EUROPEAN CHEMICALS AGENCY

For final decision: TPE-D-0000002137-79-05/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 Strontium nitrate, CAS No. 10042-76-9 (EC No. 233-131-9), 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 Strontium nitrate, CAS No. 10042-76-9 (EC No. 233-131-9), submitted by [redacted] (Registrant), latest 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 X:

- Pre-natal developmental toxicity study (OECD 414), no species, route of administration or test material specified;
- Two-generation reproduction toxicity study (OECD 416), no species, route of administration or test material specified;
- Long-term toxicity testing on fish (OECD 210, Fish early-life stage toxicity test).

The present decision relates solely to the examination of the testing proposals for the Pre-natal developmental toxicity (OECD 414) study and Long-term toxicity testing on fish (OECD 210, Fish early-life stage toxicity test). The testing proposal for the Two-generation reproductive toxicity study is addressed in a separate decision although all testing proposals were initially addressed together in the same draft decision.

The examination of the testing proposals was initiated on 8 December 2010.

ECHA opened a third party consultation for the testing proposals including testing on vertebrate animals that was held from 31 May until 15 July 2011. ECHA did receive information from third parties (see section III below).

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.

By 2 January 2012 the Registrant did not provide to ECHA comments on 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.

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.

ECHA reviewed the proposals for amendment received and decided not to amend the draft decision.

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

By 26 March the Registrant did not provide any comments on the proposals for amendment.

After discussion in the Member State Committee meeting on 24-27 April 2012 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 pre-natal developmental toxicity study and a long-term toxicity testing on fish. The Member State Committee reached unanimous agreement on the draft decision relating to the testing proposal for a pre-natal developmental toxicity study and a long-term toxicity testing on fish at the meeting on 25 April 2012 and ECHA took the decision pursuant to Article 51(6) 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 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 tests using the indicated test methods and the registered substance concerned by the present decision:

1. Pre-natal developmental toxicity study in rats, oral route (Annex IX, 8.7.2., test method: EU B.31/OECD 414).

2. Fish early-life stage (FELS) toxicity test, long-term toxicity testing on fish (Annex IX, 9.1.6.1., test method: OECD 210 - Fish).

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

In the draft decisions communicated to the Registrant the time indicated to provide the requested information was 24 months from the date of adoption of the decision. This period of time took into account the fact that the draft decisions also requested a reproductive toxicity study according to the standard information requirement of Annex X, 8.7.3 of the REACH Regulation. As the testing proposal for this study is not addressed in the present 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.

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, subject to the Annex IX, 8.7.2 column 2 requirements. If the Registrant considers that testing is necessary to fulfil this information requirement taking into account the outcome of the pre-natal developmental toxicity study on a first species and all other relevant and available data, 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 submitted by the Registrant for the registered substance and scientific information submitted by third parties.

1. Pre-natal developmental toxicity study

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

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 generate the data 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 as a first species to be used.

ECHA acknowledges the efforts made by the Registrant to gain access to data which has been generated for pharmaceutical regulatory purposes and may be capable to fulfil the information requirement of Annex IX, 8.7.2. of the REACH Regulation. However, as this information is not held by a Registrant subject to rights and obligations covered by the REACH Regulation, data-sharing provisions under the REACH Regulation do not apply and cannot be imposed on the data owner.

b) Consideration of third party information

ECHA received no third party information concerning this endpoint.

On the basis of the considerations set out above ECHA accepts the testing proposed by the Registrant. 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.

2. Long-term toxicity testing on fish

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.

The decision of ECHA is based on the examination of the testing proposal of the Registrant for the registered substance.

A long-term toxicity testing on fish is part of the information requirements as laid down in Annex IX, section 9.1.6. of the REACH Regulation. According to Column 2, Annex IX, section 9.1., long-term toxicity testing on fish shall be proposed by the Registrant if the chemical safety assessment according to Annex I indicates the need to investigate further the effects on aquatic organisms. 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.

b) Consideration of third party information

ECHA received no third party information concerning this endpoint.

On the basis of the considerations set out above ECHA accepts the testing proposed by the Registrant. Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is requested to carry out the following test: Fish early-life stage toxicity test (test method: OECD 210) using the registered substance.

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 proposals. 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.

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 reads:

"*Ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice provided for in Directive 2004/10/EC or other international standards recognised as being equivalent by the Commission or the Agency and with the provisions of Directive 86/609/EEC, if applicable.*"

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.

National authorities monitoring good laboratory practice (GLP) maintain lists of test facilities indicating the relevant areas of expertise of each facility.

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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Jukka MALM
Director of Regulatory Affairs