluation of Ba-toxicity as they include all speciation forms that will be present under natural conditions'.*

According to ECHA Guidance on the Application of the CLP Criteria (version 2.0, April 2012), Annex IV 2.1. Interpretation of aquatic toxicity data page 499, *'Ecotoxicity data of soluble inorganic compounds are used and combined to define the toxicity of the metal ion under consideration. The ecotoxicity of soluble inorganic metal compounds is dependent on the physico-chemistry of the medium, irrespective of the original metal species released in the environment. Reading across metal compounds can therefore be conducted by comparing the soluble metal ion concentration (µg Me/L) causing the ecotoxicity effect and translating this towards the compound under investigation'.*

ECHA considers that the justification given demonstrates that it is plausible that the requirements of Annex XI, section 1.5 in conjunction with article 13(1) and Annex IX, third introductory paragraph, of the REACH Regulation may be met. Specifically, adequate and reliable documentation of the applied read-across approach has been provided, and ECHA considers that there appears to be a scientific justification that ecotoxicological effects for long term toxicity on fish may be predicted from data for the substance barium chloride through the read-across approach. However, a final conclusion on the validity of the suggested approach to adapt the standard information requirement will only be possible when it has been demonstrated on the basis of test results that the conditions set out in Annex XI section 1.5 are met for this endpoint.

Therefore, ECHA emphasises that it is the Registrant's responsibility to amend and substantiate read-across and category justification according to Annex XI, section 1.5 and to use all relevant available data.

Following the update of the dossier based on the present decision, ECHA will decide whether the evidence provided is sufficient to satisfactorily address the information requirement for the substance subject to this decision as proposed by the Registrant. If, upon further consideration, the proposed approach does not satisfy the conditions set out in Annex XI, ECHA reserves the right to request the information necessary to fulfil the information requirements.

b) Information requirement

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.

c) 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 analogue substance barium chloride (CAS NO. 10361-37-2, EC NO. 233-788-1).

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