ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-0000002139-75-05/F Helsinki, 25 July 2012

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

For Strontium carbonate, CAS No 1633-05-2 (EC No 216-643-7), 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 proposal set out in the registration dossier for Strontium carbonate, CAS No 1633-05-2 (EC No 216-643-7), submitted by [redacted] (Registrant), latest submission number [redacted], for 100 to 1000 tonnes per year.

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

> Long-term toxicity test to fish according to OECD Guideline 210 (Fish, Early-Life Stage Toxicity Test), on the read-across substance strontium nitrate (CAS No. 10042-76-9).

The examination of the testing proposal was initiated on 27 October 2010.

ECHA opened a third party consultation for the testing proposal including testing on vertebrate animals that was held from 31 May until 15 July 2011. ECHA did not receive information from third parties.

On 2 December 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.

On 20 December 2011 the Registrant provided to ECHA comments on the draft decision. ECHA reviewed the further information received and did not amend the draft decision.

On 20 January 2012 ECHA notified to 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 proposal 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 proposal for amendment received and amended the draft decision accordingly.

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

On 20 March 2012 the Registrant provided comments on the proposal for amendment. The Member State Committee took the comments of the Registrant into account. The Member State Committee reached unanimous agreement on the draft decision in a written procedure launched on 28 March and closed on 11 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 proposed test using the indicated test method and the read-across substance strontium nitrate (CAS No. 10042-76-9):

> Fish, Early-Life Stage Toxicity Test, Long-term toxicity test to fish (Annex IX 9.1.6, test method: OECD 210).

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **25 July 2013** '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 proposal submitted by the Registrant for the registered substance and the read-across justification provided.

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

The Registrant proposes to perform the test according to OECD Guideline 210 (Fish, Early-Life Stage Toxicity Test) using a read-across substance, strontium nitrate (CAS No. 10042-76-9) instead of the registered substance strontium carbonate (CAS No. 1633-05-2), to cover the endpoint long-term toxicity testing on fish, Annex IX, 9.1.6. of the REACH Regulation which is not available in the registration dossier but needs to be present being part of the standard information requirement for a substance that is registered at 100 tonnes or more per year.

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According to Section 1.5 of Annex XI of the REACH Regulation a grouping or read-across approach may be applied, in case of substances whose physicochemical, ecotoxicological and toxicological properties are likely to be similar. For metals such as the strontium carbonate and strontium nitrate it is generally assumed that toxicity is controlled by the dissolved metal ion. In the environment, the element only occurs in one valence state (Sr2+), does not form strong organic or inorganic complexes and is commonly present in solution as Sr2+. Consequently, the toxicity of the strontium in the environment is largely controlled by solubility of different Sr-salts. Assuming that the toxicity due to carbonate and nitrate ions is not to be expected (or nitrate in the worst case), any considerations for the validity of the testing proposal has to be based on the availability of the strontium ions in solution. The water solubility of strontium nitrate (>10 g/L), the substance to be tested by the Registrant, is higher than the water solubility of Strontium Carbonate (> 3 mg/L) as the registered substance.

Moreover, the Registrant indicates in the Chemical Safety Report (CSR) the need for further testing as no or few ecotoxicological data are available for fish toxicity for the registered substance concerned by the present decision and that the study shall generate a no observed effect concentration (NOEC) for that substance.

In conclusion, based on the physicochemical properties (in particular water solubility) of strontium nitrate and strontium carbonate, it is acceptable to read-across from the former to the latter in relation to aquatic toxicity and the requirements of REACH Annex XI, 1.5. Consequently the testing proposal on use of read-across is accepted and the Registrant shall thus perform the proposed fish early life-stage toxicity test for provision of data on Annex IX, 9.1.6.1 of the REACH Regulation with strontium nitrate to be tested.

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 test, the sample of substance used for the new study 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 test 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 and for the read-across substance by each joint registrant. Finally, the study 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.

[redacted]

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Director of Regulatory Affairs